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Interventions for increasing the use of shared decision making by healthcare professionals (Review)

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[Intervention Review]

Interventions for increasing the use of shared decision making by healthcare professionals

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ABSTRACT

Background

Shared decision making (SDM) is a process by which a healthcare choice is made by the patient, significant others, or both with one or more healthcare professionals. However, it has not yet been widely adopted in practice. This is the second update of this Cochrane review.

Objectives

To determine the effectiveness of interventions for increasing the use of SDM by healthcare professionals. We considered interventions targeting patients, interventions targeting healthcare professionals, and interventions targeting both.

Search methods

We searched CENTRAL, MEDLINE, Embase and five other databases on 15 June 2017. We also searched two clinical trials registries and proceedings of relevant conferences. We checked reference lists and contacted study authors to identify additional studies.

Selection criteria

Randomized and non-randomized trials, controlled before-after studies and interrupted time series studies evaluating interventions for increasing the use of SDM in which the primary outcomes were evaluated using observer-based or patient-reported measures.

Data collection and analysis

We used standard methodological procedures expected by Cochrane.

We used GRADE to assess the certainty of the evidence.

Main results

We included 87 studies (45,641 patients and 3113 healthcare professionals) conducted mainly in the USA, Germany, Canada and the Netherlands. Risk of bias was high or unclear for protection against contamination, low for differences in the baseline characteristics of patients, and unclear for other domains.

Forty-four studies evaluated interventions targeting patients. They included decision aids, patient activation, question prompt lists and training for patients among others and were administered alone (single intervention) or in combination (multifaceted intervention). The certainty of the evidence was very low. It is uncertain if interventions targeting patients when compared with usual care increase SDM whether measured by observation (standardized mean difference (SMD) 0.54, 95% confidence interval (CI) -0.13 to 1.22; 4 studies; N = 424) or reported by patients (SMD 0.32, 95% CI 0.16 to 0.48; 9 studies; N = 1386; risk difference (RD) -0.09, 95% CI -0.19 to 0.01; 6 studies; N = 754), reduce decision regret (SMD -0.10, 95% CI -0.39 to 0.19; 1 study; N = 212), improve physical (SMD 0.00, 95% CI -0.36 to 0.36; 1 study; N = 116) or mental health-related quality of life (QOL) (SMD 0.10, 95% CI -0.26 to 0.46; 1 study; N = 116), affect consultation length (SMD 0.10, 95% CI -0.39 to 0.58; 2 studies; N = 224) or cost (SMD 0.82, 95% CI 0.42 to 1.22; 1 study; N = 105).

It is uncertain if interventions targeting patients when compared with interventions of the same type increase SDM whether measured by observation (SMD 0.88, 95% CI 0.39 to 1.37; 3 studies; N = 271) or reported by patients (SMD 0.03, 95% CI -0.18 to 0.24; 11 studies; N = 1906); (RD 0.03, 95% CI -0.02 to 0.08; 10 studies; N = 2272); affect consultation length (SMD -0.65, 95% CI -1.29 to -0.00; 1 study; N = 39) or costs. No data were reported for decision regret, physical or mental health-related QOL.

Fifteen studies evaluated interventions targeting healthcare professionals. They included educational meetings, educational material, educational outreach visits and reminders among others. The certainty of evidence is very low. It is uncertain if these interventions when compared with usual care increase SDM whether measured by observation (SMD 0.70, 95% CI 0.21 to 1.19; 6 studies; N = 479) or reported by patients (SMD 0.03, 95% CI -0.15 to 0.20; 5 studies; N = 5772); (RD 0.01, 95%C: -0.03 to 0.06; 2 studies; N = 6303); reduce decision regret (SMD 0.29, 95% CI 0.07 to 0.51; 1 study; N = 326), affect consultation length (SMD 0.51, 95% CI 0.21 to 0.81; 1 study, N = 175), cost (no data available) or physical health-related QOL (SMD 0.16, 95% CI -0.05 to 0.36; 1 study; N = 359). Mental health-related QOL may slightly improve (SMD 0.28, 95% CI 0.07 to 0.49; 1 study, N = 359; low-certainty evidence).

It is uncertain if interventions targeting healthcare professionals compared to interventions of the same type increase SDM whether measured by observation (SMD -0.30, 95% CI -1.19 to 0.59; 1 study; N = 20) or reported by patients (SMD 0.24, 95% CI -0.10 to 0.58; 2 studies; N = 1459) as the certainty of the evidence is very low. There was insufficient information to determine the effect on decision regret, physical or mental health-related QOL, consultation length or costs.

Twenty-eight studies targeted both patients and healthcare professionals. The interventions used a combination of patient-mediated and healthcare professional directed interventions. Based on low certainty evidence, it is uncertain whether these interventions, when compared with usual care, increase SDM whether measured by observation (SMD 1.10, 95% CI 0.42 to 1.79; 6 studies; N = 1270) or reported by patients (SMD 0.13, 95% CI -0.02 to 0.28; 7 studies; N = 1479); (RD -0.01, 95% CI -0.20 to 0.19; 2 studies; N = 266); improve physical (SMD 0.08, -0.37 to 0.54; 1 study; N = 75) or mental health-related QOL (SMD 0.01, -0.44 to 0.46; 1 study; N = 75), affect consultation length (SMD 3.72, 95% CI 3.44 to 4.01; 1 study; N = 36) or costs (no data available) and may make little or no difference to decision regret (SMD 0.13, 95% CI -0.08 to 0.33; 1 study; low-certainty evidence).

It is uncertain whether interventions targeting both patients and healthcare professionals compared to interventions of the same type increase SDM whether measured by observation (SMD -0.29, 95% CI -1.17 to 0.60; 1 study; N = 20); (RD -0.04, 95% CI -0.13 to 0.04; 1 study; N = 134) or reported by patients (SMD 0.00, 95% CI -0.32 to 0.32; 1 study; N = 150) as the certainty of the evidence was very low. There was insuffient information to determine the effects on decision regret, physical or mental health-related quality of life, or consultation length or costs.

Authors' conclusions

It is uncertain whether any interventions for increasing the use of SDM by healthcare professionals are effective because the certainty of the evidence is low or very low.

PLAIN LANGUAGE SUMMARY

A review of activities to help healthcare professionals share decisions about care with their patients

What is the aim of this review?

Healthcare professionals often do not involve their patients in decision making about their care. With shared decision making, healthcare professionals inform patients about their choices and invite them to choose the option that reflects what is important to them, including the option not to proceed with treatment. Shared decision making is said to be desirable because patient involvement is accepted as a right and patients in general want more information about their health condition and prefer to take an active role in decisions about their health. The aim of this review was to find out if activities to increase shared decision making by healthcare professionals are effective or not. Examples of these activities are training programs, giving out leaflets, or email reminders. Cochrane researchers collected and analyzed all relevant studies to answer this question, and found 87 studies.

Key messages

A great variety of activities exist to increase shared decision making by healthcare professionals, but we cannot be confident about which of these activities work best because the certainty (or the confidence) of the evidence has been assessed as very low.

What was studied in the review?

Our review examined the 87 studies that tested what kind of activities work best to help healthcare professionals involve their patients more in decision making about their care. We also examined the effect of these activities on decision regret, physical or mental health-related quality of life, length of the consultation, and cost.

The studies were so different that these activities were difficult to compare.

First, we divided the studies into ones that used outside observers to measure shared decision making and ones that used patients to measure shared decision making.

We then divided studies into ones that looked at activities a) for healthcare professionals only (e.g. training), b) for patients only (e.g. giving them a decision aid, which is a pamphlet explaining options and inviting them to think about their values and preferences), and c) for both healthcare professionals and patients (e.g. training plus a decision aid).

Finally, we subdivided each of these three categories into studies that compared the activity with usual care and studies that compared the activity with another activity.

We also looked at how certain the evidence was for our primary outcome (the extent to which healthcare professionals involve their patients more in decision making about their care) and secondary outcomes (decision regret, physical or mental health-related quality of life, length of the consultation, and cost) of interest.

What are the main results of the review?

Forty-four studies looked at activities for patients only, while 28 studies looked at activities for both healthcare professionals and patients, and 15 studies looked at activities for healthcare professionals only.

While studies in all three categories had tested many different activities to increase shared decision making by healthcare professionals, overall we cannot be confident in the effectiveness of these activities because the certainty of the evidence was weak. This is because there were many possible sources of error (e.g. not making sure the tested activities were not also provided to the comparison groups), and often poor reporting of results (i.e. not providing enough information to judge the quality of the evidence).

Although it was hard to come to any firm conclusions, we can say that compared to no activity at all, activities for healthcare professionals may slightly improve mental health-related quality of life, but make little or no difference to physical health-related quality of life (two studies). We can also say that activities targeting both healthcare professionals and patients may make little or no difference to decision regret (one study).

How up-to-date is this review?

We searched for studies published up to June 2017.

Summary of findings for the main comparison. Interventions targeting patients compared to usual care or interventions of the same type for shared decision making

Interventions targeting patients compared to usual care or to interventions of the same type for shared decision making

Patient or population: patients, including healthcare consumers and simulated patients
Settings: Australia, Canada, Germany, Namibia, Spain, Sweden, the Netherlands, UK, USA
Interventions: interventions designed to improve shared decision making among healthcare professionals that target patients (for example, patient-mediated interventions)
Comparison: usual care or interventions of the same type

Outcomes	Illustrative comparative risks* (95% CI)		Risk difference (95% CI)	No of Participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk [control]	Corresponding risk [experimental]				
a- Intervention targeting patients compared to usual care						
Shared decision making (observer based outcome measure (OBOM), continuous measures) (follow-up: up to 6 months)	-	SMD 0.54 higher (0.13 lower to 1.22 higher)	-	424 (4 randomized trials)	⊕◯◯◯ VERY LOW a,b,c,d	Scales are: OPTION (0-100) and RIAS. Higher score indicates more shared decision making use. One study was not included in the quantitative synthesis and was consistent with the pooled result
Shared decision making (patient reported outcome measure (PROM), continuous measures) (follow-up: up to 3 years)	-	SMD 0.32 higher (0.16 higher to 0.48 higher)	-	1386 (9 randomized)	⊕◯◯◯ VERY LOW a,b,c	Scales are: Patient activation measure (0-100), patient self-advocacy (1-5), COMRADE (0-100), decision evaluation scale (1-5), clinicians' participatory decision making (1-5), satisfaction with decision making process (0-100), CollaboRATE (0-100), patient role in treatment decision (1-5). Higher score indicates more shared decision making use. One study was not included in the quantitative synthesis. It is unlikely that it would change the direction of the effect size estimate given that its sample size was not very large.

Shared decision making (PROM), dichotomous measures (follow-up : up to 3 months)	Study population		-0.09 (-0.19 to 0.01)	754 (6 randomized trials)	⊕◯◯◯ VERY LOW [a,c,f]	Three studies were not included in the quantitative synthesis.The first study did not support the pooled result but given that the pooled estimate of the effect size is in favor of the control group, it is likely that adding that study would move the pooled estimate of the effect size toward a null effect. The second study did not support the pooled result but given its very large sample size, it is likely that adding this study would move the pooled estimate of the effect size toward a positive effect. The third study supported the pooled result toward the null effect.
	56 per 100	46 per 100				
	Low risk population					
	33 per 100[e]	33 per 100				
	High risk population					
	88 per 100[e]	60 per 100				
Decision regret (follow-up : 6 months)	-	SMD 0.10 lower (0.39 lower to 0.19 higher)	-	212 (1 randomized trial)	⊕◯◯◯ VERY LOW [a,c,h]	Decision regret scale (0-100). Higher score indicates more regret after decision
Health-related quality of life (physical) (follow-up: 3 months post-operatively)	-	SMD 0.00 (0.36 lower to 0.36 higher)	-	116 (1 randomized trial)	⊕◯◯◯ VERY LOW [c,g,h]	Physical component scale of SF-36 (0-100). Higher score indicate better quality of life.
Health-related quality of life (mental) (follow-up: 3 months post-operatively)	-	SMD 0.10 higher (0.26 lower to 0.46 higher)	-	116 (1 randomized trial)	⊕◯◯◯ VERY LOW [c,g,h]	Mental component scale of SF-36 (0-100). Higher score indicate better quality of life.
Consultation length (minutes)	-	SMD 0.10 higher (0.39 lower to 0.58 higher)	-	224 (2 randomized trials)	⊕◯◯◯ VERY LOW [c,f,g,h]	
Cost (£)	-	SMD 0.82 higher (0.42 higher to 1.22 higher)	-	105 (1 randomized trial)	⊕◯◯◯ VERY LOW [a,c,h]	
b- Intervention targeting patients compared to intervention of the same type						
Shared decision making (OBOM, continuous) (post-visit)	-	SMD 0.88 higher (0.39 higher to 1.37 higher)	-	271 (3 randomized trials)	⊕◯◯◯ VERY LOW [b,c,g,h]	OPTION scale (0-100). Higher score indicates more shared decision making use. Decision aid study increase the use of shared decision making compared to booklet or pamphlet

Shared decision making (PROM, continuous) (follow-up: up to 6 months)	-	SMD 0.03 higher (0.18 lower to 0.24 higher)	-	1906 (11 randomized trials)	⊕◯◯◯ VERY LOW [b,c,g,h]	Scales are: Decision making subscale of the Modified Perceived involvement in care scale (4-20), Patient Activation Measure (0-100), 1-item question on "who makes decisions about medical treatment" (1-5), Satisfaction With Decision Making Process scale (12-60), Problem-Solving Decision-Making Scale (1-5), SDM-Q9 (0-100), patient role in treatment decision (1-5), SDM-Q (0-11), Patient-reported shared decision making (0-4). Higher score indicates more shared decision making use. Two studies were not included in the quantitative synthesis but supported the pooled results.
Shared decision making (PROM, categorical or dichotomous) (follow-up : up to 6 weeks)	Study population		0.03 (-0.02 to 0.08)	2272 (10 randomized trials)	⊕◯◯◯ VERY LOW [a,c,f]	Three studies were not included in the quantitative synthesis.Two of them were consistent with the pooled results, but the third reported an increase in the use of shared decision making for the intervention group.
	38 per 100	40 per 100				
	Low risk population					
	18 per 100[e]	22 per 100				
	High risk population					
	73 per 100[e]	52 per 100				
Decision regret	-	-	-	-	-	No data available for this outcome
Health-related quality of life (physical)	-	-	-	-	-	No data available for this outcome
Health-related quality of life (mental)	-	-	-	-	-	No data available for this outcome
Consultation length (minutes)	-	SMD 0.65 lower (1.29 lower to 0.00)	-	39 (1 randomized trial)	⊕◯◯◯ VERY LOW [c,g,h]	
Cost	-	-	-	-	-	No data available for this outcome

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

a. We downgraded the certainty of evidence by two levels due to very serious limitations in the design (most of the studies are at high risk of bias (≥ 50%). Across studies, taking all low risk and unclear risk judgements together, there are ≥ 50% of unclear risk for our key domains)

b. We downgraded the certainty of evidence by two level due to unexplained high heterogeneity (I^2 ≥ 50% and P value for heterogeneity ≤ 0.05)

c. We downgraded the certainty of evidence by one level due to indirectness of evidence (important difference in populations)

d. We downgraded the certainty of evidence by two levels due to imprecision (insufficient number of participants for more than one study and large confidence interval)

e. The low and high risk values are the two extreme percentages of events.

f. We downgraded the certainty of evidence by one level due to small heterogeneity (I^2 < 50% or I^2 ≥ 50% and P value > 0.05)

g. We downgraded the certainty of evidence by one level due to serious limitations in the design (most of the studies are at unclear risk of bias (≥ 50% of the studies are at unclear risk))

h. We downgraded the certainty of evidence by one level due to imprecision (insufficient number of participants for one study and/or large confidence interval)

GRADE: Grading of Recommendations Assessment, Development and Evaluation; OBOM: Observer-based outcome measures; PROMs: Patient-reported outcome measures; RD: Risk difference; SMD: Standardized mean difference.

Summary of findings 2. Interventions targeting healthcare professionals compared to usual care or interventions of the same type for shared decision making

Interventions targeting healthcare professionals compared to usual care or interventions of the same type for shared decision making						
Patient or population: healthcare professionals responsible for patient care **Settings:** Australia, Austria, Belgium, Canada, Germany, the Netherlands, New Zealand, Norway, Switzerland, USA, UK **Interventions:** interventions designed to improve shared decision making among healthcare professionals that target healthcare professionals (for example, distribution of printed educational material, educational meetings, audit and feedback, reminders and educational outreach visits) **Comparison:** usual care or interventions of the same type						
Outcomes	**Illustrative comparative risks* (95% CI)**		**Risk difference (95% CI)**	**No of Participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk	**Corresponding risk**				
	[control]	**[experimental]**				
a- Intervention targeting healthcare professionals compared to usual care						

Shared decision making (OBOM, continuous) (follow-up: up to 3 months post-intervention)	-	SMD 0.70 higher (0.21 higher to 1.19 higher)	-	479 (6 randomized trials)	⊕◯◯◯ VERY LOW [a,b,c,d]	Scales are: Fours Habits Coding Scheme (23-115), OPTION (0-100), Decision Support Analysis Tool (0-100), Control Preference Scale (0-4), and Family engagement (number of utterances or decision-making events that families engaged). Higher score indicates more shared decision making use. Two studies were not included in the quantitative synthesis. The first study and one sub-sample of the second study were consistent with the pooled result. The other sub-sample of the second study reported no difference between the study groups.
Shared decision making (PROM, continuous) (follow-up : up to 12 months)	-	SMD 0.03 higher (0.15 lower to 0.20 higher)	-	5772 (5 randomized trials)	⊕◯◯◯ VERY LOW [a,b,c,d]	Scales are: Physicians' participatory decision making style (0-4), short-form healthcare climate questionnaire (0-100), SDM-Q9 (0-100), and Overall PSA SDM perception (5-20). Higher score indicates more shared decision making use. One study was not included in the quantitative synthesis and reported an increase in the use of shared decision making for the intervention group.
Shared decision making (PROM, categorical or dichotomous) (follow-up: up to 8 weeks after delivery of pregnant women)	Study population		0.01 (-0.03 to 0.06)	6303 (2 randomized trials)	⊕◯◯◯ VERY LOW [a,b,c]	One study was not included in the quantitative synthesis and was consistent with the pooled results.
	21 per 100	22 per 100				
	Low risk population					
	19 per 100[e]	17 per 100				
	High risk population					
	36 per 100[e]	45 per 100				
Decision regret (follow-up: 2 weeks)	-	SMD 0.29 higher (0.07 higher to 0.51 higher)	-	326 (1 randomized trial)	⊕◯◯◯ VERY LOW [a,c,d]	Decision regret scale (0-100). Higher score indicates more regret after decision. The slight effect observed on patient decisional regret was not clinically significant.
Health-related quality of life (physical) (follow-up: 2 weeks)	-	SMD 0.16 higher (0.05 lower to 0.36 higher)	-	359 (1 randomized trial)	⊕⊕◯◯ LOW [a,c]	Scale are : Physical scale of SF-12 (0-100) and SF12v2 (0-100). Higher score indicate better quality of life.

Health-related quality of life (mental) (follow-up: 2 weeks)	-	SMD 0.28 higher (0.07 to 0.49 higher)	-	359 (1 randomized trial)	⊕⊕◯◯ LOW [a,c]	Scale are : Mental scale of SF-12 (0-100) and SF12v2 (0-100). Higher score indicate better quality of life.
Consultation length (minutes)	-	SMD 0.51 higher (0.21 higher to 0.81 higher)	-	175 (1 randomized trial)	⊕◯◯◯ VERY LOW [a,c,d]	
Cost	-	-	-	-	-	No data available for this outcome
b- Intervention targeting healthcare professionals compared to intervention of the same type						
Shared decision making (OBOM, continuous) (post-visit)	-	SMD 0.30 lower (1.19 lower to 0.59 higher)	-	20 (1 randomized trial)	⊕◯◯◯ VERY LOW [c,f]	OPTION scale (0-100). Higher score indicates more shared decision making use. Intervention group included: education meeting (in shared decision-making skill) + audit and feed-back. Control group included: educational meeting (in risk communication skills) + audit and feed-back. One study was not included in the quantitative synthesis but reported significant positive results.
Shared decision making (PROM, continuous) (follow-up: up to 4 weeks)	-	SMD 0.24 higher (0.10 lower to 0.58 higher)	-	1459 (2 randomized trials)	⊕◯◯◯ VERY LOW [a,b,c,d]	Scales are: COMRADE (0-100) and SDM-Q. Higher score indicates more shared decision making use. In one study multifaceted intervention like educational meeting, audit and feedback, educational material and educational outreach visit increase the use of shared decision making compared to educational meeting alone (control group). In the second study, no differences were found between intervention and control groups.
Decision regret	-	-	-	-	-	No data available for this outcome
Health-related quality of life (physical)	-	-	-	-	-	No data available for this outcome
Health-related quality of life (mental)	-	-	-	-	-	No data available for this outcome

Consultation length	-	-	-	-	-	No data available for this outcome
Cost	-	-	-	-	-	No data available for this outcome

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

a. We downgraded the certainty of evidence by one level due to serious limitations in the design (most of the studies are at unclear risk of bias (≥ 50% of the studies are at unclear risk))

b. We downgraded the certainty of evidence by two levels due to unexplained high heterogeneity (I^2 ≥ 50% and P value for heterogeneity ≤ 0.05)

c. We downgraded the certainty of evidence by one level due to indirectness of evidence (important difference in populations)

d. We downgraded the certainty of evidence by one level due to imprecision (insufficient number of participants for one study and/or large confidence interval)
e. The low and high risk values are the two extreme percentages of events
f. We downgraded the certainty of evidence by two levels due to imprecision (insufficient number of participants for more than one study and large confidence interval)

GRADE: Grading of Recommendations Assessment, Development and Evaluation; OBOM: Observer-based outcome measures; PROMs: Patient-reported outcome measures; RD: Risk difference; SMD: Standardized mean difference.

Summary of findings 3. Interventions targeting healthcare professionals and patients compared to usual care or interventions of the same type for shared decision making

Interventions targeting healthcare professionals and patients compared to usual care or interventions of the same type for shared decision making					
Patient or population: healthcare professionals and patients **Settings:** Australia, Canada, Denmark, Germany, Norway, the Netherlands, UK, USA **Interventions:** intervention designed to improve shared decision making among healthcare professionals that target both healthcare professionals and patients (for example, a patient-mediated intervention combined with an intervention targeting healthcare professionals) **Comparison: u**sual care or interventions of the same type					
Outcomes	**Illustrative comparative risks* (95% CI)**		**Risk difference (95% CI)**	**No of Participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk	**Corresponding risk**				

	[control]	[experimental]				
a- Interventions targeting healthcare professionals and patients compared to usual care						
Shared decision making (OBOM, continuous) (follow-up : up to 3 months)	-	SMD 1.10 higher (0.42 higher to 1.79 higher)	-	1270 (6 randomized trials)	⊕◯◯◯ VERY LOW a,b,c,d,e	OPTION scale (0-100). Higher score indicates more shared decision making use.
Shared decision making (PROM, continuous) (follow-up: up to 6 weeks)	-	SMD 0.13 higher (0.02 lower to 0.28 higher)	-	1479 (7 randomized trials)	⊕◯◯◯ VERY LOW a,c,f	Scales are: Physicians' participatory decision making style (0-4), SDM-Q9 (0-100), COMRADE (0-100), Patient activation measure (0-100), Overall PSA SDM perception (5-20), CollaboRATE (0-100), Healthcare Climate Questionnaire (0-100). Higher score indicates more shared decision making use. Two studies were not included in the quantitative synthesis. One study reported an increase in the use of shared decision making for the intervention group and the second study did not report any differences between the study groups.
Shared decision making (PROM, categorical or dichotomous) (post-visit)	Study population		-0.01 (-0.20 to 0.19)	266 (2 randomized trials)	⊕◯◯◯ VERY LOW a,c,d,f	One study was not included in the quantitative synthesis and the results were consistent with the pooled results.
	41 per 100	36 per 100				
	Low risk population					
	36 per 100g	27 per 100				
	High risk population					
	48 per 100g	58 per 100				
Decision regret (follow-up : 3 months)	-	SMD 0.13 higher (0.08 lower to 0.33 higher)	-	369 (1 randomized trial)	⊕⊕◯◯ LOW a,c	Decision regret scale (0-100). Higher score indicates more regret after decision
Health-related quality of life (physical) (follow-up: 6 weeks)	-	SMD 0.08 higher (0.37 lower to 0.54 higher)	-	75 (1 randomized trial)	⊕◯◯◯ VERY LOW a,c,d	Scale are : Physical scale of SF-12 (0-100) and SF12v2 (0-100). Higher score indicate better quality of life.

Health-related quality of life (mental) (follow-up: 6 weeks)	-	SMD 0.01 higher (0.44 lower to 0.46 higher)	-	75 (1 randomized trial)	⊕◯◯◯ VERY LOW [a,c,d]	Scale are : Mental scale of SF-12 (0-100) and SF12v2 (0-100). Higher score indicate better quality of life.
Consultation length (minutes)	-	SMD 3.72 higher (3.44 higher to 4.01 higher)	-	536 (1 randomized trial)	⊕◯◯◯ VERY LOW [a,c,d]	
Cost	-	-	-	-	-	No data available for this outcome
b- Interventions targeting healthcare professionals and patients compared to intervention of the same type						
Shared decision making (OBOM, continuous) (post-visit)	-	SMD 0.29 lower (1.17 lower to 0.6 higher)	-	20 (1 randomized trial)	⊕◯◯◯ VERY LOW [a,c,d]	OPTION scale (0-100). Higher score indicates more shared decision making use.
Shared decision making (OBOM, categorical or dichotomous) (post-visit)	Study population		-0.04 (-0.13 to 0.04)	134 (1 randomized trial)	⊕◯◯◯ VERY LOW [c,d,h]	
	8 per 100	4 per 100				
	Low risk population					
	N/A	N/A				
	High risk population					
	N/A	N/A				
Shared decision making (PROM, continuous) (post-visit)	-	SMD 0.00 (0.32 lower to 0.32 higher)	-	150 (1 randomized trial)	⊕◯◯◯ VERY LOW [a,c,d]	CollaboRATE (0-100). Higher score indicates more shared decision making use.
Decision regret	-	-	-	-	-	No data available for this outcome
Health-related quality of life (physical)	-	-	-	-	-	No data available for this outcome
Health-related quality of life (mental)	-	-	-	-	-	No data available for this outcome
Consultation length	-	-	-	-	-	No data available for this outcome
Cost	-	-	-	-	-	No data available for this outcome

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

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a. We downgraded the certainty of evidence by one level due to serious limitations in the design (most of the studies are at unclear risk of bias (≥ 50% of the studies are at unclear risk))

b. We downgraded the certainty of evidence by two levels due to unexplained high heterogeneity (I^2 ≥ 50% and P value for heterogeneity ≤ 0.05)

c. We downgraded the certainty of evidence by one level due to indirectness of evidence (important difference in populations)

d. We downgraded the certainty of evidence by one level due to imprecision (insufficient number of participants for one study and/or large confidence interval)

e. We downgraded the certainty of evidence by one level due to possible publication bias

f. We downgraded the certainty of evidence by one level due to small heterogeneity (I^2 < 50% or I^2 ≥ 50% and P value > 0.05)

g. The low and high risk values are the two extreme percentage of events

h. We downgraded the certainty of evidence by two levels due to very serious limitations in the design (most of the studies are at high risk of bias (≥ 50%). Across studies, taking all low risk and unclear risk judgements together, there are ≥ 50% of unclear risk for our key domains.

GRADE: Grading of Recommendations Assessment, Development and Evaluation; OBOM: Observer-based outcome measures; PROMs: Patient-reported outcome measures; RD: Risk difference; SMD: Standardized mean difference.

BACKGROUND

Description of the condition

There is increasing recognition of the ethical imperative to share important decisions with patients (Salzburg Global Seminar 2011). Shared decision making (SDM) can be defined as an interpersonal, interdependent process in which health professionals, patients and their caregivers *relate to and influence each other as they collaborate in making decisions* about a patient's health (Charles 1997; Légaré 2011; Légaré 2013; Towle 1999). It is considered the crux of patient-centered care (Weston 2001). Briefly, SDM depends on knowing and understanding the best available evidence about the risks and benefits across all available options while ensuring that the patient's values and preferences are taken into account (Charles 1997; Elwyn 1999; Towle 1999).

Although SDM represents a complex set of behaviors that must be achieved by both members of the patient-healthcare professional dyad (LeBlanc 2009), it is possible to specify behaviors that both parties must adopt for SDM to occur in clinical practice (Frosch 2009; Légaré 2007a). A systematic review of SDM as a concept identified 161 definitions and summarized the key elements into one integrative model of SDM in medical encounters (Makoul 2006). This model identifies nine essential elements that can be translated into specific SDM-related behaviors that healthcare professionals need to demonstrate during consultations with patients:

- define and explain the healthcare problem,
- present options,
- discuss pros and cons (benefits, risks, costs),
- clarify patient values and preferences,
- discuss patient ability and self-efficacy,
- present what is known and make recommendations,
- check and clarify the patient's understanding,
- make or explicitly defer a decision, and
- arrange follow-up.

Description of the intervention

A variety of interventions have been designed to change healthcare professionals' behavior. Based on the Effective Practice and Organisation of Care (EPOC) taxonomy of interventions (EPOC 2015), these interventions aim at changing the performance of healthcare professionals through interactions with patients, or information provided by or to patients. Interventions may include, but are not limited to, the distribution of printed educational materials, educational meetings, audit and feedback, reminders, educational outreach visits and patient-mediated interventions. In the context of SDM it is possible to identify three overarching categories of implementation intervention: 1) interventions targeting patients, 2) interventions targeting healthcare professionals, and 3) interventions targeting both.

How the intervention might work

Theoretical and empirical evidence about behavior change in healthcare professionals (Godin 2008) and complex behavior change frameworks (Michie 2009) allow us to make certain hypotheses regarding the mechanisms by which interventions might promote SDM. For example, the distribution of printed educational materials may improve professionals' attitudes to SDM by reinforcing their intention to engage in SDM (Giguère 2012). The training of professionals in SDM through educational meetings may increase professionals' perceptions of self-efficacy, or their belief in their ability to succeed in a situation, which is one of the key determinants of behavior (Godin 2008). Patient-mediated interventions could be a discussion with a nurse, a patient education program, or a decision aid, for example. Decision aids are tools (they can be pamphlets or online modules) that help patients become involved in decision making. They help patients clarify the decision that needs to be made, and give information about options and outcomes. They also invite patients to articulate their personal values and preferences regarding the options (Stacey 2017). In turn, the habits of healthcare professionals may change when patients themselves take the initiative to engage more in the decision-making process, as this may increase health professionals' knowledge and use of emerging evidence in their area of expertise (Brouwers 2010).

Regarding the association between SDM and patient outcomes, some authors have shown that communication between healthcare professionals and patients, including SDM, can lead to improved health outcomes in direct but also in indirect ways (Street 2009). Thus, according to an adapted conceptual framework linking clinician-patient communication to health outcomes, SDM can have an impact on affective-cognitive outcomes (e.g. knowledge, understanding, satisfaction, trust), behavioral outcomes (treatment decisions, adherence to recommended treatments and adoption of health behaviors), as well as health outcomes (e.g. quality of life, self-rated health and biological measures of health) (Shay 2015).

Why it is important to do this review

Policy makers perceive SDM as desirable (Shafir 2012) because: a) patient involvement is accepted as a right (Straub 2008); b) patients in general want more information about their health condition and prefer to take an active role in decisions about their health (Alston 2012; Kiesler 2006); c) SDM may reduce the overuse of options not clearly associated with benefits for all and increase the use of options clearly associated with benefits for the vast majority of the concerned population (Mulley 2012); d) SDM may reduce unwarranted healthcare practice variations (Wennberg 2004); and e) SDM may foster the sustainability of the healthcare system by increasing patient ownership of their own health care (Coulter 2006).

Nonetheless, SDM has not yet been widely implemented in clinical practice. A systematic review of 33 studies using the Observing Patient Involvement in Decision Making instrument (OPTION) showed low levels of patient-involving behaviors (Couët 2013). The rationale for this review of interventions for increasing use of SDM among healthcare professionals is to determine what kinds of intervention have been shown to increase patient-involving behaviors among healthcare professionals.

This is the second update of a previously published Cochrane review. The review was first undertaken in 2010 (Légaré 2010) and updated in 2014 (Légaré 2014). As the demand for SDM training programs for healthcare professionals is increasing internationally (Diouf 2016), we considered a second update was important to keep abreast of developments.

OBJECTIVES

To determine the effectiveness of interventions for increasing the use of SDM by healthcare professionals. We considered interventions targeting patients, interventions targeting healthcare professionals, and interventions targeting both and compared them with usual care or other type of interventions by target group.

METHODS

Criteria for considering studies for this review

Types of studies

This review considered:

- randomized trials;
- non-randomized trials;
- controlled before-after studies (CBAs); and
- interrupted time series (ITS) analyses.

To be included as a CBA, the Cochrane EPOC group (Effective Practice and Organisation of Care) requires the study to have a minimum of two intervention sites and two control sites. For ITS studies, there needs to be a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention (EPOC 2017).

Types of participants

Participants could be any healthcare professional (e.g. physicians, nurses, pharmacists, social workers), including professionals in training (for example, medical residents). We defined professionals as being licensed or registered to practice or, in the case of physicians in training, as having completed their basic pre-licensure education. Participants could also be patients, including healthcare consumers and simulated patients. However, studies that included simulated patients were deemed eligible only if the outcome was observer-reported.

Types of interventions

We included studies that evaluated an intervention designed to increase the use of SDM. Interventions were organized into three target categories using the EPOC taxonomy of interventions (EPOC 2015):

- interventions targeting patients (for example, patient-mediated interventions);
- interventions targeting healthcare professionals (for example, distribution of printed educational material, educational meetings, audit and feedback, reminders and educational outreach visits);
- interventions targeting both patients and healthcare professionals (for example, a patient-mediated intervention combined with an intervention targeting healthcare professionals).

Patient decision aids were considered a patient-mediated intervention since one of their purposes is to foster patient participation in decisions during the clinical encounter (Stacey 2017). Studies that evaluated patient-mediated interventions (for example, patients' use of patient decision aids in preparation for or during their consultation with a healthcare professional) were considered only if these studies directly assessed the healthcare professional-related outcome of interest, that is their use of SDM (see Types of outcome measures).

Types of outcome measures

Primary outcomes

Use of SDM, using objective observer-based outcome measures (OBOMs) or patient-reported outcome measures (PROMs). OBOMs are instruments used by a third observer to capture the decision-making process during an encounter between a healthcare professional and a patient/family caregiver when facing health treatment or screening decisions. They are only used in the reporting of observable concepts (e.g. signs or behaviors). Unlike clinician-reported outcome measures, OBOMs are reported by people (e.g. teachers or caregivers) who do not have professional training relevant to the measurement being made (Velentgas 2013). PROMs are instruments that collect information directly from patients. The measurement is recorded without amendment or interpretation by a clinician or other observer. The measurement can be recorded by the patient directly, or recorded by an interviewer, provided that the interviewer records the patient's response exactly (Velentgas 2013).

Secondary outcomes

Patient outcomes

Affective-cognitive outcomes

- Knowledge
- Satisfaction (satisfaction with care, with the choice, with the decision-making process, with the intervention, helpfulness of the intervention)
- Decisional conflict
- Decision regret
- Patient-clinician communication
- Self-efficacy
- Empowerment

Behavioral outcomes

- Match between preferred and actual level of participation in decision making
- Match between preferred option and decision made
- Adherence to decision made

Health outcomes

- Health status (generic instrument types)
- Health-related quality of life (generic instrument types)
- Anxiety
- Depression
- Stress
- Distress

Process outcomes

- Consultation length
- Costs
- Equity

Adverse effects (potential harms of interventions)

Search methods for identification of studies

Electronic searches

We searched for studies published up to 15 June 2017. Searches were not restricted by language. The following electronic databases were searched for primary studies.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 5) in the Cochrane Library
- Health Technology Assessment Database (HTA; 2016, Issue 4) in the Cochrane Library
- NHS Economic Evaluation Database (NHSEED; 2015, Issue 2) in the Cochrane Library
- PubMed
- Embase Ovid (1974 to 14 June 2017)
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1980 to 15 June 2017)
- PsycINFO Ovid (1967 to June Week 1 2017)

All search strategies used are provided in Appendix 1.

Searching other resources

Trial registries

We searched:

- ClinicalTrials.gov, US National Institutes of Health (NIH) at http://clinicaltrials.gov/ (search performed in week 1, August 2017);
- World Health Organization International Clinical Trials Registry Platform http://apps.who.int/trialsearch/ (search performed in week 1, August 2017).

We also:

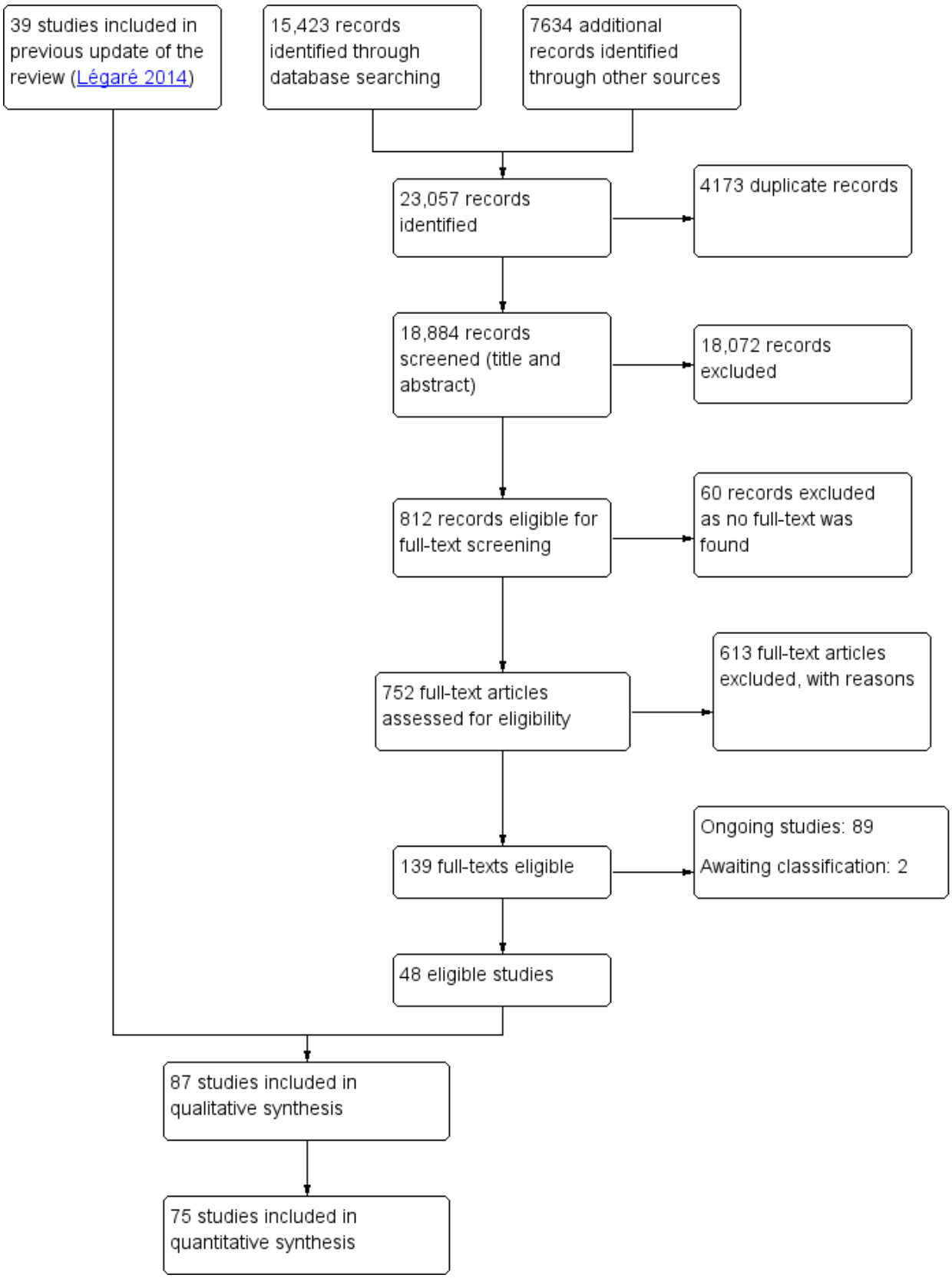
- handsearched the proceedings of the International Conference on Shared Decision Making (from 2003 to 2017)(Appendix 2);
- handsearched the proceedings of the annual North American meetings of the Society for Medical Decision Making (from 2004 to 2016) (Appendix 3); we intended to search the European Association for Communication in Healthcare (EACH) but were unable to obtain detailed information either online or in paper form);
- reviewed reference lists of all included studies, relevant systematic reviews (Appendix 4) and primary studies (Appendix 5); and
- contacted authors of relevant studies or reviews to clarify reported published information and to seek unpublished data.

Data collection and analysis

Selection of studies

Review author Rhéda Adekpedjou (RA), and graduate students Jessica Hébert (JH), Élodie Chenard (EC), Alexandrie Boucher (AB), Lionel Adisso (LA) - (see Acknowledgements) independently screened each title and abstract to find studies that met the inclusion criteria. Studies were only selected if published in English or French. We retrieved full-text copies of all studies that might be relevant or for which the inclusion criteria were not clear in the title or abstract. In this update, when more than one publication described the same study but each presented new and complementary data, we included them all. Any disagreements about selection were resolved by discussion with two review authors (ST, FL). For more details about study selection, see Figure 1.

Figure 1. Flow diagram of Cochrane update on interventions for increasing the use of shared decision making by healthcare professionals (up to 15 June 2017)



Data extraction and management

To extract data, we designed a form derived from the EPOC Review Group data collection checklist (EPOC 2017b). At least two review authors (including RA and ST) independently extracted data from eligible studies. We reached consensus about discrepancies, and any disagreement was adjudicated by discussion among the review authors (FL, RA, DS, ST, JK, IDG, AL, MCP, RT, GE, NDB). We entered data into Review Manager Software (RevMan 5) and checked for accuracy. When information regarding any of the above was unclear, we attempted to contact the study authors of to ask them to provide further details.

In addition to EPOC's standardized data collection checklist, we extracted the following characteristics of the settings and interventions.

- Level of care: primary or specialized care (as defined by the type of provider).
- Setting of care: ambulatory or non-ambulatory care (e.g. hospitalized patients in acute-care or long-term care facilities).
- Conceptual or theoretical underpinnings of the intervention (i.e. study authors stated that the intervention was based on a theory or at least referred to a theory).
- Barriers assessment (i.e. study authors stated that a barriers assessment was conducted and the intervention was designed to overcome identified barriers).
- Number of components included in the intervention based on the EPOC taxonomy (when a barriers assessment was mentioned it was considered a component of the intervention).

Assessment of risk of bias in included studies

At least two review authors (including RA and ST) independently assessed the risk of bias in each included study using the criteria outlined in the suggested risk of bias criteria for EPOC reviews (EPOC 2017c) and the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) for ITS designs. For blinding, incomplete data, and baseline outcome measurement, we assessed the primary outcomes and secondary outcomes that were selected for inclusion in the 'Summary of findings' table (see below for details of selection process). Any disagreement was resolved through discussion with FL. Each risk of bias criterion was assessed as 'Low risk', 'High risk' or 'Unclear'. The 10 standard criteria as suggested for all randomized trials and CBA studies are listed below.

- Random sequence generation (protection against selection bias)
- Concealment of allocation (protection against selection bias)
- Protection against contamination.
- Blinded assessment (protection against detection bias)
- Baseline outcome measurement
- Patient baseline characteristics
- Healthcare professional baseline characteristics
- Selective reporting outcome
- Incomplete data outcome
- Other risk of bias.

Measures of treatment effect

We structured data analysis using statistical methods developed for EPOC by Grimshaw and colleagues (Grimshaw 2004). For each study, we reported results for categorical and continuous primary outcomes separately and in natural units. When included studies assessed SDM using an adaptation of the Control Preference Scale (Degner 1992), we dichotomized into SDM versus no SDM (Légaré 2012).

For categorical measures, we calculated the difference in risk between the intervention of interest and the control intervention. We calculated standardized mean difference (SMD) for continuous measures by dividing the mean score difference of the intervention and comparison groups in each study by the pooled estimate standard deviation for the two groups. When possible, for categorical and continuous outcomes, we constructed 95% confidence intervals (CIs) to compare groups before and after the intervention, according to the recommendations in RevMan 5. The absence of a '0' value in the CI indicated that the baselines differed or that the intervention had a positive effect compared to the control intervention or to usual care. When the baseline was different between the two groups, we used the size of the difference and its associated standard error to compare them. When there were not enough quantitative data available to make these calculations, we extracted a direct quote from the primary study on the effectiveness of the intervention and on confounding factors, if available. When no baseline was reported, we considered groups to be similar prior to the intervention.

For the analysis, we divided the studies into six comparison categories: 1) interventions targeting patients compared with usual care; 2) interventions targeting healthcare professionals compared with usual care; 3) interventions targeting both patients and healthcare professionals compared with usual care; 4) interventions targeting patients compared with other types of interventions targeting patients; 5) interventions targeting healthcare professionals compared with other types of interventions targeting healthcare professionals; 6) interventions targeting both patients and healthcare professionals compared with other types of interventions targeting both patients and healthcare professionals.

We performed a meta-analysis if there were enough studies in each of the six comparison categories. When the study reported repeated measurements for an outcome for the same participants, only the measure closest in time to the consultation was kept in the meta-analysis. When studies with more than two arms reported several comparisons of different outcomes or different interventions, we kept only the comparisons that most reduced the heterogeneity of the comparison group in the meta-analysis. We considered a SMD of 0.2 as small, 0.5 as medium, and 0.8 as large (Cohen 1988).

Unit of analysis issues

We included cluster-randomized trials in the analyses along with individually-randomized trials. Comparisons that randomize or allocate clusters (groups of healthcare professionals or organizations) but do not account for clustering during the analysis have potential unit of analysis errors that can produce artificially significant P values and overly narrow CIs (Ukoumunne 1999). Therefore, when possible, we contacted study authors for missing information and attempted to re-analyze studies with potential unit

of analysis errors. When missing information was unavailable, we reported only the point estimate.

Assessment of heterogeneity

To explore heterogeneity, we designed tables that compared SMDs of the studies and their risk differences. We considered the following variables as potential sources of heterogeneity in the results of the included studies: type of intervention; characteristics of the intervention (e.g. duration); clinical setting (primary care versus specialized care); type of healthcare professional (physicians versus other healthcare professionals); level of training of healthcare professionals (e.g. in training versus in practice).

Data synthesis

We estimated a weighted intervention effect with 95% confidence intervals. For continuous measures, we used SMDs; for dichotomous outcomes, we calculated the risk difference. We analyzed all data with a random-effects model because of the diverse nature of the studies being combined and then anticipated variability in the populations and interventions of the included studies. We summarized all of the results for the primary and selected secondary outcomes and rated the strength of evidence using GRADE (Andrews 2013), and then presented these results in the 'Summary of findings' tables (Higgins 2011). As the non-randomized evidence has a high level of uncertainty and that there are few non-randomized trials, we reported only the results of randomized trials in the Summary of findings' tables. For studies not included in the quantitative synthesis, we assessed how their results could have impacted the pooled estimate of the effect size regarding the direction of the effect (Appendix 6).

'Summary of findings' tables

We evaluated the certainty of the evidence according to the GRADE guidelines (Guyatt 2011) and the methods described in Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). We assessed primary and selected secondary outcomes in all six comparison categories. For each outcome, we rated conclusions as follows:

- **high**: this research provides a very good indication of the likely effect; the likelihood that the effect will be substantially different is low;
- **moderate**: this research provides a good indication of the likely effect; the likelihood that the effect will be substantially different is moderate;
- **low**: this research provides some indication of the likely effect; however, the likelihood that it will be substantially different is high;
- **very low**: this research does not provide a reliable indication of the likely effect; the likelihood that the effect will be substantially different is very high).

From starting score of certainty of evidence according to the study design, we downgraded the rating if one or more of the five following criteria were present: study limitation, indirect evidence, inconsistency, imprecision of the observed effect and publication bias. A review author (RA) and a graduate student (AB) independently assessed the certainty of the evidence and reached consensus in collaboration with FL.

As the use of SDM is the only primary outcome of this review, we assessed this outcome using the GRADE approach and included it in the 'Summary of findings' tables. We used the method proposed in EPOC Worksheets (EPOC 2017d) to determine which secondary outcomes should be assessed and included in the 'Summary of findings' tables. First, the study co-authors generated a list of relevant secondary outcomes for the review. Then we independently selected outcomes important enough to be included in the 'Summary of findings' tables by rating them on a 9-point scale ranging from 1 (not important) to 9 (critical), and came to a consensus. Then we calculated the median of the scores we had attributed to each secondary outcome and agreed to include all that scored above 7. The selected secondary outcomes were: decision regret, health-related quality of life (mental and physical), consultation length and cost.

Subgroup analysis and investigation of heterogeneity

Analysis was pre-defined using a subgroup analysis approach, and we did not combine data from observer-based outcome measures (OBOMs) with patient-reported outcome measures (PROMs) as they measured different concepts. In addition, within each comparison category, we explored how individually-randomized trials compared to cluster-randomized trials regarding our primary outcome when applicable. We further investigated heterogeneity by exploring how the study design (cluster-randomized trials versus individually-randomized trials) affected statistical heterogeneity (Higgins 2011).

Sensitivity analysis

No sensitivity analysis were performed.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

We identified 23,057 new potentially relevant records and excluded 18,072 during abstract screening. We retrieved 752 full-text publications for more detailed screening and excluded another 613 records based on the identified inclusion criteria. We were not able to find the full text of 60 records for assessment . We included 87 studies in the review, 48 of which were newly identified for this update (Figure 1).

Included studies

This update search added 48 new studies (Adarkwah 2016; Almario 2016; Ampe 2017; Barton 2016; Branda 2013; Causarano 2014; Cooper 2013; Cox 2017; Coylewright 2016; Davison 2002; Eggly 2017; Epstein 2017; Feng 2013; Fiks 2015; Hamann 2011; Hamann 2014; Hamann 2017; Härter 2015; Hess 2016; Jouni 2017; Kennedy 2013; Koerner 2014; Köpke 2014; Korteland 2017; LeBlanc 2015a; LeBlanc 2015b; Maclachlan 2016; Maindal 2014; Maranda 2014; Mathers 2012; Perestelo-Perez 2016; Pickett 2012; Rise 2012; Sanders 2017; Schroy 2016; Sheridan 2012; Sheridan 2014; Smallwood 2017; Tai-Seale 2016; Thomson 2007; Tinsel 2013; van der Krieke 2013; van Roosmalen 2004; van Tol-Geerdink 2016; Vestala 2013; Warner 2015; Wilkes 2013; Wolderslund 2017) to the 39 original studies for a total of 87 studies.

We identified 89 ongoing studies through trial registration databases, proceedings of conferences and protocols published in electronic databases (see Characteristics of ongoing studies). For two studies, we were unable to decide whether to include them or not because not enough information was available (See Characteristics of studies awaiting classification).

All the studies were randomized trials except for four: three non-randomized controlled trials (Almario 2016; Barton 2016; Deinzer 2009) and a controlled before-after study (CBA) (Ampe 2017). Among the randomized trials, 21 were cluster-randomized trials (Branda 2013; Cox 2017; Elwyn 2004; Epstein 2017; Feng 2013; Hamann 2007; Haskard 2008; Kennedy 2013; Koerner 2014; LeBlanc 2015a; Légaré 2012; Loh 2007; Mathers 2012; O'Cathain 2002; Perestelo-Perez 2016; Sanders 2017; Tai-Seale 2016; Tinsel 2013; van Roosmalen 2004; Wetzels 2005; Wilkes 2013).

Settings and participants

Of the 87 included studies, 44 evaluated interventions targeting patients, 15 evaluated interventions targeting health professionals, and 28 targeted both patients and health professionals. The four most represented countries were the USA (37 studies), Germany (15 studies) and Canada (eight studies) and the Netherlands (eight studies). There were two studies by international collaborations. The level of care was primary care in 44 studies, specialized care in 36 studies and both primary and specialized care in one study. In six studies, the level of care was unclear. In 49 studies, the healthcare professionals involved were licensed; in 16 studies they were licensed and in training; in 22 studies their level of training was unclear. The three most frequent clinical conditions studied were cancer (22 studies), cardiovascular diseases (14 studies) and psychiatric conditions (11 studies) (see Characteristics of included studies).

Target categories

Interventions targeting patients (44 studies)

Most of the 44 studies of interventions targeting patients were conducted in Europe or the USA (36 studies). There was one study from Africa. Specialized care was the most frequent care setting (22 studies), and all but eight studies were conducted in and recruited patients in an ambulatory setting. Studies varied greatly regarding the number of patients involved, ranging from 26 (Lalonde 2006) to 913 (Hess 2016). Most of the studies did not report the number of healthcare professionals involved. The most common clinical conditions were oncologic (14 studies), cardiovascular (eight studies) and psychiatric (six studies).

Interventions targeting healthcare professionals (15 studies)

The majority of the studies of interventions targeting healthcare professionals were conducted in Europe or the USA (14 studies). There was one study by an international collaboration. The care setting was mainly primary care (11 studies), with most of the participants recruited in ambulatory care (11 studies). Among the 12 studies that used non-simulated patients, the number of patients involved ranged from 298 (Cox 2017) to 10,070 (O'Cathain 2002). Two studies did not report the number of patients involved, and three did not report the number of healthcare professionals involved. The clinical condition was different in every study.

Interventions targeting both patients and healthcare professionals (28 studies)

The majority of the 28 studies of interventions targeting both patients and healthcare professionals were conducted in Europe or the USA (27 studies). There was one study by an international collaboration. The most common care setting was primary care (16 studies), with most of the participants recruited in ambulatory care (23 studies). Among the 26 studies that used non-simulated patients, a total of 12,078 patients were enrolled, with a minimum of 60 (Fiks 2015) and a maximum of 4349 (Wolderslund 2017). Twenty-five studies reported participating healthcare professionals, ranging from 10 per study (Bieber 2006) to 156 per study (Haskard 2008).The most common clinical condition was cancer (seven studies), followed by cardiovascular diseases (four studies), psychiatric conditions (four studies) and type-2 diabetes (four studies).

Characteristics of interventions and comparisons

Some studies reported more than one comparison. For such studies, we extracted only data for the comparisons that corresponded to one or more of the six comparison categories in our review. In each category of comparison, no study was counted twice for the analysis. For details, see Characteristics of included studies.

Interventions targeting patients

Twenty-four studies compared interventions targeting patients with usual care (Almario 2016; Cooper 2011; Deen 2012; Eggly 2017; Hamann 2014; Haskard 2008; Korteland 2017; Krist 2007; Landrey 2012; LeBlanc 2015a; LeBlanc 2015b; Maclachlan 2016; Maranda 2014; Murray 2001; van Peperstraten 2010; Perestelo-Perez 2016; Pickett 2012; Sheridan 2014; Tai-Seale 2016; van der Krieke 2013; van Tol-Geerdink 2016; Vestala 2013; Vodermaier 2009; Wolderslund 2017). All but one study compared patient-mediated interventions to usual care. Patient-mediated interventions included decision aids, patient activation, question prompt lists and training for patients. The interventions were administered alone (single interventions) or in combination (multifaceted intervention).

Twenty-eight studies presented comparisons of interventions targeting patients with other interventions targeting patients (Adarkwah 2016; Barton 2016; Butow 2004; Causarano 2014; Davison 1997; Davison 2002; Deen 2012; Deschamps 2004; Dolan 2002; Eggly 2017; Hamann 2011; Hamann 2017; Jouni 2017; Kasper 2008; Köpke 2014; Krist 2007; Lalonde 2006; Montori 2011; Nannenga 2009; Raynes-Greenow 2010; Schroy 2011; Schroy 2016; Smallwood 2017; Stiggelbout 2008; Street 1995; Thomson 2007; van Roosmalen 2004; Wolderslund 2017). Of these, 18 studies compared a single intervention (these included decision aid, consultation preparation package, empowerment sessions, brochure, training of patients in shared decision making (SDM), interactive-4-hour education program, literacy-appropriate medication guide) to another single intervention (these included decision aid, booklets, information packages, patient activation, pamphlets, cognitive training, 4-hour Multiple Sclerosis specific stress management program, existing medication guide); 10 studies compared a multifaceted intervention (these included decision aid and patient activation, decision aid and literacy-appropriate medication guide, decision aid and risk assessment tool, question prompt list and assistance of a

communication coach) to a single intervention (these included decision aid, question prompt list, literacy-appropriate medication guide, existing medication guide) and three studies compared a multifaceted intervention (these included decision aid and information booklet about immunotherapy, conventional risk and genetic risk information and decision aid) to another multifaceted intervention (these included decision aid and standard information package, conventional risk information and decision aid).

Four studies reported basing their intervention on a barriers assessment (Hamann 2011; Jouni 2017; Korteland 2017; van Peperstraten 2010).

Interventions targeting healthcare professionals

Fifteen studies compared interventions targeting the healthcare professionals with usual care (Ampe 2017; Bernhard 2011; Cooper 2011; Cox 2017; Fossli 2011; Kennedy 2013; Koerner 2014; LeBlanc 2015b; Légaré 2012; O'Cathain 2002; Sanders 2017; Shepherd 2011; Stacey 2006; Tinsel 2013; Wilkes 2013). Of these, seven studies compared a single intervention (educational meeting, distribution of educational material, educational outreach visit, and reminder) to usual care and eight studies compared a multifaceted intervention (educational meeting and audit and feed-back; educational meeting and distribution of educational material; educational meeting and audit and feedback and distribution of educational material; distribution of educational materials and educational meeting and audit and feedback and barriers assessment) to usual care.

Two studies compared an intervention targeting the healthcare professional (educational meeting, reminder) with one targeting the patient (decision aid, patient coaching by community health workers) (Cooper 2011; LeBlanc 2015b).

Three studies compared interventions targeting the healthcare professional with other interventions targeting the healthcare professional (Elwyn 2004; Feng 2013; Krones 2008 (ARRIBA-Herz)). Of these, one study compared a multifaceted intervention (educational meeting and audit and feedback focusing on SDM skills) to another multifaceted intervention (educational meetings and audit and feedback focusing on risk communication skills), one study compared a single intervention (distribution of educational material) to another single intervention (distribution of educational material), and one study compared a multifaceted intervention (educational meeting, audit and feedback, distribution of educational material, and an educational outreach component) to a single intervention (educational meeting).

Four studies reported the performance of a barriers assessment and based their interventions on the identified barriers (Ampe 2017; Bernhard 2011; Murray 2010; Stacey 2006).

Interventions targeting both patients and healthcare professionals

Seventeen studies compared an intervention targeting patients and healthcare professionals with usual care (Branda 2013; Cooper 2011; Coylewright 2016; Epstein 2017; Hamann 2007; Härter 2015; Haskard 2008; Hess 2012; Hess 2016; Leighl 2011; Loh 2007; Mathers 2012; Murray 2010; Rise 2012; Tai-Seale 2016; Wetzels 2005; Wilkes 2013). Of these, 11 studies presented interventions that used educational meetings and patient-mediated interventions; one study presented a patient-mediated intervention with educational outreach visits; one study presented an arm with an intervention that used a combination of a patient-mediated intervention, distribution of educational material and educational meetings (Haskard 2008); one study presented an arm with a patient-mediated intervention and a distribution of educational material (Wilkes 2013); one study presented an arm with a patient-mediated intervention and a reminder; one study presented an arm with a combination of educational meeting, audit and feedback, distribution of educational material, educational outreach visit and barriers assessment; one study presented interventions that used educational meetings, patient-mediated interventions and distribution of educational material.

Seven studies compared interventions targeting both patients and healthcare professionals with interventions targeting patients alone (Bieber 2006; Cooper 2011; Deinzer 2009; Mullan 2009; Sheridan 2012; Tai-Seale 2016; Warner 2015). Of these, six studies compared educational meetings and patient-mediated interventions with patient-mediated interventions alone; one study compared interventions that used educational meetings, patient-mediated interventions and distribution of educational material with patient-mediated interventions alone.

Five studies compared interventions targeting both patients and healthcare professionals with interventions targeting healthcare professionals alone (Cooper 2011; Feng 2013; Fiks 2015; Maindal 2014; Roter 2012). Of these, two studies compared patient-mediated interventions and the distribution of educational materials with the distribution of educational materials alone; two study compared educational meetings and patient-mediated interventions with educational meetings alone; and one study compared patient-mediated interventions and reminders with reminders alone.

Three studies compared an intervention targeting both patients and healthcare professionals with another intervention targeting both patients and healthcare professionals (Cooper 2013; Myers 2011; Tai-Seale 2016). Of these, one study compared a multifaceted intervention including a patient-mediated intervention, educational outreach visit, distribution of educational material and audit and feedback with another multifaceted intervention including a patient-mediated intervention, educational outreach visit and distribution of educational material; one study compared a multifaceted intervention including a patient-mediated intervention and reminders with another multifaceted intervention also including a patient-mediated intervention and reminders; and one study compared a multifaceted intervention including educational meetings, patient-mediated interventions and distribution of educational material with another multifaceted intervention including educational meetings, patient-mediated interventions and distribution of educational material.

Three studies reported the performance of a barriers assessment and based its interventions on identified barriers (Cooper 2013; Coylewright 2016; Epstein 2017).

Conceptual framework

Thirty-one out of the 87 studies included in this update used or referred to a conceptual framework. Six studies referred to the Ottawa Decision Support Framework (Causarano 2014; Murray 2010; Raynes-Greenow 2010; Schroy 2011; Stacey 2006; van Peperstraten 2010); two studies referred to the RE-AIM framework

(Reach, Effectiveness, Adoption, Implementation, Maintenance) (Branda 2013; LeBlanc 2015a); two studies referred to the Four Habits model (Fossli 2011; Tai-Seale 2016); and two studies referred to the UKMRC framework (Medical Research Council guidance) (Köpke 2014; Mathers 2012). Five studies used a conceptual model but did not describe it (Bernhard 2011; Butow 2004; Hamann 2011; Hamann 2014; Loh 2007). The 14 other studies each referred to a different conceptual model, including the 4E Model (Haskard 2008); the Empowerment Model by Conger and Kanungo (Davison 1997); the LEAPS (Listen, Educate, Assess, Partner and Support) framework (Roter 2012); the Markov Model (Stiggelbout 2008); the Model of Interpersonal Interaction (Elwyn 2004); the SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) (Wetzels 2005); the Theory of Planned Behaviour (Légaré 2012); the Framework for Accountable Decision-Making (FADM) (Maranda 2014); the Integrative Theory, Protection Motivation Theory and Self-Determination Theory (Sheridan 2014); the WISE (Whole System Informing Self-management Engagement) Model (Kennedy 2013); the NIH PROMIS framework (Almario 2016); the three-step model for SDM (Ampe 2017); the Systems Engineering Initiative for Patient Safety (SEIPS) Model (Cox 2017); and the Bandura's social cognitive theory of self-efficacy (Maclachlan 2016) .

Outcome measures

Primary outcome (use of shared decision making)

Of 87 studies, 59 reported patient-reported outcome measures (PROMs), 19 reported observer-based outcome measures (OBOMs), and nine reported both OBOMs and PROMs. PROMs were used to measure patient or family caregiver's self-reported experiences of participating in the decision-making process when facing health treatment or screening decisions. Among 68 studies using PROMs, 30 unique scales or subscales were used to measure the use of SDM from a patient'S perspective. In 29 studies, PROMs were the "perceived level of control in decision making" or "role assumed during the consultation" (adaptation of the Control Preference Scale (Degner 1992). Two other PROMs were the SDMQ-9 (Kriston 2010), and the Patient Activation Measure (PAM) (Hibbard 2004; Hibbard 2005). Twenty-seven additional unique scales or subscales were used in the studies analyzed. For more details, see Characteristics of included studies. Among the 28 studies that used OBOMs, 16 unique scales or subscales were used to measure the use of SDM from an observer-based perspective. Study authors reporting observer-based outcomes used the OPTION scale (Elwyn 2003) in 15 studies, and OPTION-5 (Barr 2015) in two studies. Fourteen additional unique scales or subscales were used in the studies analyzed. For more details, see Characteristics of included studies.

Secondary outcomes

Study authors reported most on affective-cognitive outcomes, followed by health outcomes, behavioral outcomes and process outcomes. Adverse events were seldom reported. None of the studies assessed distress or equity.

Excluded studies

After full-text assessment of articles for eligibility, we initially excluded 613 articles. The reasons for exclusion were related to the design of the study, the type of participants, the type of outcome measure, the content of the intervention, and the language. Main reasons for exclusion of the 39 studies listed in Excluded studies are presented under Characteristics of excluded studies.

Risk of bias in included studies

Further details on the ratings and rationale for risk of bias are in the 'Risk of bias' tables in the Characteristics of included studies tables and displayed in Figure 2 and Figure 3. The 'Risk of bias' assessment reported there was based on the primary outcome only.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

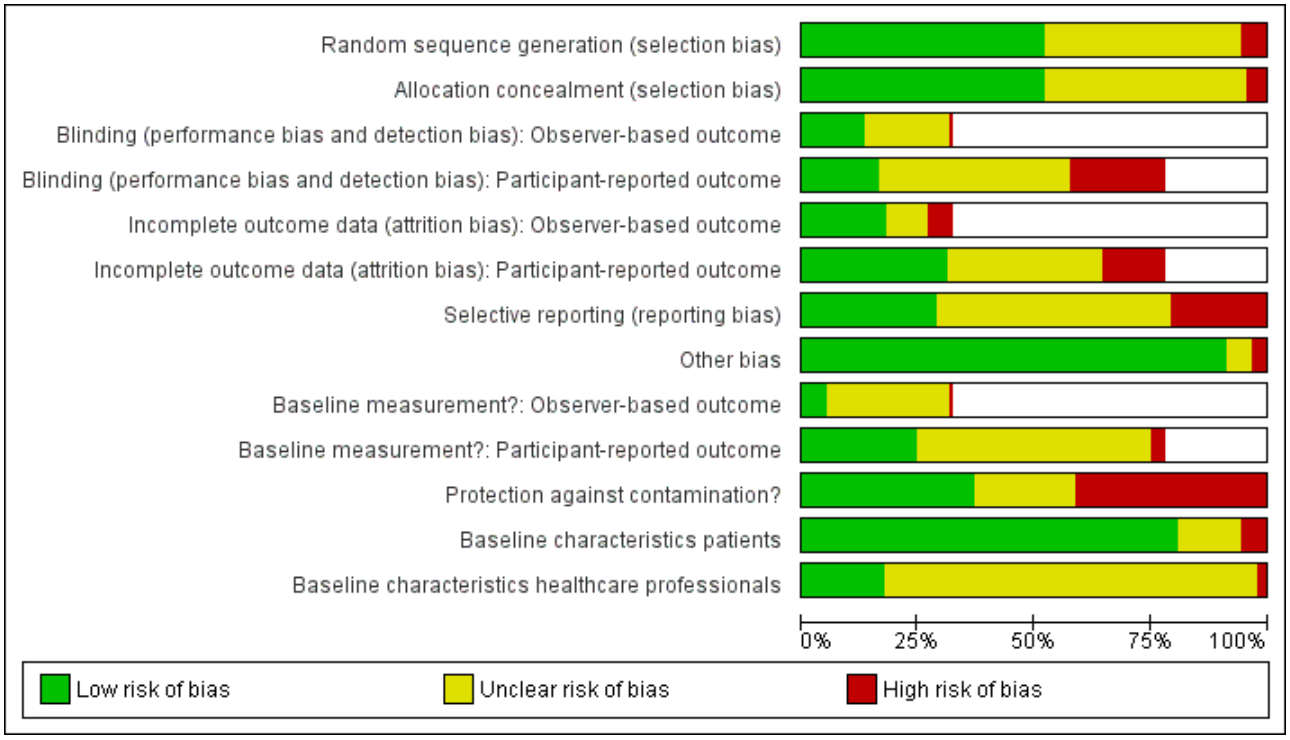


Figure 3. 'Risk of bias' summary for each included study.

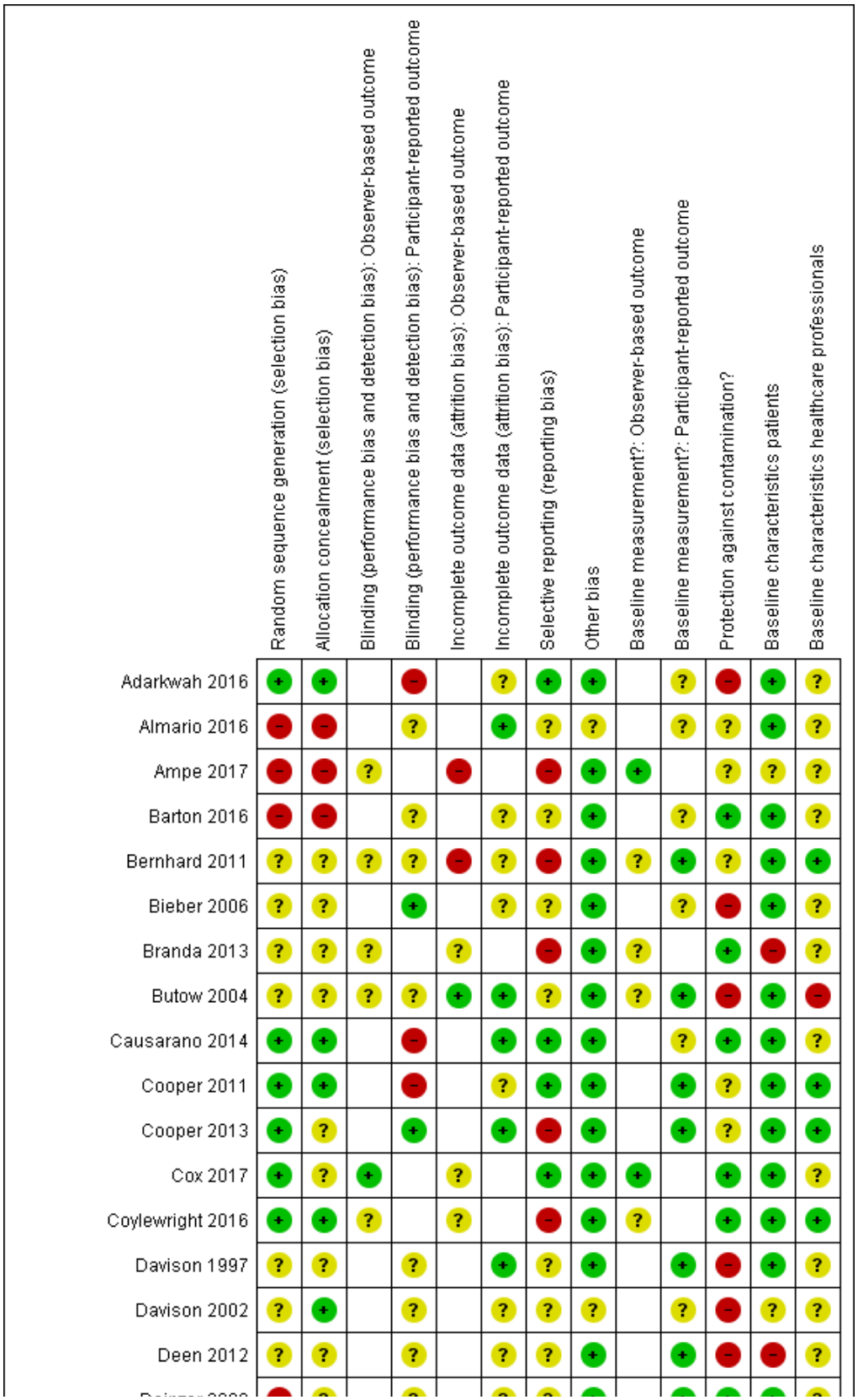


Figure 3. (Continued)

Figure 3. (Continued)

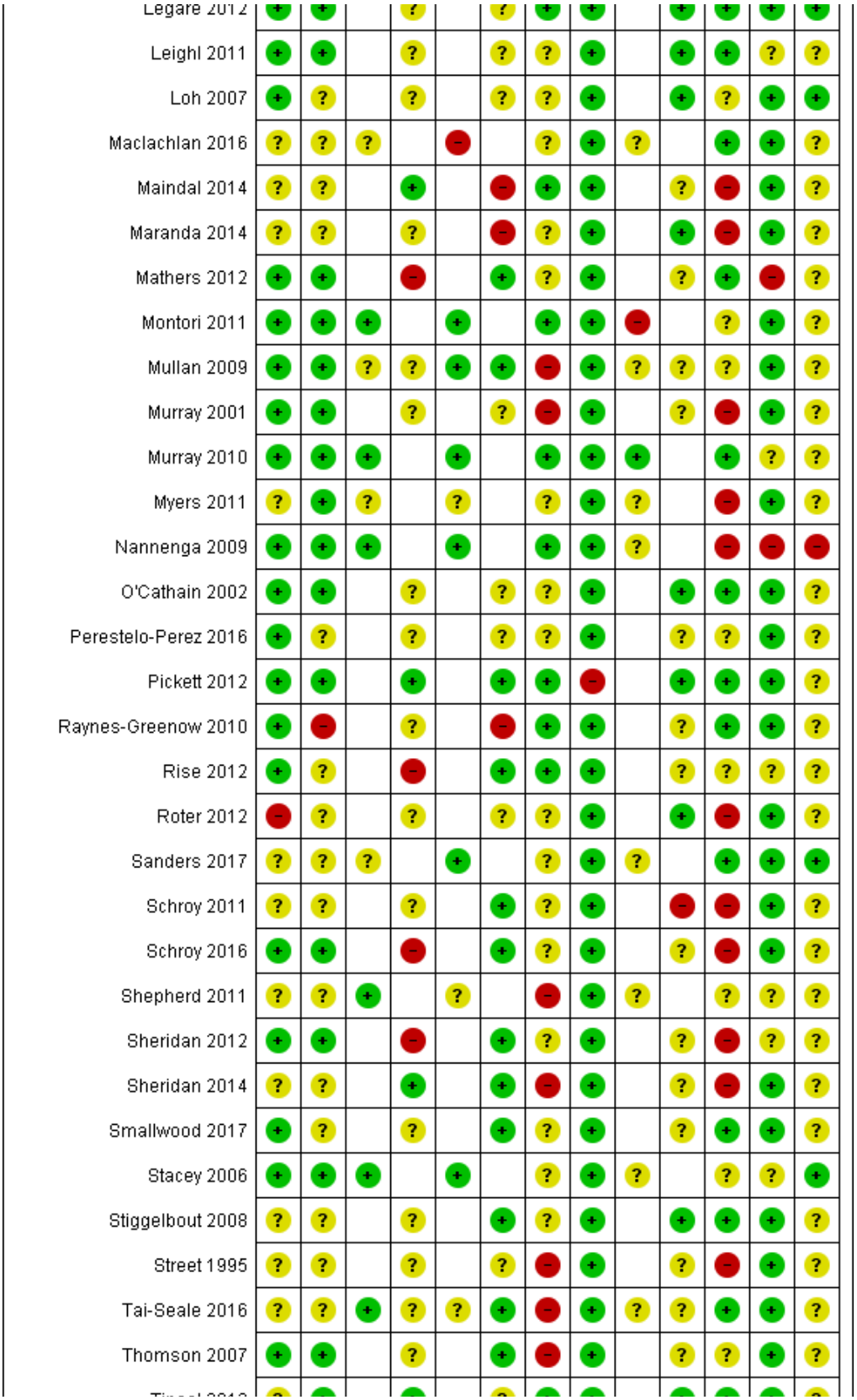
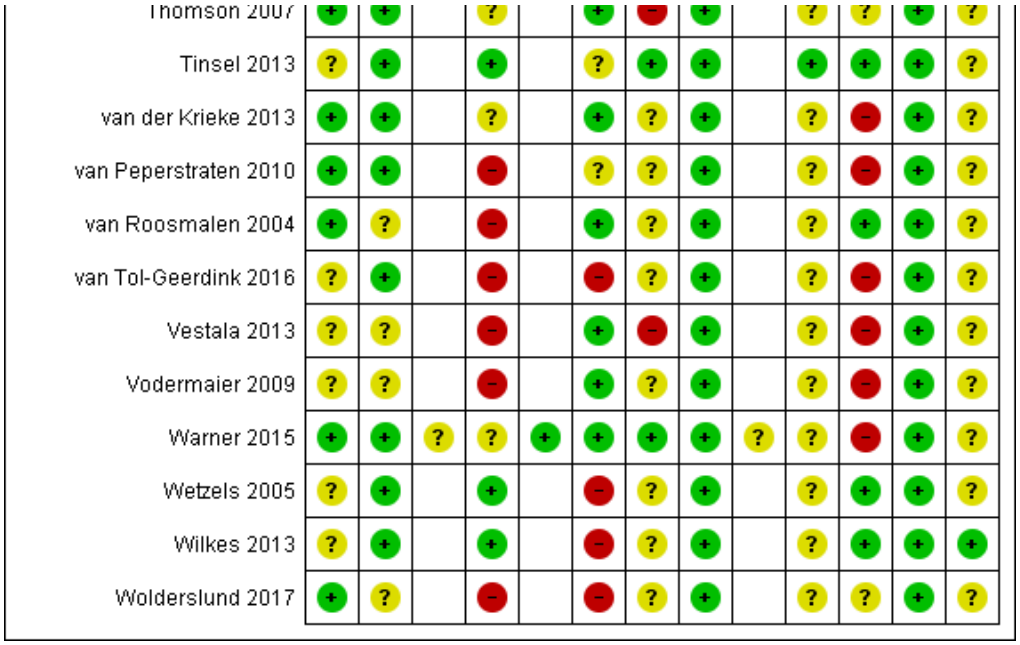


Figure 3. (Continued)



Allocation

Allocation concealment was rated as being at low risk of bias in 44 of 87 studies (51%), unclear risk of bias in 38 studies (44%) and high risk of bias in five studies (6%) .

Blinding

For assessing risk of detection bias in the 28 studies that used observer-based outcome measures (OBOMs), blinding was rated as being at low risk of bias in 11 studies (39%), unclear risk in 16 studies (57%) and high risk in one study (4%). In the 68 studies that used patient-reported outcome measures (PROMs), blinding was rated as being at low risk of bias in 14 studies (21%), unclear risk in 36 studies (53%) and high risk in 18 studies (26%).

Incomplete outcome data

Of the 28 studies that used OBOMs, incomplete outcome data were rated as being at low risk of bias in 15 studies (53%), unclear risk in eight studies (29%) and high risk in five studies (18%). Of the 68 studies that used PROMs, incomplete outcome data were rated as being at low risk of bias in 27 studies (40%), unclear risk in 29 studies (42%) and high risk in 12 studies (17%).

Selective reporting

For assessing risk of reporting bias, selective outcome reporting was rated as being at low risk of bias in 25 of 87 studies (29%), unclear risk in 44 studies (50%) and high risk in 18 studies (21%).

Other potential sources of bias

Among the 87 studies, in 79 studies other risks of bias were rated as low (91%), in five studies they were unclear (6%) and in three studies they were high (3%).

Effects of interventions

See: **Summary of findings for the main comparison** Interventions targeting patients compared to usual care or interventions of the same type for shared decision making; **Summary of findings 2** Interventions targeting healthcare professionals compared to usual care or interventions of the same type for shared decision making; **Summary of findings 3** Interventions targeting healthcare professionals and patients compared to usual care or interventions of the same type for shared decision making

Please refer to Summary of findings for the main comparison, Summary of findings 2, Summary of findings 3, Data and analyses,Table 1, Table 2, Table 3, Table 4, Table 5, Table 6, Table 7, Table 8, Table 9, Table 10, Table 11, Table 12, Figure 4, Figure 5, Figure 6, Appendix 8, Appendix 9 and Appendix 6 for detailed results.

Figure 4. Funnel plot of comparison: 1 Group 1: Interventions targeting patients compared to usual care, outcome: 1.2 Shared decision making (PROM, continuous).

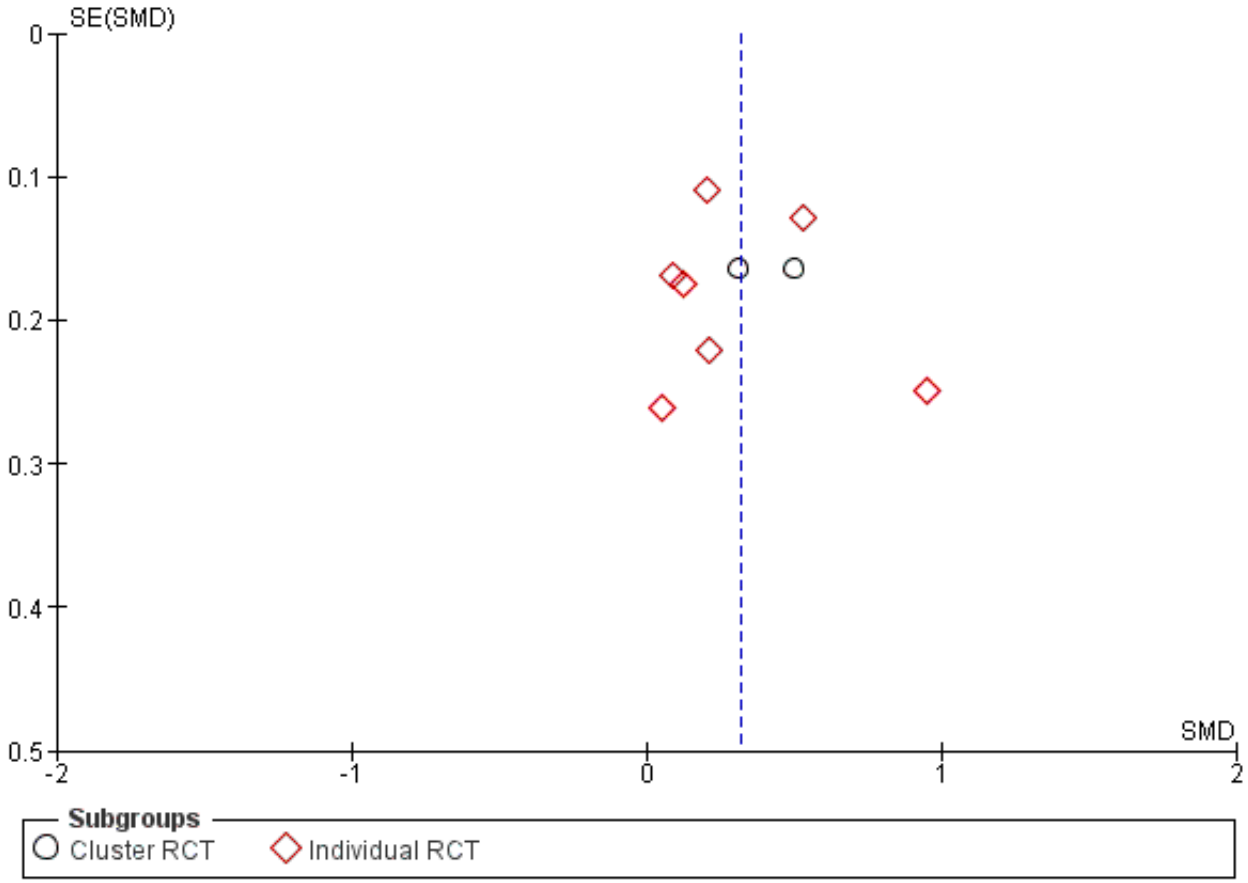


Figure 5. Funnel plot of comparison: 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, outcome: 4.2 Shared decision making (PROM, continuous).

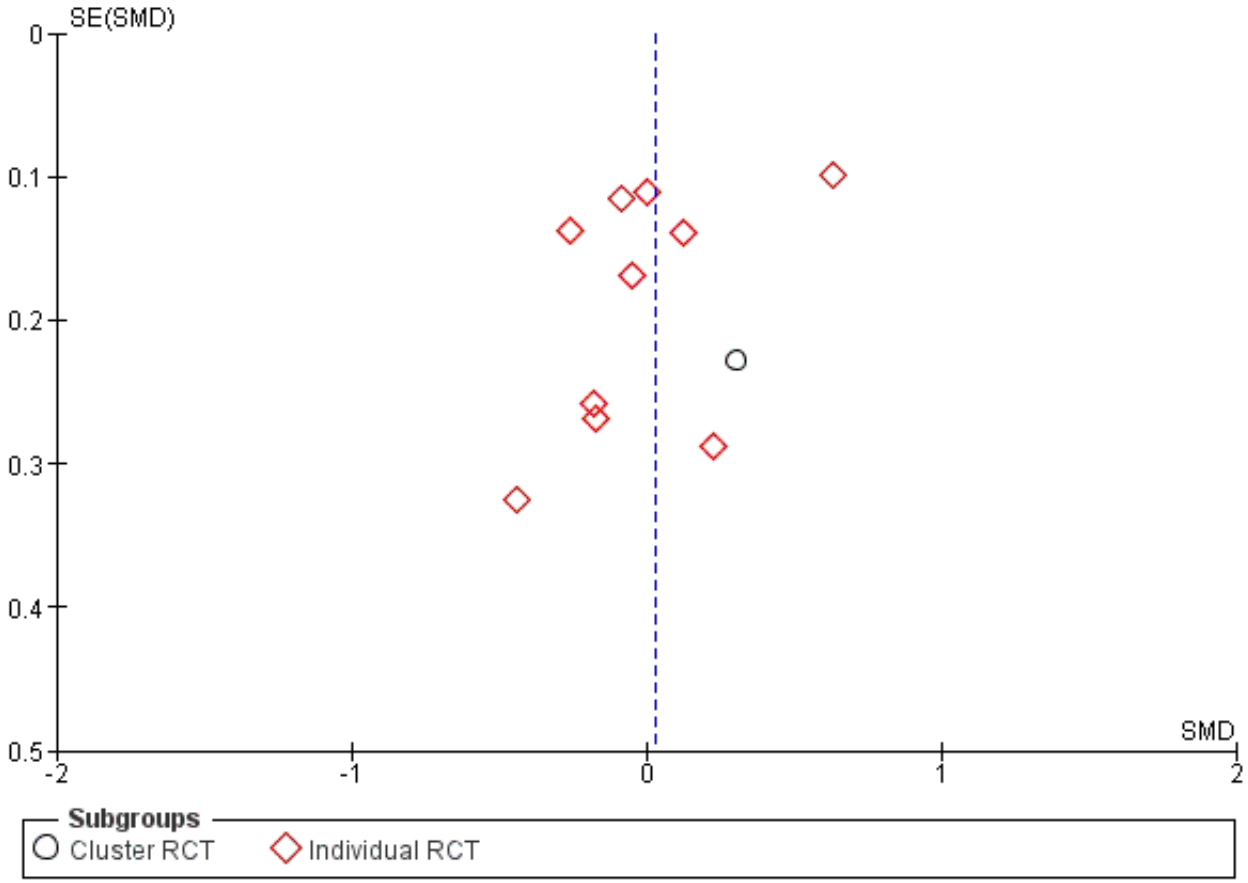
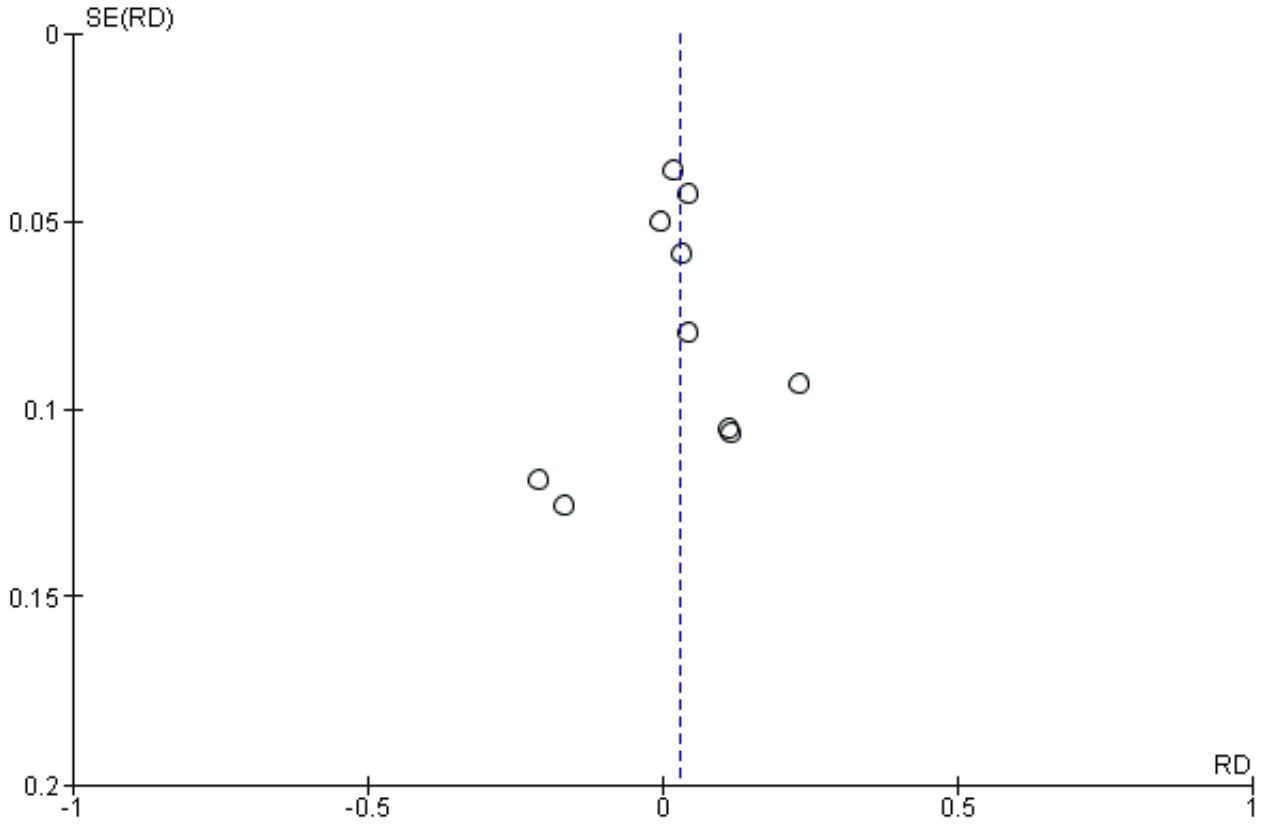


Figure 6. Funnel plot of comparison: 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, outcome: 4.6 Shared decision making (PROM, categorical).



Primary outcome - Shared decision making

Observer-based outcome measures (OBOMs) studies: comparisons with usual care

We are uncertain whether interventions increase the use of shared decision making (SDM) among healthcare professionals compared with usual care as measured by continuous OBOMs, as the certainty of the evidence was very low for all the six comparisons included in the review.

Interventions targeting patients versus usual care (six studies)

Six studies reported on seven continuous OBOMs of shared decision-making (Hamann 2014; Haskard 2008; LeBlanc 2015a; LeBlanc 2015b; Maclachlan 2016; Tai-Seale 2016). (Analysis 1.1; four studies, 424 observations, very low-certainty evidence). The estimate of the standardized mean difference (SMD) was 0.54 (95% confidence interval (CI): -0.13 to 1.22). A unit of analysis error was observed in one study, and so we could not estimate the effect size (Haskard 2008).

Interventions targeting healthcare professionals versus usual care (nine studies)

Eight randomized studies reported on seven continuous OBOMs of shared decision-making (Bernhard 2011; Cox 2017; Fossli 2011; LeBlanc 2015b; Murray 2010; Shepherd 2011; Sanders 2017; Stacey 2006). (Analysis 2.1; six studies, 479 observations, very low-certainty evidence). The pooled estimate of the SMD was 0.70 (95% CI: 0.21 to 1.19) in observer-reported SDM in favor of the group that received the intervention. We are uncertain whether the intervention increases SDM as measured by continuous OBOMs as the certainty of the evidence was very low. The two randomized studies not included in the meta-analysis reported that outcomes improved after exposure of study participants to the intervention (Bernhard 2011; Murray 2010).

One controlled before and after study (Ampe 2017) showed an effect size (SMD) of -0.10 (95% CI: -0.96 to 0.76) (Analysis 2.2; one study, 21 observations, very low-certainty evidence).

Interventions targeting both patients and healthcare professionals versus usual care (seven studies)

Seven studies reported on five continuous OBOMs of shared decision-making (Branda 2013; Coylewright 2016; Härter 2015; Haskard 2008; Hess 2012; Hess 2016; Tai-Seale 2016). Data from six studies were available for meta-analysis (Analysis 3.1; six studies, 1270 observations, very low-certainty evidence). The pooled estimate of the SMD was 1.10 (95% CI: 0.42 to 1.79) in observer-reported SDM in favor of the group that received the intervention, although we cannot be certain of the effect estimate due to the very low certainty of the evidence. A unit of analysis error was observed in one study and so we could not estimate the effect size (Haskard 2008).

Patient-reported outcome measures (PROMs) studies: comparisons with usual care

We are uncertain whether interventions increase the use of SDM among healthcare professionals compared with usual care as measured by PROMs, as the certainty of the evidence was very low for the six comparisons included in the review.

Interventions targeting patients versus usual care (19 studies)

Eleven randomized studies reported on 10 continuous PROMs (Cooper 2011; Deen 2012; Eggly 2017; Hamann 2014; Maranda 2014; Perestelo-Perez 2016; Pickett 2012; van der Krieke 2013; van Peperstraten 2010; Tai-Seale 2016; Vodermaier 2009). Data from nine studies were available for meta-analysis (Analysis 1.2; nine studies, 1386 patients, very low-certainty evidence). The pooled estimate of the SMD was 0.32 (95% CI: 0.16 to 0.48) in patient-perceived SDM in favor of the group that received the intervention, although we have very little confidence in the effect estimate due to the very low-certainty of the evidence. One of the two randomized studies not included in the meta-analysis did not report that outcomes improved after exposure of study participants to the intervention (Hamann 2014); the other study did not provide data (Vodermaier 2009).

One non-randomized study reported on one continuous PROM (Almario 2016) and showed an effect size (SMD) of 0.02 (95% CI: -0.21 to 0.25) (Analysis 1.3; one study, 303 patients, very low-certainty evidence).

Nine studies reported on two categorical PROMs (Korteland 2017; Krist 2007; Landrey 2012; Murray 2001; Sheridan 2014; van Tol-Geerdink 2016; Vestala 2013; Vodermaier 2009; Wolderslund 2017). Data from six studies were available for meta-analysis (Analysis 1.4; six studies, 754 patients, very low-certainty evidence). We calculated a 0.09 reduction in the pooled estimate of the risk difference (RD) for these outcomes (95% CI: -0.19 to 0.01). The certainty of the evidence was very low. Among the three studies not included in the meta-analysis, two studies reported that outcomes improved after exposure of study participants to the intervention (van Tol-Geerdink 2016; Wolderslund 2017), and one study found little or no improvement (Korteland 2017).

Interventions targeting healthcare professionals versus usual care (eight studies)

Six studies reported on five continuous PROMs (Cooper 2011; Kennedy 2013; Koerner 2014; Légaré 2012; Tinsel 2013; Wilkes 2013). Data from five studies were used for meta-analysis (Analysis 2.3; five studies, 5772 patients, very low-certainty evidence). The pooled estimate of the SMD was 0.03 (95% CI: -0.15 to 0.20). The one study not included in the meta-analysis reported that outcomes improved after exposure of study participants to the intervention (Légaré 2012).

Three studies reported on one categorical PROM (Bernhard 2011; Légaré 2012; O'Cathain 2002). Data from two studies were available for meta-analysis (Analysis 2.4; two studies, 6303 patients, very low-certainty evidence). The pooled estimate of the RD was 0.01 (95%CI: -0.03 to 0.06). The one study not included in the meta-analysis did not report improvement after exposure of study participants to an intervention (Bernhard 2011).

Interventions targeting both patients and healthcare professionals versus usual care (11 studies)

Ten studies reported on 11 continuous PROMs (Cooper 2011; Epstein 2017; Härter 2015; Hamann 2007; Leighl 2011; Loh 2007; Rise 2012; Tai-Seale 2016; Wetzels 2005; Wilkes 2013). Data from seven studies were available for meta-analysis (Analysis 3.2; seven studies, 1479 patients, very low-certainty evidence). The pooled estimate of the SMD was 0.13 (95% CI: -0.02 to 0.28). One of the studies not included in the meta-analysis reported that outcomes improved after exposure of study participants to the intervention (Loh 2007).

Two studies reported on one categorical PROM (Härter 2015; Mathers 2012) and were both included in the meta-analysis (Analysis 3.3; two studies, 266 patients, very low-certainty evidence). The estimate of the RD was -0.01 (95% CI: -0.20 to 0.19).

Observer-based outcome measures (OBOMs) studies: comparisons of interventions of the same type

We are uncertain whether interventions increase the use of SDM among healthcare professionals compared with other interventions of the same type, as measured by continuous OBOMs, as the certainty of the evidence was very low for all six comparisons.

Interventions targeting patients versus other interventions targeting patients (three studies)

The pooled estimate of the SMD was 0.88 (95% CI: 0.39 to 1.37) in observer-reported SDM in favor of the group that received a patient decision aid compared to the group that received a booklet (SMD of 1.21; 95% CI: 0.78 to 1.64) or a pamphlet (SMD of 1.04; 95% CI: 0.60 to 1.48) (Jouni 2017; Montori 2011; Nannenga 2009). (Analysis 4.1; three studies, 271 observations,very low-certainty evidence).

Interventions targeting healthcare professionals versus other interventions targeting healthcare professionals (two studies)

Two studies reported on two continuous OBOMs (Elwyn 2004; Feng 2013). Data from one study were available for the analysis (Analysis 5.1; one study, 20 observations, very low-certainty evidence). The SMD for this study was -0.30 (95% CI: -1.19 to 0.59). The study not included in the meta-analysis reported a significant improvement for the group that received an interactive web-based curriculum compared to the group that received a brochure (Feng 2013).

Interventions targeting both patients and healthcare professionals versus other interventions targeting both patients and healthcare professionals (two studies)

One study reported on one continuous OBOM (Tai-Seale 2016). The SMD for this study was -0.29 (95%CI: -1.17 to 0.60) (Analysis 6.1; one study, 20 observations, very low-certainty evidence).

One study reported on one categorical OBOM (Myers 2011). The RD for this study was -0.04 (95%CI: -0.13 to 0.04) (Analysis 6.2; one study, 134 observations, very low-certainty evidence).

Patient-reported outcome measures(PROMs) studies: comparisons of interventions of the same type

We are uncertain whether interventions increase the use of SDM among healthcare professionals compared with usual care, as measured by PROMs, as the certainty of the evidence was very low for all six comparisons included in the review.

Interventions targeting patients versus other interventions targeting patients (26 studies)

Thirteen randomized studies reported 11 continuous PROMs (Adarkwah 2016; Causarano 2014; Deen 2012; Eggly 2017; Hamann 2011; Hamann 2017; Jouni 2017; Lalonde 2006; Schroy 2011; Schroy 2016; Smallwood 2017; Street 1995; van Roosmalen 2004), 11 of which were available for meta-analysis (Analysis 4.2; 11 studies, 1906 patients, very low-certainty evidence). The pooled estimate of the SMD was 0.03 (95% CI: -0.18 to 0.24). The two randomized studies not included in the meta-analysis reported little or no difference between groups (Lalonde 2006; Street 1995).

One non-randomized study (Barton 2016) reported an effect size for PROM of an SMD of -0.21 (95% CI: -0.61 to 0.19) (Analysis 4.3; one study, 97 patients, very low-certainty evidence) when comparing an adapted guide with an existing medication guide. This study showed an effect size (SMD) of -0.19 (95% CI: -0.56 to 0.19) (Analysis 4.4; one study, 110 patients, very low-certainty evidence) when comparing an adapted guide combined with a decision aid with an existing medication guide. Finally, this study showed an effect size (SMD) of 0.03 (95% CI: -0.37 to 0.43) (Analysis 4.5; one study, 99 patients, very low-certainty evidence) when comparing an adapted guide combined with a decision aid with an adapted guide alone.

Twelve studies reported on four categorical PROMs (Butow 2004; Davison 1997; Davison 2002; Deschamps 2004; Dolan 2002; Kasper 2008; Köpke 2014; Krist 2007; Raynes-Greenow 2010; Stiggelbout 2008; Thomson 2007; Wolderslund 2017). Data from 10 studies were available for the meta-analysis (Analysis 4.6; 10 studies, 2272 patients, very low-certainty evidence). The pooled estimate of the RD was 0.03 (95% CI: -0.02 to 0.08).

Interventions targeting healthcare professionals versus other interventions targeting healthcare professionals (two studies)

The pooled estimate of the SMD was 0.24 (95%CI: -0.10 to 0.58) (Analysis 5.2; two studies, 1459 patients, very low-certainty evidence) (Elwyn 2004; Krones 2008 (ARRIBA-Herz)).

Interventions targeting both patients and healthcare professionals versus other interventions targeting both patients and healthcare professionals (two studies)

One study reported on one continuous PROM (Tai-Seale 2016) an SMD of 0.00 (95%CI: -0.32 to 0.32) (Analysis 6.3; 150 patients, very low-certainty evidence).

One study reported on one categorical PROM but data were not available to compute a risk difference (Cooper 2013). Authors of this study reported little or no difference between the two interventions.

Secondary outcomes

Interventions targeting patients versus usual care

Patient outcomes

Affective-cognitive outcomes

Knowledge

Eight studies reported on knowledge (Korteland 2017; Krist 2007; Landrey 2012; LeBlanc 2015a; LeBlanc 2015b; Perestelo-Perez 2016; Sheridan 2014; van Peperstraten 2010). Data from five studies were available for statistical analysis (Analysis 1.5; Analysis 1.6). On a continuous scale, the SMD was 0.38 (95% CI: 0.16 to 0.61; three studies, 565 participants; Analysis 1.5) for overall knowledge (knowledge not addressed in a decision aid) and 0.77 (95% CI: 0.44 to 1.10;) for knowledge addressed in a decision aid. This indicates an increase in knowledge for the group that received the intervention targeting patients (Analysis 1.5).

The RD was 0.17 (95% CI: 0.05 to 0.29; two studies, 312 participants) for knowledge of risk without medication/overall knowledge, indicating a small improvement for the group that received an intervention targeting patients (Analysis 1.6). Among studies that did not report enough data to perform a meta-analysis, two studies reported improvement in overall knowledge in favor of the group that received the intervention (Korteland 2017; LeBlanc 2015a) and two studies reported an improvement in knowledge addressed in decision aid in favor of the group that received the intervention (LeBlanc 2015a; LeBlanc 2015b).

Satisfaction

Nine studies reported on satisfaction (Almario 2016; Eggly 2017; Hamann 2014; Haskard 2008; Landrey 2012; LeBlanc 2015a; Murray 2001; van der Krieke 2013; Vodermaier 2009). Data from one study were available for statistical analysis (Analysis 1.7); the SMD was 0.14 (95% CI: -0.24 to 0.52; 107 participants) indicating little or no difference in satisfaction with the decision and treatment for the group that received the intervention. Among the studies not used for statistical analysis, there was little or no difference between groups in studies that reported on satisfaction with the consultation (Almario 2016; Hamann 2014); nor in the studies that reported on satisfaction with care (Haskard 2008; van der Krieke 2013). Among the studies that reported on satisfaction with the intervention (Eggly 2017; Hamann 2014; Landrey 2012; LeBlanc 2015a; Murray 2001; van der Krieke 2013), most studies reported little or no difference in satisfaction with the intervention.

Decisional conflict

Eight studies reported on decisional conflict (Korteland 2017; Krist 2007; Murray 2001; LeBlanc 2015a; LeBlanc 2015b; Perestelo-Perez 2016; Sheridan 2014; Vodermaier 2009). Data from three studies (367 participants) were available for statistical analysis (Analysis 1.8), the SMD was -0.30 (95% CI: -0.68 to 0.09) indicating little or no difference between groups. Among the five studies not included in the meta-analysis (Korteland 2017; Krist 2007; LeBlanc 2015a; LeBlanc 2015b; Sheridan 2014), most reported little or no difference between groups for decisional conflict.

Decision regret

Two studies reported on decision regret (Korteland 2017; van Tol-Geerdink 2016). Data from one study were available for statistical analysis (Analysis 1.9), the estimate of the SMD was -0.10 (95% CI: -0.39 to 0.19) and -0.20 (95% CI: -0.50 to 0.10) at six months and 12 months respectively, indicating little or no difference between groups regarding regret after the decision. We are uncertain whether the intervention has an effect on decision regret as the certainty of the evidence was very low (one study, 212 participants). The study not included in the analysis reported little or no difference between groups regarding decision regret at three months (Korteland 2017).

Patient-clinician communication

Two studies reported on patient-clinician communication during the encounter (Hamann 2014; Sheridan 2014). One study (157 participants) reported an improvement in discussion raising by patient (RD 0.29; 95% CI: 0.14 to 0.44; Analysis 1.11), patient participation in discussion (RD 0.27; 95% CI: 0.13 to 0.42;157 participants; Analysis 1.12), and interaction with provider (Sheridan 2014) in the group that received the intervention. The other study reported more dominant behavior by the physician in the usual care group than in the group that received the intervention (Hamann 2014; Analysis 1.10). However, little or no difference was found regarding the number of topics raised by patients and dominant behavior by the patient (Hamann 2014).

Self-efficacy

Two studies (274 participants) reported on decision self-efficacy (Deen 2012; Maranda 2014) and were included in the meta-analysis (Analysis 1.13). The pooled estimate of the SMD was 0.16 (95% CI: -0.08 to 0.40) indicating little or no increase in decision self-efficacy for the group that received the intervention.

Empowerment

Three studies reported on empowerment (Pickett 2012; van Peperstraten 2010; Vestala 2013). Two were used for statistical analysis. On a continuous scale, the SMD was 0.26 (95% CI: 0.05 to 0.48; one study, 342 participants), indicating an increase in empowerment just after the intervention for the group that received the intervention (Analysis 1.14). On a categorical scale, the RD was 0.18 (95% CI: 0.09 to 0.27; one study, 262 participants) for empowerment indicating a small improvement for the group that received the intervention (Analysis 1.15). The study not included in statistical analysis reported little or no difference between groups (Vestala 2013).

Behavioral outcomes

Match between preferred and actual level of participation in decision making

One study reported on match between preferred and actual level of participation in decision making (Krist 2007) and found little or no difference between groups .

Match between option preferred and decision made

No studies targeting patients compared with usual care reported on match between option preferred and decision made.

Adherence to decision made

Four studies reported on adherence (Cooper 2011; LeBlanc 2015a; LeBlanc 2015b; Perestelo-Perez 2016) and two were used for statistical analysis (Analysis 1.16). For the four measures of adherence used (proportion of patients who filled their prescription within 30 days, proportion of patients with > 80% of days covered, proportion of patients who sometimes forgot to take their cholesterol medicine, proportion of patients who did not miss a dose the previous week) little or no difference between groups were found. The two studies not included in statistical analysis reported little or no difference between groups (Cooper 2011; LeBlanc 2015b).

Health outcomes

Health status

One study reported on health status (Murray 2001) and found little or no difference between groups.

Health-related quality of life

Two studies reported on health-related quality of life (Korteland 2017; LeBlanc 2015b). Data from one study were available for analysis, the estimate of the SMD was 0.00 (95% CI: -0.36 to 0.36) for physical components of quality of life (Analysis 1.17) and 0.10 (95% CI: -0.26 to 0.46) for mental components of quality of life (Analysis 1.18). We are uncertain whether the intervention improves health-related quality of life, as the certainty of the evidence was very low (one study, 116 participants). The study not included in the analysis reported little or no difference between groups (LeBlanc 2015b).

Anxiety

Four studies reported on anxiety (Korteland 2017; Murray 2001; Perestelo-Perez 2016; van Peperstraten 2010), three of which were included in the statistical analysis. On a continuous scale, the SMD was -0.17 (95% CI: -0.49 to 0.14) and 0.18 (95% CI: -0.06 to 0.43; two studies, 419 participants) for anxiety and state of anxiety, respectively (Analysis 1.19). This indicated little or no difference between groups (Perestelo-Perez 2016; van Peperstraten 2010). On a categorical scale, the RD was 0.04 (95% CI: -0.07 to 0.15; one study 127 participants) for anxiety (Analysis 1.20), indicating little or no improvement for the group that received the intervention (Korteland 2017). The study not included in statistical analysis reported little or no difference between groups (Murray 2001).

Depression

Four studies reported on depression (Korteland 2017; LeBlanc 2015a; van Peperstraten 2010; Vestala 2013). For the one study included in the analysis (127 participants), the RD was 0.16 (95% CI: 0.05 to 0.28) indicating a small increase in depression for the group that received the intervention (Analysis 1.21). Among the three studies not used in statistical analysis, two reported little or no difference between groups and one reported a transient increase in frequency of subclinical depression (van Peperstraten 2010).

Stress

One study reported on diabetes-related stress (Perestelo-Perez 2016) and found little or no difference between groups.

Distress

No studies targeting patients compared with usual care reported on distress.

Process outcomes

Consultation length

Seven studies reported on consultation length (Eggly 2017; Hamann 2014; Krist 2007; LeBlanc 2015b; Maclachlan 2016; Perestelo-Perez 2016; Vodermaier 2009). Data from two studies were available for meta-analysis and the estimate of the SMD was 0.10 (95% CI: -0.39 to 0.58) (Analysis 1.22). We are uncertain whether the intervention increases consultation length (two studies, 224 participants, very low-certainty evidence). The five studies not

included in the meta-analysis reported little or no difference between groups (Eggly 2017; Krist 2007; LeBlanc 2015b; Maclachlan 2016; Vodermaier 2009).

Cost

Two studies reported on cost (Murray 2001; van Peperstraten 2010). Data from one study were available for statistical analysis, with an estimate of SMD of 0.82 (95% CI: 0.42 to 1.22) (Analysis 1.23). As the certainty of the evidence was very low, we are uncertain about the effect of the intervention on cost (one study, 105 participants). The study not included in the meta-analysis reported a decrease in cost for the group that received the intervention (van Peperstraten 2010).

Equity

No studies targeting patients compared with usual care reported on equity.

Adverse effects

No studies targeting patients compared with usual care reported on adverse effects.

Interventions targeting healthcare professionals versus usual care

Patient outcomes

Affective-cognitive outcomes

Knowledge

Five studies reported on knowledge (Bernhard 2011; LeBlanc 2015b; Murray 2010; O'Cathain 2002; Tinsel 2013). Data from three studies were available for statistical analysis (Analysis 2.5; Analysis 2.6). The SMD was 0.26 (95% CI: -0.16 to 0.69; two studies, 969 participants), indicating little or no improvement in knowledge for the group that received the intervention (Analysis 2.5). Among studies that did not report enough data to perform meta-analysis, most reported little or no difference in knowledge addressed in the decision aid and one study reported an increase in knowledge in favor of the group that received the intervention (LeBlanc 2015b).

Satisfaction

Five studies reported on satisfaction (Bernhard 2011; Fossli 2011; Murray 2010; O'Cathain 2002; Wilkes 2013). Data from two studies were available for statistical analysis. On a continuous scale, the SMD was 0.00 (95% CI: -0.18 to 0.18; one study. 479 participants) indicating little or no increase in satisfaction with the decision and treatment in the group that received the intervention (Analysis 2.7). On a categorical scale (RD), there was little or no difference between groups regarding satisfaction with the amount of information (one study, 1492 participants; Analysis 2.8), satisfaction with the decision-making process (one study, 1488 participants; Analysis 2.9), and satisfaction with the discussion with healthcare professional (Analysis 2.10). Among the studies not used for statistical analysis, there was little or no difference between the groups in studies that reported on satisfaction with the consultation, satisfaction with the decision, satisfaction with the decision-making process, satisfaction with the discussion with the healthcare professional, satisfaction with the doctor's communication, overall patient satisfaction and satisfaction with the intervention (Bernhard 2011; Fossli 2011; Murray 2010; O'Cathain 2002). One study reported an increase in satisfaction with the amount of information received in the prenatal period in favor of the group that received the intervention (O'Cathain 2002).

Decisional conflict

Three studies reported on decisional conflict (Bernhard 2011; LeBlanc 2015b; Légaré 2012), finding little or no difference between groups.

Decision regret

One study reported an increase in decision regret in the group that received the intervention (SMD 0.29; 95% CI: 0.07 to 0.51) (Analysis 2.11). As the certainty of the evidence was very low, we cannot be certain whether the intervention has an effect on decision regret (one study, 326 participants).

Self-efficacy

Kennedy 2013 (4475 participants) reported on decision self-efficacy and found little or no difference between groups either at six months (SMD -0.03; 95% CI: -0.09 to 0.03), or at 12 months (SMD -0.04; 95% CI: -0.10 to 0.03) (Analysis 2.12).

Other affective-cognitive outcomes

No studies targeting healthcare professionals compared with usual care reported on patient-clinician communication or empowerment.

Behavioral outcomes

Adherence to decision made

Three studies reported on adherence (Cooper 2011; Légaré 2012; Tinsel 2013) and one was included in statistical analysis (Analysis 2.13). SMDs were: (-0.08; 95% CI: -0.21 to 0.06), (-0.01; 95% CI: -0.16 to 0.13), and (0.10; 95% CI: -0.05 to 0.25) at six, 12 and 18 months, respectively. This indicates little or no increase in adherence to medication for the group that received the intervention. The two studies not included in statistical analysis reported little or no difference between groups (Cooper 2011; Légaré 2012).

Other behavioral outcomes

No studies targeting healthcare professionals compared with usual care reported on match between preferred and actual level of participation in decision making or match between option preferred and decision made.

Health outcomes

Health status

Kennedy 2013 reported on health status and found little or no difference between groups either regarding general health (SMD 0.02; 95% CI: -0.04 to 0.08); Analysis 2.14); or psychological well-being (SMD 0.00; 95% CI: -0.06 to 0.06); Analysis 2.15).

Health-related quality of life

Four studies reported on health-related quality of life (Bernhard 2011; Kennedy 2013; LeBlanc 2015b; Légaré 2012), two of which were included in the pooled analyses; (SMD 0.16; 95% CI: -0.05 to 0.36) for the physical component (Analysis 2.16; Légaré 2012),

(SMD 0.28; 95% CI: 0.07 to 0.49) for the mental component (Analysis 2.17; Légaré 2012), and (SMD 0.00; 95% CI: -0.06 to 0.06; 4449 participants) for quality of life in general (Analysis 2.18; Kennedy 2013). The intervention might slightly improve mental health-related quality of life (one study, 359 participants, low-certainty evidence) and for physical health-related quality of life the intervention might make little or no difference (one study, 359 participants, low-certainty evidence). The two studies not included in the analysis reported little or no difference between groups (Bernhard 2011; LeBlanc 2015b).

Anxiety

Two studies reported on anxiety (Bernhard 2011; O'Cathain 2002) and the data from one study (3003 participants) were used for statistical analysis (Analysis 2.19). The RD was -0.00 (95% CI: -0.02 to 0.02) indicating little or no increase in anxiety for the group that received the intervention targeting healthcare professionals. The study not included in the analysis reported little or no difference between groups (Bernhard 2011).

Other health outcomes

No studies targeting healthcare professionals compared with usual care reported on depression, stress and distress.

Process outcomes

Consultation length

Six studies reported on consultation length (Fossli 2011; LeBlanc 2015b; Murray 2010; Shepherd 2011; Sanders 2017; Wilkes 2013), two of which were included in the analysis. In one study, the consultation length increased in the group that received the intervention (SMD 0.51; 95% CI: 0.21 to 0.81) (Analysis 2.20). We are uncertain about the effects of the intervention on consultation length as the certainty of the evidence was very low (one study, 175 participants). Another study (479 participants) reported little or no difference between groups for a consultation length of between 10 to 20 minutes (RD -0.04; 95% CI: -0.13 to 0.05) (Analysis 2.21), indicating that the intervention might make little or no difference for consultation length as measured by 10-minute blocks. Among the four studies not included in the statistical analysis, most reported little or no difference between groups and one reported an increase in consultation length in the group that received the intervention (Murray 2010).

Other process outcomes

No studies targeting healthcare professionals compared with usual care reported on costs or equity.

Adverse effects

One study (154 participants) reported on parent perception of hospital safety (Cox 2017) and found little or no difference between groups (SMD 0.00; 95% CI: -0.32 to 0.32) (Analysis 2.22).

Interventions targeting both patients and healthcare professionals versus usual care

Patient outcomes

Affective-cognitive outcomes

Knowledge

Seven studies reported on knowledge (Branda 2013; Coylewright 2016; Hamann 2007; Hess 2012; Hess 2016; Mathers 2012; Sheridan 2012). Data from five studies were available for statistical analysis. On a continuous scale, the SMD was 0.41 (95% CI: 0.28 to 0.53; two studies, 1004 participants), indicating an increase in knowledge for the group that received the intervention (Analysis 3.4). On a categorical scale, the RD was 0.28 (95% CI: 0.05 to 0.51; four studies, 1260 participants), indicating an increase in knowledge for the group that received the intervention (Analysis 3.5). The three studies not included in the pooled analyses reported an increase in knowledge in favor of the group that received the intervention (Branda 2013; Hamann 2007; Hess 2012).

Satisfaction

Twelve studies reported on satisfaction (Branda 2013; Hamann 2007; Härter 2015; Haskard 2008; Hess 2012; Hess 2016; Leighl 2011; Loh 2007; Mathers 2012; Rise 2012; Wetzels 2005; Wilkes 2013), four of which were included in the statistical analysis. The SMD was 0.51 (95% CI: -0.34 to 1.36; two studies, 362 participants), indicating little or no increase in satisfaction with care for the group that received the intervention (Analysis 3.6). For satisfaction with the decision after consultation, the SMD was 0.24 (95% CI: 0.05 to 0.43; one study, 424 participants), indicating a small increase for the group that received the intervention (Analysis 3.7). Little or no difference between groups was found for satisfaction with the consultation (SMD 0.00; 95% CI: -0.23 to 0.23; one study, 383 participants) (Analysis 3.8).

Among the studies that did not provide enough information for statistical analysis, there was little or no difference between groups in studies that reported on satisfaction with the decision and satisfaction with the intervention. One study each reported an increase in satisfaction with the decision-making process (Hess 2012) and satisfaction with overall care (Haskard 2008), both in favor of the group that received intervention.

Decisional conflict

Seven studies reported on decisional conflict (Branda 2013; Coylewright 2016; Härter 2015; Hess 2016; Hess 2012; Leighl 2011; Mathers 2012). Data from two studies (1065 participants) were available for statistical analysis (Analysis 3.9). Results indicated little or no difference between groups (SMD -0.35, 95% CI: -0.71 to 0.01). Regarding confidence in the decision, the SMD was 0.03 (95% CI: -0.17 to 0.22; one study, 414 participants), indicating no increase in confidence post-consultation for the group that received the intervention (Analysis 3.10). Among the studies that were not pooled, most reported little or no difference between groups and one study reported lower decisional conflict in the intervention group (Hess 2012).

Decision regret

Two studies reported on decision regret (Härter 2015; Mathers 2012), of which one reported data for analysis. The estimate of the SMD was 0.13 (95% CI: -0.08 to 0.33) at two months indicating little or no difference between groups (Analysis 3.11). The intervention might make little or no difference for decision regret (one study, 369 participants, low-certainty evidence). The study not included in the analysis reported little or no difference between groups regarding decision regret at six months (Mathers 2012).

Patient-clinician communication

One study (265 participants) reported on patient-clinician communication and found little or no difference between groups regarding patient-centered communication (SMD 0.23; 95% CI: -0.01 to 0.47) (Analysis 3.12).

Self-efficacy

Epstein 2017 reported on decision self-efficacy and found little or no difference between groups.

Empowerment

No studies targeting both patients and healthcare professionals compared with usual care reported on empowerment.

Behavioral outcomes

Match between preferred and actual level of participation in decision making

Three studies reported on match between preferred and actual level of participation in decision making (Härter 2015; Sheridan 2012; Leighl 2011) and two (185 participants) were used for statistical analysis (Analysis 3.13). The estimate of the RD was -0.03 (95% CI: -0.16 to 0.10) indicating that the intervention may make little or no difference to increase in match between preferred and actual level of participation. The study not included in the analysis reported little or no difference between groups regarding the match between preferred and actual level of participation in decision making (Leighl 2011).

Adherence to decision made

Four studies reported on adherence (Cooper 2011; Branda 2013; Hamann 2007; Loh 2007) and three were used for statistical analysis. On a continuous scale, the SMD was 0.44 (95% CI: -0.17 to 1.05) for patient's self-assessment of adherence and 0.62 (95% CI: 0.37 to 0.87) for physician's assessment of adherence, indicating an improvement in adherence to medication for the group that received the intervention (Analysis 3.14). On a categorical scale, the RD was 0.00 (95% CI: -0.15 to 0.15; two studies, 145 participants), indicating little or no difference between groups in adherence to medication as reported by patients (Analysis 3.15). The one study not included in statistical analysis reported little or no difference between groups for adherence to medication as reported by patients (Cooper 2011).

One study reported on persistence with the chosen option (Mathers 2012) and found that patients in the intervention group were more likely to persist with their chosen option.

Other behavioral outcomes

No studies targeting both patients and healthcare professionals compared with usual care reported on match between option preferred and decision made.

Health outcomes

Health-related quality of life

Two studies reported on health-related quality of life (Epstein 2017; Rise 2012). The SMDs were 0.08 (95% CI: -0.37 to 0.54) for the physical component (Analysis 3.17), 0.01 (95% CI: -0.44 to 0.46) for the mental component (Analysis 3.18), and SMD 0.08 (95% CI: -0.16 to 0.33; one study, 265 participants) for quality of life in general (Analysis 3.16). We are uncertain whether the intervention improves physical health-related quality of life or mental health-related quality of life as the certainty of the evidence has been assessed as very low (one study; 75 participants).

Anxiety

Two studies reported on anxiety (Härter 2015**;** Leighl 2011) and one was included in statistical analysis (Analysis 3.19). The SMD was -0.12 (95% CI: -0.31 to 0.08; one study, 419 participants) post-consultation and -0.85 (95% CI: -1.06 to -0.63) at three months, indicating an increase in anxiety for the group that received usual care. The study not included in statistical analysis reported little or no difference between groups (Leighl 2011).

Depression

Two studies reported on depression (Härter 2015**;** Loh 2007) and one was included in statistical analysis (Analysis 3.20). The SMD was -0.14 (95% CI: -0.33 to 0.05) post-consultation and -0.59 (95% CI: -0.80 to -0.38) at three months, indicating an increase in depression for the group that received usual care. The study not included in statistical analysis reported little or no difference between groups (Loh 2007).

Other health outcomes

No studies targeting both patients and healthcare professionals compared with usual care reported on health status, stress or distress.

Process outcomes

Consultation length

Three studies reported on consultation length (Hess 2016; Loh 2007; Wetzels 2005) and one was used for the analysis (Analysis 3.21). The SMD was 3.72 (95% CI: 3.44 to 4.01), indicating an increase in consultation length for the group that received the intervention, although the very low-certainty evidence means we have very little confidence in the effect estimate (one study, 536 participants). The two other studies reported little or no difference between groups (Loh 2007; Wetzels 2005).

Other process outcomes

No studies targeting both patients and healthcare professionals compared with usual care reported on costs or equity.

Adverse effects

One study reported on safety (Hess 2016) and found little or no difference between groups regarding occurrence of major adverse cardiac events (Analysis 3.22).

Comparisons of interventions of the same type

Interventions targeting patients versus other interventions targeting patients

Patient outcomes

Affective-cognitive outcomes

Knowledge

Ten studies reported on knowledge (Barton 2016; Köpke 2014; Krist 2007; Lalonde 2006; Montori 2011; Nannenga 2009; Raynes-Greenow 2010; Schroy 2011; Street 1995; Thomson 2007), and four were included in the statistical analysis. On a continuous scale, the SMD was 0.30 (95% CI: 0.13 to 0.47; one study, 596 participants), indicating an improvement in knowledge for the group that received an audio and non-audio decision aid compared to the group that received a pamphlet (Analysis 4.7). On a categorical scale, the RD was 0.16 (95% CI: -0.10 to 0.42; three studies, 706 participants), indicating little or no difference between groups (Analysis 4.8). Among the seven studies not pooled, most found little or no difference between groups. Two studies reported an increase in knowledge in the group that received a decision aid compared to the group that received patient educational material (pamphlet) (Nannenga 2009; Schroy 2011), and one study reported an increase in knowledge in favor of the group that received an interactive four-hour education program compared to the group that received a four-hour Multiple Sclerosis-specific stress management program (Köpke 2014).

Satisfaction

Fourteen studies reported on satisfaction (Barton 2016; Butow 2004; Causarano 2014; Davison 2002; Deschamps 2004; Hamann 2011; Hamann 2017; Jouni 2017; Kasper 2008; Köpke 2014; Lalonde 2006; Montori 2011; Raynes-Greenow 2010; Warner 2015). Data from five studies were available for statistical analysis. Little or no difference between groups were found regarding satisfaction with the decision (SMD 0.07; 95% CI: -0.10 to 0.24; one study, 596 participants; Analysis 4.9), satisfaction with treatment (SMD -0.09; 95% CI: -0.34 to 0.16; two studies, 267 participants; Analysis 4.10), satisfaction with consultation (SMD -0.14; 95% CI: -0.42 to 0.13; ;one study, 207 participants; Analysis 4.11), and satisfaction with information provided (SMD 0.11; 95% CI: -0.52 to 0.73; one study, 39 participants; Analysis 4.12). Among the studies that did not provide enough information for statistical analysis, most studies reported little or no difference between groups. One study reported an increase in satisfaction with the intervention in favor of the group that received a decision aid and an information booklet about immunotherapy compared to the group that received a decision aid and a standard information package (Kasper 2008).

Decisional conflict

Fourteen studies reported on decisional conflict (Adarkwah 2016; Barton 2016; Causarano 2014; Deschamps 2004; Dolan 2002; Köpke 2014; Krist 2007; Lalonde 2006; Montori 2011; Nannenga 2009; Raynes-Greenow 2010; Smallwood 2017; Thomson 2007; van Roosmalen 2004), six of which were included in a pooled analysis. Regarding decisional conflict, the SMD was -0.20 (95% CI: -0.48 to 0.08, five studies, 1088 participants), indicating little or no difference between groups (Analysis 4.13). Little or no difference was found for decision uncertainty (1, 80 participants; Analysis 4.14). Among the eight studies that did not provide enough information for statistical analysis, most reported little or no difference between groups. One study reported lower decisional conflict in the intervention group with routine education and educational meeting for patients compared to the group with routine education alone (Causarano 2014); another study reported a decrease in decisional conflict in the group with a computerized decision aid compared to the group with guidelines (Thomson 2007), and finally, a third study reported a decrease in decisional conflict in the group with a decision aid and low-literacy medication guide compared to the group with the existing medication guide (Barton 2016).

Patient-clinician communication

One study reported on patient-clinician communication (Stiggelbout 2008) and found that the group who received an individualized brochure had better understanding (84%) than the group who received a general brochure (62%).

Self-efficacy

Two studies (100 participants) reported on decision self-efficacy (Analysis 4.15). The pooled estimate of the SMD was -0.02 (95% CI: -0.41 to 0.37), indicating little or no difference between groups.

Other affective-cognitive outcomes

No studies targeting patients compared with other interventions targeting patients reported on decision regret or empowerment.

Behavioral outcomes

Match between preferred and actual level of participation in decision making

Five studies reported on the match between preferred and actual level of participation in decision making (Butow 2004; Davison 2002; Dolan 2002; Kasper 2008; Krist 2007). Data from four studies (1206 participants) were available for meta-analysis (Analysis 4.16). The estimate of the RD was -0.10 (95% CI: -0.16 to -0.05), indicating a very small increase in match between preferred and actual level of participation in decision making for the group that received a discussion with a research nurse compared to the group that received computer-generated information and decision-preference profiles and a computer-generated prompt sheet; and a better match for the group that received a decision aid and a standard information package than for the group that received a decision aid and an information booklet about immunotherapy. The study not included in the meta-analysis reported little or no difference between groups (Krist 2007).

Match between option preferred and decision made

Two studies (363 participants) reported on match between option preferred and decision made (Causarano 2014; Schroy 2016). Data from both studies were available (Analysis 4.17). The estimate of the RD was -0.20 (95% CI: -0.60 to 0.20) indicating little or no difference between groups.

Adherence to decision made

Six studies reported on adherence (Barton 2016; Deschamps 2004; Hamann 2017; Köpke 2014; Montori 2011; Thomson 2007) and four were used for statistical analysis. On a continuous scale, the SMD was 0.05 (95% CI: -0.35 to 0.44) at six months, one study 100 participants, indicating little or no difference between groups (Analysis 4.18). On a categorical scale, the RD was 0.01 (95% CI: -0.10 to 0.12), three studies, 301 participants, indicating little or no difference between groups in adherence to medication (Analysis 4.19). One study (Köpke 2014) reported little or no difference between groups regarding medication discontinuation (RD: -0.14; 95% CI: -0.31 to 0.02). Among the studies not included in statistical analysis, one study reported that participants in the group using a decision aid were less likely to make a definite decision to

start or continue medication than participants in the group using guidelines (Thomson 2007). One study reported on persistence with the chosen option (Montori 2011), finding little or no difference between groups.

Health outcomes

Health status

One study (88 participants) reported on general health (Analysis 4.20). Little or no difference between groups was reported at three months (SMD -0.19 ; 95% CI: -0.61 to 0.23). At nine months, the SMD was 0.53 (95% CI: 0.09 to 0.97), indicating an improvement in general health in the intervention group receiving a SDM intervention and decision aid compared to the group receiving a decision aid alone.

Health-related quality of life

One study reported on health-related quality of life (Stiggelbout 2008) and found little or no difference between groups.

Anxiety

Seven studies reported on anxiety (Butow 2004; Davison 1997; Köpke 2014; Raynes-Greenow 2010; Stiggelbout 2008; Thomson 2007; van Roosmalen 2004) and two (682 participants) were used for statistical analysis (Analysis 4.21). The SMD was -0.11 (95% CI: -0.27 to 0.05) indicating little or no difference between groups. Studies not included in statistical analysis reported little or no difference between groups.

Depression

Five studies reported on depression (Butow 2004; Davison 1997; Köpke 2014; Stiggelbout 2008; van Roosmalen 2004) and one study (86 participants) was included in statistical analysis (Analysis 4.22)). Little or no difference between groups was reported at three (SMD -0.27 ; 95% CI: -0.69 to 0.16) or nine months (SMD -0.39 ; 95% CI: -0.82 to 0.03). The studies not included in statistical analysis reported little or no difference between groups.

Other health outcomes

No studies targeting patients compared with other interventions targeting patients reported on stress or distress.

Process outcomes

Consultation length

Five studies reported on consultation length (Butow 2004; Causarano 2014; Krist 2007; Montori 2011; Nannenga 2009), one of which was included in the analysis (Analysis 4.23). The SMD was -0.65 (95% CI: -1.29 to -0.00) suggesting an increase in consultation length for the group that received routine education compared to the group that received routine education and a patient educational meeting. The certainty of evidence was very low (one study, 39 participants). Among the four studies not included in the analysis, most reported little or no difference between groups and one reported an increase in consultation length for the group that received decision aid compared to the group that received usual care and booklet (Montori 2011).

Other process outcomes

No studies targeting patients compared with other interventions targeting patients reported on costs or equity.

Adverse effects

No studies targeting patients compared with other interventions targeting patients reported on adverse effects.

Interventions targeting healthcare professionals versus other interventions targeting healthcare professionals

Patient outcomes

Affective-cognitive outcomes

Knowledge

Krones 2008 (ARRIBA-Herz) reported on knowledge, finding little or no difference between groups.

Satisfaction

Elwyn 2004 reported on satisfaction finding little or no difference between groups either in satisfaction with the information provided or in satisfaction with the decision.

Decision regret

One study reported on decision regret at six months (Krones 2008 (ARRIBA-Herz)), and found less decision regret in the group that received an educational meeting, audit and feedback, educational material and an educational outreach visit than in the group that received an educational meeting alone.

Other affective-cognitive outcomes

No studies targeting healthcare professionals compared with other interventions targeting healthcare professionals reported on decisional conflict, patient-clinician communication, self-efficacy or empowerment.

Behavioral outcomes

No studies targeting healthcare professionals compared with other interventions targeting healthcare professionals reported on match between preferred and actual level of participation in decision making, match between option preferred and decision made or adherence to decision made.

Health outcomes

Health status

One cross-over study (295 participants) reported on mental and physical health status at two points in time (Elwyn 2004). The SMD was 0.24 (95% CI: 0.01 to 0.47) for mental health status at time point 1 (Analysis 5.3), indicating a small improvement in the group that received training in SDM compared to the group that received training in risk communication. Little or no difference between groups was observed for physical health status (Analysis 5.4).

Anxiety

Elwyn 2004 reported on anxiety at three points in time. The SMD was 0.25 (95% CI: 0.02 to 0.49) for anxiety at time point 2, indicating a small increase in the group that received training in shared

decision making compared to the group that received training in risk communication (Analysis 5.5).

Other health outcomes

No studies targeting healthcare professionals compared with other interventions targeting healthcare professionals reported on health-related quality of life, depression, stress or distress.

Process outcomes

Consultation length

One study reported on consultation length (Elwyn 2004) and found little or no difference between groups.

Other process outcomes

No studies targeting healthcare professionals compared with other interventions targeting healthcare professionals reported on costs or equity.

Adverse events

No studies targeting healthcare professionals compared with other interventions targeting healthcare professionals reported on adverse events.

Interventions targeting both patients and healthcare professionals versus other interventions targeting both patients and healthcare professionals

Patient outcomes

Affective-cognitive outcomes

Satisfaction

Cooper 2013 reported on satisfaction with the intervention and found that, at 12 months, compared with patients in the standard group, patients in the patient-centered group had higher odds of rating their depression case manager as extremely helpful at identifying concerns (odds ratio (OR), 3.00; 95% CI, 1.23 to 7.30) and improving adherence to treatment (OR, 2.60; 95% CI, 1.11 to 6.08).

Decisional conflict

One study (286 participants) reported on decisional conflict (Myers 2011) and found little or no difference between groups (SMD -0.07; 95% CI -0.30 to 0.16; Analysis 6.4).

Other affective-cognitive outcomes

No studies targeting both patients and healthcare professionals compared with other interventions targeting both patients and other healthcare professionals reported on knowledge, decision regret, patient-clinician communication, self-efficacy or empowerment.

Behavioral outcomes

No studies targeting both patients and healthcare professionals compared with other interventions targeting both patients and other healthcare professionals reported on match between preferred and actual level of participation in decision making, match between option preferred and decision made or adherence to decision made.

Health outcomes

Depression

Cooper 2013 reported on depression and found little or no difference between study groups.

Other health outcomes

No studies targeting both patients and healthcare professionals compared with other interventions targeting both patients and other healthcare professionals reported on health status, health-related quality of life, anxiety, stress or distress.

Process outcomes

No studies targeting both patients and healthcare professionals compared with other interventions targeting both patients and other healthcare professionals reported on consultation length, costs or equity.

Adverse events

No studies targeting both patients and healthcare professionals compared with other interventions targeting both patients and other healthcare professionals reported on adverse events.

Subgroup analysis and investigation of heterogeneity

We performed subgroup analysis by study design. We observed a significant difference between the subgroup of individual randomized trials and that of cluster-randomized trials when interventions targeting healthcare professionals were compared with other interventions targeting healthcare professionals and assessed using OBOMs on a continuous scale. The study within the subgroup of individual trials showed an effect size (SMD) of 0.40 (95% CI: 0.28 to 0.52) (Analysis 5.2; 1132 observations) in favor of the group that received educational meeting and audit and feedback and educational material and educational outreach visit when compared with the group that received educational meeting alone (Krones 2008 (ARRIBA-Herz). The study within the subgroup of cluster trials did not show any effect (Elwyn 2004). No differences between subgroups were observed for the other comparisons categories. For more details see Analysis 1.1, Analysis 1.2, Analysis 2.1, Analysis 2.3, Analysis 3.1, Analysis 3.2, Analysis 3.3, Analysis 4.2.

Statistical heterogeneity among studies measuring the use of SDM by healthcare professionals was partly explained by methodological heterogeneity namely, the study design. Looking only at cluster-randomized trials, when interventions targeting patients were compared to usual care and assessed using OBOMs on a continuous scale, the I^2 statistic moved from 84% (P = 0.0002) to 31% (P = 0.23) (Analysis 1.1). When the same comparison was assessed using PROMs on a continuous scale, the I^2 moved from 50% (P = 0.04) to 0% (P = 0.40) (Analysis 1.2). When interventions targeting both patients and healthcare professionals were compared to usual care and assessed using OBOMs on continuous scale, the I^2 moved from 96% (P < 0.00001) to 0% (P = 0.37) (Analysis 3.1). Other potential sources of variation could be other methodological heterogeneity (the studies differed in their risk of bias from one domain to another) and extensive clinical heterogeneity (the studies differed considerably in types of interventions studied and in clinical contexts).

DISCUSSION

Summary of main results

This updated search added 48 new studies to the 39 studies from the first update of the original Cochrane review, for a total of 87 studies that recruited a total of 48,754 participants: 3113 healthcare professionals, with a minimum enrolment of one and a maximum of 363; and 45,641 patients, with a minimum of 26 patients and a maximum of 10,070. The number of included studies more than doubled in five years. This is not surprising considering that this field is rapidly expanding. Evidence shows that shared decision making (SDM) publications increased exponentially in major medical journals from 1996 to 2011. The absolute number of publications per journal ranged from two to 273 over 16 years (Blanc 2014). This growth reflects increased dissemination of the SDM concept to the medical community and increasing inclusion of SDM in health policy in many countries (Harter 2017). Most countries represented were in Europe or the USA. Consistent with a recent update on international accomplishments in SDM policy, research and implementation (Harter 2017), we observed few studies by international collaborations and only one conducted in a low-income country. Primary care was the setting of most of the studies. In addition, most studies focused on licensed healthcare professionals, demonstrating the need for further studies involving healthcare professionals in training as well. The most common clinical conditions targeted were cancer, psychiatric and cardiovascular diseases. Implementation studies in SDM are thus addressing the diseases that have been identified as among the most important causes of the global burden of disease (Institute for Health Metrics and Evaluation 2013).

To assess the effect of interventions for increasing the use of SDM by healthcare professionals, we divided studies based on the population targeted (patients, healthcare professionals, or both), and what the intervention was being compared with (usual care or other interventions of the same type), resulting in six comparisons. We also considered whether the primary outcome of interest was measured with observer-based outcome measures (OBOMs), used by a third-party observer during an encounter between a healthcare professional and a patient, or patient-reported outcome measures (PROMs), which collect information directly from patients. We graded the certainty of the evidence for the primary outcome of interest as very low for all the six comparisons and, for secondary outcomes (decision regret, physical and mental health-related quality of life, consultation length and cost), as low to very low. Studies did not report any adverse effects associated with the interventions.

Overall completeness and applicability of evidence

Overall, when reviewing studies assessing the impact of any interventions for increasing the use of SDM by healthcare professionals, we observed that the evidence was of low or very low certainty. There is still no consensus on which type of measure (OBOMs or PROMs) is most accurate for SDM. Therefore, we decided to include studies that had either used OBOMs, PROMs or both to ensure completeness of this review. Had we favored one type of measure over the other, this review would not have reflected the state of the science regarding the impact of any interventions for increasing the use of SDM by healthcare professionals. In OBOM studies, the most commonly used instrument was OPTION (Elwyn 2003), and in PROM studies the “perceived level of control in decision making” scale (adapted from the Control Preference Scale) (Degner 1992) was most common. As for studies not using either of these two scales, there were as many instruments as there were studies. These findings confirm that there is still no standardized instrument for assessing the use of SDM by healthcare professionals. They also confirm that measurement of SDM clearly needs improvement.

It is important to note that in line with the EPOC taxonomy of interventions, in our 'Summary of findings' tables, we refer to patient-mediated interventions (i.e. interventions targeting patients) as single entities. Unlike in the last update, this time we used head-to-head comparisons to disentangle the separate components of multifaceted patient-mediated interventions. This allowed us to investigate which of these separate interventions were more effective than others.

We have not reported on comparisons between different target categories (e.g. interventions targeting patients compared with interventions targeting healthcare professionals) because not enough additional studies were found for this update and therefore no further conclusions were possible.

Certainty of the evidence

Surprisingly, the large number of eligible studies did not translate into more certainty of the evidence for the primary outcome of interest, namely the use of SDM by healthcare professionals. Overall, the certainty of the evidence for the main outcome of this review, i.e. use of SDM by healthcare professionals, was graded as very low, which means we have very little confidence in the effect estimate. The 87 studies reviewed in this study (including the 48 added for this update) either did not provide reliable indication of the likely effect, or else there was high likelihood of the effect being substantially different. Evidence on secondary outcomes, i.e. decision regret, physical and mental health-related quality of life, consultation length and cost, was also uncertain.

A number of factors may explain this. First, only 22 of the 87 included studies had the same primary outcome as the primary outcome of interest of this review, i.e. the use of SDM by healthcare professionals, and therefore they may not have been sufficiently powered to accurately assess it. Second, in our assessment of risk of bias within studies, we scored several studies as “high risk” regarding protection against contamination. This was mostly because randomization was at the patient level instead of at the cluster level (e.g. clinics). This issue was reflected in the high methodological heterogeneity that occurred when cluster-randomized studies were mixed with individual-randomized studies. Further studies should address risk of contamination by adopting cluster-level randomization. When this is not possible, study authors should report in detail what steps they took to mitigate the risk of contamination. Third, we observed the use of a large number of diverse SDM measures. If researchers agreed on a common set of validated measures for evaluating the impact of interventions to increase the use of SDM, the certainty of the evidence would also improve. Fourth, except for decision aids, very few studies assessed the impact of the same intervention. Lastly, it should also be noted that when assessing risk bias, for many studies we scored key domains “unclear risk” mainly because we did not have enough information to make a judgement. Authors should report the methods and results of their trials in more detail

by following reporting guidelines more strictly (Campbell 2012; Schulz 2010).

The effects of interventions as measured with PROMs were not consistent with those as measured with OBOMs. Although we scored the evidence as of very low certainty, in three of the six comparisons OBOM studies indicated the intervention had an effect, while PROM studies did not; in one comparison, it was the reverse; and in the remaining two comparisons, OBOM and PROM studies were in agreement that the intervention had no effect. Different understandings of what constitutes participation in decisions between patients and healthcare professionals may partly explain these findings. For example, discrepancies between patients' interpretation of the Control Preferences Scale and its intended meaning have been reported (Davey 2004; Entwistle 2001). To ensure validity and reliability of PROMs, further investigation of how patients interpret and understand instructions, items and response options on which these measures rely is essential (Barr 2016).

In conclusion, studies in this field of research are no different from those in other fields in that their methods may be inadequate; they may be too small; many fail to deal adequately with bias; and most are not replicated (Chalmers 2009). Therefore, more and better research is required to strengthen the certainty of the evidence.

Potential biases in the review process

Assessment of publication bias within comparison categories did not show any clear evidence of reporting bias. However, since funnel plots were used to perform this assessment, the number of studies in some comparison categories may not have been sufficient.

Overall, we were unable to extract much information regarding the general context of the included studies. We relied on published and publicly available material and contacted authors of included studies to obtain more information when needed. However, we were not able to always get an answer from them.

Agreements and disagreements with other studies or reviews

We found no other review assessing the impact of interventions for increasing the use of SDM by healthcare professionals with the same primary outcome as our review, namely the use of SDM by healthcare professionals. However, we found reviews that had assessed the impact of interventions for increasing the use of SDM by healthcare professionals on other outcomes, such as levels of patient satisfaction or knowledge, namely the secondary outcomes of this review. In a Cochrane systematic review of interventions to facilitate SDM to address antibiotic use for acute respiratory infections in primary care, Coxeter and colleagues found that interventions to promote SDM reduce antibiotic use for acute respiratory infections in the short term (immediately after or within six weeks of the consultation), compared with usual care, without decreasing satisfaction with the consultation (Coxeter 2015). With pediatric patients, Wyatt and colleagues found that interventions to engage pediatric patients, parents, or both in medical decisions significantly improved knowledge and reduced decisional conflict (Wyatt 2015). However, none of these reviews could inform us about the effect of these interventions on the use of SDM by healthcare professionals.

Shay and Lafata systematically reviewed the empirical evidence linking patient outcomes with SDM, and identified which measurement perspectives (OBOM or PROM) are associated with which types of patient outcomes (affective-cognitive, behavioral, and health) (Shay 2015). As in our review, in a high number of their included studies (33 out of 39), the measures of SDM were patient-reported. Of 97 unique patient outcomes assessed, 42 studies (43%) found a significant and positive relationship between SDM and the patient outcome. This proportion varied according to the measurer (patient or observer) and the outcome category. The authors reported that more than half of outcomes assessed with patient-reported SDM were significant and positive, compared with 21% of those that were observer-rated. These results, along with ours, confirm two important facts: 1) patient-reported measures are those most commonly used in the assessment of patient involvement in decision making; 2) results vary according to the perspective (observer-based or patient-reported). This investment in patient-reported measures may be related to increasing interest among researchers in assessing whether health systems deliver what matters most to patients. Reliance on clinical indicators gives only a partial view of what patients and their caregivers prefer or value. What people care about is the impact of health services on their well-being and their ability to play an active role in decision making. The only way to evaluate this is to ask patients themselves. Therefore it is not surprising that Patient-Reported Experience Measures (PREMs) and Patient-Reported Outcome Measures (PROMs) seem poised to become the methods of choice for comparative performance assessment in research involving patients and their caregivers (Coulter 2017).

AUTHORS' CONCLUSIONS

Implications for practice

The results of this Cochrane review update allow us to confirm the conclusions of the previous update regarding the types of intervention that are the most effective for increasing the use of shared decision making (SDM).

It is uncertain whether any interventions for increasing the use of SDM by healthcare professionals (i.e. those targeting solely patients or healthcare professionals or both) as measured by observers or reported by patients are effective because the certainty of the evidence is very low.

Implications for research

There are several gaps in knowledge about the effectiveness of interventions focused on increasing shared decision making (SDM) among healthcare professionals.

- Future studies should be designed to minimize bias regarding risk of contamination and should have enough power to estimate the effects of active interventions on increased use of SDM among healthcare professionals (primary outcome).
- Future studies should report their methods and results in enough detail and according to the recommended reporting guidelines to allow extensive assessment of risk of bias.
- Further research is needed to develop better patient-derived measures of SDM. Improved methods for measurements might produce consistency between ratings of SDM by external observers and ratings by patients.

- Further research is required to assess the same intervention across multiple clinical contexts, health professionals and also across diverse jurisdictions (i.e. international collaborations).
- Further research is required to more clearly determine the cost of interventions to increase the use of SDM and the impact of different clinical care payment mechanisms on the use of SDM.

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REFERENCES

References to studies included in this review

Adarkwah 2016 *{published data only}*

Adarkwah CC, Jegan N, Heinzel-Gutenbrunner M, Kuhne F, Siebert U, Popert U, et al. Time-to-event versus ten-year-absolute-risk in cardiovascular risk prevention - does it make a difference? Results from the Optimizing-Risk-Communication (OptRisk) randomized-controlled trial. *BMC Medical Informatics and Decision Making* 2016;**16**(1):152.

Almario 2016 *{published data only}*

Almario CV, Chey WD, Khanna D, Mosadeghi S, Ahmed S, Afghani E, et al. Impact of National Institutes of Health gastrointestinal PROMIS measures in clinical practice: results of a multicenter controlled trial. *American Journal of Gastroenterology* 2016;**111**(11):1546-56.

Ampe 2017 *{published data only}*

Ampe S, Sevenants A, Smets T, Declercq A, Van Audenhove C. Advance care planning for nursing home residents with dementia: Influence of 'we DECide' on policy and practice. *Patient Education & Counselling* 2017;**100**(1):139-46.

Barton 2016 *{published data only}*

Barton JL, Trupin L, Schillinger D, Evans-Young G, Imboden J, Montori V M, et al. Use of low-literacy decision aid to enhance knowledge and reduce decisional conflict among a diverse population of adults with rheumatoid arthritis: results of a pilot study. *Arthritis Care Research* 2016;**68**(7):889-98.

Bernhard 2011 *{published data only}*

* Bernhard J, Butow P, Aldridge J, Juraskova I, Ribi K, Brown R. Communication about standard treatment options and clinical trials: can we teach doctors new skills to improve patient outcomes?. *Psycho-Oncology* 2011;**21**(12):1265–74. [DOI: 10.1002/pon.2044]

Butow P, Brown R, Aldridge J, Juraskova I, Zoller P, Boyle F, et al. Can consultation skills training change doctors' behaviour to increase involvement of patients in making decisions about standard treatment and clinical trials: a randomized controlled trial. *Health Expectations* 2015;**18**(6):2570-83. [PUBMED: 24975503]

Bieber 2006 *{published data only}*

Bieber C, Muller KG, Blumenstiel K, Schneider A, Richter A, Wilke S, et al. Long-term effects of a shared decision-making intervention on physician-patient interaction and outcome in fibromyalgia. A qualitative and quantitative 1 year follow-up of a randomized controlled trial. *Patient Education and Counseling* 2006;**63**(3):357-66. [CENTRAL: 00571329]

Branda 2013 *{published data only}*

Branda ME, LeBlanc A, Shah ND, Tiedje K, Ruud K, Van Houten H, et al. Shared decision making for patients with type 2 diabetes: A randomized trial in primary care. *BMC Health Services Research* 2013;**13**:301.

Butow 2004 *{published and unpublished data}*

Butow P, Devine R, Boyer M, Pendlebury S, Jackson M, Tattersall MH. Cancer consultation preparation package: changing patients but not physicians is not enough. *Journal of Clinical Oncology* 2004;**22**(21):4401-9. [CENTRAL: 00492482]

Causarano 2014 *{published data only}*

Causarano N, Platt J, Baxter NN, Bagher S, Jones JM, Metcalfe KA, et al. Pre-consultation educational group intervention to improve shared decision-making for postmastectomy breast reconstruction: a pilot randomized controlled trial. *Support Care Cancer* 2015;**23**(5):1365–75. [DOI: 10.1007/s00520-014-2479-6]

Cooper 2011 *{published and unpublished data}*

Cooper LA, Roter DL, Carson KA, Bone LR, Larson SM, Miller ER 3rd, et al. A randomized trial to improve patient-centered care and hypertension control in underserved primary care patients. *Journal of General Internal Medicine* 2011;**26**(11):1297-304. [DOI: 10.1007/s11606-011-1794-6]

Cooper 2013 *{published data only}*

Cooper LA, Ghods Dinoso BK, Ford DE, Roter DL, Primm AB, Larson SM, et al. Comparative effectiveness of standard versus patient-centered collaborative care interventions for depression among African Americans in primary care settings: the BRIDGE Study. *Health Research and Educational Trust* 2013;**48**(1):150-74. [DOI: 10.1111/j.1475-6773.2012.01435.x]

Cox 2017 *{published data only}*

Cox ED, Jacobsohn GC, Rajamanickam VP, Carayon P, Kelly MM, Wetterneck TB, et al. A family-centered rounds checklist, family engagement, and patient safety: a randomized trial. *Pediatrics* 2017;**139**(5):e20161688.

Coylewright 2016 *{published and unpublished data}*

Coylewright M, Dick S, Zmolek B, Askelin J, Hawkins E, Branda M, et al. PCI Choice Decision Aid for stable coronary artery disease: a randomized trial. *Circulation: Cardiovascular Quality and Outcomes* 2016;**9**(6):767-76.

Davison 1997 *{published data only}*

Davison BJ, Degner LF. Empowerment of men newly diagnosed with prostate cancer. *Cancer Nursing* 1997;**20**(3):187-96. [CENTRAL: 00140696]

Davison 2002 *{published data only}*

Davison BJ, Degner LF. Feasibility of using a computer-assisted intervention to enhance the way women with breast cancer communicate with their physicians. *Cancer Nursing* 2002;**25**(6):417-24.

Deen 2012 *{published data only}*

Deen D, Lu WH, Weintraub MR, Maranda MJ, Elshafey S, Gold MR. The impact of different modalities for activating patients in a community health center setting. *Patient Education and Counseling* 2012;**89**(1):178-83. [DOI: 10.1016/j.pec.2012.04.012]

Deinzer 2009 *{published data only}*

Deinzer A, Veelken R, Kohnen R, Schmieder RE. Is a shared decision-making approach effective in improving hypertension management?. *Journal of Clinical Hypertension* 2009;**11**(5):266-70. [PUBMED: 19534034]

Deschamps 2004 *{published and unpublished data}*

Deschamps MA, Taylor JG, Neubauer SL, Whiting S, Green K. Impact of pharmacist consultation versus a decision aid on decision making regarding hormone replacement therapy. *International Journal of Pharmacy Practice* 2004;**12**(1):21-8. [EMBASE: 2004506946]

Dolan 2002 *{published data only}*

Dolan JG, Frisina S. Randomized controlled trial of a patient decision aid for colorectal cancer screening. *Medical Decision Making* 2002;**22**(2):125-39. [CENTRAL: 00408555]

Eggly 2017 *{published and unpublished data}*

Eggly S, Hamel LM, Foster TS, Albrecht TL, Chapman R, Harper FWK, et al. Randomized trial of a question prompt list to increase patient active participation during interactions with black patients and their oncologists. *Patient Education and Counseling* 2017;**100**(5):818-26.

Elwyn 2004 *{published and unpublished data}*

Edwards A, Elwyn G, Hood K, Atwell C, Robling M, Houston H, et al. Patient-based outcome results from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice. *Family Practice* 2004;**21**(4):347-54. [DOI: 10.1093/fampra/cmh402]

* Elwyn G, Edwards A, Hood K, Robling M, Atwell C, Russell I, et al. Study Steering Group. Achieving involvement: Process outcomes from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice. *Family Practice* 2004;**21**(4):337-46. [CENTRAL: 00490204]

Longo MF, Cohen DR, Hood K, Edwards A, Robling M, Elwyn G, et al. Involving patients in primary care consultations: assessing preferences using discrete choice experiments. *British Journal of General Practice* 2006;**56**(522):35-42. [PUBMED: 16438813]

Epstein 2017 *{published and unpublished data}*

Epstein RM, Duberstein PR, Fenton JJ, Fiscella K, Hoerger M, Tancredi DJ, et al. Effect of a patient-centered communication intervention on oncologist-patient communication, quality of life, and health care utilization in advanced cancer: The VOICE randomized clinical trial. *JAMA Oncology* 2017;**3**(1):92-100.

Feng 2013 *{published data only}*

Feng B, Srinivasan M, Hoffman JR, Rainwater JA, Griffin E, Dragojevic M, et al. Physician communication regarding proatate cancer screening: analysis of unannounced standardized patient visits. *Annals of Family Medicine* 2013;**11**(4):315-23. [DOI: 10.1370/afm.1509]

Fiks 2015 *{published data only}*

Fiks AG, Mayne SL, Karavite DJ, Suh A, O'Hara R, Localio AR, et al. Parent-reported outcomes of a shared decision-making portal in asthma: a practice-based RCT. *Pediatrics* 2015;**135**(4):e965-73.

Fossli 2011 *{published and unpublished data}*

Fossli JB, Gulbrandsen P, Dahl FA, Krupat E, Frankel RM, Finset A. Effectiveness of a short course in clinical communication skills for hospital doctors: results of a crossover randomized controlled trial (ISRCTN22153332). *Patient Education and Counseling* 2011;**84**(2):163-9. [PUBMED: 21050695]

Hamann 2007 *{published data only}*

Hamann J, Cohen R, Leucht S, Busch R, Kissling W. Shared decision making and long-term outcome in schizophrenia treatment. *Journal of Clinical Psychiatry* 2007;**68**(7):992-7. [PUBMED: 17685733]

Hamann 2011 *{published data only}*

Hamann J, Mendel R, Meier A, Asani F, Pausch E, Leucht S, et al. "How to Speak to Your Psychiatrist": Shared Decision-Making Training for Inpatients with Schizophrenia. *Psychiatric Services* 2011;**62**(10):1218-21. [DOI: 10.1176/appi.ps.62.10.1218]

Hamann 2014 *{published data only}*

Hamann J, Maris N, Iosifidou P, Mendel R, Cohen R, Wolf P, et al. Effects of a question prompt sheet on active patient behaviour: a randomized controlled trial with depressed outpatients. *International Journal of Social Psychiatry* 2014;**60**(3):227–35. [DOI: 10.1177/0020764013482311]

Hamann 2017 *{published and unpublished data}*

Hamann J, Parchmann A, Sassenberg N, Bronner K, Albus M, Richter A, et al. Training patients with schizophrenia to share decisions with their psychiatrists: a randomized-controlled trial. *Social Psychiatry and Psychiatric Epidemiology* 2017;**52**(2):175-82.

Härter 2015 *{published data only}*

Bieber C, Nicolai J, Gschwendtner K, Muller N, Reuter K, Buchholz A, et al. How does a Shared Decision-Making (SDM) intervention for oncologists affect participation style and preference matching in patients with breast and colon cancer?. *Journal of Cancer Education* 2016;**[Epub ahead of print]**:1-8. [PUBMED: 27966192]

* Härter M, Buchholz A, Nicolai J, Reuter K, Komarahadi F, Kriston L, Kallinowski B, Eich W, Bieber C. Shared decision making and the use of decision aids. *Deutsches Ärzteblatt International* 2015 Oct;**112**(40):672-9. [DOI: 10.3238/arztebl.2015.0672]

Haskard 2008 *{published and unpublished data}*

Haskard KB, Williams SL, DiMatteo MR, Rosenthal R, White MK, Goldstein MG. Physician and patient communication training in primary care: effects on participation and satisfaction. *Health Psychology* 2008;**27**(5):513-22. [CENTRAL: 00670391]

Hess 2012 *{published data only}*

Hess EP, Knoedler MA, Shah ND, Kline JA, Breslin M, Branda ME, et al. The chest pain choice decision aid: a randomized trial. *Circulation: Cardiovascular Quality and Outcomes* 2012;**5**(3):251-9. [DOI: 10.1161/CIRCOUTCOMES.111.964791]

Hess 2016 *{published data only}*

Hess EP, Hollander JE, Schaffer JT, Kline JA, Torres CA, Diercks DB, et al. Shared decision making in patients with low risk chest pain: prospective randomized pragmatic trial. *BMJ* 2016;**355**:i6165.

Jouni 2017 *{published data only}*

Jouni H, Haddad RA, Marroush TS, Brown SA, Kruisselbrink TM, Austin EE, et al. Shared decision-making following disclosure of coronary heart disease genetic risk: results from a randomized clinical trial. *Journal of Investigative Medicine* 2017;**65**(3):681-8.

Kasper 2008 *{published data only}*

Kasper J, Köpke S, Mühlhauser I, Nübling M, Heesen C. Informed shared decision making about immunotherapy for patients with multiple sclerosis (ISDIMS): a randomized controlled trial. *European Journal of Neurology* 2008;**15**(12):1345-52. [PUBMED: 17503119]

Kennedy 2013 *{published data only}*

Kennedy A, Bower P, Reeves D, Blakeman T, Bowen R, Chew-Graham C, et al. Implementation of self management support for long term conditions in routine primary care settings: cluster randomised controlled trial. *BMJ* 2013 May 13;**346**:f2882. [DOI: 10.1136/bmj.f2882]

Koerner 2014 *{published data only}*

Koerner M, Wirtz M, Michaelis M, Ehrhardt H, Steger AK, Zerpies E, et al. A multicentre cluster randomized controlled study to evaluate a train-the-trainer programme for implementing internal and external participation in medical rehabilitation. *Clinical Rehabilitation* 2014;**28**(1):20–35. [DOI: 10.1177/0269215513494874]

Köpke 2014 *{published data only}*

Köpke S, Kern S, Ziemssen T, Berghoff M, Kleiter I, Marziniak M, et al. Evidence-based patient information programme in early multiple sclerosis: a randomised controlled trial. *Journal of Neurology, Neurosurgery and Psychiatry* 2014 Apr;**85**(4):411-8. [DOI: 10.1136/jnnp-2013-306441]

Korteland 2017 *{published and unpublished data}*

Korteland NM, Ahmed Y, Koolbergen DR, Brouwer M, de Heer F, Kluin J, et al. Does the use of a decision aid improve decision making in prosthetic heart valve selection? A multicenter randomized trial. *Circulation: Cardiovascular Quality and Outcomes* 2017;**10**(2):e003178.

Krist 2007 *{published data only}*

Krist AH, Woolf SH, Johnson RE, Kerns JW. Patient education on prostate cancer screening and involvement in decision making. *Annals of Family Medicine* 2007;**5**(2):112-9. [CENTRAL: 00579543]

Krones 2008 (ARRIBA-Herz) *{published and unpublished data}*

Hirsch O, Keller H, Albohn-Kuhne C, Krones T, Donner-Banzhoff N. Satisfaction of patients and primary care physicians with shared decision making. *Evaluation and the health professions* 2010;**33**(3):321-42. [DOI: 10.1177/0163278710376662]

* Krones T, Keller H, Sonnichsen A, Sadowski EM, Baum E, Wegscheider K, et al. Absolute cardiovascular disease risk and shared decision making in primary care: a randomized controlled trial. *Annals of Family Medicine* 2008;**8**(23):218-27. [DOI: 10.1370/afm.854]

Lalonde 2006 *{published and unpublished data}*

Lalonde L, O'Connor AM, Duguay P, Brassard J, Drake E, Grover SA. Evaluation of a decision aid and a personal risk profile in community pharmacy for patients considering options to improve cardiovascular health: the OPTIONS pilot study. *International Journal of Pharmacy Practice* 2006;**14**(1):51-62. [CENTRAL: 00622580]

Landrey 2012 *{published and unpublished data}*

Landrey A, Matlock DD, Andrews L, Bronsert M, Denberg T. Shared decision making in prostate-specific antigen testing: the effect of a mailed patient flyer prior to an annual exam. *Journal of Primary Care and Community Health* 2012;**4**(1):67-74. [DOI: 10.1177/2150131912447074]

LeBlanc 2015a *{published data only}*

LeBlanc A, Herrin J, Williams MD, Inselman JW, Branda ME, Shah ND, et al. Shared decision making for antidepressants in primary care: a cluster randomized trial. *JAMA Internal Medicine* 2015;**175**(11):1761-70.

LeBlanc 2015b *{published and unpublished data}*

LeBlanc A, Wang AT, Wyatt K, Branda ME, Shah ND, Van Houten H, et al. Encounter decision aid vs. clinical decision support or usual care to support patient-centered treatment decisions in osteoporosis: the Osteoporosis Choice Randomized Trial II. *PLOS One* 2015;**10**(5):e0128063.

Légaré 2012 *{published and unpublished data}*

Légaré F, Guerrier M, Nadeau C, Rhéaume C, Turcotte S, Labrecque M. Impact of DECISION + 2 on patient and physician assessment of shared decision making implementation in the context of antibiotics usefor acute respiratory infections. *Implementation Science* 2013 Dec 26;**8**:144. [DOI: 10.1186/1748-5908-8-144]

* Légaré F, Labrecque M, Cauchon M, Castel J, Turcotte S, Grimshaw J. Training family physicians in shared decision-making to reduce the overuse of antibiotics in acute respiratory infections: a cluster randomized trial. *Canadian Medical Association Journal* 2012;**184**(13):E726-34. [DOI: 10.1503/cmaj.120568]

Leighl 2011 *{published data only}*

Leighl NB, Shepherd HL, Butow PN, Clarke SJ, McJannett M, Beale PJ, et al. Supporting treatment decision making in advanced cancer: a randomized trial of a decision aid for patients with advanced colorectal cancer

considering chemotherapy. *Journal of Clinical Oncology* 2011;**29**(15):2077-84.

Loh 2007 *{published data only}*

Loh A, Simon D, Wills CE, Kriston L, Niebling W, Harter M. The effects of a shared decision-making intervention in primary care of depression: a cluster-randomized controlled trial. *Patient Education and Counseling* 2007;**67**(3):324-32. [CENTRAL: 00609803]

Maclachlan 2016 *{published data only}*

Maclachlan EW, Shepard-Perry MG, Ingo P, Uusiku J, Mushimba R, Simwanza R, et al. Evaluating the effectiveness of patient education and empowerment to improve patient-provider interactions in antiretroviral therapy clinics in Namibia. *AIDS Care* 2016;**28**(5):620-7.

Maindal 2014 *{published data only}*

* Maindal HT, Carlsen AH, Lauritzen T, Sandbaek A, Simmons RK. Effect of a participant-driven health education programme in primary care for people with hyperglycaemia detected by screening: 3-year results from the Ready to Act randomized controlled trial (nested within the ADDITION-Denmark study). *Diabetic Medicine* 2014 Aug;**31**(8):976-86. [DOI: 10.1111/dme.12440]

Maindal HT, Sandbæk A, Kirkevold M, Lauritzen T. Effect on motivation, perceived competence, and activation after participation in the ''Ready to Act'' programme for people with screen-detected dysglycaemia: a 1-year randomised controlled trial, Addition-DK. *Scandinavian Journal of Public Health* 2011 May;**39**(3):262-71. [DOI: 10.1177/1403494811402721]

Maranda 2014 *{published data only}*

Maranda MJ, Deen D, Elshafey S, Herrera M, Gold MR. Response to a patient activation intervention among Spanish-speaking patients at a community health center in New York City. *Journal of Health Care for the Poor and Underserved* 2014 May;**25**(2):591-604. [DOI: 10.1353/hpu.2014.0110]

Mathers 2012 *{published data only}*

Mathers N, Ng CJ, Campbell MJ, Colwell B, Brown I, Bradley A. Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices: a cluster randomised controlled trial (PANDAs) in general practice. *BMJ Open* 2012 Nov 5;**2**(6):pii: e001469. [DOI: 10.1136/bmjopen-2012-001469]

Montori 2011 *{published and unpublished data}*

Montori VM, Shah ND, Pencille LJ, Branda ME, Van Houten HK, Swiglo BA, et al. Use of a decision aid to improve treatment decisions in osteoporosis: the osteoporosis choice randomized trial. *American Journal of Medicine* 2011;**124**(6):549-56.

Mullan 2009 *{published and unpublished data}*

Mullan RJ, Montori VM, Shah ND, Christianson TJ, Bryant SC, Guyatt GH, et al. The diabetes mellitus medication choice decision aid: a randomized trial. *Archives of Internal Medicine* 2009;**169**(17):1560-8.

Murray 2001 *{published data only}*

Murray E, Davis H, Tai SS, Coulter A, Gray A, Haines A. Randomised controlled trial of an interactive multimedia decision aid on benign prostatic hypertrophy in primary care. *BMJ* 2001;**323**(7311):493-6. [DOI: 10.1136/bmj.323.7311.493]

Murray 2010 *{published data only}*

Murray MA, Stacey D, Wilson KG, O'Connor AM. Skills training to support patients considering place of end-of-life care: a randomized control trial. *Journal of Palliative Care* 2010;**26**(2):112-21. [PUBMED: 20718396]

Myers 2011 *{published data only}*

Myers RE, Daskalakis C, Kunkel EJ, Cocroft JR, Riggio JM, Capkin M, et al. Mediated decision support in prostate cancer screening: a randomized controlled trial of decision counselling. *Patient Education and Counseling* 2011;**83**(2):240-6. [PUBMED: 20619576]

Nannenga 2009 *{published and unpublished data}*

Jones LA, Weymiller AJ, Shah N, Bryant SC, Christianson TJH, Guyatt GH, et al. Should clinicians deliver decision aids? Further exploration of the statin choice randomized trial results. *Medical Decision Making* 2009;**29**(4):468-74. [DOI: 10.1177/0272989X09333120]

* Nannenga MR, Montori VM, Weymiller AJ, Smith SA, Christianson TJ, Bryant SC, et al. A treatment decision aid may increase patient trust in the diabetes specialist. The Statin Choice randomized trial. *Health Expectations* 2009;**12**(1):38-44. [PUBMED: 19250151]

Weymiller AJ, Montori VM, Jones LA, Gafni A, Guyatt GH, Bryant SC, et al. Helping patients with type 2 diabetes mellitus make treatment decisions: statin choice randomized trial. *Archives of Internal Medicine* 2007;**167**(10):1076-82.

O'Cathain 2002 *{published data only}*

O'Cathain A, Walters SJ, Nicholl JP, Thomas KJ, Kirkham M. Use of evidence based leaflets to promote informed choice in maternity care: randomised controlled trial in everyday practice. *BMJ* 2002;**324**(7338):643. [DOI: 10.1136/bmj.324.7338.643]

Perestelo-Perez 2016 *{published data only}*

Perestelo-Perez L, Rivero-Santana A, Boronat M, Sanchez-Afonso JA, Perez-Ramos J, Montori VM, et al. Effect of the statin choice encounter decision aid in Spanish patients with type 2 diabetes: a randomized trial. *Patient Education and Counselling* 2016;**99**(2):295-9.

Pickett 2012 *{published data only}*

Pickett SA, Diehl SM, Steigman PJ, Prater JD, Fox A, Shipley P, et al. Consumer empowerment and self-advocacy outcomes in a randomized study of peer-led education. *Community Mental Health Journal* 2012;**48**(4):420-30. [DOI: 10.1007/s10597-012-9507-0]

Raynes-Greenow 2010 *{published data only}*

Raynes-Greenow CH, Nassar N, Torvaldsen S, Trevena L, Roberts CL. Assisting informed decision making for labour

analgesia: a randomised controlled trial of a decision aid for labour analgesia versus a pamphlet. *BMC Pregnancy and Childbirth* 2010;**10**:15. [PUBMED: 20377844]

Rise 2012 *{published data only}*

Rise MB, Eriksen L, Grimstad H, Steinsbekk A. The long-term effect on mental health symptoms and patient activation of using patient feedback scales in mental health out-patient treatment. A randomised controlled trial. *Patient Education and Counselling* 2016;**99**(1):164-8.

* Rise MB, Eriksen L, Grimstad H, Steinsbekk A. The short-term effect on alliance and satisfaction of using patient feedback scales in mental health out-patient treatment. A randomised controlled trial. *BMC Health Services Research* 2012 Oct 3;**12**:348. [DOI: 10.1186/1472-6963-12-348]

Roter 2012 *{published data only}*

Roter DL, Wexler R, Naragon P, Forrest B, Dees J, Almodovar A, et al. The impact of patient and physician computer mediated communication skill training on reported communication and patient satisfaction. *Patient Education and Counseling* 2012;**88**(3):406-13. [DOI: 10.1016/j.pec.2012.06.020]

Sanders 2017 *{published data only}*

Sanders AR, Bensing JM, Essed MA, Magnee T, de Wit NJ, Verhaak PF. Does training general practitioners result in more shared decision making during consultations?. *Patient Education and Counselling* 2017;**100**(3):563-74.

Schroy 2011 *{published data only}*

Schroy PC 3rd, Emmons K, Peters E, Glick JT, Robinson PA, Lydotes MA, et al. The impact of a novel computer-based decision aid on shared decision making for colorectal cancer screening: a randomized trial. *Medical Decision Making* 2011;**31**(1):93-107. [DOI: 10.1177/0272989X10369007]

Schroy 2016 *{published and unpublished data}*

Schroy PC 3rd, Duhovic E, Chen CA, Heeren TC, Lopez W, Apodaca DL, et al. Risk stratification and shared decision making for colorectal cancer screening: a randomized controlled trial. *Medical Decision Making* 2016;**36**(4):526-35.

Shepherd 2011 *{published and unpublished data}*

Shepherd HL, Barratt A, Trevena LJ, McGeechan K, Carey K, Epstein RM, et al. Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Education and Counseling* 2011;**84**(3):379-85. [DOI: 10.1016/j.pec.2011.07.022]

Sheridan 2012 *{published data only}*

Sheridan SL, Golin C, Bunton A, Lykes JB, Schwartz B, McCormack L, et al. Shared decision making for prostate cancer screening: the results of a combined analysis of two practice-based randomized controlled trials. *BMC Medical Informatics and Decision Making* 2012 Nov 13;**12**:130. [DOI: 10.1186/1472-6947-12-130]

Sheridan 2014 *{published data only}*

Sheridan SL, Draeger LB, Pignone MP, Rimer B, Bangdiwala SI, Cai J, et al. The effect of a decision aid intervention on decision making about coronary heart disease risk reduction: secondary analyses of a randomized trial. *BMC Medical Informatics and Decision Making* 2014 Feb 28;**14**:14. [DOI: 10.1186/1472-6947-14-14]

Smallwood 2017 *{published and unpublished data}*

Smallwood AJ, Schapira MM, Fedders M, Neuner JM. A pilot randomized controlled trial of a decision aid with tailored fracture risk tool delivered via a patient portal. *Osteoporosis International* 2017;**28**(2):567-76.

Stacey 2006 *{published data only}*

* Stacey D, O'Connor AM, Graham ID, Pomey MP. Randomized controlled trial of the effectiveness of an intervention to implement evidence-based patient decision support in a nursing call centre. *Journal of Telemedicine and Telecare* 2006;**12**(8):410-5. [DOI: 10.1258/135763306779378663]

Stacey D, Taljaard M, Drake ER, O'Connor AM. Audit and feedback using the brief Decision Support Analysis Tool (DSAT-10) to evaluate nurse–standardized patient encounters. *Patient Education and Counseling* 2008;**73**(3):519-25. [DOI: 10.1016/j.pec.2008.07.016]

Stiggelbout 2008 *{published data only}*

Stiggelbout AM, Molewijk AC, Otten W, Van Bockel JH, Bruijninckx CM, Van der Salm I, et al. The impact of individualized evidence-based decision support on aneurysm patients' decision making, ideals of autonomy, and quality of life. *Medical Decision Making* 2008;**28**(5):751-62. [PUBMED: 18626126]

Street 1995 *{published data only}*

Street RL Jr, Voigt B, Geyer C Jr, Manning T, Swanson GP. Increasing patient involvement in choosing treatment for early breast cancer. *Cancer* 1995;**76**(11):2275-85. [CENTRAL: 00124857]

Tai-Seale 2016 *{published and unpublished data}*

Dillon EC, Stults CD, Wilson C, Chuang J, Meehan A, Li M, et al. An evaluation of two interventions to enhance patient-physician communication using the observer OPTION5 measure of shared decision making. *Patient Education and Counseling* 2017;**100**(10):1910-7. [PUBMED: 28532861]

* Tai-Seale M, Elwyn G, Wilson C J, Stults C, Dillon E C, Li M, et al. Enhancing shared decision making through carefully designed interventions that target patient and provider behavior. *Health Affairs* 2016;**35**(4):605-12.

Thomson 2007 *{published data only}*

Thomson RG, Eccles MP, Steen IN, Greenaway J, Stobbart L, Murtagh MJ, May CR. A patient decision aid to support shared decision-making on anti-thrombotic treatment of patients with atrial fibrillation: randomised controlled trial. *Quality & Safety in Health Care* 2007 Jun;**16**(3):216-23. [DOI: 10.1136/qshc.2006.018481]

Tinsel 2013 *{published data only}*

Tinsel I, Buchholz A, Vach W, Siegel A, Dürk T, Buchholz A, et al. Shared decision-making in antihypertensive therapy: a cluster

randomised controlled trial. *BMC Family Practice* 2013 Sep 11;**14**:135. [doi: 10.1186/1471-2296-14-135]

van der Krieke 2013 *{published data only}*

van der Krieke L, Emerencia AC, Boonstra N, Wunderink L, de Jonge P, Sytema S. A web-based tool to support shared decision making for people with a psychotic disorder: randomized controlled trial and process evaluation. *Journal of Medical Internet Research* 2013 Oct 7;**15**(10):e216. [10.2196/jmir.2851]

van Peperstraten 2010 *{published data only}*

* van Peperstraten A, Nelen W, Grol R, Zielhuis G, Adang E, Stalmeier P, et al. The effect of a multifaceted empowerment strategy on decision making about the number of embryos transferred in in vitro fertilisation: randomised controlled trial. BMJ 2010:341:c2501. [DOI: 10.1136/bmj.c2501]

van Peperstraten AM, Hermens RP, Nelen WL, Stalmeier PF, Wetzels AM, Maas PH, et al. Deciding how many embryos to transfer after in vitro fertilisation: development and pilot test of a decision aid. *Patient Education and Counselling* 2010;**78**(1):124-9. [DOI: 10.1016/j.pec.2009.04.007]

van Roosmalen 2004 *{published data only}*

van Roosmalen MS, Stalmeier PF, Verhoef LC, Hoekstra-Weebers JE, Oosterwijk JC, Hoogerbrugge N, et al. Randomized trial of a shared decision-making intervention consisting of trade-offs and individualized treatment information for BRCA1/2 mutation carriers. *Journal of Clinical Oncology* 2004 Aug 15;**22**(16):3293-301. [DOI: 10.1200/JCO.2004.05.066]

van Tol-Geerdink 2016 *{published and unpublished data}*

van Tol-Geerdink JJ, Leer JW, Wijburg CJ, van Oort IM, Vergunst H, van Lin EJ, et al. Does a decision aid for prostate cancer affect different aspects of decisional regret, assessed with new regret scales? A randomized, controlled trial. *Health Expectations* 2016;**19**(2):459-70.

Vestala 2013 *{published data only}*

Vestala H, Frisman GH. Can participation in documentation influence experiences of involvement in care decision-making?. *Open Nursing Journal* 2013 May 16;**7**:66-72. [DOI: 10.2174/1874434620130516002]

Vodermaier 2009 *{published data only}*

Vodermaier A, Caspari C, Koehm J, Kahlert S, Ditsch N, Untch M. Contextual factors in shared decision making: a randomised controlled trial in women with a strong suspicion of breast cancer. *British Journal of Cancer* 2009;**100**(4):590-7. [DOI: 10.1038/sj.bjc.6604916]

Warner 2015 *{published data only}*

Warner DO, LeBlanc A, Kadimpati S, Vickers KS, Shi Y, Montori VM. Decision aid for cigarette smokers scheduled for elective surgery. *Anesthesiology* 2015;**123**(1):18-28.

Wetzels 2005 *{published data only}*

Wetzels R, Wensing M, van Weel C, Grol R. A consultation leaflet to improve an older patient's involvement in general practice care: a randomized trial. *Health Expectations* 2005;**8**(4):286-94. [CENTRAL: 00531671]

Wilkes 2013 *{published data only}*

Wilkes MS, Day FC, Srinivasan M, Griffin E, Tancredi DJ, Rainwater JA, et al. Pairing physician education with patient activation to improve shared decisions in prostate cancer screening: a cluster randomized controlled trial. *Annals of Family Medicine* 2013;**11**(4):324-34. [DOI: 10.1370/afm.1550]

Wolderslund 2017 *{published data only}*

Wolderslund M, Kofoed PE, Holst R, Axboe M, Ammentorp J. Digital audio recordings improve the outcomes of patient consultations: a randomised cluster trial. *Patient Education and Counselling* 2017;**100**(2):242-9.

References to studies excluded from this review

Alexander 2006 *{published data only}*

Alexander SC, Keitz SA, Sloane R, Tulsky JA. A controlled trial of a short course to improve residents' communication with patients at the end of life. *Academic Medicine* 2006;**81**(11):1008-12. [DOI: 10.1097/01.ACM.0000242580.83851.ad]

Aljumah 2015 *{published data only}*

Aljumah K, Hassali MA. Impact of pharmacist intervention on adherence and measurable patient outcomes among depressed patients: a randomised controlled study. *BMC Psychiatry* 2015;**15**:219.

Allen 2009 *{published data only}*

Allen JD, Mohllajee AP, Shelton RC, Drake BF, Mars DR. A computer-tailored intervention to promote informed decision making for prostate cancer screening among African American men. American Journal of Men's Health 2009; Vol. 3, issue 4:340-51. [DOI: 10.1177/1557988308325460]

Boehmer 2014 *{published data only}*

Boehmer KR, Egginton JS, Branda ME, Kryworuchko J, Bodde A, Montori VM, et al. Missed opportunity? Caregiver participation in the clinical encounter. A videographic analysis. *Patient Education and Counseling* 2014;**96**(3):302-7. [DOI: 10.1016/j.pec.2014.05.016]

Boyd 2010 *{published data only}*

Boyd CM, Reider L, Frey K, Scharfstein D, Leff B, Wolff J, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomesfrom a cluster-randomized controlled trial. *Journal of General Internal Medicine* 2010;**25**(3):235-42. [DOI: 10.1007/s11606-009-1192-5]

Brinkman 2013 *{published data only}*

Brinkman WB, Hartl Majcher J, Poling LM, Shi G, Zender M, Sucharew H, et al. Shared decision-making to improve attention-deficit hyperactivity disorder care. *Patient Education and Counseling* 2013;**93**(1):95-101. [DOI: 10.1016/j.pec.2013.04.009]

Brown 2004 *{published data only}*

Brown RF, Butow PN, Sharrock MA, Henman M, Boyle F, Goldstein D, et al. Education and role modelling for clinical decisions with female cancer patients. *Health Expectations* 2004;**7**(4):303-16. [CENTRAL: 00504159]

Davison 2007 *{published data only}*

Davison BJ, Goldenberg SL, Wiens KP, Gleave ME. Comparing a generic and individualized information decision support intervention for men newly diagnosed with localized prostate cancer. *Cancer Nursing* 2007;**30**(5):E7-15. [DOI: 10.1097/01.NCC.0000290819.22195.d6]

Golnik 2012 *{published data only}*

Golnik A, Scal P, Wey A, Gaillard P. Autism-specific primary care medical home intervention. Journal of Autism and Developmental Disorders 2012; Vol. 42, issue 6:1087-93. [DOI: 10.1007/s10803-011-1351-5]

Green 2011 *{published data only}*

Green MJ, Levi BH. Teaching advance care planning to medical students with a computer-based decision aid. *Journal of Cancer Education* 2011;**26**(1):82-91. [PUBMED: 20632222]

Hack 2007 *{published data only}*

Hack TF, Pickles T, Bultz BD, Ruether JD, Degner LF. Impact of providing audiotapes of primary treatment consultations to men with prostate cancer: a multi-site, randomized, controlled trial. *Psycho-Oncology* 2007;**16**(6):543-52. [PUBMED: 16991107]

Hanson 2011 *{published data only}*

Hanson LC, Carey TS, Caprio AJ, Lee TJ, Ersek M, Garrett J, et al. Improving decision-making for feeding options in advanced dementia: A randomized, controlled trial. *Journal of the American Geriatrics Society* 2011;**59**(11): 2009-16. [DOI: 10.1111/j.1532-5415.2011.03629.x.]

Harmsen 2014 *{published data only}*

Harmsen CG, Kristiansen IS, Larsen PV, Nexøe J, Støvring H, Gyrd-Hansen D, et al. Communicating risk using absolute risk reduction or prolongation of life formats: cluster-randomised trial in general practice. *British Journal of General Practice* 2014;**64**(621):e199-207. [DOI: 10.3399/bjgp14X677824]

Hermansen Kobulnicky 2002 *{published data only}*

Hermansen Kobulnicky CJ. The behavioral impact of teaching patients to monitor side effects of chemotherapy: an intervention study. Madison: MI: University of Michigan, 2002.

Hoffman 2014 *{published data only}*

Hoffmann TC, Bennett S, Tomsett C, Del Mar C. Brief training of student clinicians in shared decision making: a single-blind randomized controlled trial. *Journal of General Internal Medicine* 2014;**29**(6):844-9. [DOI: 10.1007/s11606-014-2765-5]

Jangland 2012 *{published data only}*

Jangland E, Carlsson M, Lundgren E, Gunningberg L. The impact of an intervention to improve patient participation in a surgical care unit: a quasi-experimental study. *International Journal of Nursing Studies* 2012 May;**49**(5):528-38. [DOI: 10.1016/j.ijnurstu.2011.10.024]

Koekkoek 2012 *{published data only}*

Koekkoek B, van Meijel B, Schene A, Smit A, Kaasenbrood A, Hutschemaekers G. Interpersonal Community Psychiatric Treatment for non-psychoticchronic patients and nurses in outpatient mental health care: a controlled pilot study on feasibility and effects. *International Journal of Nursing Studies* 2012;**49**(5):549-59. [DOI: 10.1016/j.ijnurstu.2011.11.003]

Kopke 2009 *{published data only}*

Köpke S, Kasper J, Mühlhauser I, Nübling M, Heesen C. Patient education program to enhance decision autonomy in multiple sclerosis relapse management: a randomized-controlled trial. *Multiple Sclerosis* 2009;**15**(1):96-104. [DOI: 10.1177/1352458508095921]

Kupke 2013 *{published data only}*

Kupke J, Wicht MJ, Stützer H, Derman SH, Lichtenstein NV, Noack MJ. Does the use of a visualised decision board by undergraduate students during shared decision-makingenhance patients' knowledge and satisfaction? A randomised controlled trial. *European Journal of Dental Education* 2013;**17**(1):19-25. [DOI: 10.1111/eje.12002]

Langewitz 1998 *{published data only}*

Langewitz WA, Eich P, Kiss A, Wössmer B. Improving communication skills a randomized controlled behaviorally oriented intervention study for residents in internal medicine. *Psychosomatic Medicine* 1998;**60**(3):268-76. [PUBMED: 9625213]

Leader 2012 *{published data only}*

Leader A, Daskalakis C, Braddock CH 3rd, Kunkel EJ, Cocroft JR, Bereknyei S, et al. Measuring informed decision making about prostate cancer screening in primary care. Medical Decision Making 2012; Vol. 32, issue 2:327-36. [DOI: 10.1177/0272989X11410064]

LeBlanc 2017 *{published data only}*

LeBlanc A, Egginton J, Inselman J, Dick S, Schuerman J, Branda M, et al. Dissemination and Implementation of Evidence-Based Medicine in Primary Care Through The Use of Encounter Decision Aids: The ShareEBM Pragmatic Trial. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Oral communications. 2017.

Man-Son-Hing 1999 *{published data only}*

Man-Son-Hing M, Laupacis A, O'Connor AM, Biggs J, Drake E, Yetisir E, et al. A patient decision aid regarding antithrombotic therapy for stroke prevention in atrial fibrillation: a randomized controlled trial. *JAMA* 1999;**282**(8):737-43. [DOI: 10.1001/jama.282.8.737]

Maslin 1998 *{published data only}*

Maslin AM, Baum M, Walker JS, A'Hern R, Prouse A. Using an interactive video disk in breast cancer patient support. *Nursing Times* 1998;**94**(44):52-5. [PUBMED: 9919256]

McCormack 2011 *{published data only}*

McCormack L, Treiman K, Bann C, Williams-Piehota P, Driscoll D, Poehlman J, et al. Translating medical evidence

to promote informed health care decisions. Health Services Research 2011; Vol. 46, issue 4:1200-23. [DOI: 10.1111/j.1475-6773.2011.01248]

NCT01550731 *{published data only}*

NCT01550731. Preparing older veterans with serious and cronic illness for decision making (PREPARE). https://clinicaltrials.gov/ct2/show/NCT01550731 (accessed 25 September 2017).

NCT02033499 *{published data only}*

NCT02033499. Three approaches to glucose monitoring in non-insulin treated diabetes. https://clinicaltrials.gov/show/NCT02033499 (accessed December 2016).

NCT02319525 *{published data only}*

NCT02319525. Individualized patient decision making for treatment choices among minorities with Lupus. https://clinicaltrials.gov/ct2/show/NCT02319525 (accessed 25 September 2017).

Ockhuysen-Vermey 2008 *{published data only}*

Ockhuysen-Vermey CF, Henneman L, van Asperen CJ, Oosterwijk JC, Menko FH, Timmermans D. Design of the BRISC study: a multicentre controlled clinical trial to optimize the communication of breast cancer risks in genetic counselling. *BMC Cancer* 2008;**8**:283. [DOI: 10.1186/1471-2407-8-283]

Price-Haywood 2014 *{published data only}*

Price-Haywood EG, Harden-Barrios J, Cooper LA. Comparative effectiveness of audit-feedback versus additional physician communication training to improve cancer screening for patients with limited health literacy. *Journal of General Internal Medicine* 2014;**29**(8):1113-21. [DOI: 10.1007/s11606-014-2782-4]

Riippa 2014 *{published data only}*

Riippa I, Linna M, Rönkkö I. The effect of a patient portal with electronic messaging on patient activation among chronically ill patients: controlled before-and-after study. *Journal of Medical Internet Research* 2014 Nov 19;**16**(11):e257. [DOI: 10.2196/jmir.3462.]

Roelands 2004 *{published data only}*

Roelands M, Van Oost P, Stevens V, Depoorter A, Buysse A. Clinical practice guidelines to improve shared decision-making about assistive device use in home care: a pilot intervention study. *Patient Education and Counseling* 2004;**55**(2):252-64. [DOI: 15530763]

Schwalm 2012 *{published data only}*

Schwalm JD, Stacey D, Pericak D, Natarajan MK. Radial artery versus femoral artery access options in coronary angiogram procedures: randomized controlled trial of a patient-decision aid. Circulation: Cardiovascular Quality and Outcomes 2012; Vol. 5, issue 3:260-6. [DOI: 10.1161/CIRCOUTCOMES]

Simon 2012 *{published data only}*

Simon D, Kriston L, von Wolff A, Buchholz A, Vietor C, Hecke T, et al. Effectiveness of a web-based, individually tailored decision aid for depression or acute low back pain: a randomized controlled trial. *Patient Education and Counseling* 2012;**87**(3):360-8. [DOI: 10.1016/j.pec.2011.10.009]

Smith 2010a *{published data only}*

Smith SK, Trevena L, Simpson JM, Barratt A, Nutbeam D, McCaffery KJ. A decision aid to support informed choices about bowel cancer screening among adults with low education: randomised controlled trial. BMJ 2010; Vol. 341:c5370. [DOI: 10.1136/bmj.c5370]

Spertus 2011 *{unpublished data only}*

Spertus J. Testing evidence-based, individualized informed consent forms to improve patients' experiences with percutaneous coronary intervention. Late-Breaking Clinical Trial and Clinical Science: Special Reports Abstracts from the American Heart Association's Scientific Sessions 2011.

van Tol-Geerdink 2008 *{published data only}*

van Tol-Geerdink JJ, Leer JW, van Lin EN, Schimmel EC, Huizenga H, van Daal WA, et al. Offering a treatment choice in the irradiation of prostate cancer leads to better informed and more active patients, without harm to well-being. *International Journal of Radiation Oncology, Biology, Physics* 2008;**70**(2):442-8. [PUBMED: 17765404]

Wagner 2012 *{published data only}*

Wagner PJ, Dias J, Howard S, Kintziger KW, Hudson MF, Seol YH, et al. Personal health records and hypertension control:a randomized trial. *Journal of the American Medical Informatics Association* 2012;**19**(4):626-34. [DOI: 10.1136/amiajnl-2011-000349]

Whelan 2003 *{published data only}*

Whelan T, Sawka C, Levine M, Gafni A, Reyno L, Willan A, et al. Helping patients make informed choices: a randomized trial of a decision aid for adjuvant chemotherapy in lymph node-negative breast cancer. *Journal of the National Cancer Institute* 2003;**95**(8):581-7. [DOI: 10.1093/jnci/95.8.581]

References to studies awaiting assessment

Simmons 2017 *{published data only}*

Simmons M. 'If I could see on a piece of paper options for treatment that would just be insane': Shared decision making in mental health. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Posters Sessions. 2017.

van Veenendaal 2017 *{published data only}*

van Veenendaal H, Voogdt-Pruis H, Schuurman M, Visserman E, Oskam J, Ubbink D, et al. Implementing shared decision-making (SDM) and time-out for breast cancer patients in six Dutch Hospitals. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Posters Sessions. 2017.

References to ongoing studies

ACTRN12614000593639 *{published data only}*

ACTRN12614000593639. Improving the engagement of patients suffering from wisdom tooth problems in shared clinical decision making using different formats of health information toward achieving better healthcare outcomes. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12614000593639 (accessed 25 September 2017).

ACTRN12616000213448 *{published data only}*

ACTRN12616000213448. Development and evaluation of an Australian adult health literacy program for socially disadvantaged adults attending TAFE. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12616000213448 (accessed 25 September 2017).

ACTRN12616000644460 *{published data only}*

ACTRN12616000644460. Evaluating decision aids for acute respiratory infections on the use of antibiotics in general practice. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12616000644460 (accessed 25 September 2017).

ACTRN12617000614392 *{published data only}*

ACTRN12617000614392. Whakapai e Te Ara Ha: Asthma self-management programme for the whanau of tamariki Maori with asthma. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12617000614392 (accessed 25 September 2017).

ACTRN12617000840381 *{published data only}*

ACTRN12617000840381. Enhancing decision-making about treatment in bipolar II disorder: evaluation of a treatment decision-aid for patients and their family. https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12617000840381 (accessed 25 September 2017).

Adekpedjou ongoing *{published data only}*

Adekpedjou R, Stacey D, Brière N, Freitas A, Garvelink M, Turcotte S, et al. Improving the decision-making process with caregivers of elderly people about housing options: a cluster randomised trial. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Oral communications. 2017.

Altshuler 2016 *{published data only}*

Altshuler L, Plaksin J, Zabar S, Wallach A, Sawicki C, Kundrod S, et al. Transforming the patient role to achieve better outcomes through a patient empowerment program: a randomized wait-list control trial protocol. *JMIR Research Protocols* 2016;**5**(2):e68.

DRKS00000191 *{published data only}*

DRKS00000191. Umsetzung des Modells der Partizipativen Entscheidungsfindung in der hausärztlichen Praxis am Beispiel der Patientenverfügung-Patientenverfügung im Partizipativen Prozess (PPP). http://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00000191 (accessed 25 September 2017).

DRKS00010880 *{published data only}*

DRKS00010880. Shared Decision Making PLUS – eine Cluster-randomisierte Studie mit stationär behandelten Patienten mit Schizophrenie. http://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00010880 (accessed 25 September 2017).

Dwinger ongoing *{published data only}*

Dwinger S, Gschwendtner K, Müller N, Bieber C, Härter M, Bergelt C. Development and pilot testing of a face-to-face SDM coaching intervention for oncologists. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Oral communications. 2017.

Fagerlin ongoing *{published data only}*

Fagerlin A, Holmes-Rovner M, Scherer LD, Kahn VC, Ubel PA. The impact of shared decision making on patient involvement in two prostate cancer decision aid trials. ISDM2015. Sydney, Australia: Joint International Shared Decision-Making and International Society for Evidence-Based Health Care Conference. 2015.

Finderup 2017 *{published data only}*

Finderup J, Dam Jensen JK, Lomborg K. Developing and pilot testing a shared decision-making intervention for dialysis choice. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Oral communications. 2017.

Henselmans ongoing *{published data only}*

Henselmans H, van Laarhoven HWM, de Haes HCJM, Tokat M, Engelhardt EG, van Maarschalkerweerd P, et al. Effect of a Skills Training for oncologists on shared decision making about palliative chemotherapy in simulated encounters. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Posters Sessions. 2017.

ISRCTN37929939 *{published data only}*

ISRCTN37929939. Nurse-led immunotherapy decision coaching in persons with relapsing-remitting multiple sclerosis (DECIMS). http://www.isrctn.com/ISRCTN37929939 (accessed 25 September 2017).

ISRCTN46305518 *{published data only}*

ISRCTN46305518. Informed shared decision making supported by decision coaches for women with ductal carcinoma in situ. http://www.isrctn.com/ISRCTN46305518 (accessed 25 September 2017).

ISRCTN63110516 *{published data only}*

ISRCTN63110516. ACTION: cancer patient involvement in medical decision making. http://www.isrctn.com/ISRCTN63110516 (accessed 25 September 2017).

Lifford ongoing *{published data only}*

Lifford K, Burton M, Armitage F, Collins K, Reed M, Wyld L, et al. Bridging the Age Gap trial of decision support interventions for older women with breast cancer: Preliminary process evaluation. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Posters Sessions. 2017.

Ludden ongoing *{published data only}*

Ludden T, Taylor Y, Kuhn L, McWilliams A, Dulin M, Tapp H. "Who Made the Decision Today?" Surveying asthma patients level of shared decision making in an RCT. ISDM2015. Sydney, Australia: Joint International Shared Decision-Making and International Society for Evidence-Based Health Care Conference. 2015.

NCT01485627 *{published data only}*

NCT01485627. VOICE: Values and Options in Cancer Care (VOICE). https://clinicaltrials.gov/show/NCT01485627 (accessed 16 December 2016).

NCT01519999 *{published data only}*

NCT01519999. Colorectal cancer screening with iImproved shared decision making. https://clinicaltrialbase.com/study/NCT01519999 (accessed 19 December 2016).

NCT01828567 *{published data only}*

NCT01828567. Will veterans engage in prevention after HRA-guided shared decision making? (ACTIVATE). https://clinicaltrials.gov/show/NCT01828567 (accessed 16 December 2016).

NCT01837953 *{published data only}*

NCT01837953. Stepped care for binge eating disorder: predicting response to minimal intervention in a randomized controlled trial. https://clinicaltrials.gov/show/NCT01837953 (accessed 16 December 2016).

NCT01838226 *{published data only}*

NCT01838226. Randomized controlled trial of group prevention coaching. https://clinicaltrials.gov/show/NCT01838226 (accessed 16 December 2016).

NCT01866228 *{published data only}*

NCT01866228. Clinical trial of the impact of treatment consultation recordings on cancer patient outcomes. https://ClinicalTrials.gov/show/NCT01866228 (accessed 16 December 2016).

NCT01992926 *{published data only}*

NCT01992926. Facilitating anemia treatment risk communication for patients with kidney disease: decision aid trial. https://clinicaltrials.gov/ct2/show/NCT01992926 (accessed 25 September 2017).

NCT02047929 *{published data only}*

NCT02047929. Comparing types of implementation of a shared decision making intervention (ADAPT-NC). https://clinicaltrials.gov/show/NCT02047929 (accessed 16 December 2016).

NCT02063087 *{published data only}*

NCT02063087. Shared decision making in parents of children with head trauma: Head CT Choice (Head CT Choice). https://clinicaltrials.gov/show/NCT02063087 (accessed 16 December 2016).

NCT02136732 *{published data only}*

NCT02136732. Chronic care management for adults at FQHCs. https://clinicaltrials.gov/show/NCT02136732 (accessed 16 December 2016).

NCT02138448 *{published data only}*

NCT02138448. Implementing personal health records to promote evidence-based cancer screening. https://clinicaltrials.gov/show/NCT02138448 (accessed 16 December 2016).

NCT02146573 *{published data only}*

NCT02146573. Pediatric Continuity Care Intensivist (CCI). https://clinicaltrials.gov/show/NCT02146573 (accessed 16 December 2016).

NCT02165735 *{published data only}*

NCT02165735. Get Ready And Empowered About Treatment (GREAT). https://clinicaltrials.gov/ct2/show/NCT02165735 (accessed 25 September 2017).

NCT02198690 *{published data only}*

NCT02198690. Trial of a mammography decision aid for women aged 75 and older. https://clinicaltrials.gov/show/NCT02198690 (accessed 16 December 2016).

NCT02278900 *{published data only}*

NCT02278900. Supporting doctor-patient communication in oncology. https://clinicaltrials.gov/show/NCT02278900 (accessed 16 December 2016).

NCT02282722 *{published data only}*

NCT02282722. Improving informed consent for palliative chemotherapy. https://clinicaltrials.gov/show/NCT02282722 (accessed 16 December 2016).

NCT02285881 *{published data only}*

NCT02285881. Shared decision making between patients and GPs in the treatment of Type 2 diabetes in primary care. https://clinicaltrials.gov/ct2/show/NCT02285881 (accessed 25 September 2017).

NCT02328326 *{published data only}*

NCT02328326. Caring Others Increasing EngageMent in PACT (CO-IMPACT). https://clinicaltrials.gov/show/NCT02328326 (accessed 16 December 2016).

NCT02344576 *{published data only}*

NCT02344576.. PCORI-1310-06998 Trial of a decision support intervention for Patients and Caregivers Offered Destination Therapy Heart Assist Device (DECIDE-LVAD) (accessed 25 September 2017).

NCT02379078 *{published data only}*

NCT02379078. Impact of an interprofessional shared decision-making and goal-setting decision aid for patients with diabetes (accessed 25 September 2017).

NCT02429115 *{published data only}*

NCT02429115. Peer-mentoring, quality of life and caregiver burden in patients with chronic kidney disease and their

caregivers. https://clinicaltrials.gov/show/NCT02429115 (accessed 25 September 2017).

NCT02507349 *{published data only}*

NCT02507349. Person-centered versus measurement-based care in mental health (PCORI-SDM). https://clinicaltrials.gov/show/NCT02507349 (accessed 25 September 2017).

NCT02592525 *{published data only}*

NCT02592525. Implementing shared decision making in interprofessional home care teams (IPSDM-SW). https://clinicaltrials.gov/show/NCT02592525 (accessed 25 September 2017).

NCT02611050 *{published data only}*

NCT02611050. Treatment decisions for multi-vessel CAD. https://clinicaltrials.gov/show/NCT02611050 (accessed 25 September 2017).

NCT02623335 *{published data only}*

NCT02623335. PCORI-1502-27462 Navigating high risk surgery: empowering older adults to ask questions that inform decisions about surgical treatment. https://clinicaltrials.gov/show/NCT02623335 (accessed 25 September 2017).

NCT02631200 *{published data only}*

NCT02631200. Advance Care Planning with older patients who have End-stage Kidney Disease (ACREDiT). https://clinicaltrials.gov/show/NCT02631200 (accessed 25 September 2017).

NCT02646423 *{published data only}*

NCT02646423. Effect of a Patient-Centered Decision App on TOLAC (PROCEED). https://clinicaltrials.gov/show/NCT02646423 (accessed 25 September 2017).

NCT02653170 *{published data only}*

NCT02653170. Michigan Stroke Transitions Trial (MISTT). https://clinicaltrials.gov/show/NCT02653170 (accessed 25 September 2017).

NCT02663245 *{published data only}*

NCT02663245. INTEGRA Study: Primary care intervention in Type 2 diabetes patients with poor glycaemic control. https://clinicaltrials.gov/show/NCT02663245 (accessed 25 September 2017).

NCT02668900 *{published data only}*

NCT02668900. Decision support for adults facing implantable cardioverter-defibrillator pulse generator replacement. https://clinicaltrials.gov/show/NCT02668900 (accessed 25 September 2017).

NCT02674360 *{published data only}*

NCT02674360. RCT regarding SDM online training and face-to-face SDM training. https://clinicaltrials.gov/show/NCT02674360 (accessed 25 September 2017).

NCT02686775 *{published data only}*

NCT02686775. The PACO Project: a clinical study of a PAtient COach program in vulnerable lung cancer patients (PACO). https://clinicaltrials.gov/show/NCT02686775 (accessed 25 September 2017).

NCT02721810 *{published data only}*

NCT02721810. Patient Engagement Initiative (PEI). https://clinicaltrials.gov/show/NCT02721810 (accessed 25 September 2017).

NCT02759939 *{published data only}*

NCT02759939. Right For Me: birth control decisions made easier. https://clinicaltrials.gov/show/NCT02759939 (accessed 25 September 2017).

NCT02823262 *{published data only}*

NCT02823262. A breast cancer treatment decision aid for women aged 70 and older. https://ClinicalTrials.gov/show/NCT02823262 (accessed 25 September 2017).

NCT02842047 *{published data only}*

NCT02842047. The mediating effects of decentering on self-management of stress and end of life planning. https://clinicaltrials.gov/show/NCT02842047 (accessed 25 September 2017).

NCT02866799 *{published data only}*

NCT02866799. Multi-PAP RCT: improving prescription in primary care patients with Multimorbidity and Polypharmacy (Multi-PAP). https://clinicaltrials.gov/show/NCT02866799 (accessed 25 September 2017).

NCT02868983 *{published data only}*

NCT02868983. Integrating Behavioral Health and Primary Care for comorbid behavioral and medical problems (IBHPC). https://clinicaltrials.gov/show/NCT02868983 (accessed 25 September 2017).

NCT02890615 *{published data only}*

NCT02890615. CanDirect: effectiveness of a telephone-supported Depression Self-care Intervention for Cancer Survivors (CanDirect). https://clinicaltrials.gov/show/NCT02890615 (accessed 25 September 2017).

NCT02905032 *{published data only}*

NCT02905032. SDM for Stroke Prevention in Atrial Fibrillation (SDM4Afib). https://clinicaltrials.gov/show/NCT02905032 (accessed 25 September 2017).

NCT02917603 *{published data only}*

NCT02917603. Shared decision making to improve palliative care in the nursing home. https://clinicaltrials.gov/show/NCT02917603 (accessed 25 September 2017).

NCT02920086 *{published data only}*

NCT02920086. Improving Partnerships with family members of ICU patients (IMPACT). https://clinicaltrials.gov/show/NCT02920086 (accessed 25 September 2017).

NCT02935920 *{published data only}*

NCT02935920. A study on optimizing follow-up for postmenopausal women with breast cancer treated with

adjuvant endocrine therapy. https://clinicaltrials.gov/show/NCT02935920 (accessed 25 September 2017).

NCT02971163 *{published data only}*

NCT02971163. Syncope Decision Aid for emergency care (SynDA). https://clinicaltrials.gov/show/NCT02971163 (accessed 25 September 2017).

NCT02987608 *{published data only}*

NCT02987608. A feasibility trial of power up. https://clinicaltrials.gov/show/NCT02987608 (accessed 25 September 2017).

NCT02988661 *{published data only}*

NCT02988661. Women Empowered to Live with Lupus study (WELL). https://clinicaltrials.gov/show/NCT02988661 (accessed 25 September 2017).

NCT03012087 *{published data only}*

NCT03012087. Using m-Health tools to reduce the misuse of opioid pain relievers. https://clinicaltrials.gov/ct2/show/NCT03012087 (accessed 25 September 2017).

NCT03037112 *{published data only}*

NCT03037112. Resetting the default: improving provider-patient communication to reduce antibiotic misuse. https://clinicaltrials.gov/show/NCT03037112 (accessed 25 September 2017).

NCT03084159 *{published data only}*

NCT03084159. Multi-disciplinary participatory design of a process to deliver a CKD diagnosis in primary care. https://clinicaltrials.gov/show/NCT03084159 (accessed 25 September 2017).

NCT03109145 *{published data only}*

NCT03109145. MyHealtheVet to enable shared decision making regarding menopausal in postmenopausal women veterans (MEANS). https://clinicaltrials.gov/show/NCT03109145 (accessed 25 September 2017).

NCT03134092 *{published data only}*

NCT03134092. The Life STORRIED Study. https://clinicaltrials.gov/show/NCT03134092 (accessed 25 September 2017).

NCT03136367 *{published data only}*

NCT03136367. What matters most: choosing the right breast cancer surgery for you. https://clinicaltrials.gov/show/NCT03136367.

NCT03216109 *{published data only}*

NCT03216109. Improving supportive care for patients with thoracic malignancies. https://clinicaltrials.gov/show/NCT03216109 (accessed 25 September 2017).

NCT03221556 *{published data only}*

NCT03221556. Improving outcomes for low-income mothers with depression. https://clinicaltrials.gov/show/NCT03221556 (accessed 25 September 2017).

NCT03228615 *{published data only}*

NCT03228615. IBD shared decision making intervention. https://clinicaltrials.gov/show/NCT03228615 (accessed 25 September 2017).

NCT03234322 *{published data only}*

NCT03234322. The impact of a diabetes risk prediction model in primary care. https://clinicaltrials.gov/show/NCT03234322 (accessed 25 September 2017).

NTR4554 *{published data only}*

NTR4554. Prostate Cancer Patient-centered Care (PCPCC): impact of a treatment decision aid in a pragmatic, cluster randomized controlled trial. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4554 (accessed 26 September 2017).

NTR4879 *{published data only}*

NTR4879. Implementation of shared decision making in a clinical setting; how to make it fit in the daily workflow?. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4879 (accessed 26 September 2017).

NTR5177 *{published data only}*

NTR5177. (Cost-)effectiveness and implementation of a decision aid for patients with localized prostate cancer and their partners: study protocol of a stepped wedge cluster randomized controlled trial. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=5177 (accessed 26 September 2017).

NTR5262 *{published data only}*

NTR5262. Shared decision making in mental health with Routine Outcome Monitoring (ROM) as an information source. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=5262 (accessed 26 September 2017).

NTR5489 *{published data only}*

NTR5489. CHOICE: CHOosing treatment together In Cancer at the End of life. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=5489.

NTR5677 *{published data only}*

NTR5677. Empowerment in mental health care using e-health in a redesigned intake process: a cluster randomised controlled trial. Study protocol. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=5677 (accessed 26 September 2017).

NTR6106 *{published data only}*

NTR6106. A decision aid for the treatment of Benign Prostatic Hyperplasia: a prospective cohort study to investigate the effect. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=6106 (accessed 26 September 2017).

NTR6227 *{published data only}*

NTR6227. Secondary manifestations of arterial disease - influence of cardiovascular prognosis and treatment effect predictions on patient and physician decision-making: a three-armed, blinded, randomized controlled trial. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=6227 (accessed 26 September 2017).

NTR6379 *{published data only}*

NTR6379. Shared decision making in patients with Castration-Resistant Prostate Cancer - The impact of implementation of a treatment decision aid in CRPC patients. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=6379 (accessed 26 September 2017).

NTR6487 *{published data only}*

NTR6487. A multicentre stepped-wedge cluster-randomised trial studying the level of shared decision-making during vascular surgical consultation before and after the introduction of decision support tools. http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=6487 (accessed 26 September 2017).

Simmons ongoing *{published data only}*

Simmons L, Meyer C, Marques F, Leavitt L, Sepucha K. Skills training for shared decision making: a randomized pilot study. ISDM2017. Lyon, France: 9th International Shared Decision Making Conference. Book of Abstract, Oral communications. 2017.

Steele Gray 2016 *{published data only}*

Steele Gray C, Wodchis W P, Upshur R, Cott C, McKinstry B, Mercer S, et al. Supporting goal-oriented primary health care for seniors with complex care needs using mobile technology: evaluation and implementation of the health system performance research network, bridgepoint electronic patient reported outcome tool. *JMIR Research Protocols* 2016;**5**(2):e126.

Thompson 2017 *{published data only}*

Thompson W, Farrell B, Welch V, Tugwell P, Bjerre L M. Should I continue taking my acid reflux medication? Design of a pilot before/after study evaluating a patient decision aid. *Canadian Pharmacists Journal (Ott)* 2017;**150**(1):19-23.

UMIN000009239 *{published data only}*

UMIN000009239. Comparison of Shared Decision Making (SDM) and routine care for University students in psychiatric outpatient clinic. A randomized controlled trial. https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000010849 (accessed 25 September 2017).

UMIN000022832 *{published data only}*

UMIN000022832. A shared decision making communication training program for clinicians treating: a pilot clustered randomised controlled trial. https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000025946 (accessed 25 September 2017).

Additional references

Alston 2012

Alston C, Paget L, Halvorson G, Novelli B, Guest J, McCabe P, et al. Communicating with patients on health care evidence. Washington, DC: Institute of Medicine of the National Academes. 2012.

Andrews 2013

Andrews JC, Schunemann HJ, Oxman AD, Pottie K, Meerpohl JJ, Coello PA, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *Journal of Clinical Epidemiology* 2013;**66**(7):726-35. [PUBMED: 23570745]

Barr 2015

Barr PJ, O'Malley AJ, Tsulukidze M, Gionfriddo MR, Montori V, Elwyn G. The psychometric properties of Observer OPTION(5), an observer measure of shared decision making. *Patient Education and Counseling* 2015;**98**(8):970-6. [PUBMED: 25956069]

Barr 2016

Barr PJ, Elwyn G. Measurement challenges in shared decision making: Putting the 'patient' in patient-reported measures. *Health Expectations* 2016;**19**(5):993-1001.

Blanc 2014

Blanc X, Collet TH, Auer R, Fischer R, Locatelli I, Iriarte P, et al. Publication trends of shared decision making in 15 high impact medical journals: a full-text review with bibliometric analysis. *BMC Medical Informatics and Decision Making* 2014;**14**:71. [PUBMED: 25106844]

Brouwers 2010

Brouwers M, Stacey D, O'Connor A. Knowledge creation: synthesis, tools and products. *Canadian Medical Association Journal* 2010;**182**(2):E68-72. [DOI: 10.1503/cmaj.081230]

Campbell 2012

Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. *BMJ (Clinical research ed.)* 2012;**345**:e5661. [PUBMED: 22951546]

Chalmers 2009

Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. *Lancet (London, England)* 2009;**374**(9683):86-9. [PUBMED: 19525005]

Charles 1997

Charles C, Gafni A. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). *Social Science & Medicine* 1997;**44**(5):681-92. [DOI: 1016/S0277-9536(96)00221-3]

Cohen 1988

Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd Edition. Hillsdale, NJ: L Erlbaum Associates, 1988.

Coulter 2006

Coulter A. Engaging patients in their healthcare. How is the UK doing relative to other countries?. Oxford: Picker Institute Europe 2006.

Coulter 2017

Coulter A. Measuring what matters to patients. *BMJ* 2017;**356**:j816. [DOI: 10.1136/bmj.j816]

Couët 2013

Couët N, Desroches S, Robitaille H, Vaillancourt H, Leblanc A, Turcotte S, et al. Assessments of the extent to which health-care providers involve patients in decision making: a systematic review of studies using the OPTION instrument. *Health Expectations* 2013;**Epub ahead of print**:1-20. [DOI: 10.1111/hex.12054]

Coxeter 2015

Coxeter P, Del Mar CB, McGregor L, Beller EM, Hoffmann TC. Interventions to facilitate shared decision making to address antibiotic use for acute respiratory infections in primary care. *Cochrane Database of Systematic Reviews* 2015, Issue 11. [DOI: 10.1002/14651858.CD010907.pub2]

Davey 2004

Davey HM, Lim J, Butow PN, Barratt AL, Redman S. Women's preferences for and views on decision-making for diagnostic tests. *Social Science & Medicine* 2004;**58**(9):1699-707. [DOI: 10.1016/S0277-9536(03)00339-3]

Degner 1992

Degner LF, Sloan JA. Decision making during serious illness: what role do patients really want to play?. *Journal of Clinical Epidemiology* 1992;**45**(9):941-50. [PUBMED: 1432023]

Diouf 2016

Diouf NT, Menear M, Robitaille H, Painchaud Guérard G, Légaré F. Training health professionals in shared decision making: Update of an international environmental scan. *Patient Education and Counselling* 2016;**99**(11):1753-8. [DOI: 10.1016/j.pec.2016.06.008]

Elwyn 1999

Elwyn G, Edwards A, Kinnersley P. Shared decision-making in primary care: the neglected second half of the consultation. *British Journal of General Practice* 1999;**49**(443):477-82. [PUBMED: 10562751]

Elwyn 2003

Elwyn G, Edwards A, Wensing M, Hood K, Atwell C, Grol R. Shared decision making: developing the OPTION scale for measuring patient involvement. *Quality & safety in health care* 2003;**12**(2):93-9. [PUBMED: 12679504]

Entwistle 2001

Entwistle VA, Skea ZC, O'Donnell MT. Decisions about treatment: interpretations of two measures ofcontrol by women having a hysterectomy. *Social Science & Medicine* 2001 Sep;**53**(6):721-32.

EPOC 2015

Effective Practice, Organisation of Care (EPOC). EPOC Taxonomy; 2015. Available at: https://epoc.cochrane.org/epoc-taxonomy.

EPOC 2017

Cochrane Effective Practice, Organisation of Care (EPOC). What study designs should be included in an EPOC review? EPOC resources for review authors, 2017. Available at: http://epoc.cochrane.org/resources/epoc-resources-review-authors.

EPOC 2017b

Cochrane Effective Practice, Organisation of Care (EPOC). Data collection form. EPOC Resources for review authors, 2017. Available at: http://epoc.cochrane.org/resources/epoc-resources-review-authors.

EPOC 2017c

Cochrane Effective Practice, Organisation of Care (EPOC). Suggested risk of bias criteria for EPOC reviews. EPOC Resources for review authors, 2017. http://epoc.cochrane.org/resources/epoc-resources-review-authors.

EPOC 2017d

Cochrane Effective Practice, Organisation of Care (EPOC). EPOC worksheets for preparing a Summary of Findings (SoF) table using GRADE. EPOC Resources for review authors, 2017. Available at: http://epoc.cochrane.org/resources/epoc-resources-review-authors.

Frosch 2009

Frosch DL, Légaré F, Fishbein M, Elwyn G. Adjuncts or adversaries to shared decision-making? Applying the Integrative Model of behavior to the role and design of decision support interventions in healthcare interactions. *Implementation Science* 2009;**4**:73. [DOI: 10.1186/1748-5908-4-73]

Giguère 2012

Giguère A, Légaré F, Grimshaw J, Turcotte S, Fiander M, Grudniewicz A, et al. Printed educational materials: effects on professional practice and healthcare outcomes. *Cochrane Database of Systematic Reviews* 2012, Issue 10. [DOI: 10.1002/14651858.CD004398.pub3]

Godin 2008

Godin G, Belanger-Gravel A, Eccles M, Grimshaw J. Healthcare professionals' intentions and behaviours: a systematic review of studies based on social cognitive theories. *Implementation Science* 2008;**3**:36. [DOI: 10.1186/1748-5908-3-36]

Grimshaw 2004

Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technology Assessment* 2004;**8**(6):1-72. [PUBMED: 14960256]

Guyatt 2011

Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *Journal of Clinical Epidemiology* 2011 Apr;**64**(4):383-94. [DOI: 10.1016/j.jclinepi.2010.04.026]

Harter 2017

Harter M, Moumjid N, Cornuz J, Elwyn G, van der Weijden T. Shared decision making in 2017: International accomplishments in policy, research and implementation. Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen 2017; Vol. 123-124:1-5. [PUBMED: 28546053]

Hibbard 2004

Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing

and measuring activation in patients and consumers. *Health Services Research* 2004;**39**(4 Pt 1):1005-26. [PUBMED: 15230939]

Hibbard 2005

Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. *Health Services Research* 2005;**40**(6 Pt 1):1918-30. [PUBMED: 16336556]

Higgins 2011

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org 2011.

Institute for Health Metrics and Evaluation 2013

Institute for Health Metrics and Evaluation. The Global Burden of Disease: Generating Evidence, Guiding Policy. Seattle: Institute for Health Metrics and Evaluation (IHME), 2013.

Kiesler 2006

Kiesler DJ, Auerbach SM. Optimal matches of patient preferences for information, decision-making and interpersonal behavior: evidence, models and interventions. *Patient Education and Counseling* 2006 Jun;**61**(3):319-41. [DOI: 10.1016/j.pec.2005.08.002]

Kriston 2010

Kriston L, Scholl I, Holzel L, Simon D, Loh A, Harter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Education and Counseling* 2010;**80**(1):94-9. [PUBMED: 19879711]

LeBlanc 2009

LeBlanc A, Kenny DA, O'Connor AM, Legare F. Decisional conflict in patients and their physicians: a dyadic approach to shared decision making. *Medical Decision Making* 2009;**29**(1):61-8. [DOI: 10.1177/0272989X08327067]

Légaré 2007a

Légaré F, Graham ID, O'Connor AC, Aubin M, Baillargeon L, Leduc Y, et al. Prediction of health professionals' intention to screen for decisional conflict in clinical practice. *Health Expectations* 2007;**10**(4):364-79. [DOI: 10.1111/j.1369-7625.2007.00465.x]

Légaré 2011

Légaré F, Stacey D, Pouliot S, Gauvin FP, Desroches S, Kryworuchko, J, et al. Interprofessionalism and shared decision-making in primary care: a stepwise approach towards a new model. *Journal of Interprofessional Care* 2011;**25**(1):18-25. [DOI: 10.3109/13561820.2010.490502]

Légaré 2013

Légaré F, Witteman HO. Shared decision making: examining key elements and barriers to adoption into routine clinical practice. *Health Affairs (Millwood)* 2013 Feb;**32**(2):276-84. [DOI: 10.1377/hlthaff.2012.1078]

Makoul 2006

Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. *Patient Education and Counseling* 2006;**60**(3):301-12. [DOI: 10.1016/j.pec.2005.06.010]

Michie 2009

Michie S, Fixsen D, Grimshaw JM, Eccles MP. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implementation Science* 2009;**4**:40. [DOI: 10.1186/1748-5908-4-40]

Mulley 2012

Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. *BMJ* 2012;**345**:e6572. [DOI: 10.1136/bmj.e6572]

Salzburg Global Seminar 2011

Salzburg Global Seminar. Salzburg Global Seminar 2011.

Schulz 2010

Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Annals of Internal Medicine* 2010;**152**(11):726-32. [PUBMED: 20335313]

Schünemann 2011

Schünemann HJ, Oxman AD, Vist GE, Higgins JPT, Deeks JJ, Glasziou P, et al. Chapter 12: Interpreting results, drawing conclusions. In: Higgins JPT. Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011.. Available from http://training.cochrane.org/handbook.

Shafir 2012

Shafir A, Rosenthal J. Shared Decision Making: Advancing Patient-Centered Care through State and Federal Implementation. National Academy for State Health Policy, 2012:1-38.

Shay 2015

Shay LA, Lafata JE. Where is the evidence? A systematic review of shared decision making and patient outcomes. *Medical Decision Making* 2015 Jan;**35**(1):114-31. [DOI: 10.1177/0272989X14551638]

Stacey 2017

Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews* 2017, Issue 4. [DOI: 10.1002/14651858.CD001431.pub5]

Straub 2008

Straub C, Nebling T, Muller H. Translating research into practice: a German sickness fund supporting patient participation. *Patient Education and Counseling* 2008;**73**(3):544-50. [DOI: 10.1016/j.pec.2008.07.019]

Street 2009

Street RL Jr, Makoul G, Arora NK, Epstein RM. How does communication heal? Pathways linking clinician-patient

communication to health outcomes. *Patient Education and Counseling* 2009;**74**(3):295-301. [PUBMED: 19150199]

Towle 1999

Towle A, Godolphin W. Framework for teaching and learning informed shared decision making. *BMJ (Clinical research ed.)* 1999;**319**(7212):766-71. [DOI: 10.1136/bmj.319.7212.766]

Ukoumunne 1999

Ukoumunne OC, Gulliford MC, Chinn S, Sterne JA, Burney PG. Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review. *Health Technology Assessment* 1999;**3**(5):iii-92. [PUBMED: 10982317]

Velentgas 2013

Velentgas P, Dreyer NA, Wu AW. Outcome definition and measurement. In: Velentgas P, Dreyer NA, Nourjah P, Smith SR, Torchia MM editor(s). Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide. Rockville (MD): Agency for Healthcare Research and Quality (US), 2013 Jan.

Wennberg 2004

Wennberg JE. Practice variation: implications for our health care system. *Managed Care* 2004;**13**(9 Suppl):3-7. [PUBMED: 15493217]

Weston 2001

Weston WW. Informed and shared decision-making: the crux of patient-centered care. *Canadian Medical Association Journal* 2001;**165**(4):438-9. [PUBMED: 11531054]

Wyatt 2015

Wyatt KD, List B, Brinkman WB, Prutsky Lopez G, Asi N, Erwin P, et al. Shared decision making in pediatrics: a systematic review and meta-analysis. *Academic Pediatrics* 2015 Nov-Dec;**15**(6):573-83. [DOI: 10.1016/j.acap.2015.03.011]

References to other published versions of this review

Légaré 2007

Légaré F, Ratté S, Stacey D, Kryworuchko J, Gravel K, Turcot L, et al. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database of Systematic Reviews* 2007, Issue Issue 3. [DOI: 10.1002/14651858.CD006732]

Légaré 2010

Légaré F, Ratté S, Stacey D, Kryworuchko J, Gravel K, Graham ID, et al. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database of Systematic Reviews* 2010, Issue 5. [DOI: 10.1002/14651858.CD006732.pub2]

Légaré 2014

Légaré F, Stacey D, Turcotte S, Cossi MJ, Kryworuchko J, Graham ID, et al. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database of Systematic Reviews* 2014, Issue 9. [DOI: 10.1002/14651858.CD006732.pub3]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Adarkwah 2016

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: primary care, Germany **Health professionals**: 32; general practitioners; fully trained **Patients**: 304; cardiovascular risk prevention; male and female
Interventions	**Single intervention: patient-mediated intervention (Computerised decision aid (TTE))** Quote: "Immediately after giving their informed consent, patients were randomized to consultation with the emoticons (Fig. 2) or the TTE illustration (Fig. 3). GPs entered a study ID into the decision support software, which automatically allocated each patient into one of the two conditions according to an a priori randomized sequence. GPs learned about each patient's allocation by the illustration displayed by the software. They then started a discussion with their patients on the basis of the allocated display, i.e. either emoticons, or TTE, respectively." Page 3, figure 3

Adarkwah 2016 *(Continued)*

	Single intervention: patient-mediated intervention (Computerised decision aid (emoticon)). Figure 2
Outcomes	PEF-FB-9 (SDM-Q9) (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "GPs entered a study ID into the decision support software, which automatically allocated each patient into one of the two conditions according to an a priori randomized sequence." page 3
Allocation concealment (selection bias)	Low risk	Quote: "GPs entered a study ID into the decision support software, which automatically allocated each patient into one of the two conditions according to an a priori randomized sequence." page 3
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Performance bias. Quote: "GPs recorded the decision made, such as specific medications, dose adjustments, behavioral measures or no change at all." page 3 Quote: "GPs learned about each patient's allocation by the illustration displayed by the software." page 3
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: we cannot assume that all patients replied to all questions related to outcomes. Missing outcome data were not specified.
Selective reporting (reporting bias)	Low risk	Comment: relevant outcomes pre-specified in the study protocol were reported in the results (Clinical Trials Register Platform (ICTRP, ID DRKS00004933)).
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of primary outcome.
Protection against contamination?	High risk	Comment: patients were randomized.
Baseline characteristics patients	Low risk	Quote: "Both study arms were well-balanced regarding socio demographic and clinical variables." page 6. See Table 1
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Almario 2016

Methods	**Study design**: non-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient

Almario 2016 *(Continued)*

	Power calculation: unclear
Participants	**Care setting**: ambulatory care, specialized care, USA **Health professionals**: various types; fully trained and in training **Patients**: 371; gastrointestinal disorders; male and female
Interventions	**Single intervention - patient-mediated (GI PROMIS)** Quote: "Intervention patients completed GI PROMIS symptom questionnaires on an e-portal one week before their visit." page 1 Quote: "Using modern psychometric techniques, such as item response theory and computerized adaptive testing,(14, 15) PROMIS offers state-of-the-art psychometrics, establishes common-language benchmarks for symptoms across conditions, and identifies clinical thresholds for action and meaningful clinical improvement or decline. PROMIS questionnaires are administered electronically and efficiently, allowing implementation in busy clinical settings. Because of the extraordinary burden of illness from digestive diseases, the PROMIS consortium added a gastrointestinal (GI) item bank, which our group developed." page 3 **Usual care** Quote: "Usual care patients were managed according to customary practices." page 2
Outcomes	SDM-Q-9 (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Comment: no randomization.
Allocation concealment (selection bias)	High risk	Quote: "We used a pragmatic, off-on study design alternating weekly between the PROMIS intervention and control arms." page 4
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: insufficient information to make a judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Quote: "Specifically, the missing outcome data for this group was imputed to the corresponding mean value calculated from controls for each item. Because this assumption biases towards the null, we also performed a sensitivity analysis using a per-protocol approach where we excluded patients without follow-up data." page 6
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available.
Other bias	Unclear risk	Quote: "We only evaluated patients with GI symptoms, so we cannot know whether using other PROMIS questionnaires, such as those for fatigue, physical function, or pain, among many others, would also fail to show a difference vs. usual care." page 8
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: insufficient information to make a judgement.

Almario 2016 *(Continued)*

Protection against contamination?	Unclear risk	Comment: insufficient information to make a judgement.
Baseline characteristics patients	Low risk	Quote: "No differences were seen in gender and race/ethnicity between groups (Appendix Table 2)." page 7
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Ampe 2017

Methods	**Study design**: non-randomized trial **Unit of allocation**: practice **Unit of analysis**: provider **Power calculation**: unclear
Participants	**Care setting**: non-ambulatory care, primary care, Belgium **Health professionals**: 90; various types; fully trained and in training; male and female **Patients**: advance care planning, dementia care units
Interventions	**Single intervention - educational meeting (We DECide)** "We DECide' was a communication intervention for nursing home staff working in dementia care units, in which competences were trained for realizing SDM in ACP conversations with residents with dementia and their families. It was developed for this study and aimed at practising how to conduct ACP conversations with residents with dementia and their family caregivers, by applying the three-step model for SDM by Elwyn and colleagues. This model describes the three steps that are necessary for realizing SDM in a clinician-patient encounter: the 'Choice talk', talking about the fact that different choices exist; the 'Option talk', talking about the different options and choices; and the 'Decision talk', talking about a final decision. 'We DECide' consisted of three modules (two 4-hour workshops and a homework assignment) that were based on the three steps of the model for SDM. Each module was designed to train the specific competences that are necessary to complete the corresponding step. Three types of conversations that are crucial for talking about ACP in the nursing home were used as a prototype for the 'Choice talk' in the first workshop, since these conversations are crucial for indicating that certain choices for care exist. As a homework assignment participants were to practise the 'Option talk' by engaging in conversations with residents about preferences in routine care situations, and thus to talk about the different care options. Conversations in crisis situations were used as a prototype for the 'Decision talk' in the second workshop (which took place after the homework assignment), since the urgency of crisis situations require that certain decisions have to be made. The overview of the 'we DECide'- modules are represented in Fig. 1. 'We DECide' was taught in small groups (approximately 10 participants per session) by an experienced communication trainer, in order to ensure active participation of each participant. The intervention took place in a time span of maximum 4 weeks." page 140 **Usual care (control group)**
Outcomes	OPTION (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Ampe 2017 *(Continued)*

Random sequence generation (selection bias)	High risk	Comment: no randomization.
Allocation concealment (selection bias)	High risk	Quote: "Therefore, because 'we DECide' was designed for participants with sufficient learning opportunities, the nine care units with the lowest scores were included in the intervention group." pages 140-141 Quote: "We created participant groups of comparable size and composition. In order to make groups with staff from two nursing home units, we chose to include a unit from the control group." page 141
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	COmment: insufficient information to make a judgement.
Incomplete outcome data (attrition bias) Observer-based outcome	High risk	Quote: "Thirteen units recorded one or more conversations. Five units (two from the intervention group) did not record any conversations, due to one of the following reasons: no admission of new residents with dementia due to relocation of the care unit to a new building, or absence of staff members due to illness... A total of 21 conversations were analysed." page 142 "Only a small number of conversation recordings was provided. Maybe a longer time period would have allowed dementia care units to conduct more conversations and to provide a more complete picture of resident involvement in ACP in the dementia care unit." page 145
Selective reporting (reporting bias)	High risk	Comment: Some relevant outcomes prespecified in the study protocol were not reported in the results (see IFC questionnaire).
Other bias	Low risk	Comment: No evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Low risk	Quote: "When OPTION scores at pre-test and post-test were compared, no statistically significant differences were found for the intervention group (average pre-test score: 41.32/100, SD 10.84), nor the control group (average pre-test score: 47.61/100, SD 20.54 (see Table 6)." page 143
Protection against contamination?	Unclear risk	Insufficient information to make a judgement. Quote: "To increase standardisation of the intervention, we created participant groups of comparable size and composition. In order to make groups with staff from two nursing home units, we chose to include a unit from the control group. In this way, the training could be offered to five small groups separately, each of which contained staff from two different nursing home units." page 141
Baseline characteristics patients	Unclear risk	No report of characteristics
Baseline characteristics healthcare professionals	Unclear risk	Characteristics are mentioned in text but no data were presented. Quote: "We created participant groups of comparable size and composition." page 141

Barton 2016

Methods	**Study design**: non-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient

Barton 2016 *(Continued)*

	Power calculation: done
Participants	**Care setting**: ambulatory care, specialized care, USA **Health professionals**: unclear type; fully trained **Patients**: 166; rheumatoid arthritis; male and female
Interventions	**Single intervention - patient-mediated intervention: (adapted guide prior to visit)** **Patient-mediated intervention** Quote: "Briefly, the existing AHRQ guide was discussed in patient and clinician focus groups; transcripts and field notes were analyzed and informed the content of the adapted guide, which included chapters on “What is RA?” and “What can RA medicines do for you?” The design and development process for RA Choice was based on a tool created for diabetes mellitus medications for use in the clinic to facilitate a conversation between clinician and patient. Tool development involved field-testing low-fidelity prototypes (drafts or incomplete versions) in real clinical encounters followed by modifications and iterative field testing." page 891. "All participating clinicians received brief (5 minutes), in-person training about RA Choice." page 891 **Single intervention - patient-mediated intervention: (adapted guide + decision aid during visit)** Literacy-appropriate medication guide and decision aid (RA Choice) **Single intervention - patient-mediated intervention: Control Group** Quote: "Patients received existing medication guide prior to clinic visit." page 889
Outcomes	The Interpersonal Processes of Care (IPC) (Continous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "We used this method rather than randomizing by physician to allow for the broadest possible group of physicians to participate in arm 3, to allow for additional time to complete the design and testing of materials, and to avoid contamination of the groups." page 890
Allocation concealment (selection bias)	High risk	Quote: "After completing enrollment for the control group, patients were enrolled into arm 2, in which patients received the adapted guide prior to the clinic visit, and then into arm 3, where patients received the adapted guide prior to the visit and the decision aid (used in the clinical encounter). We used this method rather than randomizing by physician to allow for the broadest possible group of physicians to participate in arm 3, to allow for additional time to complete the design and testing of materials, and to avoid contamination of the groups." page 890
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: insufficient information to make a judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: insufficient information to make a judgement.
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available.

Barton 2016 *(Continued)*

Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	Low risk	Quote: "We used this method rather than randomizing by physician to allow for the broadest possible group of physicians to participate in arm 3, to allow for additional time to complete the design and testing of materials, and to avoid contamination of the groups" page 890
Baseline characteristics patients	Low risk	Quote: "There were no significant differences in characteristics across the 3 study arms with the exception of sex (more women in arms 1 and 3; P 5 0.02) and clinic site (78% in arm 1 were from the county hospital compared to 60% each in arms 2 and 3) the possibility that patients enrolled in arm 1 may have differed in characteristics from those in arm 2 or 3; however, the only significant differences were in sex and clinic site 2- Adjusted models control for clinic site and sex." page 893
Baseline characteristics healthcare professionals	Unclear risk	Comment: No report of characteristics

Bernhard 2011

Methods	**Study design**: clinician-randomized trial **Unit of allocation**: clinician **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: specialized care; ambulatory care; Australia, New Zealand, Switzerland, Germany, and Austria **Health professionals**: 62; various type of physician (medical, surgical, radiation and gynacological oncologists); fully trained **Patients**: 694; breast cancer; female
Interventions	**Multifaceted intervention:** educational meeting, audit and feedback, distribution of educational materials (interactive face-to face workshop and two follow-up telephone calls) Quote: "The training consisted of a 7 hours interactive face to-face workshop with one to two follow-up telephone calls over 2 months. The elements of this training were evidence-based .... The training focused on four key concepts: ... The workshops were held at the participating centres and conducted in the local language by one to two clinical psychologists ... The teaching materials were in English .... Before the workshop, participants were expected to have read the strategies document." Page 1267 **Usual care (control):** No training workshop Quote: "Following baseline assessment and before the scheduled training workshop, they were randomly assigned to ... or control (no training workshop) group." Page 1267
Outcomes	Patient involvement preference and actual involvement; SDM framework (DAS-O subscale) (qualitative)
Notes	**Additional information**

Bernhard 2011 *(Continued)*

Number of approached patients (eligible): SGA (Swiss/German/Austrian): 429; ANZ (Australian/New Zealand): 340

Number of patients per physician: SGA (Swiss/German/Austrian): 41; ANZ (Australian/New Zealand): 21

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "They were randomly assigned to the experimental (training workshop) or control (no training workshop) group." page 1266
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Quote: "Two raters applied the DAS-O coding system to the consultations." page 7 (Butow 2014). Comment: in the paper, it is not specified if the raters were unaware of the allocation of the audiotaped record.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: Not specified in the paper.
Incomplete outcome data (attrition bias) Observer-based outcome	High risk	Quote: "53 (85,5%) doctors… were assessable with regard to the primary endpoint for this analysis: doctor behavior…" page 3 (Butow 2014). In the ANZ group, 75% of the consultation requested were audiotaped. In the SGA group, 9 doctors did not provide the an audiotape (7 were gynecologists). 74 % of the requested consultation among the 32 who provided audiotape were audiotaped. Quote: "Characteristics of doctors with... and without... audio tapes were compared... results suggest a difference in doctor speciality... Physicians without tapes were also younger" page 4-5 (Butow 2004). Comment: it is likely that the missing primary outcome data (non audiotaped) were related to doctors behaviors. If the missing outcomes were related to a characteristic that is related to the intervention, it may be a selection bias. However, age and specialty are similar at baseline among doctors.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: for our primary outcome, but low risk for the primary outcome of the study (decisional conflict).
Selective reporting (reporting bias)	High risk	Comment: outcomes of interest are reported incompletely so they cannot be entered in a meta-analysis.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment; no baseline measure of our primary outcome.
Baseline measurement? Participant-reported outcome	Low risk	Quote: "Within two weeks of their initial consultation discussing treatment options, patients gave informed consent and completed a baseline questionnaire gathering demographics; preferences for information (degree of detail required on a Likert scale from 'prefer few details' to 'prefer as many details ... " page 1266

Bernhard 2011 *(Continued)*

Protection against contamination?	Unclear risk	Comment: physicians within centre were allocated to intervention or control.
Baseline characteristics patients	Low risk	Quote: "Baseline characteristics of eligible patients are summarised for the pre-randomisation and post-randomisation cohorts in Table 2." page 1268
Baseline characteristics healthcare professionals	Low risk	Quote: "Baseline characteristics of eligible doctors are shown in Table 1." page 1268

Bieber 2006

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not clear
Participants	**Care setting**: specialized care and ambulatory care (Rheumatologic Outpatient Clinic of the University of Heidelberg); Germany **Health professionals**: 10; internal medicine; fully trained **Patients**: 149; fibromyalgia syndrome; male and female
Interventions	**Multifaceted intervention**: educational meeting with physician (18 hours); patient-mediated intervention (computer-based visualized information tool). The computer-based tool provided information on fibromyalgia syndrome, combining textual information with diagrams and short video sequences. The educational meeting involved training physicians to improve patient-centered communication and interaction skills. **Single intervention (control):** patient-mediated intervention (computer-based visualized information tool) The tool was the same as the multifaceted intervention.
Outcomes	Doctor-patient interaction, from the patient perspective, using the QQPPI (Questionnaire on the Quality of Physician-Patient Interaction) (continuous); joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: patients were randomized but the method was unspecified.
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.

Bieber 2006 *(Continued)*

Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "Patients were informed on the intervention but they were blinded to the fact in which group they were being treated." Page 359
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: 64/149 (43%) patients were excluded after randomization (did not meet inclusion criteria, refused to complete questionnaire); Information about missing data in our primary outcome were lacking.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: baseline measurements for the FAPI are not reported, nor were they measured.
Protection against contamination?	High risk	Comment: it was the patients who were randomized in an university outpatient setting.
Baseline characteristics patients	Low risk	Quote: "All three patient group were comparable as to socio-economic (see Table 1) and health related variables (see Table 3)." page 359
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Branda 2013

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: practice **Unit of analysis**: provider and patient **Power calculation**: not done
Participants	**Care setting**: primary care; ambulatory care; USA **Health professionals**: 41; various type (physician, nurse practitioner, physician assistant, resident/fellow); fully trained and in training **Patients**: 110; Type 2 diabetes; male and female
Interventions	**Multifaceted intervention:** patient-mediated intervention, educational meeting. Quote: "The intervention will consist of the use of a decision aid (Statin Choice and Aspirin Choice, or Diabetes Medication Choice) by patients and their primary care clinician during the clinical encounter ." page 3 of the study protocol. Quote: "A study team member will conduct a demonstration showing how to use the decision aid at the time of the initial in-person discussion with clinics. The focal points of the demonstration will be that decision aids serve as guides for conversation rather than scripted discussions... Brief video clips and storyboards that demonstrate the basic use of decision aids are publicly available at http://kercards.e-bm.info for clinicians to review at their convenience. A study team member will remain available to do one-on-one demonstrations after the initial group demonstration if needed." page 4 of the study protocol

Branda 2013 *(Continued)*

	Usual care (control): Quote: "For patients in the usual care arm, clinicians will manage the discussion about medication regimen as usual, without using decision aids. " page 4 of the study protocol.
Outcomes	Level of patient engagement (OPTION) (continuous)
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: not described in the paper.
Allocation concealment (selection bias)	Unclear risk	Quote: "A study statistician will perform the randomization centrally after the practice has been enrolled." (Study protocol page 3, column 2). However, intervention and usual care patients were recruited within each practice (diabetes DA and UC, statin DA and UC). Investigators, clinicians were not blinded to the practice status. If the persons who enrolled the patients were not blinded too, it may have biased the selection.
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Comment: data collectors and analysts were blinded to allocation (p7 para 1) but it is not specified whether investigators who assessed videos recorded were blinded.
Incomplete outcome data (attrition bias) Observer-based outcome	Unclear risk	Quote: "We were able to obtain video recordings from 38% of encounters. This limits our ability to use our checklist and to obtain an OPTION score in all encounters thus reducing our confidence in the inferences related to fidelity and clinicians' efforts to engage patients in decision making, respectively." page 6 para 3 DA: 41,5% UC: 34%
Selective reporting (reporting bias)	High risk	Comment: see study protocol: not all the study's prespecified relevant outcomes were reported (quality of life, costs and resources utilization). Morevover some relevant outcomes are specified differently in the results: e.g. decision comfort instead of decisional conflict, patient satisfaction with knowledge transfer instead of satisfaction with decision making.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	Low risk	Comment: intervention and usual care patients were recruited within each practice (diabetes DA and UC, statin DA and UC).
Baseline characteristics patients	High risk	Quote: "All patient factors were well balanced across both arms with a difference found in the type of discussion that patients had (statins vs. diabetes medication; Table 1); subsequent results adjust for this difference." page 4 column 2 Comment: there is imbalance in race and HbA1c too.

Branda 2013 *(Continued)*

Baseline characteristics healthcare professionals	Unclear risk	Comment: there is mention of participant characteristics in table 2 but comparisons between intervention and control arms were not presented.

Butow 2004

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not clear
Participants	**Setting of care**: specialized care; ambulatory care (University of Sydney teaching hospital); Australia **Healthcare professionals**: 4; medical oncologists (2) and radiation oncologists (2); fully trained **Patients**: 164; cancer; male or female
Interventions	**Single intervention:** patient-mediated intervention (consultation preparation package: booklet "How treatment decisions are made" + brochure "Your right and responsibilities" + question prompt sheet) Patients received an information package at least 48 hours before their first oncology appointment. The information package included a question prompt sheet, booklets on clinical decision making and patient rights, and an introduction to the clinic. **Single intervention (control):** patient-mediated intervention (booklet NSW Cancer council booklet on living with cancer). Patients received the control booklet at least 48 hours before their first oncology appointment. This booklet contained only the introduction to the clinic.
Outcomes	Quote: "Physician encouragement of patient participation in the consultation and decision making process" (page 4404) subscale of the behaviours coding system (categorical); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process Perceived level of control in the decision making process; SDM is assessed as the joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information** Number of approached patients (eligible): 246 Number of patients per physician: Not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Research nurse assigned an identification to consenting patients, determined random assignment, and sent the appropriate package with a consent form…" page 4403
Allocation concealment (selection bias)	Unclear risk	Quote: "Research nurse assigned an identification to consenting patients, determined random assignment, and sent the appropriate package with a consent form…" page 4403
Blinding (performance bias and detection bias)	Unclear risk	Comment: not specified in the paper.

Butow 2004 *(Continued)*

Observer-based outcome		
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in paper.
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: for our primary outcome, 160/164.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: for our primary outcome, similar proportion in the two groups (Cancer Consultation Package Group (CCPP) group: 62/80; Booklet group: 69/84).
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: No evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: baseline measurements are not reported for Quote: "Physician behaviours facilitating patient involvement".
Baseline measurement? Participant-reported outcome	Low risk	Quote: "There were no significant differences between the groups in information and involvement preferences measured before the consultation." age 4406
Protection against contamination?	High risk	Comment: one of the outcomes is patient reported and the intervention is patient allocated; consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Quote: "Given that no significant differences were found on demographic or disease variables between control and intervention arms... " Page 4404
Baseline characteristics healthcare professionals	High risk	Comment: not specified in the paper.

Causarano 2014

Methods	**Study design**: patient-randomized trial (pilot) **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Setting of care**: specialized care; Canada **Healthcare professionals**: various types (plastic surgeon, breast reconstruction clinical nurse specialist, social worker); fully trained **Patients**: 41; post-mastectomy breast reconstruction; female
Interventions	**Single intervention:** patient-mediated intervention (routine education + educational meeting to patient)

Causarano 2014 *(Continued)*

	Quote: "Patients randomized to the intervention group participated in a pre-consultation educational group intervention in addition to receiving routine education." page 1367 **Single intervention (control):** patient-mediated intervention (routine education)
Outcomes	Decision making subscale (M-PICS) (continuous)
Notes	**Additional information** Number of approached patients (eligible): 57 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A computer generated random allocation sequence was created with a 1:1 allocation to the intervention or routine education (control) in blocks of 10. To achieve allocation concealment, the randomization allocation list was developed by a statistician independent from the coordinator using PROC PLAN in SAS." Page 1366
Allocation concealment (selection bias)	Low risk	Quote: "A computer generated random allocation sequence was created with a 1:1 allocation to the intervention or routine education (control) in blocks of 10. To achieve allocation concealment, the randomization allocation list was developed by a statistician independent from the coordinator using PROC PLAN in SAS." Page 1366
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "patients were not blinded to their treatment arm; the surgeon leading the intervention could not be blinded as she/he also conducted the consultation." page 1366 last paragraph. Comment: it is not mentioned if patients were aware of the objective of the study but outcome measurement is likely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: although reasons of non completion of the entire outcome questionnaires by 2 patients are not specified, missing outcome data are balanced in numbers across groups. Retention rate was 95% (39/41).
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	Low risk	Quote: "Consultations were scheduled in batches to prevent contamination, such that the two groups were not in the clinic waiting room at the same time." page 1367
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 2).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Cooper 2011

Methods	**Study design**: randomized trial (factorial design) **Unit of allocation**: physician and patient **Unit of analysis**: physician and patient **Power calculation**: unclear
Participants	**Care setting**: primary care, ambulatory care (especially low SES service), USA **Health professionals**: 41, physicians fully trained **Patients**: 279, hypertensive; 184 female
Interventions	**Four arms:** • **patient-mediated intervention**, educational meeting (physician communication skills training and patient coaching by community health workers) • **educational meeting: p**hysician communication skills training • **patient-mediated intervention**: patient coaching by community health workers • **patient and physician minimal intervention:** (control) Quote: "The physician communication skills program was designed to provide physicians with personalized feedback based on their videotaped performance with a simulated patient scheduled for an office appointment. ... Intervention group physicians reviewed the videotape of their personal interviews with the simulated patient and completed exercises on the CD-ROM or in the workbook." page 1298 Quote: "Control group physicians participated in the simulated visit but did not receive any feedback until the end of the study" page 1298
Outcomes	Participatory Decision making (PDM); Patient involvement in care
Notes	**Additional information** Number of approached patients (eligible): 980 Number of patients per physician: 50

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Random blocks of size two and four were used, and a list of random numbers between zero and one was generated in Stata version 7.0." protocol
Allocation concealment (selection bias)	Low risk	Quote: "The study statistician generated the allocation sequence for both physicians and patients and placed the intervention assignment for each subject in opaque envelopes to be opened by research assistants." Protocol
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "Due to the nature of the interventions, complete masking of participants, investigators and CHWs was not possible." page 1299
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: we do not know if missing outcomes were balanced across intervention groups. Imputation was used by assuming that data are MAR but the mechanism and the reasons of missing data were not reported.

Cooper 2011 *(Continued)*

Selective reporting (reporting bias)	Low risk	Comment: outcomes were described in the protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: process measures at baseline and change at 12-month follow-up by intervention group.
Protection against contamination?	Unclear risk	Comment: professionals were allocated within a clinic.
Baseline characteristics patients	Low risk	Comment: see table 2.
Baseline characteristics healthcare professionals	Low risk	Comment: see table 1.

Cooper 2013

Methods	**Study design**: provider-randomized trial **Unit of allocation**: provider **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: primary care; USA **Health professionals**: 36 (but 27 contributed patients); various type (general internists, family physicians, nurse practitioners); fully trained **Patients**: 132; major depressive disorders; male and female
Interventions	**Multifaceted intervention (Patient-centered group):** patient-mediated intervention, educational outreach visit, distribution of educational material, audit and feedback Quote: "Table 1 provides the rationale and expected outcomes for each intervention component and a comparison of the two intervention approaches." page 154 **Multifaceted intervention (Standard group):** patient-mediated intervention, educational outreach visit, distribution of educational material Quote: "Table 1 provides the rationale and expected outcomes for each intervention component and a comparison of the two intervention approaches." page 154
Outcomes	Patient rating of their clinicians participatory decision-making skills (PDM) (categorical)
Notes	**Additional information** Number of approached patients (eligible): 1486 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Cooper 2013 *(Continued)*

Random sequence generation (selection bias)	Low risk	Comment: within each study site (stratum), a randomization schedule was generated through computer by the study statistician using the Moses and Oakford algorithm page 5, randomization.
Allocation concealment (selection bias)	Unclear risk	Comment: there was an allocation concealment but the method of concealment was not described in sufficient details to make a judgement.
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "Interviewers who collected data at 6 and 12 months were masked to clinician and patient intervention assignment. Outcome assessors at 18 months were not blinded to intervention assignment. The 12-month assessments remained the primary outcome." page 158 paragraph 2
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: see patient flow chart of the study protocol Quote: "Overall, 89 percent (N = 117) of the sample completed the 6-month interview, 85 percent (N = 113) completed the 12-month interview, and 55 percent (N = 73) completed the 18-month interview. Follow-up rates for standard and patient-centered groups were as follows: 88 percent versus 90 percent at 6 months and 83 percent versus 88 percent at 12 months. There were no significant differences in characteristics between participants who completed the trials and those who were lost to follow-up." page 162-163 In addition: reasons for missing data were similar across groups.
Selective reporting (reporting bias)	High risk	Comment: see table 3 and 4 of the study protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: see Table 3.
Protection against contamination?	Unclear risk	Comment: allocation was by clinician within a clinic.
Baseline characteristics patients	Low risk	Quote: "patients in then standard group had higher mean scores on readiness for treatment (7.2 vs. 6.6, p = .02). A higher proportion of patients in the patient-centered group received care from an African American clinician (race-concordant relationship) (61.2 percent vs. 6.2 percent, p < .001)." page 162 Quote: "However, because race concordance between clinicians and patients is an important predictor of patient-reported outcomes (Cooper et al. 2003a), it was included as a covariate. Clinician age and patient attitudes were also included as covariates in separate mean models to examine the robustness of main inferences." page 161
Baseline characteristics healthcare professionals	Low risk	Comment: see table 2 Clinician race was taken into account in the analysis through the race concordance.

Cox 2017

Methods	**Study design**: randomized trial **Unit of allocation**: other **Unit of analysis**: other

Cox 2017 *(Continued)*

	Power calculation: not done
Participants	**Care setting**: non-ambulatory care, specialized care, USA **Health professionals**: various types; fully trained and in training **Patients**: 298; hospitalized children (general pediatric hospital services, the pulmonary service, and the hematology/oncology service) for breathing problems, gastrointestinal problems, and fever; male and female
Interventions	**Multifaced intervention : Distribution of educational material and Educational meeting (FRC Cheklist intervention), page 2** Quote: "To optimize implementation, the checklist was bundled with a 1-hour interactive training, a brief refresher training, tools to monitor implementation, and laminated checklists for use as prompts, constituting the FCR checklist intervention (toolkit available at www. hipxchange. org/ familyrounds)." page 2 **Usual care: page 2** Usual care services (the other hospitalist service and the pulmonary service)
Outcomes	Family engagement communication (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "One research team member (R.L.B.) used a computer algorithm to randomly designate intervention (1 hospitalist service and the hematology/oncology service) and usual care services (the other hospitalist service and the pulmonary service)." page 2
Allocation concealment (selection bias)	Unclear risk	Comment: allocation concealment method is not clearly described.
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "Coders were blinded to intervention or usual care status. Page 8 Coders were blinded, but they may have been able to distinguish between arms after coding multiple videos." page 3
Incomplete outcome data (attrition bias) Observer-based outcome	Unclear risk	Comment: insufficient information to make a judgement.
Selective reporting (reporting bias)	Low risk	Comment: relevant outcomes pre-specified in the study protocol were reported in the results (NCT02625142).
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Low risk	Seem similar according to Table 1 Descriptive Characteristics of the Participants and Study Outcomes for Usual Care and Intervention Services, Pre- and Postintervention.
Protection against contamination?	Low risk	Practices (service) were randomized.

Cox 2017 *(Continued)*

Baseline characteristics patients	Low risk	Usual care and intervention arms were comparable across numerous patient and parent characteristics. The only significantly different characteristic was length of stay (χ2, P = .04) (Table 1).
Baseline characteristics healthcare professionals	Unclear risk	No report of characteristics.

Coylewright 2016

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: ambulatory care, specialized care, USA **Health professionals**: 36; various types; fully trained; male and female **Patients**: 132 (124 included in analysis); stable coronary artery disease; male and female
Interventions	**Single intervention - Patient mediated intervention and educational meeting** Quote: "The decision aid arm included use of a paper-based decision aid that was stratified by angina type (CCS class I–II angina versus class III angina; Figure 2A and 2B). The decision aid was designed with a user-centered approach for use during the clinical encounter (in visit), and its development is described elsewhere." page 769 Educational meeting: Quote: "Training sessions were given on the decision aid to all participating clinicians in the form of several grand round presentations and at the time of initial consent into the study. In addition, the study coordinator and principal investigator offered just-in time training before each visit to review decision aid content and recommendations for its use; this took 1 to 3 minutes. A video was created demonstrating use of the decision aid and was available for viewing." page 769 **Usual care (control group)**
Outcomes	OPTION (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The study coordinator then randomized the patient to UC versus decision aid (Figure 1), with a dynamic allocation balanced across sex and presence of type 2 diabetes mellitus. The randomization took place on a secure study website using a computer generated allocation sequence, which randomized patients in a concealed fashion to decision aid versus UC." page 768
Allocation concealment (selection bias)	Low risk	Quote: "The randomization took place on a secure study website using a computer- generated allocation sequence, which randomized patients in a concealed fashion to decision aid versus UC." page 768
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Quote: "Blinding was not possible for patients and involved clinicians, given physical presence of the decision aid." page 768 Comment: we did not know if coders were blinded

Coylewright 2016 *(Continued)*

Incomplete outcome data (attrition bias) Observer-based outcome	Unclear risk	Quote: "Because of the fact that less than half of clinic visits were recorded (decision aid: 34/65, 52%, and UC: 20/59, 37%, total 45%), these results are deemed hypothesis-generating only. Reasons for a lack of recording were not formally documented and ranged from clinician, patient, or family preference or lack of availability of recording equipment because of simultaneous patient enrollment." page 773 Comment: missing outcome unbalanced between groups and we don't know if reasons of not recording are well balanced between groups.
Selective reporting (reporting bias)	High risk	Comment: primary outcome measures: Efficacy of the PCI choice decision aid vs. usual care assessed by patient and provider surveys, and encounter Video/Audio recordings (time frame: baseline to three months) Efficacy in improving measures of patient knowledge and involvement, decision making quality, treatment choice and clinician satisfaction of the decision aid.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measure of primary outcome.
Protection against contamination?	Low risk	Patients were randomized but, Quote: "Detailed analysis of the recorded visits suggested high fidelity of decision aid delivery and did not demonstrate evidence of contamination." page 774
Baseline characteristics patients	Low risk	Quote: "There were no significant differences in any of the baseline characteristics." page 770
Baseline characteristics healthcare professionals	Low risk	Comment: clinical visits per clinician for usual care and DA are similar (Table 2).

Davison 1997

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not clear
Participants	**Care setting**: specialized care and ambulatory care (Winnipeg Community Clinic); Canada **Health professionals**: 2; urologist; fully trained **Patients**: 60; prostate cancer; men
Interventions	**Single intervention**; patient-mediated intervention (individual empowerment sessions) This session helped them to think on how to discuss with the doctor what treatment is best for them and what questions to ask the physician. **Single intervention** (control); patient-mediated intervention (information package) A list of questions, also found in the empowerment session.

Davison 1997 *(Continued)*

Outcomes	Perceived level of control in the decision-making process (categorical); joint process between health-care professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 60 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The group to which subjects were assigned was predetermined by a block randomization procedure" n.p.
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: for our primary outcome (n = 60).
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Quote: "At the pre-test, no significant differences were found between the role preference of the groups ($Chi^2 = 4.365$, P = 0.113)." page 194
Protection against contamination?	High risk	Comment: it was the patients who were randomized in one community clinic.
Baseline characteristics patients	Low risk	Quote: "The two groups were not significantly different from one another with reference to: age category, years of education, education category, marital status, residence, days from first interview, and intended/received treatment" n.p.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Davison 2002

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient

Davison 2002 *(Continued)*

	Power calculation: unclear
Participants	**Care setting**: ambulatory care, specialized care, Canada **Health professionals**: various types; fully trained **Patients**: 749 (736 for assumed role 734 for type of assumed role); oncology, breast cancer, female
Interventions	**Single intervention : patient MI (computer)** Section Procedure: Quote: "The first part of the computer program used the Control Preferences Scale developed by Degner 35 to elicit patients' preferences for control over treatment decision making. The tool consists of 5 statements about different roles individuals can assume in treatment decision making. After an introductory screen provides the patient with instructions, two statements appear on each screen in a fixed order. When the patient makes a choice between the two statements, the next two statements appear on the screen... The second part of the computer program is based on a paper-and-pencil survey questionnaire previously developed and validated with a group of women with breast cancer. The 9 information categories include chances of cure, spread of disease, side effects, treatment options, social activities, effect on family; family risk, home self-care, and sexuality." page 3 **Single intervention - control group : patient-mediated intervention (discussion with research nurse)** Quote: "Women in the control group did not use the computer program. They were asked to select the 1 statement from the 5 statements of the CPS that best described their preferred roles in decision making with their physicians that day. The RN talked to this group of women about general issues for the same length of time it took to generate the computer printouts (approximately 15 minutes)." page 3
Outcomes	Assumed role in decision (CPS) (categorical)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Subject were assigned in the order of accrual." page 4
Allocation concealment (selection bias)	Low risk	Quote: "Separate consents were used to conceal group assignment because only women in the experimental group used the computer program." page 4
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: insufficient information to make a judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: not enough information about missing data and how they were treated.
Selective reporting (reporting bias)	Unclear risk	Comment: insufficient information to make a judgement.
Other bias	Unclear risk	Comment: selection bias: perhaps only women who were contemplating treatment-related discussions with their physician should have been recruited into this study.
Baseline measurement?	Unclear risk	Comment: prior to the intervention, all women completed short demographic questionnaires. No other measures before the computer program.

Davison 2002 *(Continued)*

Participant-reported outcome		
Protection against contamination?	High risk	Comment: Patients were randomized
Baseline characteristics patients	Unclear risk	Quote p.7 : « Women in the control group were more likely to have less than a high school education». The autor also said : « The two groups were remarkably similar»
Baseline characteristics healthcare professionals	Unclear risk	Comment: No report of characteristics

Deen 2012

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: primary care; specialized care and ambulatory care (health center); USA **Health professionals**: not mentioned in paper **Patients**: 279; no one particular type of clinical condition; 103 males and 176 females
Interventions	**Four arms:** • **Pptient-mediated intervention** (decision aid (DA) and patient activation (PA)) • **patient-mediated intervention** (PA) • **patient-mediated intervention** (DA) • **control** (doctor visit) Quote: "Individuals agreeing to participate provided informed consent and were then randomly assigned to one of 4 groups: no intervention (control = data collection and doctor visit), pre-visit exposure to a PAI, pre-visit exposure to the DA, and pre-visit exposure to both DA and the intervention (DA + PAI). The DA selected for this project, ..., to impart general information to patients about their role in gaining information and care within a medical setting." page 179
Outcomes	Patient Activation Measure (PAM); the fostering by healthcare professional of active participating of patients in the decision-making process.
Notes	**Additional information** Number of approached patients (eligible): 945 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Individuals agreeing to participate provided informed consent and were then randomly assigned to one of 4 groups." page 179

Deen 2012 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: no information about the number of participants excluded in the analysis in the study arms. Exclusion of participants after the randomization may not preserve the benefit of randomization.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Quote: "Pre and post-visit data were collected in the CHC waiting room prior to and following a physician visit"
Protection against contamination?	High risk	Comment: It was the patients who were randomised
Baseline characteristics patients	High risk	Comment: gender and race/ethinicty were not evenly distributed across the study arms (page 182). Moreover, PAM scores were associated with ethnicity (table 1). Analysis did not adjust for these variables.
Baseline characteristics healthcare professionals	Unclear risk	Comment: No report of characteristics

Deinzer 2009

Methods	**Study design**: non-randomized trial **Unit of allocation**:patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: specialized palliative care, non-ambulatory care, Germany **Healthcare professionals**: >15 (total only reported in intervention group); physicians: fully trained **Patients**: 86, hypertensive, male and female
Interventions	**Multifaceted intervention**: educational meetings (training for physicians), patient-mediated intervention (patient education program); training for physicians with 4 special consultations Quote: "The SDM interventions were performed ... by physicians who had undergone special communication Training ... " page 267 "Subjects in both the SDM and control groups took part in the patient education program which consisted of modules on the main topics of hypertension ..." page 267 **Single intervention**: patient-mediated intervention (patient education program)

Deinzer 2009 *(Continued)*

	Quote: "Subjects in both the SDM and control groups took part in the patient education program which consisted of modules on the main topics of hypertension ..." page 267 Quote: "Physicians of control patients were just informed about patient empowerment." page 267
Outcomes	COMRADE (continuous, score); SDM is assessed as the joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Comment: non-randomised trial.
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: n for outcomes were not specified in the paper.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Quote: "The degree of SDM was significantly higher in the SDM group at baseline and after 1 year visits." page 268
Protection against contamination?	Low risk	Quote: "Physicians of control patients did not take part in such a special communication program thereby avoiding any contamination with the SDM group." page 267
Baseline characteristics patients	Low risk	Comment: see table 2. Differences in duration of HTA may be due to chance alone.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Deschamps 2004

Methods	**Study design**: patient-randomized trial

Deschamps 2004 *(Continued)*

	Unit of allocation: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: primary and ambulatory care (a family medicine clinic); Canada **Health professionals**: unknown number; general practitioners; unclear level of training **Patients**: 128; hormone replacement therapy; female
Interventions	**Multifaceted intervention**: patient-mediated intervention (pharmacist consultation, patient-specific information and a 40-minute consultation with pharmacist) and other (a letter to the patient's physicians). The letter to the physician highlights the decision made during the pharmacist consultation. **Single intervention** (control): patient-mediated intervention (decision aid: "Making choices: hormones after menopause") The decision aid package was created by the Ottawa Health Decision Centre; it describes both the risks and the benefit of the therapy or therapies.
Outcomes	Perceived level of control in the decision making process (categorical); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Volunteers were randomly assigned to one of the two study arms." page 22
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: patient-mediated intervention and patient reported outcome, so the patient was not really blinded.
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: 24/67 missing (35,8%, pharmacist consultation) vs 13/61 missing (21,3%, decision aid).
Selective reporting (reporting bias)	Unclear risk	Comment: No evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: No evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.

Deschamps 2004 *(Continued)*

Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Comment: see Table 1.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Dolan 2002

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not clear
Participants	**Care setting**: primary and ambulatory care (two practices in Rochester New York); USA **Health professionals**: 6, general internist; 5 fully trained and 1 in training **Patients**: 96; colorectal cancer screening patients; male and female
Interventions	**Single intervention**: patient-mediated intervention (preliminary phase + detailed analysis of the decision using the analytic hierarchy process (decision aid) Quote: "The preliminary phase describes colorectal cancer, the study, administers a demographic survey, ask about family and personal history, established past screening and patients' preference and a knowledge test." pages 126 - 127) **Single intervention** (control): patient-mediated intervention (preliminary phase and educational phase) Quote: "The educational phase consisted of a short description of colorectal cancer and the 5 screening programs for average risk patients." page 127
Outcomes	Perceived level of control in the decision making process (categorical); Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 178 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "All randomisation schedules were created using a computer random number generator before the onset of patient enrolment." page 126
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias)	Unclear risk	Comment: patient-mediated intervention and patient reported outcome, so the patient was not really blinded.

Dolan 2002 *(Continued)*

Participant-reported outcome		
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: 43/50 missing (86%, experimental) vs 43/47 missing (91%, control).
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Quote: "There were no significant differences between study groups in pre-intervention views about how screening decisions should be made (chi-square = 4.54 df=2 P = 0.10) or in patients' perception about how decisions should be made (Chi^2 = 2.1 df = 2 P = 0.34)." page 132
Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Comment: see Table 1.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Eggly 2017

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: ambulatory care, specialized care, USA **Health professionals**: 18; specialists; fully trained; male and female **Patients**: 114; breast, colon, or lung cancer; male and female
Interventions	**Single intervention (QPL-only) - patient MI** Quote: "QPL booklet : The QPL was a booklet designed to be accessible to patients with low levels of education and health literacy. The booklet included 43 questions related to diagnosis, treatment, chemotherapy, side effects, daily life during treatment, treatment plan and schedule, help with costs, and help with coping." page 820 **Single intervention (QPL + Coach) - patient MI** Quote: "Discussion with a communication coach. Coaches were three Black female research staff trained to use a strategy developed by the investigators called'GPS: Generate, Prioritize, Summarize.' Specifically, they read each question aloud (“generate”), and then asked patients whether they wanted to ask the oncologist this question, and why or why not (“prioritize”). Coaches reviewed questions patients indicated wanting to ask (“summarize”), asked if there were other questions they wanted to ask, and offered the opportunity to practice asking the questions." page 821 **Usual Care (control group)**

Eggly 2017 *(Continued)*

	Quote: "Patients assigned to the usual care arm (Arm 1) did not receive the QPL booklet or any other intervention." page 821
Outcomes	Patient role in treatment decision (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Following completion of baseline measures, the software randomized patients (1:1:1) to either the usual care arm or one of two intervention arms (QPL-Only or QPL-plus-Coach)." page 820
Allocation concealment (selection bias)	Low risk	Quote : "Interested patients met with research staff to provide consent and complete baseline measures, using a tablet device with survey software (Qualtrics©). Following completion of baseline measures, the software randomized patients (1:1:1) to either the usual care arm or one of two intervention arms (QPL-Only or QPL-plus-Coach)." page 820
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: no report about if patients were aware or not of their arm. Insufficient information to make a judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: for the outcome Patient Role in Treatment Decision the sample size was n = 85, and the total sample size was n = 114. Eight patients were excluded after randomization because they provided incomplete responses to baseline or outcome measures.
Selective reporting (reporting bias)	Unclear risk	Comment: Insufficient information to make a judgement
Other bias	Unclear risk	The possibility of a selection bias exists. Quote : "Also, many eligible patients could not be reached, and among those who were contacted, only half agreed to participate. Thus, the possibility of a selection bias exists; however, an analysis of zip codes of participants and non-participants suggested they came from areas with similar socio-demographic characteristics." page 825
Baseline measurement? Participant-reported outcome	Unclear risk	Comment : no baseline mesures for Patient Role in Treatment Decision
Protection against contamination?	High risk	Comment : Patients were randomized Quote: "Patients assigned to the QPL-Only arm (Arm 2) received the QPL booklet, along with a brief explanation and encouragement to read it, show it to friends and family, and bring it to the visit because “asking questions during medical visits is important." page 821
Baseline characteristics patients	Low risk	Comment : Patient characteristics across study arms are similar (Table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: Insufficient information to make a judgement.

Elwyn 2004

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: provider (one per practice) **Unit of analysis**: provider **Power calculation**: done
Participants	**Care setting**: primary care; ambulatory care (usual practice and protected research clinics; urban and rural in Gwent, South Wales); UK **Healthcare professionals**: 21; general practitioners; fully trained **Patients**: 747 included in COMRADE, 352 in OPTION; non-valvular atrial fibrillation or prostatism or menorrhagia or menopausal symptoms; male or female
Interventions	**Multifaceted intervention**: educational meeting (SDM skills) and audit and feedback; 5 hours Practitioners attended two workshops. During the first workshop, the background literature on SDM was outlined and participants were asked to debate its relevance to clinical practice. The skills of SDM were described and demonstrated using simulated consultations. This provided opportunities for all the participants to comment on the method, using an observational competence checklist. Simulated patients were also encouraged to comment. Participants were asked to consult with the simulated patients using pre-prepared scenarios involving the study conditions. At the second workshop, participants were asked to consider the competences in more depth. By the end of the workshop, all participants had conducted and received feedback from at least one consultation with a simulated patient. **Multifaceted intervention** (control): educational meeting (risk communication skills) with audit and feedback; 5 hours A risk communication aid was presented for the four study conditions. The risk data were based on systematic reviews and presented as the best evidence available at the time of the trial. The participants were provided with treatment outcome information for the study conditions. Participants were asked to use them in simulated patient consultations. The consultations were conducted in pairs, where colleagues alternated between clinician and observer roles. This was repeated until each participant had received feedback after conducting two or three consultations using the risk communication aids across a range of conditions. A plenary group discussion, which included the patient simulators, allowed the group to share learning points and consider the application of the materials in clinical practice.
Outcomes	OPTION (continuous); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process COMRADE (continuous); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 2585 Number of patients per physician:12 or 24 patients per physician according the phase (baseline, first and second intervention)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "All randomizations were undertaken by random number generation, and allocations by the trial statistician (KH) were concealed from those implementing the interventions or assessments." page 339

Elwyn 2004 *(Continued)*

Allocation concealment (selection bias)	Low risk	Comment: unit of allocation was by provider or practice.
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "All consultation recordings were intended to be rated by two raters and rating were undertaken blind to study group allocation of clinicians or patients." page 340
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "Both clinicians and patients were informed that the trial was investigating "communication skills" but were otherwise blinded to the decision-making or risk communication focus of the intervention." page 339
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: one summary measure for all physician.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: follow-up was not clear in the 2 articles.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	Low risk	Quote: "Unit of allocation is the provider. Only one practitioner per practice would be recruited." page 338
Baseline characteristics patients	Low risk	Comment: see Table 1 in Edwards et al. page 351
Baseline characteristics healthcare professionals	Unclear risk	Comment: no mention of provider characteristics in the two papers.

Epstein 2017

Methods	**Study design**: randomized trial **Unit of allocation**: provider **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: ambulatory care, specialized care, USA **Health professionals**: 38; specialists; fully trained; male and female **Patients**: 265; non hematologic cancer; male and female

Epstein 2017 *(Continued)*

Interventions	**Multifaced intervention Patient MI + educational meeting** Quote: "(1) a 2-session in-office physician training (1.75 hours) using a brief video, feedback from standardized patients portraying roles of patients with advanced cancer, audio recorded study patient visits, and (2) a single 1-hour patient and caregiver coaching session incorporating a question prompt list to help patients bring their most important concerns to their oncologist's attention at an upcoming office visit, plus up to 3 follow-up phone calls (Table 1; eTable 2 in Supplement 3). Trainers and coaches underwent 3-day on-site training. To promote patient centered communication about disease course, prognosis, treatment decisions and end-of-life care, physician and patient interventions focused on the same 4 key domains of patient centered communication." page 94 **Usual care** Quote from the abstract : "Control participants received no training."
Outcomes	Health Care Climate Questionnaire (HCCQ) (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to make a judgement
Allocation concealment (selection bias)	Low risk	Quote: "Only the study statisticians were aware of the random number sequences and treatment assignment, preserving blinding among transcriptionists, coders, and abstractors." Page 95
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: insufficient information to permit judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: missing outcome data were not specified.
Selective reporting (reporting bias)	High risk	Comment: some relevant outcomes prespecified in the study protocol were not reported in the results: preferred role and actual role in decision making, PEACE (NCT01485627).
Other bias	Low risk	
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: insufficient information to permit judgement.
Protection against contamination?	Unclear risk	Comment: professionals were allocated within a clinic or practice and it is possible that communication between intervention and control professionals could have occurred.
Baseline characteristics patients	Low risk	Comment: see Table 1: no statistically significant differences between intervention and control for pre-randomization or cluster-RCT
Baseline characteristics healthcare professionals	Low risk	COmment: eTable 1: no statistically significant differences between intervention and control for pre-randomization or cluster-RCT

Feng 2013

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: waiting area **Unit of analysis**: provider **Power calculation**: unclear
Participants	**Care setting**: primary care; ambulatory care; USA **Health professionals**: 118; general practitioners;fully trained **Patients**: prostate cancer screening; male
Interventions	**Three arms:** **Distribution of educational material (intervention A):** Quote: "...intervention physicians were exposed to an interactive, 30-minute, Web-based curriculum that included interactive roulette wheels, illustrative video vignettes, and other content to illustrate the potential harms, benefits, and downstream consequences of receiving prostate cancer screening, as well as methods of enhancing shared decision making." page 316 "Intervention physicians were further divided into those who participated in the intervention (intervention A), and those who participated in the intervention and had up to 3 of their regular clinic patients activated to discuss prostate cancer screening by participating in a similar patient-focused, Web-based tool immediately before a scheduled clinic visit (intervention B)." page 316 **Patient mediated intervention, distribution of educational material (intervention B):** Quote: "Intervention physicians were further divided into those who participated in the intervention (intervention A), and those who participated in the intervention and had up to 3 of their regular clinic patients activated to discuss prostate cancer screening by participating in a similar patient-focused, Web-based tool immediately before a scheduled clinic visit (intervention B).The patient intervention included video vignettes that depict the potential harms and benefits of undergoing prostate cancer screening." page 316 **Distribution of educational material (brochure, control):** "Control physicians received a brochure on prostate cancer screening that was distributed by the Centers for Disease Control and Prevention..." page 316
Outcomes	Prostate Cancer Screening Abstraction Tool (continuous)
Notes	**Additional information** Number of approached physicians (eligible): 130 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.

Feng 2013 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Comment:iInsufficient information to make a judgement.
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Comment: insufficient information to make a judgement.
Incomplete outcome data (attrition bias) Observer-based outcome	High risk	Comment: as treated analysis with 19,5% of physicians allocated to intervention A who moved to control group and 22,2% of physicians allocated to intervention B who moved to control group.
Selective reporting (reporting bias)	Low risk	Comment: the study is registered (under the number NCT 00207649) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	Unclear risk	Comment: insufficient information to make a judgement.
Baseline characteristics patients	Unclear risk	Comment: not reported.
Baseline characteristics healthcare professionals	Unclear risk	Comment: not clear in the paper.

Fiks 2015

Methods	**Study design**: randomized trial **Unit of allocation**: other **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: ambulatory care, primary care, USA **Health professionals**: various types; unclear level of training and gender **Patients**: 60; pediatric asthma; unclear gender
Interventions	**Multifaced intervention : patient-mediated intervention + reminder (EHR-linked SDM portal (MyAsthma)** Quote: "MyAsthma was developed with input from families and clinicians with the goal of fostering ongoing SDM. MyAsthma provided decision support to both clinicians and parents. The clinician interface appeared seamlessly in the EHR, and the parent interface appeared seamlessly within MyChart, the EHR vendor's patient portal. The features of MyAsthma (Supplemental Appendix 1) include identification of parents' concerns and goals for asthma treatment; monthly tracking of symptoms, medication side effects, and progress toward goals; asthma educational content including videos; and access to the child's asthma care plan. Parents were encouraged with E-mail reminders to complete monthly portal surveys with input from their affected child (Supplemental Appendix 2). In response to these surveys, families and clinicians received guideline-based decision support that directed them to speak to

Fiks 2015 *(Continued)*

	one another if asthma was not well-controlled or if there were side effects, or to continue current therapy." page e966 **Single intervention - reminder** Quote: "Families in the control group did not have access to the portal; however, clinicians caring for control group children had access to a clinician focused decision support system proven effective in fostering guideline-based care." page e967
Outcomes	Parent Patient Activation Measure (PPAM-13) (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to make judgement. Quote: "A randomization sequence was generated by the study coordinator (SLM)." page e966
Allocation concealment (selection bias)	Low risk	Quote: "Sealed envelopes were used to ensure blinding of study staff to treatment condition before enrollment and randomization." page e966
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Patients were not blinded. Quote: "Sealed envelopes were used to ensure blinding of study staff to treatment condition before enrollment and randomization." page e966
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Quote (discussion): "We found that more than half of intervention families completed portal surveys for at least 5 of the 6 study months and 77% completed the survey more than once." page e970 Quote (bottom of table 4): "At baseline, n = 30 for each group. At follow-up, n = 26 for intervention, n = 27 for control." page e970 Comment: missing data similar in the 2 groups. The remaining 7 families were unable to be reached by phone or E-mail.
Selective reporting (reporting bias)	High risk	Comment: some relevant outcomes prespecified in the study protocol were not reported in the results: preferred role and actual role in decision making, PEACE (NCT01715389): Observing Parent Involvement (OPTION) scale.
Other bias	High risk	Selection bias: study participants were a convenience sample; some were recommended by their primary care providers and others were enrolled based on EHR rosters. Quote: "...because this study was confined to practices within 1 health system with an interest in improving asthma care, this sample may not be representative of the larger population of children with asthma." page e971 Because of the small number of subjects in this study, randomization did not fully balance asthma severity between intervention and control subjects." page e971
Baseline measurement? Participant-reported outcome	Low risk	Comment: there were no significant differences in baseline control, quality of life, or parent activation between the 2 study arms (page 2 for all comparisons).
Protection against contamination?	High risk	Comment: Family were randomized within practices

Fiks 2015 *(Continued)*

Baseline characteristics patients	Low risk	Comment : See table 1 Quote: "No significant differences between intervention and control groups" (bottom of table 1) ; Quote: "We did not observe any significant difference between frequent users and other intervention families in demographic characteristics;" page e968
Baseline characteristics healthcare professionals	Unclear risk	Comment: No report of characteristics

Fossli 2011

Methods	**Study design**: clinician-randomized, cross-over trial **Unit of allocation**: clinician **Unit of analysis**: clinician **Power calculation**: done
Participants	**Setting of care**: primary care, ambulatory care; Norway **Healthcare professionals**: 72; various types of physician (residents, consultants, medical surgeons, neurologist, podiatrists, gynecologist), fully trained and residents **Patients**: not reported
Interventions	**Multifaceted intervention**: educational meeting, distribution of educational materials, Audit and feedback after role-play Quote: "Doctors participated in the 20 hours (a 45 min) course over two consecutive days. …The course consisted of a 50/50 mix of theory and 45 min group sessions (3–7 participants and two teachers per group) including role-plays, with plenary debriefs after each group." page 2 "Our course was based on the same content as the 5-day course Communication Skills Intensive offered by Kaiser Permanente." page 2 "At the conclusion of the course, all participants received a one-sheet overview of the Four Habits to carry in their pockets as reminder in everyday work." page 3 **Usual care (control)**
Outcomes	Four Habits Coding Scheme (continuous, score); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported, planned for eight video consultations per physicians

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The doctors were randomized to receive the intervention in the summer of 2007 or the winter of 2008." page 3

Fossli 2011 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Comment: unit of allocation is the doctor within a clinic. No details on allocation procedure.
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "Raters were blinded to all information about the doctors and the encounters, including whether the video was made before or after the intervention." page 3
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: reasons for missing outcome data unlikely to be related to outcome.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases
Baseline measurement? Observer-based outcome	Low risk	Quote: "All included doctors had two encounters videotaped before the first course (period A - baseline)." page 2
Protection against contamination?	Unclear risk	Comment: doctor were allocated within a clinic.
Baseline characteristics patients	Unclear risk	Comment: not reported
Baseline characteristics healthcare professionals	Unclear risk	Comment: No comparison between intervention and control group

Hamann 2007

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: group of providers for wards **Unit of analysis**: patient **Power calculation**: not clear
Participants	**Care setting**: specialized and non-ambulatory care (12 acute psychiatric wards of two state hospitals); Germany **Health professionals**: unknown number; specialists (psychiatrists) **Patients**: 107; schizophrenic; male and female
Interventions	**Multifaceted intervention**: patient-mediated intervention (decision aid) + educational meeting with nurses, aided by various charts, lasting 30-60 minutes. A nurse assisted the patient work through the decision aid. Patients met with their physician 24 hours after having consulted the decision aid. **Usual care** (Control)
Outcomes	COMRADE (continuous); Joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information** Number of approached patients (eligible): not reported

Hamann 2007 *(Continued)*

	Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization of the wards", page 993
Allocation concealment (selection bias)	Low risk	Quote: "Randomization of the wards", page 993
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: missing data on outcomes (see table 4 of Hamann 2006) but insufficient reporting to permit judgement.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper
Protection against contamination?	Low risk	Comment: wards were randomized, patients remained in their respective wards.
Baseline characteristics patients	Low risk	Comment: see table 1 of reference 11 (Hamann 2006). Covariates that were unbalanced were adjusted in the analysis.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Hamann 2011

Methods	**Study design**: patient-randomized trial (pilot) **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not clear
Participants	**Care setting**: specialized and non-ambulatory care; Germany **Health professionals**: unknown number; specialists (psychiatrists) **Patients**: 61; schizophrenia and schizoaffective disorder; male and female
Interventions	**Single intervention:** patient-mediated intervention (SDM training)

Hamann 2011 *(Continued)*

	Quote: "The training consisted of five one hour sessions for a group of five to eight patients. The content of the training was derived from theoretical considerations about patients' contributions to the shared decision-making process, from an adaptation of related approaches from somatic medicine, and from pilot testing the training. The training sessions included motivational aspects (such as prospects of participation) and behavioral aspects (including role-play exercises). The training emphasized interaction between moderators and patients as well as mutual support. All sessions were led by a psychiatrist and a psychologist, neither of whom was in charge of the specific care of these patients." page 1218 **Single intervention (Control):** patient-mediated intervention (cognitive training) Quote: "Patients in the control condition participated in a five-session cognitive training group." page 1218
Outcomes	Patients were asked who was making important medical decisions concerning their health (continuous); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: insufficient information about the sequence generation process.
Allocation concealment (selection bias)	Low risk	Comment: numbered closed-allocation concealment envelopes.
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Comment: see protocol in clinical trial register (masking: open-label).
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: for our primary outcome. 25% in intervention group and 12% in control group. No reasons for missing data to permit judgement.
Selective reporting (reporting bias)	Low risk	Comment:the study is registered at clinicaltrial.gov (under the number NCT01313013) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	High risk	Comment: randomization was made by patient within one single practice.
Baseline characteristics patients	Unclear risk	Comment: characteristics are mentioned in text but no data were reported.

Hamann 2011 *(Continued)*

Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Hamann 2014

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not clear
Participants	**Care setting**: specialized and ambulatory care; Germany **Health professionals**: 1, specialist, fully trained **Patients**: 100; affective disorders; male and female
Interventions	**Single intervention:** patient-mediated intervention Quote: "The QPS for outpatients with an affective disorder was developed by four experienced clinicians (two psychiatrists, two psychologists)...The final version of the QPS was a one-page leaflet in which patients were encouraged to behave actively in the consultation ('Make the best out of the consultation'), to write down notes about their wishes for today's consultation and to tick up to 15 standard questions that were provided on the QPS (e.g. 'What is my diagnosis?', 'What treatment options are still available for my complaints?' etc.). Finally, the QPS stated that patients could refer to the leaflet during the consultation..." page 228 **Usual care (Control):** patient-mediated intervention (cognitive training) Quote: "Patients in the control condition went to the consultation without receiving the QPS." page 228
Outcomes	Patients self-report of who made the decision during the day's consultation (continuous); Third-party assessment of who made the decision during the day's consultation (continuous).
Notes	**Additional information** Number of approached patients (eligible): 152 Number of patients per physician: 100 (only one physician)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Comment: insufficient information to make a judgement
Allocation concealment (selection bias)	Low risk	Quote: "Every patient was given a numbered, sealed, allocation concealment envelope that contained allocation to their group and all study materials." page 228 column 2
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Comment: insufficient information to permit judgement
Blinding (performance bias and detection bias)	Unclear risk	Comment: insufficient information to permit judgement

Hamann 2014 *(Continued)*

Participant-reported outcome		
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Quote: "All consultations were audio-taped and subsequently analysed." page 229 column 1
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: I cannot assume that all patient replied to all questions related to outcomes. Missing outcome data were not specified.
Selective reporting (reporting bias)	High risk	Comment: participant flow was not fully drawn and missing outcomes data were not specified. One outcome was not specified but reported in table 2: Quote: "what influence did you have on what had been decided during the consultation?" Oucomes like: number of questions ticked among the 15, number of patients who ticked at least 1 question in the QPS, topics raised in the QPS and factors associated with the number of questions ticked were not pre-specified in the paper. As median and range are mostly reported, it will be difficult to compute an effect size for a meta-analysis.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	Low risk	Quote: "All patients in the intervention group were provided with the QPS prior to the consultation… and were asked to work through it in a separate room." page 228 column 2
Baseline characteristics patients	Low risk	Comment: reported and similar (table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Hamann 2017

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: non-ambulatory care, specialized care, Germany **Health professionals**: specialists; fully trained **Patients**: 264 (215 included in analysis); psychiatric hospital - schizophrenia; male and female

Hamann 2017 *(Continued)*

Interventions	**Single intervention : patient mediated intervention (SDM Training for patients)** Quote: "5-session training (60 min/session) addressing patient competencies for SDM. "The group was led by a psychiatrist (J.H. or A.P.), who was not involved in the patients' treatment, and another mental health professional (e.g. nurse, psychologist) and comprised 5–8 patients. The content of the group builds upon conceptual and empirical research on patient competences in the medical encounter (e.g. [15, 16]) and had been subject to extensive pilot testing. The intervention follows a structured manual which is available on request from the authors. Group sessions took place twice a week and addressed the following topics: • Patient rights • Prospects of SDM (better health) • Communication skills (asking questions, information provision, being assertive) • Preparing for ward rounds and consultations The skills were introduced and rehearsed using role plays and homework (e.g. pose a question to the doctor in charge, prepare oneself for the next ward round). Patients in the control condition received a 5-session cognitive training (finding differences, completing lists etc) including also elements of euthymic therapy (e.g. 'using all five senses')but with no reference to doctor-patient communication." page 176 **Single intervention : patient mediated intervention (Training for patients)** 5-sessions of cognitive training with no reference to doctor-patient communication
Outcomes	Who makes important decision about your medical treatment? (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not enough information to make judgement about sequence generation. Quote: "Separate randomization lists for every study center (block size = 4) and numbered closed allocation concealment envelopes were generated prior to the study by our statistical department. Patients were recruited until group size was reached, then randomized to the intervention/control condition." page 177
Allocation concealment (selection bias)	Low risk	Quote: "numbered closed allocation concealment envelopes were generated prior to the study by our statistical department." page 177
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "As to the nature of our intervention patients were not blinded. Psychiatrists in charge who also did the ratings were neither informed about allocation of their patients nor intentionally blinded." page 177
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: did not mention how missing data was treated (105 between T1 and T3). Responsibility for decision-making, N = 192 ; Responsibility for decision-making, N = 118 ; Responsibility for decision-making, N = 87 Quote: "49 patients dropped out of the trial during the inpatient and intervention phase, most of them because they were suddenly discharged or left the hospital against their doctor's advice, and were therefore excluded from the analysis." page 177
Selective reporting (reporting bias)	Unclear risk	Comment: insufficient information to make a judgement. Protocol not available
Other bias	High risk	Quote: "Selection bias = As only patients who were judged to tolerate a 60 min intervention were recruited, we surely had a recruitment bias towards less ill

Hamann 2017 *(Continued)*

		patients which results in a possible lack of generalizability of our data." page 179
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measures.
Protection against contamination?	High risk	Comment: patients were randomized.
Baseline characteristics patients	Low risk	Quote: "Apart from duration of illness there were no significant differences between the intervention and the control group with regard to socio-demographic or clinical variables at baseline." page 177
Baseline characteristics healthcare professionals	Unclear risk	Comment: no characteristics reported.

Haskard 2008

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: provider **Unit of analysis**: provider **Power calculation**: not done
Participants	**Care setting**: primary care; ambulatory care (a west coast university medical centre, a Department of Veterans Affairs clinic and a staff model HMO); USA **Healthcare professionals**: 156; from three primary care specialties, Various type of physician (obstetrics/gynecology, family medicine, internal medicine); fully trained (87) and in training (69) **Patients**: 2196; various clinical conditions; male or female
Interventions	**Multifaceted intervention** (physician and patient trained arm): educational meeting + distribution of educational materials + patient-mediated intervention; 20 hours and 20 minutes. Physician received a 3X6 hours interactive workshop over a period of 3 months. The first workshop focused on core communication skills in healthcare (engaging; empathising; educating patients of diagnosis, prognosis, and treatment; and enlisting patients in mutually agreed upon treatment plans). The second workshop focused on patient adherence, enhancing patients' health lifestyles, reducing health risk behaviours, and building confidence and conviction in patients to make healthy behaviour changes. The third workshop focused on sources and nature of interpersonal difficulties between clinicians and patients, recognizing and assessing tension in relationships, acknowledging problems, discovering meaning, showing compassion, setting boundaries, and helping patients find additional support. Each workshop was followed by the utilization and distribution of educational materials about the main topic covered during the workshop. Patient received a 20-minute waiting room pre-visit intervention. This intervention involved listening to audio CD with accompanying patient guide book focusing on planning and organizing concerns and questions for physician and encouragement to discuss treatment choices, negotiate best plan, repeat their understanding of the plan, follow up of care with their physician, asking questions about medications, tests, procedures, and referrals. **Multifaceted intervention (physician only trained arm)**: educational meeting + distribution of educational materials; 20 hours See the above description for the physician intervention

Haskard 2008 *(Continued)*

	Single intervention (patient only trained arm): patient-mediated intervention; 20 minutes See the above description for the patient intervention **No intervention (control)**
Outcomes	Physician-patient global rating (continuous). SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision making process
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: up to 24 patients per physician

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "… physicians were randomised to one of four conditions using a computer-generated random order." page 515
Allocation concealment (selection bias)	Unclear risk	Comment: unit of allocation is the provider and not separated by practice. No details on allocation procedure.
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: some physician dropped out before training was completed and post training assessments. Reasons were balanced across groups. Although reasons for loss to follow up were not reported, loss to follow up were quite balanced in numbers across groups. Proportion of missing data was 18.6%.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	Unclear risk	Comment: unit of allocation is the provider and not separated by practice.
Baseline characteristics patients	Unclear risk	Comment: not reported
Baseline characteristics healthcare professionals	Unclear risk	Comment: there is mention of participant characteristics on page 514 but comparison between intervention and control arms were not presented.

Hess 2012

Methods	**Study design**: patient randomized trial **Unit of allocation**: patient **Unit of analysis**: patient

Hess 2012 *(Continued)*

	Power calculation: done
Participants	**Care setting**: tertiary care; ambulatory care, USA **Health professionals**: 102; physicians, residents; fully trained and in training **Patients**: 204; chest pain; male and female: 120 females, 84 males
Interventions	**Multifaceted intervention:** patient-mediated intervention (one brief demonstration of the use of the decision aid) and educational meeting (one hour training session) Quote: "Participating clinicians were oriented during a 1-hour training session given by the lead investigator (E.P.H.) as well as a brief (3 min) demonstration from the study coordinator on how to use the decision aid before meeting the first enrolled patient and as needed." page 252 **No intervention, standard care (control)**
Outcomes	Observing Patient Involvement (OPTION) scores; The fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information** Number of approached patients (eligible)**:** 310 Number of patients per physician: 208 patients for 51 clinicians

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomised to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion …" page 253
Allocation concealment (selection bias)	Unclear risk	Comment: the centralized randomization scheme was unclear
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "Third investigator (H.H.T.), who was also blinded to allocation, reviewed all potentially positive outcomes." page 254
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: 3 missing outcomes in DA and 5 in control group. Reasons unlikely to be related to our outcome of interest.
Selective reporting (reporting bias)	Low risk	Comment: pre-specified relevant outcomes were reported in the results (see clinical tria.gov NCT 01077037).
Other bias	Low risk	Comment: no other evidence of risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	Low risk	Comment: it was the patients who were randomized in an ED Hospital.
Baseline characteristics patients	Low risk	Comment: see table 1 for patient baseline characteristics, page 255

Hess 2012 *(Continued)*

Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Hess 2016

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: ambulatory care, primary care, USA **Health professionals**: 361; various types; fully trained **Patients**: 913 (898 included in analysis); emergency: low risk chest pain; male and female
Interventions	**Multifaceted intervention - Patient mediated intervention (Decision aid) + reminder (quantitative pretest probability web-based tool**) Quote: "For patients randomized to the decision aid, a study coordinator collected each of the variables needed to populate the quantitative probability web tool, 14 asked the treating clinician to sign off on their accuracy, and calculated the patient's pretest probability of acute coronary syndrome, incorporating the result of the first troponin test but prior to subsequent biomarker testing (fig 2). After selecting the decision aid corresponding to the appropriate level of risk, the study coordinator offered to provide the clinician with a concise refresher of the content. The treating clinician, after evaluating the patient and the results of the initial ECG and cardiac troponin tests, then used the decision aid to educate the patient about the results of the two tests, the potential need for observation and further cardiac testing, subsequent cardiac troponin testing to definitively rule out acute myocardial infarction, if required, and their personalized 45 day risk for acute coronary syndrome. The clinician then engaged the patient in selecting the management option most closely aligned to his or her values and preferences." page 2 **Control group - usual care** Quote: "For patients randomized to usual care, a study coordinator instructed the clinician to discuss the results of diagnostic investigations and management options according to the clinician's usual manner. Clinicians treating patients in the usual care arm did not have access to the quantitative probability web tool or to the decision aid. As the trial was intentionally pragmatic in design, usual care was not standardized." page 4
Outcomes	OPTION (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: online randomization algorithm
Allocation concealment (selection bias)	Low risk	Quote: "Allocation was concealed by an online password protected randomization algorithm (Medidata Balance; Medidata Solutions, New York City, NY)." page 2

Hess 2016 *(Continued)*

Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "Patients, study coordinators, and treating clinicians were not masked to allocation. All other investigators were blinded to allocation." Coders were blinded." page 2
Incomplete outcome data (attrition bias) Observer-based outcome	Unclear risk	Quote: "The main reasons recordings were not obtained were clinician and patient refusal and technical difficulties with recording equipment." Quote: "We were unable to obtain video recordings in 40% of the encounters." page 9 Comment: we do not know how missing outcome data are balanced between groups.
Selective reporting (reporting bias)	Low risk	Quote: "There is only one primary outcome for the study: patient knowledge. The sentence “Test if Chest Pain Choice safely improves validated patient-centered outcome measures” refers to the five additional outcome measures listed as secondary outcomes at clinicaltrials.gov (a through e) and is redundant. This is documented in the study protocol, which was published prior to completion of enrollment for the trial." (ClinicalTrials.gov NCT01969240), page 5
Other bias	Low risk	Comment: no evidence of other risk of biases
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measure of primary outcome.
Protection against contamination?	Low risk	Randomisation was done by patients. Quote: "To limit the risk of contamination, the quantitative pretest probability web tool was password protected, and coordinators did not provide clinicians access to the decision aid. However, even if contamination were to occur, this would bias the results of the trial toward the null, and we observed a positive effect of the intervention despite the potential for contamination." page 9
Baseline characteristics patients	Low risk	Quote: "There were no significant differences in baseline characteristics between the study arms." page 6
Baseline characteristics healthcare professionals	Unclear risk	Comment: no characteristics reported.

Härter 2015

Methods	**Study design**: provider randomized trial **Unit of allocation**: provider **Unit of analysis**: provider and patient **Power calculation**: unclear
Participants	**Care setting**: ambulatory and non-ambulatory care, Germany **Health professionals**: 86; type: specialists; level of training: unclear **Patients**: 160; breast and colon cancer; male and female
Interventions	**Multifaceted intervention:** patient-mediated intervention (decision aid) and educational meeting (training)

Härter 2015 *(Continued)*

	Quote: "Physicians in the intervention group participated in shared decision making training consisting of 12 training units, including a unit on the use of patient decision aids." page 673 **Usual care (control)** Quote "Physicians in the control group provided treatment as usual." page 673
Outcomes	Observing Patient Involvement (OPTION) scores (continuous); SDM-Q-9 (continuous); Patient perception scale (PPS) (categorical).
Notes	**Additional information** Number of approached physicians (eligible)**:** 900 Number of patients per physician (mean): at T1 4 in the intervention group and 6 in the control group; at T2 3 in the intervention group and 5 in the control group.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Physicians were randomized to the intervention group or control group at a ratio of 1:1 by an independent statistician, using a computer-based procedure." page 674
Allocation concealment (selection bias)	Low risk	Quote: "Physicians were randomized to the intervention group or control group at a ratio of 1:1 by an independent statistician, using a computer-based procedure." page 674
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Comment: insufficient information to permit judgement
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "Patient were blinded to the group to which they had been randomized." page 674
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: although there are more than 20% of lost to follow-up at T1 among physicians, lost to follow-up are balanced in number and reasons across groups (24 vs 29) (OPTION scale was assessed at T1).
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: insufficient reporting of attrition/exclusions to permit judgement.
Selective reporting (reporting bias)	Low risk	Comment: the study is registered in the German Clinical Trials Register (under the number DRKS00000539) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measure of outcome.
Baseline measurement?	Unclear risk	Comment: no baseline measure of outcome.

Härter 2015 *(Continued)*

Participant-reported outcome		
Protection against contamination?	Unclear risk	Comment: insufficient information to make a judgement.
Baseline characteristics patients	Low risk	Comment: reported and similar (table 1)
Baseline characteristics healthcare professionals	Low risk	Comment: reported and similar (table 1)

Jouni 2017

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: ambulatory care, USA **Health professionals**: 6; various types; fully trained; unclear gender **Patients**: 207; coronary heart disease; male and female
Interventions	**Single intervention : patient-mediated intervention (CRS: 10-year risk of CHO based on conventional risk factors alone)** Quote: "The Statin Choice decision aid was originally developed to disclose CHD risk and help patients as well as clinicians review the benefits and downsides of taking a statin medi cation to reduce CHD risk. The tool displays the 10-year probability of CHD based on CRS in addition to the absolute risk reduction with the use of statin drugs, and the associated costs/side effects. lt can be freely accessed online at http://statindecisionaid.mayoclinic.org.The modified tool can be accessed online at http://migenesstudy.mayoclinic.org (password: migenes-use of this decision aid should be limited to research purposes only). Afterwards, the provider can discuss the benefits of starting standard versus high dose statins as well as potential sicle effects (figure 3). CHD risk was disclosed using scripted language as follows: 'Out of 100 people like you ...' The benefit of statins was conveyed in a similar manner stressing the absolute risk reduction while minimizing framing by presenting the groups helped and not helped by using statins." page 683 **Single intervention : patient-mediated intervention (CRS + GRS: conventional risk factors alone with a genetic risk score)** Quote: "The tool was also equipped with a report generating function and a frequently asked questions page that includes additional information about GRS." page 683
Outcomes	SDM-Q and OPTION5 (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote:"Randomization was performed by means of a computer-generated random sequence with stratification for age, gender, and positive family history for CGD using the Pocock and Simon method." page 682

Jouni 2017 *(Continued)*

Allocation concealment (selection bias)	Low risk	Quote: "One of the investigators (HJ) generated the random allocation sequence and study arm assignment using the computer software described earlier." page 682
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Quote: A random sample of 40 CRS encounters and 40 age- and sex-matched CRS*GRS encounters was obtained and video recordings were analyzed by one of the authors (TSM). page 683 Comment : it is not said if the author was blinded.
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "The study sample size was relatively small and the intervention was not blinded." page 1186 (primary article)
Incomplete outcome data (attrition bias) Observer-based outcome	High risk	All encounters were not recorded. Quote: "Encounters with the genetic counselor and physician were video-recorded in 187 patients who consented to the recording." page 682 Quote: "A random sample of 40 CRS encounters and 40 age- and sex-matched CRS*GRS encounters was obtained and video recordings were analyzed by one of the authors (TSM)." page 683
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: The SDM survey was completed by 206 study participants, and the physician visit satisfaction survey was completed by al study participants (one missing data for SDM).
Selective reporting (reporting bias)	High risk	Comment: some relevant outcomes pre-specified in the study protocol were not reported in the results (Trial registration number NCT01936675).
Other bias	Unclear risk	Quote: "Our study participation had higher than average educational and socioeconomic background and may have been more adept in understanding genetic results." Comment: Selection bias ; Study participants were recruited from the Maya Clinic BioBank and may not be fully representative of the general population." page 687
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measure of primary outcome.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of primary outcome.
Protection against contamination?	High risk	Comment: patients were randomized.
Baseline characteristics patients	Low risk	Quote: "Baseline characteristics including age, sex, smoking status, and other CHD conventional risk factor were similar between the two groups." page 684
Baseline characteristics healthcare professionals	Unclear risk	Comment: no characteristics reported.

Kasper 2008

Methods	**Study design**: patient randomized trial **Unit of allocation**: patient **Unit of analysis**: patient Power calculation: done
Participants	**Care setting**: specialized care and ambulatory care (Hamburg University Hospital); Germany **Health professionals**: unknown number; physicians; unclear level of training **Patients**: 297; multiple sclerosis; male and female
Interventions	**Single intervention**: patient-mediated intervention (decision aid including a patient information booklet about immunotherapy options and an interactive workshop) The decision aid was formulated after assessing patients' needs and determining its feasibility. **Single intervention (control)**; patient-mediated intervention (decision aid consisting of a standard information package) This information can be found on the Internet.
Outcomes	Perceived level of control in the decision-making process (categorical); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 304 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was carried out by concealed allocation using computer generated random numbers." page 1346
Allocation concealment (selection bias)	Low risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "To preserve blinding assessors explicitly asked patients not to refer to details of the information materials … However, [the treating physicians] were not informed about their patient's allocation and did not receive the patient information." Page 1347
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: missing outcomes are not well-balanced in number and reasons but the proportion of missing outcome is 6,4% and the ratio of participants with missing data to participants with events (SDM) is 0,17.
Selective reporting (reporting bias)	Low risk	Comment: see protocol ISRCTN25267500. Relevant pre-specified outcomes were included in the analysis.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Quote: "In the intervention, 18 preferred shared and 122 prefer another style, in the control group 34 prefer shared, 109 prefer another style. This yields a Chi2 value of 5.96, p<0.05." page 1349

Kasper 2008 *(Continued)*

Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Comment: see table 2 and 3 and the support for judgement of the criteria baseline outcome.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Kennedy 2013

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: practice **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: primary care; ambulatory care; UK **Health professionals**: various type (doctors, nurses, technicians, administration staff); fully trained **Patients**: 5599; diabetes, COPD, irritable bowel syndrome; male and female
Interventions	**Single intervention:** educational meeting Quote: "Training (developed and piloted with two non-trial practices) was delivered in each practice over two sessions, which we estimated through informed feedback was the maximum feasible in UK primary care using current educational structures." page 2 **Usual care (control):** Quote: "We used a wait list comparator group." page 3
Outcomes	Shared decision making (short-form healthcare climate questionnaire) - 12 month vs baseline (continuous).
Notes	**Additional information** Number of approached practices (eligible): 51 Number of patients per cluster (mean): 121 in the intervention group, 151 in the control group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Using a minimisation procedure based on practice size…" page 3
Allocation concealment (selection bias)	Low risk	Comment: practices were randomized
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "There is no blinding of patients or outcome assessors, although all outcomes are self-report." study protocol page 6

Kennedy 2013 *(Continued)*

Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: missing outcome data balanced in proportion across intervention groups (71,9% vs 73,5%) but not in number (646 vs 877). No reasons for missing data were provided. Missing outcomes were not imputed but I do not know if to address it is widely acknowledged (and what the assumption underlying the use). However, a sensitivity analysis has been performed.CM6
Selective reporting (reporting bias)	High risk	Comment: results of cost-effectiveness analysis that was prespecified in the study protocol were not reported. Techniques for treatment of missing data was not prespecified in the protocol; moreover, assumptions underlying the techniques used were not reported in the paper. One prespecified secondary outcome: management options was not reported. The authors treated the 6-month score of the 3 main outcome measures and self care activity as additional secondary outcomes but it was not prespecified in the study protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: no difference across groups for our primary outcome (Table 1).
Protection against contamination?	Low risk	Comment: practices were randomized.
Baseline characteristics patients	Low risk	Comment: Reported and similar (Table 1)
Baseline characteristics healthcare professionals	Unclear risk	Comment: No report of characteristics

Koerner 2014

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: practice **Unit of analysis**: provider and patient **Power calculation**: unclear
Participants	**Care setting**: specialized care; non-ambulatory care; Germany **Health professionals**: 363; various type (physicians, nurses, psychosocial therapists, physical therapists); fully trained **Patients**: 1326; chronic diseases; male and female
Interventions	**Single intervention: e**ducational meeting Quote: "The train-the-trainer programme 'Fit for Shared Decision-Making' (see Appendix 1, available online) was implemented in the intervention clinics after the first data collection period (preintervention)..." page 22 **Usual care (control):** Quote: "...whereas the control clinics were offered training after the data collection had been completed in all clinics (waiting control group)." page 22

Koerner 2014 *(Continued)*

Outcomes	SDM-Q-9 score (continuous)
Notes	**Additional information** Number of approached practices (eligible):92 Number of patients per practice: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "We put the name of each clinic of a pair on a piece of paper, placed them in a bag so that the name could not be seen and drew out one name which was allocated to the intervention group. The other was placed into the control group. One centre was not matched,and was allocated to the intervention group, as we expected more cancellations in the intervention." page 22
Allocation concealment (selection bias)	Low risk	Comment: practices were randomized.
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "The patients were not aware of which group they were in… but the study coordinators and those analysing the data… were." page 22 column 2
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: see: flow chart and comments in the text, data analysis (missing values) and limitation of the study in the discussion.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: see Table 5.
Protection against contamination?	Low risk	Comment: practices were randomized.
Baseline characteristics patients	Low risk	Comment: reported and similar (table 2).
Baseline characteristics healthcare professionals	Low risk	Comment: reported and similar (table 3).

Korteland 2017

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient

Korteland 2017 *(Continued)*

	Power calculation: unclear
Participants	**Care setting**: ambulatory care, specialized care, the Netherlands **Health professionals**: specialists; fully trained **Patients**: 155; prosthetic heart valve selection; male and female
Interventions	**Single intervention : patient MI (PDA decision tool)** Quote: "The final PDA is an online tool (www.hartklepkeuze.nl) and contains 2 sections: an information section on heart function, heart valve disease, available heart valve prostheses, the operation, living with a heart valve prosthesis, and hyperlinks for further information; and the actual PDA, which is made up of 7 parts: (1) introduction and personal information (patients may optionally enter age and sex), (2) information on the 2 options (mechanical or biological valve), (3) a comparison of the options (if patient has entered age and sex, then age- and sex-specific estimates of the lifetime risk of bleeding with a mechanical prosthesis and reoperation with a biological valve are displayed), (4) exploration of personal feelings about the 2 options, (5) a knowledge quiz, (6) exploration of patient preference, and (7) a summary of the results of the PDA that can be printed or e-mailed for use in the doctor's office." page 2 **Usual care : standard preoperative care (control group)**
Outcomes	Involvement in decision making (qualitative)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly assigned (1:1) to standard preoperative care or standard preoperative care plus additional use of the PDA with permuted block sizes of 10, stratified by center. The randomization sequence was generated by an independent statistician using a random number generator." page 4
Allocation concealment (selection bias)	Low risk	Quote: "Allocations were placed in serially numbered, opaque, sealed envelopes by 2 independent research assistants." page 4
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "Because of the nature of the intervention, it was not possible to blind investigators and patients to the allocation." page 4
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: missing outcome data were not specified for our primary outcome.
Selective reporting (reporting bias)	Low risk	Comment: relevant outcomes prespecified in the study protocol are reported in the results (NTR4350).
Other bias	Unclear risk	Comment 1: not all randomized patients completed the preoperative questionnaire, which may have resulted in selection bias. Comment 2: selection bias page 9 Quote: "Mainreasons were the absence of a computer at home, a language barrier (the Netherlands has an increasingly diverse population with many nationalities and cultural backgrounds)" Comment: Desirability ?? Quote: "Questionnaires were completed at home, and patients may have been influenced by family members or friends." page 8

Korteland 2017 *(Continued)*

Baseline measurement? Participant-reported outcome	Unclear risk	COmment: no baseline measure of primary outcome.
Protection against contamination?	High risk	Comment: patients were randomized.
Baseline characteristics patients	Low risk	Quote: "As there seemed to be potential imbalances in the baseline characteristics preoperative consultation and involved in prosthetic valve choice, we first performed an ordinal regression analysis to assess the effect of the use of the DA on the primary outcome DCS without correction for these potential imbalances, and next, a multivariable ordinal regression analysis with the 2 baseline characteristics included." page 4
Baseline characteristics healthcare professionals	Unclear risk	Comment: no characteristics reported.

Krist 2007

Methods	**Study design**: patient randomized trial **Unit of allocation:** patient **Unit of analysis**: patient **Power calculation**: not clear
Participants	**Care setting**: primary care and ambulatory care (1 large family practice centre in suburban northern Virginia); USA **Health professionals**: 29; family physicians; 13 fully trained and 16 in training **Patients**: 497; prostate cancer screening; male
Interventions	**Single intervention**: patient-mediated intervention (mailed paper version of the decision aid) The brochure duplicated the content of the website. **Single intervention (control):** patient-mediated intervention (Internet-based decision aid) The web-based decision aid was created by the author and reviewed by experts, presents evidence of prostate cancer. **No intervention (control)**
Outcomes	Perceived level of control in the decision-making process (categorical). Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 1073 Number of patients per physician: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Krist 2007 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "At the time of enrolment, the allocation was concealed from the coordinator … the coordinator referred to pre-generated randomisation tables to inform the participant to which arm he was randomised." page 113-114
Allocation concealment (selection bias)	Unclear risk	Quote: "The allocation was concealed from the coordinator…" page 113
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: patient-mediated intervention and patient-reported outcome, so the patient was not really blinded.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Quote: "Questionnaires were completed by 87% of patients and 91% of physicians overall." page 114
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Comment: baseline demographics for the control, brochure, and Web site groups were similar (Table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Krones 2008 (ARRIBA-Herz)

Methods	**Study design**: clinician-randomized trial **Unit of allocation**: clinician **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: primary care; ambulatory care (CME groups in Hessen); Germany **Health professionals**: 91; family doctors; fully trained **Patients**: 1132; cardiovascular; male and female (Krones 2008)
Interventions	**Multifaceted intervention**: educational meeting, audit and feedback, distribution of educational materials, educational outreach visit Educational meeting two 2 hr sessions (risk of CVD, ethics of SDM, practical communication strategies), audit and feedback (after role-play feedback was given by their peers), distribution of educational materials (ARRIBA-Heart counseling sheet), educational outreach (CME members were invited to moderate the sessions).

Krones 2008 (ARRIBA-Herz) *(Continued)*

	Quote: "In the sessions they discussed epidemiological background of global cardiovascular disease risk calculation and ethics of SDM. ... emphasis on practical communication strategies ... Use of script-like decision aid was practiced through role play, participants received feedback from their peers ...." page 324 The participating family doctors were taught how to moderate a session **Single intervention** (control):placebo educational meeting Quote: "Family doctors in the control arm were offered seminars on defined alternative topics that would not interfere with CVD prevention." page 324
Outcomes	Patient Participation scale, SDM-Q; Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): NA Number of patients per physician: at least one patient per physician (Hirsch 2010)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization to intervention or control group was stratified by the rural or urban location of member practices…" page 219
Allocation concealment (selection bias)	Low risk	Comment: CME groups (group of providers) were randomized
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Quote: "Patients were informed that different kinds of risk communication and decision support would be assessed; they were unaware of their physicians' group allocation.." page 219
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: 19% of patients were lost to follow up; 16.3% in one group and 19.9% in the other. 37.8% vs 41 % of the lost to follow-up patient were lost because their physicians no longer participated in the study. Reasons for the rest of the lost to follow-up patients were not documented. In addition, reasons for study discontinuation by physician were not reported. 50% vs 50% of physicians/practices were analyzed (balanced) although reasons of discontinuation may be related to the outcomes... The proportion of missing outcome among the physicians is very high and may have a potential impact on the results. Missing data for our primary outcome are not specified.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	High risk	Quote: "Patients' participation preference in decision making also differed significantly in the 2 study arms, which might represent a selection bias in the intervention effect." page 222

Krones 2008 (ARRIBA-Herz) *(Continued)*

Protection against contamination?	Low risk	Comment: the intervention was stratified in accordance to CME groups.
Baseline characteristics patients	Low risk	Comment: see table 3. Quote: "…we included diabetes… in addition to CVD… as covariate in our analysis… page 222
Baseline characteristics healthcare professionals	Low risk	Comment: see table 2. Quote: "Because there were slight imbalances with regard to family doctors' age and practice size, we included these characteristics in all multivariate analyses…" page 222

Köpke 2014

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: ambulatory care; Germany **Health professionals**: type: unclear; level of training: unclear **Patients**: 192; clinical isolated syndrome or definite relapsing-remitting multiple sclerosis; male and female
Interventions	**Single intervention:** patient-mediated intervention (interactive-4-hour education program) Quote: "The intervention group (IG) received an interactive 4-h education programme, presenting the best available evidence regarding diagnostic testing in MS, prognosis of MS and early MS DMD therapy (table 1)." Page 412 **Single intervention: p**atient mediated-intervention (4-hour MS-specific stress management program) Quote: "To control for unspecific attention effects and enable patient blinding, control group (CG) participants took part in a 4-h MS-specific stress management programme led by a specially trained psychologist." page 412
Outcomes	Decision autonomy (qualitative)
Notes	**Additional information** Number of approached patients (eligible): 252 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "We performed a double-blind randomised controlled trial with a follow-up of 12 months using computer-generated randomisation lists for concealed allocation of participants by external central telephone." page 411
Allocation concealment (selection bias)	Unclear risk	Comment: allocation concealment method is not clearly described.

Köpke 2014 *(Continued)*

Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "Participants were blinded to study groups as they were not informed about the 'active' intervention. Outcomes were assessed via blinded telephone calls and mailed questionnaires." page 412
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: For our primary outcome (decision autonomy) proportion of missing values are balanced in number and proportion across groups: 23 (24,7%) vs 27 (27,3%). But reasons for missing were not reported.
Selective reporting (reporting bias)	Low risk	Comment: there is no evidence that outcomes were selectively reported (all relevant outcomes in the trial registry are reported in the results section).
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: incomplete information to permit judgement.
Protection against contamination?	High risk	Comment: patients were randomized.
Baseline characteristics patients	Low risk	Quote: "Baseline demographics were similar between groups (table 2). Results from the cognitive items of the quality of life and the disability assessment indicate few participants with important cognitive impairment with no differences between groups (data not shown)." page 413
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Lalonde 2006

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: primary care and ambulatory care (10 community pharmacies in Montréal); Canada **Health professionals**: unknown number; pharmacist; unclear level of training **Patients**: 26; cardiovascular problems; male and female
Interventions	**Multifaceted intervention**: distribution of educational materials (decision aid + personal risk profile) + patient-mediated intervention (decision aid) The decision aid is made of a booklet providing general information on the illness, the risk factors and lifestyle change and treatment option.Quote: "A four-step decision making strategy is suggested (Page 52)". It also included a personal worksheet which summarizes their risk and allows them to create an action plan. **Multifacted intervention (control)**; distribution of educational materials (decision aid + personal risk assessment) + patient-mediated intervention (personal risk profile)

Lalonde 2006 *(Continued)*

	The risk profile identifies the patient risk factors and estimates a 10-year CVD risk, changing as the patient changes their risk factors. It also includes a four-page information handout.
Outcomes	Decision satisfaction inventory (continuous). Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 42 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomisation was stratified by community pharmacy." page 52
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: In all, 88% of the patients were included in the follow-up. Missing data were balanced in number across groups.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	High risk	Comment: imbalances between patient characteristics (table 1 and p54).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Landrey 2012

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient

Landrey 2012 *(Continued)*

	Power calculation: not clear
Participants	**Care setting**: primary care and ambulatory care, USA **Health professionals**: 44, physicians; fully trained **Patients**: 303; prostate cancer screening; male Males with no history of prostate cancer
Interventions	**Single intervention (mailed flyer),** patient-mediated intervention Quote: "One week prior to their upcoming annual health maintenance visits, eligible patients were randomised to receive a mailed flyer (intervention group) or no flyer (usual care group)." page 2 **No intervention (control)**
Outcomes	Control Preference Scale (CPS). Joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information** Number of approached patients (eligible): 752 Number of patients per physician: 303 patients for 44 providers

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Eligible patients were randomized to receive a mailed flyer (intervention group) or no flyer (usual care group)." page 2
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "Two research assistants blinded to group assignment collected chart outcome information by reviewing clinic notes following patient appointment." page 2
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: missing outcomes were balanced in numbers across groups. At the follow-up survey 50% of outcome were missing and reasons for lost to follow-up were not documented.
Selective reporting (reporting bias)	Low risk	Comment: prespecified outcomes in the protocol were reported in the results. NCT01516801
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	High risk	Comment: there was no baseline, a follow-up telephone survey consisting of 13 items was conducted within 2 weeks of the clinic visit.
Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Quote: "There were no significant study group differences in baseline characteristics." page 69, table 1

Landrey 2012 *(Continued)*

Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

LeBlanc 2015a

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: practice **Unit of analysis**: provider and patient **Power calculation**: done
Participants	**Care setting**: primary care and ambulatory care, USA **Health professionals**: 117, various types (physician, nurse practitioner, physician assistant (see study protocol page 3)); fully trained and in training **Patients**: 301; depression; male and female
Interventions	**Single intervention**: patient-mediated intervention Quote: "Clinicians in the intervention group were to use the decision aid during the consultation with their patients..." page 1764 **Usual care (control)**: Quote: "...whereas clinicians in the control arm did not have access to the decision aid (usual care)." page 1764
Outcomes	OPTION (continuous)
Notes	**Additional information** Number of approached practices (eligible): not reported Number of patients per physician: 2, number of patients per practice: 34; number of clinician per practice: 7

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Allocation concealment (selection bias)	Low risk	Quote: "The lead study statistician therefore stratified practices by their history of accrual and the presence of the DIAMOND [Depression Improvement Across Minnesota - Offering New Direction] program (a practice redesign initiative to improve depression care present in numerous Minnesota practices at the time of the study), and centrally randomized practices within these strata to either care with or without Depression Medication Choice." page 1763
Blinding (performance bias and detection bias) Observer-based outcome	High risk	Quote: "Study team members, practices, and clinicians were aware of the assigned arms." page 8
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: "There was no difference in the attrition of participants or completeness of the data across arms (Figure 2)." page 11
Selective reporting (reporting bias)	Low risk	Comment: The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.

LeBlanc 2015a *(Continued)*

Other bias	Low risk	Comment: No evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment:No baseline measure of our primary outcome.
Protection against contamination?	Low risk	Comment: practices were randomized.
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 1).
Baseline characteristics healthcare professionals	Low risk	Comment: reported and similar (See table 1).

LeBlanc 2015b

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: patient **Unit of analysis**: provider and patient **Power calculation**: done
Participants	**Care setting**: ambulatory care, primary care, USA **Health professionals**: 41; general practitioners; male and female; fully trained **Patients**: 79; osteoporosis; female
Interventions	**Single intervention: patient-mediated intervention (Decision aid)** Quote: ''The intervention in the first arm (Decision Aid) consisted of the use of the Osteoporosis Choice decision aid by the clinician and patient during the clinical encounter (Fig 1). The decision aid included (a) the individualized 10-year risk of having a bone fracture (estimated using the FRAX calculator) with and without use of bisphosphonates (i.e., showing the absolute reduction with bisphosphonates) represented using an evidence-based pictograph and assuming a treatment-related reduction in overall fractures of 40%[10]; and (b) potential harms and other downsides of using bisphosphonates.'' page 3 **Single intervention : reminder** Quote: ''The intervention in the second arm (FRAX) consisted of giving clinicians a copy of the patient's individualized 10-year risk of having a bone fracture estimated using the FRAX calculator before the visit for use during the clinical encounter.'' page 4 **Usual care (control)** Quote: ''In the third arm (Usual Care), clinicians discussed risk of fractures and treatment as usual without any research-related intervention. No specific guidance was provided to support decisions about non-pharmacological interventions to reduce falls and fractures in any of the three arms.'' page 4
Outcomes	OPTION (qualitative)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

LeBlanc 2015b *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "Patients were the unit of randomization and were allocated using a computer-generated sequence that randomized them 1:1:1 in a concealed fashion." page 5
Allocation concealment (selection bias)	Low risk	Quote: "... using a computer-generated sequence that randomized them 1:1:1 in a concealed fashion" page 5.
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Quote: "Patients and clinicians were aware of the overall objective, presented as improvement in communication between patients and clinicians during the clinical encounter, but remained blinded to the specific aims." page 5 "After randomization, only data analysts remained blind to allocation." page 5 Comment: however authors did not talk about blinding of those who coded OPTION.
Incomplete outcome data (attrition bias) Observer-based outcome	Unclear risk	Comment: insufficient information about our primary outcome to make a judgement.
Selective reporting (reporting bias)	Low risk	Comment: the protocol was registered (Identifier: NCT00949611). The main outcomes pre-specified in the protocol were reported in the results.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	No baseline measure of the primary outcome.
Protection against contamination?	Low risk	Quote: "there was no evidence of contamination as clinicians in the FRAX/Usual Care arm covered significantly fewer items [17%, 95%CI (12, 23), t-test p< 0.0001]." page 9
Baseline characteristics patients	Low risk	Caracteristics between groups were similar at baseline (table 1).
Baseline characteristics healthcare professionals	Low risk	Similar repartition between groups (Table 1).

Leighl 2011

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: specialized care,aAmbulatory care; Australia, Canada **Health professionals**: 13 oncologists; fully trained **Patients**: 207, advanced colorectal cancer; male and female: 120 males, 87 females
Interventions	**Multifaceted intervention:** Patient-mediated intervention (decision aid), physician training (educational meeting) Decision aid: booklet with accompanying narration on an audiotape or CD

Leighl 2011 *(Continued)*

	Quote: "The DA used in this study was developed as a booklet with accompanying narration on an audiotape or compact disc for patients to take home ... Oncologists were trained to use the DA during the consultation and instructed to have patients return after the initial consultation for a final treatment decision as part of the study." page 2079 **No intervention, (control): s**tandard consultation
Outcomes	Modified Control Preferences Scale. Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible)**:** 229 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization lists, stratified by the consulting oncologists, were computer-generated…" page 2078
Allocation concealment (selection bias)	Low risk	Quote: "…and the code was concealed in a sealed envelope until the time of random assignment." page 2078
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: losses to follow-up were balanced in number and percentage across group (overall) but reasons for lost to follow-up were not reported. Missing data related to our primary outcome are not reported.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: see table 1 for measurement prior to consultation, page 2078
Protection against contamination?	Low risk	Quote: "Those receiving the DA were counselled not to share it with others in the waiting room to avoid contamination of the standard arm. To further minimize contamination between the arms, five consultations were audiotaped before study commencement as a baseline for comparison with consultations in the standard arm." page 2078
Baseline characteristics patients	Unclear risk	Comment: "Patient characteristics were well balanced between the groups (Table 2), although more patients randomly assigned to receive the DA reported English as their first language." page 2080. Comment: language may be related to some outcomes namely patient understanding and decision involvement but the authors did not specified if they adjusted that variable in the multivariate analysis.

Leighl 2011 *(Continued)*

Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Loh 2007

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: provider **Unit of analysis**: patient **Power calculation:** not done
Participants	**Care setting**: primary care and ambulatory care (Department of Primary Care at University Hospital of Freiburg); Germany **Health professionals**: 30; primary care physicians; fully trained **Patients**: 405; depressive disorders; male and female
Interventions	**Multifaceted intervention**: educational meeting with physicians and patient-mediated intervention (decision aid as well as a patient information leaflet); 20 hours(educational meeting) Quote: "Physician followed modules (lectures, round discussions, facilitation practice, role-play, videos, standardized case vignettes and case studies) for guidelines concerning depression care, including how to how to include patients in the decision. The SDM portion was based on the works of Towle and Godlphin, as well as those of Elwyn and colleagues." page 326 The physicians were given the decision aid and patient information leaflet to be used during the consultation. The patient's leaflet was based on the Clinical Practice Guideline on Depression in Primary Care of the Agency for Health Care and Policy. **No intervention** (control)
Outcomes	Man-Son-HIng Instrument (continuous). joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "… were randomly assigned by drawing blinded lots under supervisions of the principal investigators…" page 326
Allocation concealment (selection bias)	Unclear risk	Comment: unit of allocation is the provider and not separated by practice. No details on allocation procedure.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.

Loh 2007 *(Continued)*

Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: 29,1% of patient were lost to follow-up (27.4% in intervention group vs 32,4% in control group) but reasons were not documented for pre and post-intervention phases.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: baseline measurements for our primary outcome were reported.
Protection against contamination?	Unclear risk	Comment: unit of allocation is the provider and not separated by practice.
Baseline characteristics patients	Low risk	Quote: "Statistically significant differences were found between groups and measurement points for age, family status and educational level; therefore all outcome analyses were controlled for these variables." page 329, table1
Baseline characteristics healthcare professionals	Low risk	Quote: "Gender, age, and professional experience did not differ significantly between the study groups (p > .10)." page 328

Légaré 2012

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: family practice teaching units **Unit of analysis**: family physicians and patients **Power calculation**: done
Participants	**Care setting**: primary care (family practice), ambulatory care, Canada **Health professionals**: 270 family physician; teachers and residents; fully trained and in training **Patients**: 712; acute respiratory infections; male and female
Interventions	**Multifaceted intervention:** educational meeting, distribution of educational materials (online tutorial and workshop) Quote: "DECISION+2 consisted of a 2-hour online tutorial followed by a 2-hour on-site interactive workshop" **Usual care (control): Quote:** "Physicians in the control group were asked to provide usual care" Page E728
Outcomes	Control Preference Scale (CPS). Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Légaré 2012 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A biostatistician used Internet-based software to simultaneously randomise all 12 family practice teaching units to either the intervention group (DECISION+2) or control group." page E728
Allocation concealment (selection bias)	Low risk	Comment: practice were randomized.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: not enough information to make a judgement regarding our primary outcome (M-CPS).
Selective reporting (reporting bias)	Low risk	Comment: relevant outcomes prespecified in the trial register (NCT01116076) were reported in the result paper.
Other bias	Low risk	Comment: no evidence of other risk of biases
Baseline measurement? Participant-reported outcome	Low risk	Quote: Family physicians' intentions to engage in shared decision-making … were recorded at baseline and again at the end of the study." page E729
Protection against contamination?	Low risk	Quote: To avoid contamination bias, access to the online tutorial was denied to participants in the control group during the trial." page E728
Baseline characteristics patients	Low risk	Comment: in general, key characteristics of the patients (Table 1) and family practice teaching units and physicians (Table 2) in the DECISION+ 2 group were similar to those in the control group. E730
Baseline characteristics healthcare professionals	Low risk	Comment: in general, key characteristics of the patients (Table 1) and family practice teaching units and physicians (Table 2) in the DECISION+ 2 group were similar to those in the control group. E730

Maclachlan 2016

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: ambulatory care, primary care, Namibia **Health professionals**: general practitioners **Patients**: 592; HIV, male and female

Maclachlan 2016 *(Continued)*

Interventions	**Single intervention:** patient-mediated intervention (Trainings for patients) Quote: "The intervention consisted in three, two-hour trainings in active participation, patient empowerment, and communication." page 621. **Usual care (control, wait list)** Quote: "Six months after their enrollment date, participants in the control group (Group 2) were also offered training sessions as an ethically important intervention benefit." page 621-622
Outcomes	RIAS for patients (Patient activation and engagement) (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no information about sequence generation.
Allocation concealment (selection bias)	Unclear risk	Commnent: not enough information to make a judgement.
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Quote: "The same clinicians at each site saw both groups of patients but were blinded to the extent possible as to participant group assignment." page 622. Comment: however authors did not talk about blinding of those who coded RIAS.
Incomplete outcome data (attrition bias) Observer-based outcome	High risk	Comment: level of losses of follow-up is high: 14% (intervention group) and 9% (control group) of losses to follow-up. Some of the reasons of follow-up could be linked to the intervention such as, "withdrew" or "did not return" (these reasons are not well-balanced between the groups).
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available to permit judgement.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measure of our primary outcome
Protection against contamination?	Low risk	Comment: patients were randomized and intervention and control groups were in the same hospital.
Baseline characteristics patients	Low risk	Comment: characteristics between groups were similar at baseline (table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about clinicians at baseline.

Maindal 2014

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patients

Maindal 2014 *(Continued)*

	Unit of analysis: patients **Power calculation**: done
Participants	**Care setting**: primary care, ambulatory care, Denmark **Health professionals**: number: not reported; various types; level of training: unclear **Patients**: 509; type 2 diabetes, impaired fasting glucose/impaired glucose tolerance; male and female
Interventions	**Multifaceted intervention:** patient mediated-intervention, educational meeting Quote: "GPs of participants in the ADDITION-Denmark treatment arm were trained to provide target-driven intensive behavioural and pharmacological treatment for people with Type 2 diabetes." page 978 Quote: "The intervention group received intensive treatment of diabetes and routine care of impaired fasting glucose/ impaired glucose tolerance and an invitation to take part in the Ready to Act health education programme. The programme aimed to promote health-related action competence including motivation, informed decision-making, action experience and social involvement. Before the programme, nurses, dieticians, physiotherapists and GPs received formal training in autonomy support, participant-centred communication and action plan support." pages 978-979 **Single intervention (control):** educational meeting Quote: "All general practioners (GPs) in the ADDITION study were trained to motivate and to provide target driven intensive nonpharmacological and pharmacological treatment to people with screen-detected T2D." page 263 of reference 14
Outcomes	PAM-13 (continuous)
Notes	**Additional information** Number of approached patients (eligible): 521 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported. Comment: the pre-randomization scheme may include confounding because the participants who did not signed up for the intervention program may imbalance the characteristics between the group and hinder the benefice of the randomization.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to make a judgement
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "Measurements, data entry and laboratory analysis were conducted by people blinded to the participants' study group allocation." page 979
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: more than 20% of missing data for primary outcome and no reasons for missing data.
Selective reporting (reporting bias)	Low risk	Comment: relevant outcomes in the trial registry are reported in the results.

Maindal 2014 *(Continued)*

Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	High risk	Comment: patients were randomized.
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Maranda 2014

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: primary care, ambulatory care, USA **Health professionals**: number: not reported; types: unclear; level of training: unclear **Patients**: 132; context: not specified; male and female
Interventions	**Single intervention:** patient-mediated intervention Quote: "The patient activation intervention (PAI) objective is to help patients identify medical decisions and the questions that inform those decisions, and then to use that information to prepare questions for their impending doctor visit. The PAI was developed and implemented previously at community health centers in NYC24 and is based on principles that empower patients who are not effective advocates for themselves." page 593 **Usual care (control): n**o exposure to the PAI
Outcomes	PAM (continuous)
Notes	**Additional information** Number of approached patients (eligible): 945 Number of patients per physician: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Comment: insufficient information about the sequence generation process.

Maranda 2014 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Comment: allocation concealment method is not clearly described.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: insufficient information to permit judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Quote: "Data collection was incomplete for 43 individuals who were excluded from the analysis. Reasons for incomplete data collection included: participant was called in to see the physician before finishing the pre- visit questionnaire; participant failing to complete the PAM; or participant left without completing the post- visit interview." page 596 Comment: missing outcome data are likely to bias the results because: more participants were lost from the control than from the intervention group (26 vs 16); so the exposure may be associated to the selection - because some excluded participants were called before finishing the pre-visit questionnaire and some participants failed to complete the PAM, the outcome (PAM) maybe associated to the selection (those patient may have low level of PAM).
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: see Table 1.
Protection against contamination?	High risk	Comment: patients rather than professionals were randomized at 1 CHC.
Baseline characteristics patients	Low risk	Table 1, Quote: "The control group had a smaller proportion of participants with less than a high school education (45.9%) than the intervention group (58.6%); however, this difference was not statistically significant." page 596
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Mathers 2012

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: practice **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: primary care, ambulatory care, UK **Health professionals**: number: not reported; various type (doctors and nurses); level of training: unclear **Patients**: 175; type 2 diabetes mellitus; male and female

Mathers 2012 *(Continued)*

Interventions	**Multifaceted intervention:** patient-mediated intervention, educational meeting Quote: "This was a complex intervention comprising three components: PDA; healthcare professional training workshop and use of the PDA in a consultation." page 3 **Usual care (control): Quote:** "In the control group, the GP and the practice nurse did not receive any training and the PANDAs decision aid was not used. The GPs or the nurses conducted a normal consultation with the patient." page 3
Outcomes	Modified control preference scale (categorical)
Notes	**Additional information** Number of approached patients (eligible): 182 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "This was a pragmatic trial and all eligible and willing practices were randomly allocated by a computer to two groups: the intervention group used the PANDAs decision aid when making the specified treatment choices and the control group delivered usual care." page 3
Allocation concealment (selection bias)	Low risk	Quote: "A statistician generated the random allocation sequence while a secretary who was not involved in the research study assigned participants to either the intervention or control groups." page 3, column 1
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied." page 3, column 1
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: missing outcome not enough to have clinically relevant impact on the intervention effect.
Selective reporting (reporting bias)	Unclear risk	Comment: protocol not available. All primary outcomes were reported. However duration of consultation was not reported though prespecified. In addition, some information is missing in table 9 (SD of the means, denominators of the percentage).
Other bias	Low risk	
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: No baseline measure of our primary outcome
Protection against contamination?	Low risk	Comment: Practices were randomised
Baseline characteristics patients	High risk	Comment: Imbalance with number with diabetic complications (table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: No report of characteristics

Montori 2011

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: physicians and patients **Power calculation**: done
Participants	**Care setting**: primary care, ambulatory care, USA **Health professionals**: 60; primary care physicians;fully trained **Patients**: 100 osteopenia/osteoporosis; 100% of female
Interventions	**Single intervention:** patient-mediated intervention; decision aid,Osteoporosis Choice decision aid Quote: "The Osteoporosis Choice decision aid provides the patient's individualized 10-year risk estimate risk of having a major osteoporotic fracture ... .The decision aid also showed the absolute risk reduction in fracture risk with alendronate, ... In addition, the decision aid described the potential downsides of taking bisphosphonates. The decision aid also prompted further discussion with the question What would you like to do?" page 550 **Other single intervention (control):** usual care and booklet Quote: "In addition to usual care ... , patients randomised to the control group received the National Osteoporosis Foundation booklet, "Boning Up On Osteoporosis: A Guide To Prevention and Treatment." page 550
Outcomes	OPTION to quantify the extent to which clinicians are able to involve patients in the decision-making process.
Notes	**Additional information** Number of approached patients (eligible): 14,060 Number of patients per physician: 13 clinicians enrolled more than one patient; five clinicians enrolled more than two

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A computer-generated allocation sequence randomised patients 1:1 in a concealed fashion (using a secure study website) to control (usual care booklet) or intervention (Osteoporosis Choixe decision aid)." page 551
Allocation concealment (selection bias)	Low risk	Quote: "A computer-generated allocation sequence randomised patients 1:1 in a concealed fashion (using a secure study website) to control (usual care booklet) or intervention (Osteoporosis Choixe decision aid)." page 551
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "After randomisation, data collectors and data analysts were blind to allocation." page 551
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: 38 (73%) decision aid visits and 32 (66%) usual care visits were video recorded. Reasons for non recording were non agreement.
Selective reporting (reporting bias)	Low risk	Comment: outcomes were described in the protocol.

Montori 2011 *(Continued)*

Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	High risk	Comment: not specified in the paper.
Protection against contamination?	Unclear risk	Comment: despite of the exploration of possible clinician contamination descriptively, the unit of allocation is the patient and not separated by the 10 general medicine.
Baseline characteristics patients	Low risk	Comment: see table1, balanced risk factors.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Mullan 2009

Methods	**Study design**: clinician-randomized trial **Unit of allocation**: clinicians **Unit of analysis**: patient **Power calculation**: done
Participants	**Setting of care**: primary care, ambulatory care, USA **Healthcare professionals**: 40; various healthcare professional and inter-professional (physicians, physicians assistant, nurse practitioners managing diabetes); Fully trained and residents **Patients**: 85; diabetes type 2; males and females
Interventions	**Multifaceted intervention**: patient-mediated intervention (decision aid used during the clinical encounter); and educational training (how to use decision aid) Quote: "[The Diabetes Medication choice decision aid tool] is designed to enable clinicians to discuss with patients the potential advantages and disadvantages of adding an [antihyperglycemics pharmaceutical] agent." page 1562 « Ideally, the clinician presents all 6 cards [describing the possible side effect of the medication] to the patient and asks which of the cards the patient would like to discuss first. After reviewing and discussing the cards that the patient and the clinician choose [what] to discuss." page 1562 Quote; "The patient receives a copy of the cards in the form of a take-home pamphlet." page 1562 "Clinicians randomised to the intervention arm received a brief demonstration from the study coordinator on how to use the decision aid prior to meeting the first enrolled patient." page 1562 **Single intervention (control)**: patient-mediated intervention (decision aid). Quote: "... 12-page general pamphlet on oral antihyperglycemics medication to take home." page 1562
Outcomes	OPTION (continuous, score) and validated pictorial instrument ; SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process.
Notes	**Additional information** Number of approached patients (eligible): 1341 Number of patients per physician: at least one, page 1563

Mullan 2009 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A computer-generated allocation sequence, unavailable to personnel enrolling patients or clinicians, randomized clinicians to intervention (decision aid) or usual care and was accessed by the study coordinators via telephone." page 1562
Allocation concealment (selection bias)	Low risk	Quote: "A computer-generated allocation sequence, unavailable to personnel enrolling patients or clinicians, randomized clinicians to intervention (decision aid) or usual care and was accessed by the study coordinators via telephone." page 1562
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: 18 vs 16 visits were recorded. In both groups reasons were either because patient/clinician did not wish to be recorded or technical difficulties.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: lost to follow-up patients were balanced in number and reasons across groups (fig 2).
Selective reporting (reporting bias)	High risk	Comment: the PROM was not reported (validated pictorial instrument).
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	Unclear risk	Comment: unit of allocation is the clinician and not separated by primary care and family medicine sites.
Baseline characteristics patients	Low risk	Comment: see table 1.
Baseline characteristics healthcare professionals	Unclear risk	Comment: insufficient data about provider in table 1. There are more physicians and nurses in the DA group.

Murray 2001

Methods	**Study design**: patient-randomized trial

Murray 2001 *(Continued)*

	Unit of allocation: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: primary care and ambulatory care (33 practices in two urban areas (Oxford and London), one suburban area (Harrow),and one in a semi-rural area (Thames and the Chilterns); UK **Health professionals**: unknown number; general practitioners; level of training unclear **Patients**: 112; benign prostatic hypertrophy; male
Interventions	**Single-intervention**: patient-mediated intervention (decision aid); 60 minutes Information of the decision aid HealthDialog interactive videodisc on options, outcomes, clinical problem, outcome probability, and other's opinion. **Usual care (control)**
Outcomes	Percived level of control in decision making process (categorical); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 159 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomisation schedule, stratified according to recruitment centre, was generated by computer." page 3
Allocation concealment (selection bias)	Low risk	Quote: "Allocations were sealed in opaque numbered envelopes, opened by the study nurse after collection of the baseline data." page 3
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: "In all, 91% patients were included in the follow up. However, imbalance in reasons, number and proportion of lost to follow up patients (5,2% vs 23,6%). Reasons for lost to follow in the control group at 3 months were not specified." page 4
Selective reporting (reporting bias)	High risk	Comment: Time spent during the consultation, patients' choice and satisfaction with the choice, prostatectomy rate were relevant outcome prespecified but not reported in the analysis.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	High risk	Comment: outcome is patient reported and the intervention is patient allocated. Consequently patients could discuss the intervention among themselves.

Murray 2001 *(Continued)*

Baseline characteristics patients	Low risk	Comment: see table 1.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Murray 2010

Methods	**Study design**: clinician-randomized trial **Unit of allocation**: clinician **Unit of analysis**: clinician **Power calculation**: done
Participants	**Setting of care**: specialized palliative care, non-ambulatory care, Canada **Healthcare professionals**: 88; various healthcare professional (nurses, pharmacists, non-nurse case managers, social works); fully trained **Patients**: 5; simulated patients
Interventions	**Multifaceted intervention**: including educational meetings, audit and feedback, distribution of education materials; educational outreach; barriers assessment. Interventions were chosen to target identified barriers to providing decision support for place of end-of-life care and were based on their proven effectiveness in improving practitioners' decision support knowledge and skills Quote: "Three components were delivered over six weeks. The first was an online, self-directed, module-based tutorial. ... The second component was a three-hour skills building workshop … Participants were given feedback on their decision support skills during their baseline standardized calls. Next, participants viewed and rated the quality of decision support ... then they practised providing decision support using the [Place-of-care patient decision aid] during role-playing sessions. ... Based on evidence from social marketing, education outreach was chosen as the third component." page 114 **Usual care** (control)
Outcomes	DSAT10 (continuous, score); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process.
Notes	**Additional information** Number of approached patients (eligible): not applicable, the patients are simulated Number of patients per physician: 1

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Allocation was conducted through a computer-generated random numbers table provided centrally by a statistician external to the study." page 114

Murray 2010 *(Continued)*

Allocation concealment (selection bias)	Low risk	Quote: "Allocation was conducted through a computer-generated random numbers table provided centrally by a statistician external to the study." page 114
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "DSAT10 scoring was done by one of two raters who were blinded to group assignment." page 115
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: in total 88 consented, 78 were included in the analysis (N = 36 intervention; n = 42 control), yielding a 88% follow-up.
Selective reporting (reporting bias)	Low risk	Comment: relevant outcomes pre-specified in the trial protocol are reported in the results (trial registry number NCT00614003).
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Low risk	Quote: "Baseline scores for non-retained calls were non significantly different from baseline scores for complete cases (P = 0.866). The baseline score change from baseline …" page 116
Protection against contamination?	Low risk	Comment: separated geographically.
Baseline characteristics patients	Unclear risk	Comment: simulated patients.
Baseline characteristics healthcare professionals	Unclear risk	Comment: characteristics are mentioned in the text but no data were presented.

Myers 2011

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Setting of care**: primary care, ambulatory care, USA **Healthcare professionals**: 22 physicians; fully trained (board certified practitioners) **Patients**: 313; eligible for prostate cancer screening; males
Interventions	**Multifaceted intervention**: Including patient-mediated interventions (pamphlet and counseling) and reminders (prompting) Quote: "... mailed a12-page information brochure on prostate cancer and screening to all participants." page 241 "The nurse educators met EI Group men at the office visit, reviewed the content of the mailed booklet, and conducted a structured decision counselling session about prostate cancer. [The nurses] elicited factors that were likely to influence the participant's screening decision, align with their relative influence and strength. Then nurse educator then used a hand-held computer with a pre-programmed algorithm to compute each participants's decision preference score ..." page 241

Myers 2011 *(Continued)*

	"... the nurse educator also placed a generic note on each EI group participant's medical chart to prompt the physician to discuss prostate cancer screening." page 241 **Multifaceted intervention**: Including patient-mediated interventions and reminders (prompting) (control). The brochure and the prompt were the same as those in the intervention group.
Outcomes	Informed decision-making scale; SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process.
Notes	**Additional information** Number of approached patients (eligible): 1245 Number of patients per physician: median number of patients per physician is 8.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Using a system of sealed envelopes, the nurse educator then determined the participants's study group assignment to either …" page 241
Allocation concealment (selection bias)	Low risk	Quote: "Using a system of sealed envelopes, the nurse educator then determined the participants's study group assignment to either …" page 241
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Observer-based outcome	Unclear risk	Comment: for the entire study, there was an over 90% follow-up, however, only 50% audio-recorded encounters (46% in SI group, 55% in EI group); 84% of the audio.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	High risk	Quote: "Certain patients in either the groups received their unassigned interventions." page 242
Baseline characteristics patients	Low risk	Comment: "The data show that the two groups were well balanced on all the measured variables." page 242 (table 2)
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Nannenga 2009

Methods	**Study design**: provider-randomized trial (factorial 2 x 2 randomized trial) **Unit of allocation**: provider and patient **Unit of analysis**: patient

Nannenga 2009 *(Continued)*

	Power calculation: not done
Participants	**Setting of care**: specialized care; ambulatory care (clinic for diabetes at Mayo Clinic in Rochester, MN); USA **Healthcare professionals**: 16; endocrinologists; fully trained **Patients**: 98; Type 2 diabetes; male or female
Interventions	**Single intervention:** decision aid administered by provider during visit Statin Choice decision aid is a one-page document tailored to the individual patient including the patients name, cardiovascular risk factors and estimated cardiovascular risk. Benefits and downsides were presented **Single intervention**: patient-mediated intervention (decision aid administered by researcher prior to visit). See the above description of the decision aid. **Single intervention (control)**: pamphlet administered by provider during visit. The standard Mayo patient education pamphlet outlined guidelines for reducing hyperlipidemia, cholesterol, and triglycerides without consideration of patient-specific cardiovascular risk. It defined lipid disorders and provided primarily dietary guidelines for control of cholesterol along with general statements encouraging exercise and smoking cessation. **Single intervention (control)**: patient-mediated intervention (pamphlet administered by researcher prior to visit). See the above description of the pamphlet.
Outcomes	OPTION (continuous); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process.
Notes	**Additional information**: Number of approached patients (eligible): 260 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A computer-generated allocation sequence, unavailable to personnel enrolling patients, randomized providers to intervention (decision aid) or control groups …." (Page 1077, Weymiller)
Allocation concealment (selection bias)	Low risk	Quote: "randomized by concealed central allocation to a 2 x 2 cluster factorial design…." page 40
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "Using the videotaped encounters, reviewers blinded to questionnaire result quantified encounter duration and used the OPTION scale to quantify the extent to which clinicians invited patient participation in decision making." page 41
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: 48/52 (intervention); 43/46 (control).
Selective reporting (reporting bias)	Low risk	Comment: relevant outcomes pre-specified in the trial protocol are reported in the results (trial registry number NCT00217061).
Other bias	Low risk	Comment: no evidence of other risk of biases.

Nannenga 2009 *(Continued)*

Baseline measurement? Observer-based outcome	Unclear risk	Comment: not specified in the paper
Protection against contamination?	High risk	Comment: professionals and patients were randomized within a single-centered study.
Baseline characteristics patients	High risk	Quote: "Baseline cardiovascular risk factors were generally well-balanced (Table 1), although the decision aid group had significantly fewer women, greater high school completion, and a higher baseline HbA1C. Distance from place of residence to Mayo Clinic was similar for intervention and control groups." Page 41
Baseline characteristics healthcare professionals	High risk	Comment: Insufficient data about diabetologists

O'Cathain 2002

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: group of providers **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: primary care and ambulatory care (maternity units); UK **Health professionals**: unknown number; physicians in maternity care and midwives; unclear level of training **Patients**: 10,070; maternity care; female
Interventions	**Multifaceted-intervention**: education meeting with staff + distribution of educational materials ; 2 hours (educational meeting) The educational materials consisted of pairs of "Informed Choice" leaflets (given at different periods during gestation) which provided information concerning the benefits and risks of available options concerning labour, and a detailed professional leaflet. The staff in the units receiving the units were trained **Usual care** (control)
Outcomes	Perceived level of control in decision-making process (categorical); joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information** Number of approached patients (eligible): 10,070 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Members of pairs were randomly assigned by tossing a coin to receive the set of leaflets (five intervention units) or to the continue with usual care (five control units)" Page 1

O'Cathain 2002 *(Continued)*

Allocation concealment (selection bias)	Low risk	Quote: "We randomised maternity units rather the individual women because of the risk of women sharing the leaflets in an individual level trial" Page 1
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: the patients before the intervention are not the same as the patients after intervention. However responses rates were similar across group in each samples. Reasons for non responses were not reported.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: baseline measurements for our primary outcome were reported.
Protection against contamination?	Low risk	Quote: "We randomised maternity units rather the individual women because of the risk of women sharing the leaflets in an individual level trial." page 1
Baseline characteristics patients	Low risk	Comment: see table 1 before the intervention.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about professionals.

Perestelo-Perez 2016

Methods	**Study design**: randomized trial **Unit of allocation**: provider **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: ambulatory care, primary care, Spain **Health professionals**: general practitioners; fully trained **Patients**: 168; diabetes; male and female
Interventions	**Single intervention**: patient-mediated intervention (decision aid) Quote: "Physicians in the intervention group were trained to apply the DA by a member of the research team, in group sessions of one hour." page 296 **Usual care (control)**
Outcomes	Satisfaction with decision making process (SDMP) (continuous)
Notes	

Perestelo-Perez 2016 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: computer-generated list.
Allocation concealment (selection bias)	Unclear risk	Comment: not enough information to make a judgement.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: Not enough information to make a judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: too many losses in the follow up, however proportion of lost to follow-up were well balanced between groups and reasons of losses to follow-up were not reported.
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available to permit judgement.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no outcome measure at baseline.
Protection against contamination?	Unclear risk	Comment: physicians were allocated within a primary care center and it is possible that communication between intervention and control professionals could have occurred (e.g. physicians within practices were allocated to intervention or control).
Baseline characteristics patients	Low risk	Comment: the characteristics at baseline were different. But the authors tried to adjust for those variables to minimize confounding.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about clinicians at baseline.

Pickett 2012

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: level of care: unclear; ambulatory care; USA **Health professionals**: unknown number; type: unclear; unclear level of training **Patients**: 428; mental illness; male and female
Interventions	**Single intervention**: patient-mediated intervention

Pickett 2012 *(Continued)*

	Quote: "...BRIDGES [Building Recovery of Individual Dreams and Goals] is an 8-week, manualized peer-led education course designed to empower adults with psychiatric disabilities and enhance their recovery...Topics covered in the BRIDGES curriculum include: self-advocacy; communication and problem-solving skills; philosophy of recovery; social support; psychiatric diagnoses, medications and mental health treatment; and crisis planning." page 424 **Usual care (control):** Quote: "As described above, a total of 216 participants were randomly assigned to a BRIDGES course waiting list (control condition) and were guaranteed an opportunity to receive BRIDGES from the study after completing their third and final interview. During their participation in the project, control group participants received services as usual..." page 425
Outcomes	Patient self-advocacy (continuous)
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was performed by UIC SRL [University of Illinois Survey Research Laboratory] research staff at the end of each T1 interview. A random allocation sequence programmed into the CAPI administration software blinded both interviewers and participants to subjects' study assignment (Gluud 2006)." page 422
Allocation concealment (selection bias)	Low risk	Quote: "Randomization was performed by UIC SRL research staff at the end of each T1 interview. A random allocation sequence programmed into the CAPI administration software blinded both interviewers and participants to subjects' study assignment (Gluud 2006)." page 422
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "A random allocation sequence programmed into the CAPI administration software blinded both interviewers and participants to subjects' study assignment (Gluud 2006). To monitor the integrity of the blind, interviewers were asked at the end of each follow-up interview whether subjects had directly or indirectly shared their study status; this occurred in only 7.2 % of all T2 and T3 interviews." page 422
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Quote: "A total of 343 subjects (80.1 %) completed T2 interviews, and 320 subjects (74.8 %) completed T3 interviews, for an attrition rate of 25.2 %. There were no statistically significant differences in follow-up rates between intervention and control conditions. At T2, interviews were completed by 171 (80.7 %) intervention group participants and 172 (79.6 %) control group participants (X1 2 = 0.071, p = .810). At T3, assessments were completed by 157 (74.1 %) intervention group participants 163 (75.5 %) of the control group (X1 2 = 0.112, p = .740)." page 427
Selective reporting (reporting bias)	Low risk	Comment: there is selective outcome reporting because of the objective of the paper. The other outcomes were reported in another paper. ClinicalTrials.gov: NCT01297985
Other bias	High risk	Quote: "although we assessed changes in participants' self-reported empowerment and self-advocacy, we did not observe their interactions with their treatment providers. Thus, we do not know if BRIDGES participants actually asked questions and/or asserted themselves in treatment discussions with providers." page 428

Pickett 2012 *(Continued)*

Baseline measurement? Participant-reported outcome	Low risk	Comment: see table 2.
Protection against contamination?	Low risk	Quote: "No BRIDGES classes were offered outside of the study in any of the sites during the intervention or 6-months follow-up period; thus, the intervention was not available to any control group participants." page 425
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Raynes-Greenow 2010

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: Specialized care (2 obstetric hospital, Sydney); ambulatory care; Australia **Health professionals**: unknown; unclear level of training **Patients**: 596; primiparous women in their final trimester planning a vaginal birth of a single infant; female
Interventions	**Single intervention**: patient-mediated intervention (decision aid: booklet and audio guide) **Single intervention** : patient-mediated intervention (decision aid: booklet) The booklet was 55 pages and the audio guide 40 minutes. Quote: "Information was presented in a style that was sparse." page 2 The content included both pharmacological and non-pharmacological analgesics **Single intervention** (comparison group): patient-mediated (pamphlet) Same booklet as intervention group, page 2
Outcomes	Perceived level of control in decision-making process (continuous)
Notes	**Additional information** Number of approached patients (eligible): 1065 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Treatment allocation was randomly generated computer using random variable block sizes." page 3

Raynes-Greenow 2010 *(Continued)*

Allocation concealment (selection bias)	High risk	Quote: "It was not possible to conceal allocation once randomised" Page 3
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: patient-mediated intervention and patient-reported outcome, so the patient was not really blinded.
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: in all, 76%patients were present at follow-up. Moreover, incomplete data forms/lost to follow-up in DA group were double of those in the PA. Voir page 6
Selective reporting (reporting bias)	Low risk	Comment: relevant outcomes pre-specified in the trial protocol are reported in the results (trial registry number ISRCTN52287533).
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	Low risk	Quote: "It was not possible to conceal allocation once randomized; however, to minimize contamination a research assistant worked at each centre and the antenatal staff were kept blinded to the treatment allocation and the actual content of the decision aid." page 4 (Raynes-Greenow 2009)
Baseline characteristics patients	Low risk	Quote: "As seen in Table 2, maternal demographic characteristics and baseline measures of cognitive and affective outcomes were comparable between these two groups." page 6
Baseline characteristics healthcare professionals	Unclear risk	Comment: No report of characteristics

Rise 2012

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: specialized care; ambulatory care; Norway **Health professionals**: 25; various type; fully trained **Patients**: 75; mental health; male and female
Interventions	**Multifaceted intervention:** Patient mediated intervention (PCOMS), Educational meeting (training of therapists) Quote: "The intervention therapists were trained to administer the feedback system Partners for Change Outcome Management System (PCOMS) [30] during the treatment they usually provide. PCOMS therapists received 12 h of training during two days, with four weeks apart, with respectively eight and four hours of training...The use of the PCOMS consisted of administering two

Rise 2012 *(Continued)*

	feedback scales in every treatment session, one at the beginning of the session (the Outcome Rating Scale, or ORS), and one at the end (the Session Rating Scale, or SRS)... In the ORS the patients rate their own functioning during the last week, or since the last treatment session, individually, interpersonally, socially, and generally. On the SRS, the patients rate the current session on relations with the therapist and the degree of agreement on goals, methods, and treatment approach...The intervention thus consisted of systematically using the ORS and SRS scales to assess feedback from the patient on treatment outcome and the quality of the session." page 4 **Usual care (control):** Quote: "The controls received treatment as usual." page 4
Outcomes	Treatment Alliance Scale (continuous), Patient Activation Measure (continuous), Patient Participation (continuous)
Notes	**Additional information** Number of approached patients (eligible): 395 Number of patients per therapist (median): 5 in the intervention group, 1.5 in the control group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "University internet based computerised randomisation service" page 6
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "This was an open study and no blinding was performed." page 6
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: there are missing data, but sensitivity analysis was performed comparing intention-to-treat analyses to per-protocol analyses and the results of the outcomes were similar. Number lost to follow-up and reasons for loss to follow-up were well-balanced between groups.
Selective reporting (reporting bias)	Low risk	The protocol was registered (Identifier: NCT01083225) The main outcomes pre-specified in the protocol were reported in the results.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no applicable for Treatment Alliance Scale, done for Patient Activation Measure, but not done for Patient Participation
Protection against contamination?	Unclear risk	Quote: "To fortify fidelity of the treatment as usual group the therapists were repeatedly instructed to avoid using any feed-back scales during treatment" Page 4
Baseline characteristics patients	Unclear risk	Comment: Table 1: imbalance between groups for some factors (gender (female), living alone, can confide in 2 or more persons, level of education, working). But it is not specified if some of those factors are known risk factors of the issues. Moreover, The sample size is not that large.
Baseline characteristics healthcare professionals	Unclear risk	Comment: No report of characteristics

Roter 2012

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: physicians and patients **Power calculation**: unclear
Participants	**Care setting**: primary care, ambulatory care; USA **Health professionals**: 29 family physicians fully-trained and in training **Patients**: 197; type of clinical condition not mentioned; 50 females and 80 males
Interventions	**Multifaceted intervention:** patient-mediated intervention (decision aid); distribution of educational materials Separate interactive video glossaries demonstrating communication skills organized by the LEAPS (Listen, Educate, Assess, Partner and Support) heuristic. Quote: "The interventions were comprised of separate interactive video glossaries demonstrating communication skills organized by the LEAPS heuristic. The patient glossary included the performance of 228 10-s video clips demonstrating the 18 targeted patient communication skills in various ways ... " page 407 **Single intervention (control):** distribution of educational materials. Quote: "Since control group patients would have benefited from seeing web exposed physicians as well as intervention group patients." page 412
Outcomes	Separate interactive video glossaries demonstrating communication skills to patients and to clinicians
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Some practices assigned patients to study groups on alternating days and others used a random numbering system." page 407
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.

Roter 2012 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Quote: "Communication behaviours were assessed at baseline and after a follow-up visit through an 18-item self-report questionnaire." page 408
Protection against contamination?	High risk	Comment: Outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Comment: study groups did not differ on any of these characteristics. Table 3 page 410
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Sanders 2017

Methods	**Study design**: randomized trial **Unit of allocation**: provider **Unit of analysis**: provider and patient **Power calculation**: not done
Participants	**Care setting**: Ambulatory care, primary care, Netherlands **Health professionals**: 42; general practitioners; male and female; fully trained **Patients**: 175; back pain; male and female
Interventions	**Multifaceted intervention:** educational meeting + audit and feed back Quote: "GPs in the intervention group received two training sessions that were each two and a half hours in duration and were held in small groups of approximately three to five participants. The training focused on the SDM process and evidence-based treatment of low back pain according to professional guidelines" Page 564 "In addition to receiving training sessions, the GPs in the intervention group received personalised feedback on each videotaped consultation for a maximum of two consultations between the training sessions and for all consultations with recruited patients." page 565 **Usual care (Control): Quote:** GPs in the control group were not trained and provided usual care." page 565
Outcomes	OPTION (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no information about sequence generation.

Sanders 2017 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Quote: "Control GPs were not blind to the allocation or scope of the intervention, but they were not familiar with the content of the intervention." Page 569. No test was done to know if GPs were familiar or not or the level of familiarity with the content of the intervention "Two blind observers (AL and IvdE) scored the videotapes using Observer (Noldus, 7th edition), a program designed to aid in the observation of videotapes." page 566
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Quote: "Not all trained GPs videotaped consultations. However, we do not believe that this limitation induced selection bias because we did not find differences in the baseline variables between recruited and non-recruited patients." page 569
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available to permit judgement.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no measure of the outcome at baseline.
Protection against contamination?	Low risk	Comment: possible contamination, because it is in the same hospital.However the GPs from different groups were not present at the same working time.
Baseline characteristics patients	Low risk	Comment: characteristics between groups were similar at baseline (table 1)
Baseline characteristics healthcare professionals	Low risk	Comment: characteristics at baseline for HCP were similar.

Schroy 2011

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: primary care (Boston Medical Care centre, South Boston Community Health Centre); ambulatory care; USA **Health professionals**: 50; Various healthcare professional with inter-professional (board-certified general internist, nurse practitioners); fully trained **Patients**: 666; colorectal cancer screening; female and male
Interventions	**Single (first intervention group)**: patient-mediated intervention (DVD audio-visual touch screen decision aid explaining screening importance, epidemiology of disease, recommended methods and their comparison, and decision guidance: Your Disease risk assessment tool with feedback). **Single intervention (second intervention group)**: patient-mediated intervention (DVD audio-visual touch screen decision aid explaining screening importance, epidemiology of disease, recommended methods and their comparison, and decision guidance).

Schroy 2011 *(Continued)*

	Single intervention (control): educational materials (a modified Quote: “9 ways to stay healthy and prevent disease").
Outcomes	12-item satisfaction with the decision-making process scale (categorical)
Notes	**Additional information** Number of approached patients (eligible): 9869 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: patients were randomized but the method was unspecified.
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: in all, 100% of the patiens were included at follow-up. Page 5. figure 2
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	High risk	Quote: "Patient satisfaction with the decision-making process was assessed on the posttest using the validated 12-item Satisfaction with the Decision-Making Process Scale (Appendix 2)." page 6
Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves
Baseline characteristics patients	Low risk	Comment: as shown in Table 1, the 3 study arms were well-balanced with respect to patient age, sex, race, ethnicity, education, prior FOBT, insurance status.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Schroy 2016

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient

Schroy 2016 *(Continued)*

	Power calculation: done
Participants	**Care setting**: ambulatory care, primary care, USA **Health professionals**: various types; fully trained **Patients**: 341; colorectal cancer; male and female
Interventions	**Multifaceted intervention : patient-mediated intervention (decision aid + risk assessment tool):** Quote: "An updated web-based version (http://www.colorectalcancerscreening4u.com) of our validated DVD-formatted decision aid 9 was employed in this study." Page 528 "The risk index employed is this study was developed from a cross sectional study of 3457 average-risk patients undergoing screening colonoscopy at BMC." page 528 "After completing the electronic risk assessment tool, patients received a printed form describing their risk category (low versus intermediate/high) and pictographs with absolute risk estimates." page 528 **Single intervention: patient-mediated intervention (decision aid):** Quote: "An updated web-based version (http://www.colorectalcancerscreening4u.com) of our validated DVD-formatted decision aid was employed in this study." page 528.
Outcomes	OPTION (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were then randomized 1:1 via a preset block randomization table within the study website." page 527
Allocation concealment (selection bias)	Low risk	Quote: "Patients were then randomized 1:1 via a preset block randomization table within the study website that was inaccessible to study coordinators to a control arm (decision aid only) or experimental arm (decision aid plus risk assessment), within strata by provider." page 527
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "A prospective, unblinded, parallel-group randomized controlled trial was conducted between September 2012 and September 2014 at Boston Medical Center (BMC) to evaluate the impact of risk stratification for ACN on shared decision-making for CRC screening." page 527
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: very low level of lost to follow-up.
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available to permit judgement.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no outcome measure at baseline.

Schroy 2016 *(Continued)*

Protection against contamination?	High risk	Comment: randomized patients were in the same medical center.
Baseline characteristics patients	Low risk	Comment: characteristics between groups were similar at baseline (Table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about clinicians at baseline.

Shepherd 2011

Methods	**Study design**: randomized trial (cross-over trial) **Unit of allocation**: the order of the standardized patients visits **Unit of analysis**: physicians and patients **Power calculation**: done
Participants	**Care setting**: Primary care, ambulatory care, Australia **Health professionals**: 36; family physicians; Fully trained **Patients**: 2, depression ; patients are simulated, male or female not reported
Interventions	**Single intervention:** educational outreach visit. Healthcare professional visited by an unannounced and standardized patient who asked three questions. **Usual care** (control): no intervention (the control standardized patient did not ask the three questions).
Outcomes	Assessing Communication about Evidence and Patient Preferences (ACEPP); Observing Patient Involvement (OPTION) scores; The fostering by healthcare professionals of active participation of patients in the decision-making process.
Notes	**Additional information** number of approached patients (eligible): NA, simulated patients were used in the study number of patients per physician: NA, simulated patients were used in the study

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The order of the standardized patient visits (intervention vs control) was allocated randomly." page 380
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "The transcribed consultations were analysed using ACEPP and OPTION by two trained coders who were not investigators on the study and blinded to the study purpose …." page 381
Incomplete outcome data (attrition bias)	Unclear risk	Comment: not specified in the paper.

Shepherd 2011 *(Continued)*

Observer-based outcome		
Selective reporting (reporting bias)	High risk	Comment: some outcomes prespecified in the trial registry are not reported in the results paper: assessment of nature and variability of patient-doctor communication in both general and specialist practice in Australia; differences in management recommended in consultations (see Australian New Zealand Clinical Trials Registry no.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	Unclear risk	Comment: not specified in the paper.
Baseline characteristics patients	Unclear risk	Comment: simulated patients.
Baseline characteristics healthcare professionals	Unclear risk	Comment: insufficient information about professionals.

Sheridan 2012

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: level of care not clear, ambulatory care, USA **Health professionals**: 28; type: unclear; level of training: unclear **Patients**: 128, prostate cancer screening, male
Interventions	**Multifaceted intervention:** patient-mediated intervention (video + coaching session), Educational meeting Quote: "Our intervention consisted of 2 components designed by investigators (see Table 1): 1) a video-based decision aid for patients and 2) a coaching session for patients." page 3 **Single intervention (control):** Quote: "Highway safety control video." page 5
Outcomes	Shared decision post-visit (qualitative)
Notes	**Additional information** Number of approached patients (eligible): 474 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Sheridan 2012 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "Randomization used computer-generated random numbers that were sealed in opaque envelopes." page 5 column 1
Allocation concealment (selection bias)	Low risk	Quote: "Randomization used computer-generated random numbers that were sealed in opaque envelopes." page 5 column 1
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Comment: no blinding.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: 2 false inclusions. No missing at follow-up.
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not seen, but the preference in participation in DM was not reported.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome (it is preference in participation not actual participation that was measured at baseline).
Protection against contamination?	High risk	Allocation by patients within a practice : Quote: "Third, because we randomized at the patient level, physicians saw patients in both the intervention and control groups, creating the possibility for contamination." page 9 column 2
Baseline characteristics patients	Unclear risk	Baseline imbalance. Quote: "Second, despite randomization, the small size of our study resulted in differential distribution of confounders among study groups. We controlled for this in multivariate analysis, but recognize the potential that unmeasured confounders may have affected our results." page 9 column 2
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Sheridan 2014

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: specialized care, ambulatory care, USA **Health professionals**: 24; specialists; fully trained and in training **Patients**: 160, coronary heart disease risk reduction, male and female
Interventions	**Single intervention:** patient-mediated intervention (decision aid) Quote: "Our intervention consisted of two parts: a decision aid delivered prior to a provider visit (at the primary study visit) and a series of three tailored adherence messages delivered between the primary

Sheridan 2014 *(Continued)*

	and follow-up study visits. In this paper, we focus on the independent effects of the decision aid, which includes three components: individualized risk assessment and education; values clarification; and coaching..." page 3 **Usual care (control):** Quote: "Patients randomized to the control group did not present early to their previously scheduled clinic visit and received usual care from their provider." page 3
Outcomes	Shared decision (categorical)
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: 24 eligible providers enrolled in the study 160 eligible patients.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "Staff told patients only that they were participating in a study about “prevention of heart disease.” Physicians were not blinded and saw patients in both the intervention and control group." page 2 column 2 (Sheridan 2011)
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: similar reasons for missing data across groups (visit no shows, declined further participation). The proportion of missing outcomes compared with observed event not enough to have relevant impact on the intervention effect estimate (4/81 vs 2/11) (see flow chart Sheridan 2011).
Selective reporting (reporting bias)	High risk	Comment: authors did not compute between group comparisons of the effect of the decision aid on knowledge, accuracy of risk perception and values clarity (in post visit) NCT00494052
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome (it is preference in participation not actual participation that was measured at baseline).
Protection against contamination?	High risk	Comment: allocation by patients within a practice.
Baseline characteristics patients	Low risk	Comment: imbalance for education but this variable was adjusted for in the analysis.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Smallwood 2017

Methods	**Study design**: pilot-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: ambulatory care, primary care, USA **Health professionals**: various types; fully trained **Patients**: 50; female; osteoporosis
Interventions	**Single Intervention : patient-mediated intervention (decision aid):** Quote: "The final decision aid included information about osteoporosis including causes, risk factors, how to determine if you have osteoporosis personalized fracture risk based on FRAX, details about medication and nonprescription treatment, and a values elicitation exercise related to the treatment decision." page 568. **Single intervention: patient-mediated intervention (web-based information):** Quote: "Participants in the experimental group received the decision aid, while those in the control group were directed to the National Institute on Aging homepage (www.nia.nih.gov) rather than the decision aid. This control site provided web-based information relevant to aging but not specific to osteoporosis." page 568.
Outcomes	Shared Decision Making (continuous)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Two predetermined block randomization schedules for osteoporosis and osteopenia were created using a computer random number generator and maintained electronically.'' page 568.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Quote: "Neither patients nor physicians could be adequately blinded to their treatment arm'' page 575
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: no loss to follow-up and no missing data for primary outcome.
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available to permit judgement.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement?	Unclear risk	Comment: no outcome measure at baseline.

Smallwood 2017 *(Continued)*

Participant-reported outcome		
Protection against contamination?	Low risk	Comment: participants in the experimental group and the control group were on different platform.
Baseline characteristics patients	Low risk	Comment: characteristics between groups were similar at baseline (Table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about clinicians at baseline.

Stacey 2006

Methods	**Study design**: provider-randomized trial **Unit of allocation**: provider **Unit of analysis**: provider **Power calculation**: done
Participants	**Setting of care**: primary care; ambulatory care (province-wide health call centre in British Columbia); Canada **Healthcare professionals:** 41; nurse; fully trained **Patients**: simulated patients; decisions about amniocentesis, treatment for attention deficit disorder and herniated disk, decisions about allergy injections, and treatment for gall bladder attacks and borderline hypercholesterolemia.
Interventions	**Multifaceted intervention:** distribution of educational materials, educational meeting, as well as audit and feedback; barriers assessment; 6 hours. The intervention involved a structured coaching protocol, a 3-hour online tutorial and a 3-hour skill-building workshop that included performance feedback from baseline calls with simulated patients. The coaching protocol was introduced in the tutorial, used in the workshop and available exclusively to trained nurses for use with routine calls. **Usual care** (control)
Outcomes	Decision Support Analysis Tool (continuous); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process.
Notes	**Additional information** Number of approached patients (eligible): not reported (simulated patients) Number of patients per physician: not reported (simulated patients).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The allocation schedule was computer-generated centrally by a statistician." page 411

Stacey 2006 *(Continued)*

Allocation concealment (selection bias)	Low risk	Quote: "The allocation schedule was computer-generated centrally by a statistician. Allocation was concealed until after the nurses completed their baseline simulated call." page 411
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Quote: "In the present study, two of five raters trained in the use of the DSAT and blinded to group assignment, assessed the recorded calls independently." page 412
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: Of 41 randomized nurses, 2 dropped out and 1 baseline call was not recorded due to technical errors. There was a 93% follow up rate. Page 411
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	Unclear risk	Comment: Unit of allocation is the provider within a province wide call centre
Baseline characteristics patients	Unclear risk	Comment: simulated patients
Baseline characteristics healthcare professionals	Low risk	Comment: The intervention and control groups were similar in the demographic characteristics of participants and in the quality and length of their baseline calls with simulated patients (Table 2).

Stiggelbout 2008

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: specialized care and ambulatory care (outpatient clinic of 2 teaching hospitals in the west of the country); the Netherlands **Health professionals**: 15; vascular surgeon; fully trained and in training **Patients**: 113; abdominal aortic aneurysm; male and female
Interventions	**Single-intervention**: patient-mediated intervention (individualized brochure) This brochure contained an output providing information on three strategies concerning the management of the patient, ranked in accordance to the patients' risk. **Single-intervention (control)**: patient-mediated intervention (general brochure)
Outcomes	Patients' decisional role subscale (continuous); joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information**

Stiggelbout 2008 *(Continued)*

	Number of approached patients (eligible): 136 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomized to receive an individualized brochure (IB) or a general brochure (GB) about surgery for abdominal aneurysm. Randomization was stratified by the surgeon." page 752
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: in all, 88% of the patients are present in the follow-up. Lost to follow-up were balanced in numbers across groups.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Quote: "…whereas the IB group had preferred a (non significant) more active decision-making role before hand (mean 2,9, SD 1,3 versus mean 2,5, SD 0,9, P = 0,15)." page 757
Protection against contamination?	Low risk	Quote: "The fact that we did not randomize surgeons may also have led to some of the similarities between the arms of the trial, because one runs a risk of contamination if a surgeon sees both intervention and control patients. But it is highly unlikely that surgeons could have reproduced the individualized information without access to the model." page 758
Baseline characteristics patients	Low risk	Comment: patients in the index and control arm were similar with respect to sociodemographic characteristics and major medical characteristics (see Table 2).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Street 1995

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done

Street 1995 *(Continued)*

Participants	**Care setting**: specialized care and ambulatory care (Scott and White clinic and Hospital (Texas)); USA Health professionals: 10; various type of physician (4 medical oncologists, 2 radiation oncologists, 4 surgeons); fully trained **Patients**; 60; breast cancer; female
Interventions	**Single-intervention**: patient-mediated intervention (Interactive multimedia program (decision aid));15-20 minutes. Quote: "The program "Options for treating breast cancer" is an interactive program using a touch-screen monitor containing audio-visual elements. It provides an introductions, elaborate the problem, treatment options and provides testimonies of other women's experiences." page 2277 **Single-intervention** (control): patient-mediated intervention (brochure (decision aid)) Quote: "This is an eight page brochure entitled "Care of patients with early breast cancer". It contains comments by other women, elaborates the problem and presents treatment options. The medical information is the same in both the multimedia format and the brochure format." page 2278
Outcomes	Perceived decision control (continuous); joint process between healthcare professionals and patients to make decisions.
Notes	**Additional information** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: patients were randomized but the method was unspecified.
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Selective reporting (reporting bias)	High risk	Comment: patient participation in the consultations was not reported in each study group but according to age and education (contrary to the hypotheses 2). Thus, we are not able to see if patient using the computer program will be more involved in the DM than will patients reading the brochure.
Other bias	Low risk	Comment: no evidence of other risk of biases
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.

Street 1995 *(Continued)*

Protection against contamination?	High risk	Comment: outcome is patient reported and the intervention is patient allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Quote: "… there were no significant differences between the multimedia or brochure group with respect to the patient's age, education, disease stage, or ethnicity." page 2277
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Tai-Seale 2016

Methods	**Study design**: pilot-randomized trial **Unit of allocation**: practice **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: primary care and ambulatory care, USA **Health professionals**: 26; various type; unclear level of training; male and female **Patients**: 300; clinical context: biomedical, health behavior, mental health and psychosocial; male and female.
Interventions	**Multifaceted intervention:** educational material (video) + patient-mediated intervention (booklet) + educational meeting (coaching session for providers) **Multifaceted intervention:** OpenCom + patient-mediated intervention (one-page ASK Handout) **Single intervention:** patient-mediated intervention (one-page ASK Handout) **Usual care (Control)** Quote: ''A multidimensional intervention, called Open Communication (OpenComm), emerged from our work. The first element of this intervention was a two-minute animated video, developed to illustrate open communication behaviors for patients and primary care providers. The video normalized setting a joint agenda, asking questions, and requesting information on other options. The second component was a Visit Companion booklet for patients that enabled them to delineate issues that matter the most to them before their visit and to review and record their next steps during the visit... Lastly, in an initiative modeled after the VOICE study, a standardized patient instructor provided communication coaching for primary care providers, consisting of two thirty-minute, individually tailored sessions that occurred during usual clinic time at the providers' practices. These sessions occurred approximately one month apart.'' page 606 ''As we stated earlier, our pilot examined the efficacy of our novel intervention by comparing it to an existing intervention, ASK, which poses three questions: "What are my options? What are the possible benefits and risks of each option? How likely are the benefits and risks of each option to occur? ASK has been used to improve patients' involvement in health care consultations. To undertake this comparison, we handed patients a one-page ASK handout before their visits.'' page 607 "We compared OpenComm (which we designed), ASK, OpenComm plus ASK, and usual care, in a fully crossed 2x2 factorial design.'' page 607.
Outcomes	Collaborate (continuous); OPTION5 (continuous)
Notes	

Tai-Seale 2016 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no information about sequence generation.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	Comment: rating was done by two members of the research team, ED and CS, who were blinded to each visit's intervention arm.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not enough information to make a judgement.
Incomplete outcome data (attrition bias) Observer-based outcome	Unclear risk	Comment: two PCPs chose not to participate in audio-recording.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: no follow-up or small rate of loss to follow-up.
Selective reporting (reporting bias)	High risk	Comment: one outcome that was pre-specified in the protocol was not reported in the results (NCT02522286).
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no baseline measurement.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measurement.
Protection against contamination?	Low risk	Quote: "Four primary care clinics were randomized, one to each arm.'' page 607
Baseline characteristics patients	Low risk	Comment: characteristics between groups were similar at baseline (Table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: not enough information to make a judgement.

Thomson 2007

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient

Thomson 2007 *(Continued)*

	Power calculation: unclear
Participants	**Care setting**: setting: unclear; primary care; UK **Health professionals**: number unknown; type: unclear; level of training: unclear **Patients**; 145; atrial fibrillation; male and female
Interventions	**Single-intervention**: patient-mediated intervention (computerized-decision aid) Quote: "All participants were seen in one of two research clinics each conducted by a single doctor, trained in delivering either the decision aid or guidelines but blinded to the alternative method." table 1,page 217 **Single-intervention** (control): patient-mediated intervention (guidelines) Table 1, page 217
Outcomes	Decision Making role experienced (categorical)
Notes	**Additional information** Number of approached patients (assessed for eligibility): 1360 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Participants were randomised… using electronically-generated random permuted blocks via web-based randomisation service provided by the Centre for health Services Research." page 217
Allocation concealment (selection bias)	Low risk	Comment: centralized randomization scheme.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: insufficient information to permit judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: see the flow chart page 218
Selective reporting (reporting bias)	High risk	Comment: decision-making preference. Some outcomes were not reported in enough details.
Other bias	Low risk	Comment: no evidence of other risk of bias.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: insufficient information to permit judgement.
Protection against contamination?	Unclear risk	Quote: "Randomization was done by patients but "all participants were seen in one of the two research clinics each conducted by a single doctor, trained in delivering either the decision aid or guidelines but blinded to the alterna-

Thomson 2007 *(Continued)*

		tive method." page 217 (probably to avoid contamination but patient may still communicate each other in the practices where they were recruited).
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 2).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Tinsel 2013

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: practice **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: primary care and ambulatory care; Germany **Health professionals**: number unknown; general practitioners; fully trained **Patients**: 1120; hypertension; male and female
Interventions	**Multifaceted intervention**: distribution of educational material, educational meeting Quote: "Those GPs who had been allocated to the intervention group took part in an SDM training programme... which had been evaluated in various studies...The training included the following elements: (1) information on arterial hypertension, (2) physician-patient communication and risk communication, (3) the process steps of SDM, (4) motivational interviewing [40,41], (5) introduction of a decision table listing options to lower CVR, and (6) use of case vignettes for role plays simulating physician-patient consultations. Additionally, we recommended implementing a cardiovascular risk calculator for GPs which included elements of SDM... Furthermore we delivered patient information flyers...to the GPs of the intervention group." page 3 **Usual care (control)** Quote: "GPs of the control group treated their patients as usual." page 3
Outcomes	SDM-Q-9 (continuous)
Notes	**Additional information** Number of approached practices (eligible): 115 Number of patients per practices: 32.5 in intervention group, 29.9 in control group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: not reported in the paper.
Allocation concealment (selection bias)	Low risk	Comment: randomization at the GP practice level.
Blinding (performance bias and detection bias)	Low risk	Quote: "The patients were blinded to the allocation of the intervention (single-blinded study)." page 3 column 2 paragraph 1

Tinsel 2013 *(Continued)*

Participant-reported outcome		
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: lost to follow-up at T3 and non response to outcomes is higher in higher in control group than in intervention group. Was the follow up in the 2 groups comparable? Are the principal reason for missing data related to outcomes (patient desire)? What is the pattern of reasons for discontinuation across groups? There is no clear pattern of missing data.
Selective reporting (reporting bias)	Low risk	Commment: tables 1,2,3 and study protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Low risk	Comment: see table 2.
Protection against contamination?	Low risk	Comment: randomization at the GP practice level.
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 2).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about professionals.

van der Krieke 2013

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: unclear
Participants	**Care setting**: specialized and ambulatory care; the Netherlands **Health professionals**: number unknown; various type (psychiatrists, community psychiatric nurses, psychologists); fully trained **Patients**: 250; Psychotic disorders; male and female
Interventions	**Single intervention**: patient-mediated intervention Quote: "Patients in the intervention condition received care as described in the local disease management program for the treatment of people with psychosis plus they were offered the opportunity to make use of the Web-based information and decision tool..." page 3 **Usual care (control)** Quote: "Patients in the control condition received care as usual, as described in the local disease management program for the treatment of people with psychosis." page 3
Outcomes	COMRADE (continuous)
Notes	**Additional information**

van der Krieke 2013 *(Continued)*

	Number of approached patient (eligible): not reported Number of patients per provider: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization of patients was conducted by using the online Research Randomizer." page 4
Allocation concealment (selection bias)	Low risk	Quote: "Another research assistant located at our research center added the randomization conditions to the spreadsheet, assigning participants to the interventions." page 4 Comment: centralized randomization scheme.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: insufficient information to permit judgement.
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: missing outcome data balanced in numbers across groups.
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	High risk	Comment: patients in the same institution were randomized.
Baseline characteristics patients	Low risk	Comment: reported and similar (see table 2).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

van Peperstraten 2010

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient (client couple) **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: specialized care (fertilization clinics); ambulatory care; the Netherlands **Health professionals**: NA; nurses and staff at the fertilization clinics; fully trained

van Peperstraten 2010 *(Continued)*

	Patients: 308, need in vitro fertilization; females and males (client couple)
Interventions	**Single intervention:** patient-mediated intervention (decision aid, support call), reimbursement of fees; barriers assessment. Decision Aid and reimbursement; discussion; telephone call discussion Quote: "The multifaceted strategy aimed to empower couples ... The strategy consisted of a decision aid, support of a nurse specialising in vitro fertilisation, and the offer of reimbursement by way of an extra treatment cycle." page 1 **No intervention, usual care** (control) No intervention (usual discussion) Quote: "The control group received standard care for in vitro fertilisation." page 1
Outcomes	Decision Evaluation Scale (informed choice). Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 344 Number of patients per physician: Not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation took place centrally using a computer generated randomisation list. Participants were randomised in blocks of four couples. A secretary outside our department was the only person with access to the randomisation list. She randomised the couples on the day consent was received and informed the couple that same day." page 2
Allocation concealment (selection bias)	Low risk	Quote: "Randomisation took place centrally using a computer generated randomisation list. Participants were randomised in blocks of four couples. A secretary outside our department was the only person with access to the randomisation list. She randomised the couples on the day consent was received and informed the couple that same day." page 2
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "Because of the nature of the intervention it was not possible to blind the participants or in vitro fertilisation doctors to the allocation." page 2
Incomplete outcome data (attrition bias) Participant-reported outcome	Unclear risk	Comment: 124 vs 128 reported about our primary outcome (informed choice subscale of the DES). Data were missing for 28 couples in each groups (18,4% vs 17,9%). However, the reasons for missing data were not reported.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measurement for our primary outcome (see table 3, page 5).

van Peperstraten 2010 *(Continued)*

Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Quote: "Table 1 shows the characteristics of the couples in the two groups. No relevant differences were observed between the groups. " page 4.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

van Roosmalen 2004

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: family **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: specialized care; setting: unclear; the Netherlands **Health professionals**: number unknown; type: unclear; level of training: unknown **Patients**: 88, deleterious BRCA1/2 mutation; female
Interventions	**Multifaceted intervention:** patient-mediated intervention (SDMI+DA) Quote: "The SDMI was provided by a trained research assistant and consisted of three sessions with an interval of 1 to 2 weeks. In the first session, individual values for the treatment options (screening and prophylactic surgery) were assessed in a face-to-face interview by use of the TTO method.In the second session, the TTO interview was repeated by telephone...In the first part of the study (T1 to T3; Fig 1), not reported here, women were randomly assigned to the DA group (the DA was provided 2 weeks after blood sampling) or to the control group (receiving usual care)." see figure 1 pages 3294-3295 **Single intervention (control):** patient-mediated intervention (DA) Quote: "The DA was added to usual care and was to be viewed at home. It consisted of a brochure and video providing information on screening and prophylactic surgery, and the physical, emotional, and social consequences." page 3295
Outcomes	Perceived participation in decision making (continuous)
Notes	**Additional information** Number of approached patients (eligible): 453 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: computer generated.
Allocation concealment (selection bias)	Unclear risk	Comment: not specified.

van Roosmalen 2004 *(Continued)*

Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "Neither study participants nor members of the study staff were blinded to intervention assignment." page 3296
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: the follow-up at T4 was 100%. At T5, one woman from the control group was lost to follow-up.
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	Low risk	Quote: "Randomization took place by family to avoid contamination." page 3296
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

van Tol-Geerdink 2016

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: ambulatory care, specialized care, the Netherlands **Health professionals**: specialists; fully trained **Patients**: 240; prostate cancer; male
Interventions	**Single intervention: patient-mediated intervention (decision aid)** Quote: ''The decision aid explained that there are different treatment options with different pros and cons. Radial protatectomy and external beam radiotherapy were presented to all patients. A third option, bradytherapy was presented only to eligible patients.'' page 463 **Usual care (control)**
Outcomes	Patient participation (qualitative)
Notes	
Risk of bias	

van Tol-Geerdink 2016 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no information about sequence generation.
Allocation concealment (selection bias)	Low risk	Quote: "Randomization was centralized to avoid allocation bias and was blocked in groups of 3 per hospital, thus stratifying for hospital site." page 461
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "Patients and caregivers could not be blinded to the intervention." page 460
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: there are losses to follow-up after randomization and missing data and reasons were not well-balanced (flow chart of the study).
Selective reporting (reporting bias)	Unclear risk	Comment: no information about registration of the protocol.
Other bias	Low risk	
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no outcome measure at baseline.
Protection against contamination?	High risk	Comment: randomization was done at the patient level.
Baseline characteristics patients	Low risk	Quote: "Patient characteristics in the decision aid group and the usual care group were comparable for education, age, baseline physical functioning and tumour characteristics." page 465
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about clinicians at baseline.

Vestala 2013

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: level of care: unclear; non-ambulatory care; Sweden **Health professionals**: number unknown; nurses; fully trained **Patients**: 39, chronic diseases: diabetes, inflammatory bowel diseases, liver disease, coronary artery disease, COPD; male and female
Interventions	**Single intervention:** patient-mediated intervention

Vestala 2013 *(Continued)*

	Quote: "The study intervention meant that during their stay in the ward, the patient participated in the nursing documentation together with their nurse. General health status, care goals, and care plans were documented by the nurse and the patient together. The documentation was completed daily. The patients received a printed copy of his/her nursing record and documentation was changed according to the patients' comments utilizing documentation standards. The nurses used a laptop computer to complete all nursing documentation, to facilitate patient presence and direct documentation in the patient record." page 67
	Usual care (control)
Outcomes	Control Preference Scale (Categorical)
Notes	**Additional information** Number of approached patients (eligible): 70 Number of patients per provider: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to make a judgement.
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Patients were not blinded: Quote: "The patients who chose to participate were randomised either to a group participating in nursing documentation or to a control group, depending on the content of the patient information letter. " page 67, column 2
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: for perceived role in decision making: missing data balanced in number across groups (2 in intervention group, 2 in control group).
Selective reporting (reporting bias)	High risk	Comment: relevant outcomes like mastery, self-esteem, empowerment, depression were reported incompletely. Many sub-group analysis and correlations were computed but not prespecified in the methods.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	High risk	Comment: patients of a medical ward were randomized.
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Vodermaier 2009

Methods	**Study design**: patient-randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: not done
Participants	**Care setting**: specialized care and non-ambulatory care (gynecological department of the University of Munich-Grosshadern; Germany **Health professionals**: Unknown number; physicians; unclear level of training **Patients**: 152; breast cancer; female
Interventions	**Single-intervention**: patient-mediated intervention (decision aid) The decision aid took the form of three decision boards (corresponding to tumour size) relating to chemotherapy information with hormone-responsive breast cancer, for preoperative chemotherapy. They are presented in 20 minute sessions going over the options so that the patient understands and can discuss them; they also present how the patient can participate in the decision making. They receive a brochure summarizing the boards content. **Usual care** (control)
Outcomes	• Perceived level of control in the decision-making process (categorical); joint process between health-care professionals and patients to make decisions • Man-Son-Hing Instrument (continuous).
Notes	**Additional information** Number of approached patients (eligible): 246 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Random assignment was performed by means of numbered cards in envelopes for the intervention and the control group..." page 591
Allocation concealment (selection bias)	Unclear risk	Comment: not specified in the paper.
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Quote: "Blinding was not possible within the hospital procedures." page 591
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: 27% of missing outcome. However lost to follow-up were equal in numbers across groups (and unlikely to bias the results) and; exclusions from data analysis were similar in number and reasons across groups. Morevover the ratio of participants with missing data to participants with events was 12/71 = 0,17.
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.

Vodermaier 2009 *(Continued)*

Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	High risk	Comment: outcome is patient-reported and the intervention is patient-allocated. Consequently patients could discuss the intervention among themselves.
Baseline characteristics patients	Low risk	Quote: "No group differences in terms of demographic and tumour-related variables were found." (Table 2).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no report of characteristics.

Warner 2015

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: ambulatory and non-ambulatory care, specialized care, USA **Health professionals**: 24; fully trained and in training **Patients**: 130; preoperative context; male and female
Interventions	**Multifaceted intervention: Patient-mediated intervention (decision aid + patient education brochure) + education meeting:** Quote: "Patients receiving the decision aid received the decision aid packet from the personnel who brought them into the examination room and who read them the instructions printed on the packet sleeve (“You need to make a decision about how to handle smoking around the time of your surgery. Here is information to help you make that decision. Read both sides of these cards, Consider which is right for you, Choose one, and Give that card to your doctor”). A supply of the same standard patient education brochure distributed to the usual care group was made available in the rooms for use by the clinician if the patient wanted more information regarding available resources to support quitting." page 21 "Those clinicians delivering the decision aid watched an 8-min video demonstrating the use of the decision aid and had an opportunity to ask questions. The total length of the briefing did not exceed 30 min for any clinician." page 21 **Single intervention: patient-mediated intervention (patient education brochure)** Quote: "Patients receiving usual care received from the personnel who brought them into the examination room a standard patient education brochure in clinical use outlining the risk of smoking in the perioperative period, the benefits of quitting, and resources available to support quitting. Clinicians caring for these patients were not instructed regarding how to discuss smoking, but all incorporated advice to quit smoking as a part of their discussion per usual clinical practice in the POE." page 21
Outcomes	OPTION and COMRADE (continuous)
Notes	

Warner 2015 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "For each stratum, a randomization schedule was generated by the Mayo Clinic Division of Biostatistics." page 21
Allocation concealment (selection bias)	Low risk	Quote: "At the time of enrollment, group assignment was determined according to the appropriate stratum using sealed envelopes." page 21
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Comment: not enough information to make a judgement.
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Comment: not enough information to make a judgement.
Incomplete outcome data (attrition bias) Observer-based outcome	Low risk	Comment: small proportion of losses of follow up (flow chart).
Incomplete outcome data (attrition bias) Participant-reported outcome	Low risk	Comment: small proportion of losses of follow up (flow chart).
Selective reporting (reporting bias)	Low risk	Comment: the protocol was registered (Identifier: NCT01575119).
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Observer-based outcome	Unclear risk	Comment: no outcome measure at baseline.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no outcome measure at baseline.
Protection against contamination?	High risk	Comment: randomization was done at the patient level.
Baseline characteristics patients	Low risk	Comment: characteristics between groups were similar at baseline (Table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about clinicians at baseline.

Wetzels 2005

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: group of providers (a practice) **Unit of analysis**: patient

Wetzels 2005 *(Continued)*

	Power calculation: done
Participants	**Care setting**: primary care and ambulatory care (20 practices in south-eastern Netherlands) **Health professionals**: 25; general practitioners, unclear level of training **Patients**: 1246; various clinical conditions; male and female
Interventions	**Multifaceted intervention**: educational outreach visit , patient-mediated intervention; 30 minutes (educational outreach visit). All patients received a consultation leaflets by mail. The leaflet provided a motivational text, including a series of questions, encouraging patient involvement. The general practitioners received a 30-minute visit, in which they were motivated to involve the patient and to use the brochure. **No intervention (control)**
Outcomes	COMRADE (4 items, continuous); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information** Number of approached patients (eligible): 1246 Number of patients per physician: approximately 30

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "To secure blinding of allocation, practices were numbered in the order of their arrival in our mail. All participating GPs in a particular practice were randomised to the same intervention." page 287
Allocation concealment (selection bias)	Low risk	Quote: "An independent person, who was blinded for the practices as these were numbered, performed the allocation." page 287
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: All GPs in one practice were assigned to an intervention by a person blinded to the study." page 287
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: response rates were balanced in proportion across group in pre intervention (52,6% vs 52,7%) and postintervention. However, reasons for non response were not reported Quote: "Secondly, there were many missing values, suggesting that the questionnaire might have been too difficult for our study subjects." page 293
Selective reporting (reporting bias)	Unclear risk	Comment: no evidence that outcomes were selectively reported, but no protocol.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: not specified in the paper.
Protection against contamination?	Low risk	Comment: practices were randomized, GPs remained in their respective practices.

Wetzels 2005 *(Continued)*

Baseline characteristics patients	Low risk	Comment: see table 1 and 2.
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about professionals.

Wilkes 2013

Methods	**Study design**: cluster-randomized trial **Unit of allocation**: waiting areas **Unit of analysis**: provider and patient **Power calculation**: done
Participants	**Care setting**: primary care and ambulatory care; USA **Health professionals**: 120; physicians in internal and family medicine; fully trained **Patients**: 712 patients + unknown number of simulated patients; prostate cancer screening; male
Interventions	**Three arms** **Multifaceted intervention**: patient-mediated intervention, distribution of educational material Quote: "The study had 3 arms: usual practice (control) and 2 intervention arms (Figure1). Physicians in both intervention arms participated in an interactive Web-based educational program. In one intervention arm physicians saw only the educational program (MD-Ed). The other intervention also including activated patients (MD-Ed+A), who viewed a different, but related, program that both provided information and encouraged them to participate actively in the decision to pursue prostate cancer screening...Brochures on prostate cancer screening from the Centers for Disease Control and Prevention (the only materials provided for control patients) were available in the waiting areas of all enrolled practices. We developed 2, 30-minute interactive educational Web-based programs on prostate cancer screening, one for physicians and another for patients...We also sent laminated screen shots of essential diagrams to physicians in both intervention arms for use while counseling patients about likelihood of harm and benefit around prostate cancer screening...The patient program includes video vignettes to depict the potential harms for 2 scenarios: (1) not having prostate cancer screening (a regretful patient dying of advanced prostate cancer), and (2) having prostate cancer screening with a false-positive result (a regretful patient with impotence from an ostensibly nontherapeutic prostatectomy)." pages 325-326 **Single intervention:** distribution of educational material **Usual care (control)**
Outcomes	Overall PSA (prostate-specific andogen) Shared Decision Making perception (continuous)
Notes	**Additional information** Number of approached patients (eligible): 2913 in the MD-Ed+A Intervention arm, 2952 in the MD-Ed Intervention arm, 3517 in the control arm were solicited by mail; 134 physicians were assessed for eligibility Number of patients per physician: not reported
Risk of bias	

Wilkes 2013 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: not reported in the paper.
Allocation concealment (selection bias)	Low risk	Comment: waiting areas were randomized.
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	Quote: "With regard to blinding, patients and standardized patients were not aware of the multiple study arms or the arm to which their physician was assigned. The standardized patients were told that they were assessing standard differences in physician communication styles." page 325 column 2
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: imbalance of missing outcomes data across groups: control 13,6%, MD-Ed 19,5%, MD-Ed+A 4,4%. It is possible that a particular attention has been done in the follow-up of the MD-Ed+A group and this may be related to the primary outcome.
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no baseline measure of our primary outcome.
Protection against contamination?	Low risk	Quote: "We chose a cluster randomized design because we assumed that physicians who share a common waiting area (3 to 8 physicians) would interact with each other, as might their patients, creating potential contamination." page 325, column 2
Baseline characteristics patients	Low risk	Comment: reported and similar (See table 1).
Baseline characteristics healthcare professionals	Low risk	Comment: reported and similar (See table 2).

Wolderslund 2017

Methods	**Study design**: randomized trial **Unit of allocation**: patient **Unit of analysis**: patient **Power calculation**: done
Participants	**Care setting**: ambulatory care, specialized care, Denmark **Health professionals**: 49; various types; fully trained **Patients**: 4349; pediatrics
Interventions	**Multifaceted intervention:** Patient-mediated intervention (question prompt list) + other (digital audio recording)

Wolderslund 2017 *(Continued)*

	Single intervention: other (digital audio recording) **Usual care:** Quote: "The study was designed as a three-armed randomised controlled trial. One group of patients received standard care (Control), while the other two groups received either QPL in combination with a recording of their consultation (QPL-DAR) or only the recording (DAR)." page 244
Outcomes	Involvement in decision making (qualitative)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomly assigned on a weekly basis to one of the three groups using computer-generated random numbers." page 244
Allocation concealment (selection bias)	Unclear risk	Comment: not enough information to make a judgement.
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	Comment: Quote: "Neither the patients nor the health professionals were blinded to the randomisation group. Blinding would have required recordings of consultations in the control group without the patients having the possibility to replay the consultation, which we found unethical." page 248
Incomplete outcome data (attrition bias) Participant-reported outcome	High risk	Comment: very high rate of loss to follow-up and proportion of losses to follow-up were not well-balanced between groups (flow chart).
Selective reporting (reporting bias)	Unclear risk	Comment: study protocol not available to permit judgement.
Other bias	Low risk	Comment: no evidence of other risk of biases.
Baseline measurement? Participant-reported outcome	Unclear risk	Comment: no information.
Protection against contamination?	Unclear risk	Comment: not enough information to make a decision.
Baseline characteristics patients	Low risk	Comment: characteristics between groups were similar at baseline (Table 1).
Baseline characteristics healthcare professionals	Unclear risk	Comment: no information about clinicians at baseline.

ACEPP: Assessing Communication about Evidence and Patient Preferences; **ACP:** Advanced care planning; **ADDITION:** Anglo-Danish-Dutch Study of Intensive Treatment;**AHRQ:** Agency for Healthcare Research and Quality; **ASK:** Ask Share Know; **BRCA:** Breast cancer susceptibility gene; **CAPI:** Computer Assisted Personal Interviewing; **CCS:** Canadian Cardiovascular Society; **CGD:** Chronic granulomatous disorder; **CHC:** Community health centre; **CHD:** Coronary heart disease; **CHW:** Community health worker; **CME:** Continuing medical education; **COMRADE:** Combined Outcome Measure for Risk Communication and Treatment Decision-making Effectiveness; **COPD:** Chronic obstructive pulmonary disease; **CPS:** Control Preferences Scale; **CRC:** Colorectal cancer; **CRS:** Conventional risk score; **CVD:** Cardiovascular disease; **DA:** Decision aid; **DAS-O:** Decision Analysis System for Oncology; **DCS:** Decision Control Scale; **EHR:** Electronic health record; **EI:** Enhanced intervention; **FAPI:** Fragebogen zur Arzt-Patient-Interaktion (quality of physician-patient interaction scale); **FCR:** Family-centered rounds; **FRAX:** WHO online calculator for discussing treatment options; **GI:** gastrointestinal; **GP:** General practitioner; **GRS:** Genetic risk score; **HCCQ:** Health Care Communication Questionnaire; **HCP:** Healthcare professional; **HMO:** Health maintenance

organization; **ICTRP:** International Clinical Trials Registry Platform (WHO); **ID:** Identification; **IPC:** Interpersonal Processes of Care; **MI:** Mediated intervention; **MS:** Multiple sclerosis; **NA**: Not applicable; **OPTION:** Observing patient involvement; **PAM:** Patient Activation Measure; **PANDA:** Patient decision aid; **PCI:** Percutaneous coronary intervention; **PCP:** Primary care physician; **PDA:** Patient decision aid; **PDM:** Participatory Decision Making; **PEF-FB-9:** Partizipative Entscheidungsfindung-Fragebogen-9; **PP:** Patient participation; **PROM:** Patient-reported outcome measure; **PROMIS:** Patient-Reported Outcomes Measurement Information System; **QPL:** Question prompt list; **QPS:** Question prompt sheets;**QQPPI:** Questionnaire on the Quality of Physician-Patient Interaction; **RA:** Rheumatoid arthritis; **SAS:** Statistical Analysis System; **SDM-Q9:** Shared Decision Making Questionnaire (9-item); **SDM:** Shared decision making; **SDMI:** Shared decision making intervention; **SES:** Socioeconomic status; **TAS:** Treatment Alliance Scale; **TTE:** Time to event; **TTO:** Time trade-off; UC: Usual care; **VOICE**: Valuing Opinions, Individual Communication and Experience.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Alexander 2006	The design of the study was not appropriate
Aljumah 2015	Data regarding the outcome were not available
Allen 2009	The study type was not appropriate. This is a one group pre/post-test quasi-experimental design
Boehmer 2014	The outcome was not appropriate
Boyd 2010	The outcome was not appropriate
Brinkman 2013	The study design was not appropriate
Brown 2004	The outcome was inappropriate, only preference was stated
Davison 2007	The intervention was after the consultation
Golnik 2012	The design of the study was not appropriate. Inappropriate number of control sites, less than four
Green 2011	The outcome was not appropriate
Hack 2007	The intervention was after the consultation
Hanson 2011	The outcomes were not appropriate
Harmsen 2014	The intervention was not appropriate
Hermansen Kobulnicky 2002	Relevant data were not presented and are clearly unobtainable
Hoffman 2014	Hypothetical scenario
Jangland 2012	The study design was not appropriate
Koekkoek 2012	The study design was not appropriate
Kopke 2009	The outcomes were not appropriate, only the active patient was reported and not the shared decision
Kupke 2013	The outcome was not appropriate
Langewitz 1998	The outcome related to SDM is limited to a single item from an observer-based multiple instrument
Leader 2012	The outcomes of the study were not appropriate

Study	Reason for exclusion
LeBlanc 2017	The outcome was not appropriate
Man-Son-Hing 1999	The outcomes of the study were not appropriate
Maslin 1998	Relevant data were not presented and are clearly unobtainable
McCormack 2011	The design of the study was not appropriate. Inappropriate number of control sites, less than four
NCT01550731	The outcome was not appropriate
NCT02033499	The outcome was not appropriate
NCT02319525	The outcome was not appropriate
Ockhuysen-Vermey 2008	The outcomes of the study were not appropriate
Price-Haywood 2014	The outcome was reported by a standardized patient
Riippa 2014	The study design was not appropriate
Roelands 2004	The outcomes of the study were not appropriate
Schwalm 2012	The outcomes of the study were not appropriate
Simon 2012	The participants in the study were not appropriate. The healthcare professional was virtual, so it was difficult to measure SDM
Smith 2010a	The outcomes of the study were not appropriate; we could not be sure if the preference for involvement in the screening decision was the actual or preferred involvement.
Spertus 2011	The design of the study was not appropriate. This is a pre-post- cross-sectional study
van Tol-Geerdink 2008	The design of the study was not appropriate
Wagner 2012	The outcome was not appropriate
Whelan 2003	The outcomes of the study were not appropriate, only the active patient was reported and not the shared decision

SDM: shared decision making.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Simmons 2017

Methods	Study design not clear (a variety of qualitative and quantitative methods were used)
Participants	Young people with emerging or established mental disorders
Interventions	Decision aids
Outcomes	Decisional conflict, perceived involvement, choice of guideline concordant treatment option, depression scores (the list is not exhaustive)
Notes	

van Veenendaal 2017

Methods	Study design not clear (we are not sure if there is a control group)
Participants	Breast cancer patients
Interventions	The introduction of time-out periods and an participation in implementation program for SDM • 'Time-out': an explicit time break between discussing diagnoses, treatment options and the eventual decision, allowing time for deliberation and reflection. • SDM in the consultations through applying four steps: (1) informing the patient that a treatment decision is to be made and that the patient's opinion is important; (2) discuss the treatment options and their pros and cons; (3) discuss the patient's preferences and support the patient in deliberation; (4) discuss the patient's wish to make or defer the decision, and discuss follow-up. The hospitals participated in a tailor-made implementation program consisting of: • Feedback on the performance regarding SDM and time-out, using the OPTION-5 instrument and SDM-Q-9 questionnaire, and on the barriers and facilitators for implementation. • Participation of hospital teams in four collaborative training sessions aiming at process redesign, applying SDM, time-out, and tools for SDM. • A local team training on applying SDM and time-out in consultations • Support for the application of tools, such as decision aids, that enhance SDM.
Outcomes	Involvement of breast cancer patients in decision-making (OPTION5, SDM-Q9)
Notes	

OPTION: Observing **p**atien**t i**nv**o**lvemen**n**t; **SDM:** Shared decision making; **SDM-Q9:** Shared Decision Making Questionnaire (9-item)

Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12614000593639

Trial name or title	The impact of guiding patients suffering from wisdom tooth problems through Dental Open Educational Resources (DOER) on enhancing shared clinical decision-making and improving health care outcomes: a randomized controlled trial.
Methods	RCT
Participants	Inclusion criteria: participants who have been diagnosed with wisdom teeth problems otherwise fit and healthy, aged 18-39 years, internet users, signed the informed consent Exclusion criteria: non internet user, have serious health problems, non English speakers.
Interventions	**Intervention group (study group)** Participants of this group will receive a list of recommended Dental Open Educational Resources as an additional resources for patient educational materials one month before consultation. Participants can access these information at any time as they are freely accessible online. Knowledge and anxiety will be assessed in pre-consultation survey. Patient participation in SDM, satisfaction and QoL will be evaluated post intervention pre-consultation and at one month post consultation/surgery via a survey that will be posted to them. In the pre-consultation survey, participants will be asked if they reviewed the provided resources. A sample of 25 participants will be invited for structured interview that will take place face to face, online, over the phone depending on patient preference. **Control group**

ACTRN12614000593639 *(Continued)*

	Participants will receive standard care patient education (verbal communication and information leaflets) at consultation. At consultation participants will be requested to fill in a pre-consultation survey to assess their knowledge and anxiety. Patient participation in SDM, satisfaction and quality of life will be evaluated through a one-month post consultation/surgery survey that will be conducted either online or by post depending on patient preference.
Outcomes	**Primary outcomes** • Engagement in shared clinical decision-making using dyadic SDM-Q-9 for patients and SDM--9-Doc for clinicians • Oral and general heath related QoL using OHIP-14 and EuroQol-5D-5L **Secondary outcomes** • Patient knowledge measured using wisdom tooth quiz which was designed specifically for this study • Anxiety levels using IDAF-4C • Satisfaction using the satisfaction scale which was designed specifically for this study • Gap between the preferred decisional role and actual decision experience using decisional role preference scale • Decision outcomes: difference between number of teeth referred for extraction and teeth decided to be extracted, treatment pathway and anaesthetic option
Starting date	September 2014
Contact information	Dr Kamal Hanna, +61, 08, 83135626, kamal.hanna@adelaide.edu.au
Notes	

ACTRN12616000213448

Trial name or title	Development and evaluation of an Australian adult health literacy program for socially disadvantaged adults attending TAFE (Technical And Further Education).
Methods	Randomized controlled trial
Participants	People with low literacy and low health literacy
Interventions	Classes (clusters) are randomly allocated to receive either the health literacy intervention (an 18-week program with health knowledge and skills embedded in language, literacy, and numeracy training (LLN)), or the standard Language Literacy and Numeracy (LLN) program (usual LLN classes, specifically excluding health content).
Outcomes	Primary outcome: functional health literacy skills – knowing how to use a thermometer, and read and interpret food and medicine labels. Secondary outcomes: self-reported confidence, health literacy; shared decision making skills, patient activation, health knowledge and self-reported health behavior.
Starting date	February 2014
Contact information	Prof Kirsten McCaffery; +61 2 9351 7220; kirsten.mccaffery@sydney.edu.au
Notes	Recruitment is completed

ACTRN12616000644460	
Trial name or title	Effect of decision aids for acute respiratory infections on the use of antibiotics in general practice: a cluster-randomised controlled trial
Methods	RCT
Participants	**Inclusion criteria** General practice in the recruitment region, minimum age 18 years **Exclusion criteria** General practice is currently, or within the last 2 years, participated in a research study aimed at reducing antibiotic prescribing
Interventions	Brief name: Decision aids for ARIs GPs will be given copies of three patient decision aids (one each for acute otitis media, sore throat, and acute bronchitis) and a brief training package (to be completed at their convenience). Each decision aid is a two-page (double-sided) document; the training package is a short video (˜15 minutes) explaining about SDM and use of decision aids; a list of frequently asked questions (by GPs) about the decision aids will also be provided. Usual care: GPs at the control practices will not receive access to the training package or the decision aids.
Outcomes	**Primary outcome** • Rate of antibiotic dispensing of the target antibiotics for each GP (number of consultations for which one of the target antibiotics was dispensed per year) **Secondary outcomes** • Quality of the decision-making process • GPs' knowledge about benefits and harms of antibiotics for ARIs • Adverse events (patient-initiated re-consultation for the same illness episode, chest x-ray referrals, hospital or emergency room admissions) • Acceptability, sustainability, and self-reported use of resources for antibiotic prescribing in ARIs • Rate of antibiotic dispensing of the target antibiotics for each GP (for all antibiotics
Starting date	June 2016
Contact information	Prof Tammy Hoffmann, +61 7 5595 5522, thoffmann@bond.edu.au
Notes	

ACTRN12617000614392	
Trial name or title	Whakapai e Te Ara Ha: Asthma Self-Management Programme. A single-blinded, parallel group, randomised controlled trial of the impact of a culturally-relevant peer-support and self-management programme, on activation and quality of life among the parents/caregivers of Maori children aged 4-13 years old with asthma in New Zealand, and asthma control, quality of life and health-care utilization among their children.
Methods	RCT
Participants	**Inclusion criteria** Parents/caregivers will be eligible to participate if their child is:

ACTRN12617000614392 *(Continued)*

	a) between 4-13 years, b) identifies as NZ Maori ethnicity (prioritized, self-/parental-reported), c) has a doctor's diagnosis of asthma, d) has a previous hospitalization or ED presentation for asthma or wheeze (ICD-10-AM code: J45,J46 or R06.2), and e) usually resides within the geographical catchment area of the participating DHBs (District Health Boards). **Exclusion criteria** Parents/caregivers will be excluded from participating if their child: a) has previously been enrolled in the study, b) has a sibling on the study, c) does not reasonably expect to remain in the region for the duration of the intervention and follow-up, or d) have other chronic respiratory comorbidities that may be deemed to interfere with the study (e.g. bronchiectasis).
Interventions	The intervention group will receive a six-month holistic, culturally-based peer-support program. The intervention will comprise two phases: an initial 6-week intensive 'whakawhanaungatanga' (relationship building) period and an 'awhi' (support) maintenance period over the remainder of the 6 months. Usual Care: participants in the control group will receive appropriate educational resources (Children and Asthma Booklet) from the Asthma Foundation of NZ and be followed-up by their usual GP without limitation.
Outcomes	**Primary outcomes** • Parent or caregiver activation, as measured by parent or caregiver Patient Activation Measure (PAM), a validated scale of activation **Secondary outcomes** • Healthcare utilization, expressed as the number of ED presentations or hospital admissions for asthma or wheeze over the previous 12 months • Parents/Caregivers Quality of Life assessed via the Paediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ) and the EuroQol EQ-5D-Y (Proxy 1 Version) • Child Quality of Life assessed via the Paediatric Asthma Quality of Life Questionnaire (PAQLQ) and EuroQol EQ-5D-Y • Healthcare Utilisation - after hours/Urgent GP visits • Qualitative Assessment (acceptability & effectiveness)
Starting date	May 2017
Contact information	Dr Tristram Ingham, +6449186842, tristram.ingham@otago.ac.nz
Notes	

ACTRN12617000840381

Trial name or title	Phase II randomised controlled trial evaluation of treatment decision-aid for patients with bipolar II disorder and their family considering treatment options for relapse prevention
Methods	RCT
Participants	**Inclusion criteria** • Confirmed clinical diagnosis of bipolar II disorder • Out of acute episode of depression and/or hypomania (i.e. subsyndromal or euthymic) • Actively considering treatment options for relapse prevention in bipolar II disorder with a clinician (e.g. GP, psychiatrist or clinical psychologist). • Aged 18-65 years **Exclusion criteria** • Lacks English proficiency to read the decision-aid and/or complete questionnaires • Lacks capacity to provide informed consent to research • Comorbid substance abuse disorder • Comorbid neurological or major psychiatric condition
Interventions	Treatment decision-aid intervention: This decision-aid website for bipolar II disorder, developed by PI Juraskova, CIs and professional web designers/developers. The decision-aid explains main available medication and psychological treatment options for relapse prevention in bipolar II disorder, based on available guidelines; with specific sections for patients' family.The decision-aid website can be accessed by the patient participant and/or family member at any frequency and duration in the period following diagnosis and leading up to follow-up consultation/s with their managing psychiatrist, GP and/or clinical psychologist. Usual care/attention control will comprise: any information materials (e.g. fact sheets) that patients are already routinely provided with, or advised to consult during their appointment at the Black Dog Institute (recruitment site); and the existing Black Dog Institute web pages on treatments for bipolar disorder.
Outcomes	**Primary outcome** • Decisional conflict (Decisional Conflict Scale) **Secondary outcomes** • Knowledge about treatment options and outcomes • Concordance between preferred/actual levels of decision-making involvement • Informed, values-based treatment choices • Preparation for decision-making • Decisional regret • Uptake of effective treatment options • Understanding of treatment options and outcomes • Symptom severity (used as an index of safety) • Medication adherence (used as an index of safety)
Starting date	August 2017
Contact information	A/Prof Ilona Juraskova, +61 2 9351 6811, ilona.juraskova@sydney.edu.au
Notes	

Adekpedjou ongoing

Trial name or title	Improving the decision-making process with caregivers of elderly people about housing options: a cluster randomised trial (NCT02244359)
Methods	Cluster-randomised trial
Participants	Inter-professional teams involved with eligible caregivers in decision-making about planning care for their loved one, caregivers of cognitively impaired elderly people
Interventions	Training in SDM and use of a decision guide
Outcomes	Primary outcome: role assumed in the decision-making process as assessed by caregivers using a modified version of the Control Preferences Scale. Secondary outcomes: preferred option and decision made, match between role preferred and assumed in decision-making, decisional conflict, decision regret, and burden of care of caregivers.
Starting date	September 2014
Contact information	France Légaré; (418) 663-5919; france.legare@mfa.ulaval.ca
Notes	The study is completed but results of the trial are not published yet

Altshuler 2016

Trial name or title	Transforming the patient role to achieve better outcomes through a patient empowerment program: a randomized wait-list control trial protocol
Methods	Randomized controlled trial
Participants	English-speaking adult patients with type 2 diabetes mellitus from three urban clinical sites in New York City
Interventions	The PEP (Patient Empowerment Program) intervention consists of two facilitated small group sessions. Session 1 focuses on defining HCP and patient roles in the medical encounter by introducing ideal communication behaviors in each role and by providing both positive and negative examples of patient-HCP encounters. Session 2 focuses on practicing communication skills by role-playing with actors who serve as standardized healthcare providers. After the role play, participants set goals for their own health care and for future interactions with their HCPs.
Outcomes	Outcome measures include the Patient Activation Measure; Ask, Understand, Remember Assessment; Krantz Health Opinion Survey; SF-12v2 Health Survey; Diabetes Self-Management Questionnaire; and HbA1c.
Starting date	
Contact information	Lisa Altshuler, PhD; 1 (646) 501 4136; Lisa.Altshuler [at] nyumc.org
Notes	

DRKS00000191

Trial name or title	Advance directives as an example for shared decision making in the General Practitioner practice
Methods	RCT

DRKS00000191 *(Continued)*

Participants	**Inclusion criteria** • Minimum age: 18 years • Competent patients, sufficient knowledge of the German language **Exclusion criteria** • Incompetent patients, insufficient knowledge of the German language
Interventions	**Arm 1:** consultation for completing an Advance Directive after training of General Practitioners in Shared Decision Making **Arm 2:** control group, treatment as usual
Outcomes	**Primary outcome** • Patient participation in medical decision making in context of completing Advance Directives **Secondary outcome** • Patient satisfaction with a decision
Starting date	November 2009
Contact information	Lehrbereich Allgemeinmedizin Universitätsklinik Freiburg Elsässerstr. 2 79110 Freiburg i. Br. Germany
Notes	

DRKS00010880

Trial name or title	Shared Decision Making PLUS – a cluster-randomized trial with inpatients suffering from schizophrenia
Methods	RCT
Participants	**Inclusion criteria** • Age 18-65 years • Male and female patients • Inpatients of participating hospitals • Diagnosis of schizophrenia or schizoaffective disease (ICD 10: F20/F25) • Capable of participating in 60 min. group intervention • Being able to provide written informed consent **Exclusion criteria** • Mental retardation • Insufficient proficiency in German language to discuss treatment decisions
Interventions	**Arm 1**: SDM PLUS intervention: training for treatment teams how to implement SDM (2x4h workshops on SDM and other communicative techniques) + training for patients how to facilitate SDM (5 x 60 min. interactive group training)

DRKS00010880 *(Continued)*

	Arm 2: treatment as usual
Outcomes	**Primary outcome** • Perceived inclusion in decision making (SDM-Q-9) three weeks after study entry (or at discharge if earlier) **Secondary outcomes** • Therapeutic Alliance (HAS-P) • Treatment satisfaction (ZUF8) • Quality of life (WHO-5, EUROHIS-QOL) • Unmet needs (CANSAS-P) • Adherence (MARS) • Rehospitalizations
Starting date	October 2016
Contact information	Mr. Prof. Dr. Johannes Hamann Ismaninger Straße 22 81675 München Germany Telephone: 089/41404282 Fax: 089/41406688 E-mail: j.hamann at tum.de
Notes	

Dwinger ongoing

Trial name or title	Development and pilot testing of a face-to-face SDM coaching intervention for oncologists
Methods	Pilot study for a RCT
Participants	Patients and physicians
Interventions	The content of the training is based on a SDM manual evaluated in previous studies. The training is structured in two parts. First the SDM approach, including information models, definition of SDM, and the applicability of SDM are explained in a dialogue. Second the steps of SDM (team talk, option talk, decision talk) are explained and discussed using the videotape of the first consultation with the simulation patient.
Outcomes	OPTION12 and MAPPIN' SDM from three perspectives: physician, patient and observer
Starting date	Unknown
Contact information	Sarah Dwinger, University Medical Center Hamburg-Eppendorf, Department of Medical Psychology, Germany
Notes	Information retrieved from the 9th International Shared Decision Making Conference 2017 Book of Abstract

Fagerlin ongoing

Trial name or title	The impact of shared decision making on patient involvement in two prostate cancer decision aid trials
Methods	Randomized controlled trial
Participants	Men with Gleason ≤ 7 localized disease at 1 University medical center
Interventions	Decision aid
Outcomes	Self-efficacy to participate in shared decision-making skills
Starting date	
Contact information	Angela Fagerlin, PhD; 801-587-2100; Department of Population Health Sciences 295 Chipeta Way, Room: Room 1S105 Salt Lake City, UT 84108
Notes	

Finderup 2017

Trial name or title	Developing and pilot testing a shared decision-making intervention for dialysis choice
Methods	Study design not clear
Participants	Patient facing the decision to choose the dialysis modality
Interventions	Intervention for SDM targeting the choice of dialysis modality (a manual for SDM, including a variety of decision aids)
Outcomes	Dialysis choice, shared decision making (SDM-Q9)
Starting date	
Contact information	
Notes	

Henselmans ongoing

Trial name or title	Effect of a skills training for oncologists on shared decision making about palliative chemotherapy in simulated encounters
Methods	Randomized controlled trial
Participants	Oncologists and oncology residents
Interventions	**SDM training** The training was based on a 4-step model of SDM, including (1) setting the SDM agenda, (2) informing about options, (3) exploring patient values, and (4) making a decision. The training focused on SDM about palliative systemic treatment and consisted of a reader, two 3.5-hour group sessions using modeling videos and role play, a booster session including individual feedback on a au-

Henselmans ongoing *(Continued)*

	dio-recorded consultation in clinical practice, and a consultation card with the SDM steps and example phrases.
Outcomes	**Primary outcome:** observed SDM as assessed with the OPTION12 (Observing Patient Involvement). **Secondary outcomes**: observed SDM per step (self-developed instrument), general communication skills ratings (providing information and anticipating/responding to patient emotions) and oncologists' satisfaction with communication (PSQ).
Starting date	
Contact information	Inge Henselmans, PhD
Notes	

ISRCTN37929939

Trial name or title	Nurse-led immunotherapy decision coaching in persons with relapsing-remitting multiple sclerosis (DECIMS)
Methods	Evaluator-blinded cluster-randomized controlled trial
Participants	Patients with suspected or the relapsing form of MS ('relapsing-remitting MS') who are facing a decision on starting, stopping, or changing MS immunotherapy
Interventions	**Experimental intervention** One to three counseling (decision coaching) sessions with specially trained nurses, supported by an evidence-based online patient information tool prior to a decisional encounter with a physician. **Control intervention** Counselling as usual and access to an evidence-based online information tool.
Outcomes	**Primary outcomes:** informed choice (Multi-dimensional Measure of Informed Choice (MMIC)) including the sub-dimensions risk knowledge, attitude and uptake; attitude towards immunotherapy; uptake of immunotherapy; risk knowledge **Secondary outcome:** Decisional Conflict Scale (DCS); control Preference Scale (CPS); planned Behaviour in MS (PBMS); the Coping-Self-Efficacy-Scale (CSES); duration of physician encounters; decision adherence
Starting date	June 2014
Contact information	Prof. Christoph Heesen; heesen@uke.de
Notes	The study is completed but results of the trial are not published yet

ISRCTN46305518

Trial name or title	Informed shared decision making supported by decision coaches for women with ductal carcinoma in situ
Methods	RCT

ISRCTN46305518 *(Continued)*

Participants	Women are eligible if they are at least 18 years old, have no known BRCA1/2-mutation, are not pregnant and have a primary DCIS. All participants need sufficient German language skills.
Interventions	The intervention includes a four-day training program in SDM for specialized nurses, a two hour-lasting workshop in SDM for physicians and an evidence-based patient decision aid and decision coaching for women. Women in the control group receive standard care.
Outcomes	Involvement in treatment decision making and decisional conflict
Starting date	October 2014
Contact information	Martin-Luther-King-Platz 6 Hamburg 20146 Germany +49 40 42838 7152 Birte.Berger-Hoeger@uni-hamburg.de
Notes	

ISRCTN63110516

Trial name or title	ACTION: cancer patient involvement in medical decision making
Methods	Cluster-randomized trial
Participants	Adult patients with advanced stages of lung or colorectal cancer
Interventions	The 'Respecting Choices Program' is a formalized model of advance care planning developed and currently being used in the USA and Australia. In this program, a trained 'Respecting Choices Facilitator' invites patients to reflect on their personal goals, values and beliefs, to discuss and document their choices regarding their future treatment and care and to nominate someone who they may wish to be consulted about their treatment or care if they are not able to make decisions for themselves.
Outcomes	**Primary outcome:** quality of life and symptoms **Secondary outcomes:** coping with their illness, decisional Quality and Patient Activation, satisfaction with care, satisfaction with the intervention
Starting date	01/11/2014
Contact information	Miss Lesley Dunleavy; l.dunleavy@lancaster.ac.uk
Notes	The study is completed but results of the trial are not published yet

Lifford ongoing

Trial name or title	Bridging the Age Gap trial of decision support interventions for older women with breast cancer: Preliminary process evaluation
Methods	RCT
Participants	40-60 patients from a subsample of trial sites and 12-20 clinicians (surgeons, oncologists and specialist nurses)
Interventions	The decision support interventions (DESIs) consist of an online algorithm (primarily for clinicians, with a patient print-out available) which predicts personalized survival rates with each treatment, a short tool (for use within consultations) and a booklet of information with a values-clarification section (for use outside consultations).
Outcomes	Usage of the decision support interventions and levels of SDM
Starting date	Unknown
Contact information	Kate Lifford, Cardiff University, Cardiff, UK
Notes	Information retrieved from the 9th International Shared Decision Making Conference 2017 Book of Abstract

Ludden ongoing

Trial name or title	Who Made the Decision Today?" Surveying asthma patients level of shared decision making in an RCT
Methods	Randomized controlled trial
Participants	Asthma patients
Interventions	The FLOW intervention involved customized training sessions with clinics to incorporate the SDM toolkit into workflows unique to each practice.
Outcomes	Shared decision making [Who made the decision in your meeting with the care team (health coach and provider) about what your asthma treatment would be?]
Starting date	
Contact information	Dr Thomas Ludden
Notes	

NCT01485627

Trial name or title	VOICE: Values and Options in Cancer Care (VOICE)
Methods	RCT
Participants	Age : 21 Years and older **Physicians**

NCT01485627 *(Continued)*

	• Currently in clinical practice at participating institutions • Oncologist that cares for patients with solid tumors • Not planning to leave the practice during the next 6 months **Patients** • Currently a patient of an enrolled physician • Age 21 years or older • Diagnosis of advanced cancer • Able to understand spoken English (study personnel will read materials to low literacy patients) **Caregivers** • Caregiver of a patient currently enrolled in the study • Age 21 years or older • Able to understand spoken English (study personnel will read materials to low-literacy patients)
Interventions	Oncologists will receive communication training. Patients will be coached to make the most of the oncologist visit.
Outcomes	**Primary outcome:** improved patient-physician-caregiver communication; prolonged grief symptoms (Caregiver Bereavement). **Secondary outcomes:** improved patient-perceived communication; patient and caregiver well-being; caregiver physical health outcomes; health care utilization. **Other outcomes;** examine whether caregiver outcomes are mediated by patient-reported quality of life and patient healthcare utilization (quantitative). Explore caregiver perspectives on decision-making and communication processes to link bereavement outcomes with VOICE study communication outcomes (qualitative).
Starting date	April 2011
Contact information	Contact information is only displayed when the study is recruiting participants
Notes	

NCT01519999

Trial name or title	Colorectal cancer screening with improved shared decision making (CRCS-WISDM)
Methods	Non-randomized controlled trial
Participants	Patients 50-75 years seen in the participating primary care clinics during the study period who are non-adherent to CRCS recommendation
Interventions	**Behavioral:** SDM for colorectal cancer screening Quote: "Age-eligible adults in the intervention communities will be exposed to the SDM intervention when they are seen in the primary care clinics (N = all patients 50-75 years seen during the study period who are non-adherent to CRCS recommendation). Additionally, among patients with primary care visits scheduled one week or more before the visit, they will be randomized to receive either a mailed decision aid booklet or an informational flyer on shared decision making and CRCS prior to the visit. Patients with primary care visits scheduled less than one week prior to the visit will not be mailed materials in advance. The effect of the pre-visit materials on referral to SDM session and CRCS adherence between these groups will be compared. They will also be exposed to SDM tools and resources available through the community-wide intervention activities."

NCT01519999 *(Continued)*

Outcomes	Colorectal cancer screening adherence.
Starting date	May 2012
Contact information	Principal Investigator: Resa M Jones, MPH, PhD from Virginia Commonwealth University.
Notes	

NCT01828567

Trial name or title	Will veterans engage in prevention after HRA-guided shared decision making? (ACTIVATE)
Methods	RCT
Participants	Veterans enrolled in primary care at the Durham or Ann Arbor Health Care Systems and who have one modifiable risk factor identified by a healthy living assessment (physical inactivity, overweight or obese by BMI, or tobacco user)
Interventions	**Behavioral:** SDM with a prevention coach. A series of two phone sessions with a prevention coach. The first to engage the veteran to choose a preferred prevention program and link them to PACT, and a follow-up call one month later to assess the progress of the prevention plan.
Outcomes	**Primary outcome:** enrollment in prevention services. **Secondary outcomes:** patient activation measures, Framingham Risk Score
Starting date	October 2014
Contact information	Principal Investigator: Eugene Z Oddone, MD MHSc; Durham VA Medical Center, Durham, NC, United States, 27705 Principal Investigator: Laura J. Damschroder, MPH; VA Ann Arbor Healthcare System, Ann Arbor, MI, USA, 48105
Notes	

NCT01837953

Trial name or title	Stepped care for binge eating disorder: predicting response to minimal intervention in a randomized controlled trial
Methods	RCT
Participants	Adults aged 18 years and older with Binge Eating Disorder (BED)
Interventions	Two interventions. **Behavioral: Group Psychodynamic Interpersonal Psychotherapy** Quote: "For those participants randomized to the USH (Unguided Self-Help) + Group Psychodynamic Interpersonal Psychotherapy (GPIP) condition, this intervention will consist of 16 weekly 90 minute sessions of GPIP. GPIP was developed and empirically tested in a randomized controlled trial (RCT) at our Centre. GPIP will be preceded by an individual pre-group preparation session conducted by a psychologist trained in GPIP to orient the patient to the therapy. Patients are given a rationale for the treatment. Examples of the patient's cyclical relational patterns (CRPs) that may

NCT01837953 *(Continued)*

	underlie their symptoms are discussed and the patient will be encouraged to work on these in the groups. Therapists will be given a written summary of each patient's CRP." **Behavioral: USH** Quote: "All participants will first receive 10 weeks of USH. The USH will be based on Dr. Christopher Fairburn's CBT-oriented and evidence based self-help treatment plan for binge eating explained in his book, Overcoming Binge Eating. The USH program follows six steps: (1) Getting Started: Self-monitoring, weekly weighing; (2) Regular Eating: Establishing a pattern of regular eating; (3) Alternatives to Binge Eating: Substituting alternative activities; (4) Problem Solving and Taking Stock: Practicing problem solving and reviewing progress; (5) Dieting and Related Forms of Avoidance: Tackling the three forms of dieting and other forms of avoidance eating; and (6) What Next? Preventing relapse and dealing with other problems."
Outcomes	**Primary outcome:** Binge Eating Episodes in the Past 28 Days. **Secondary outcomes:** Body Mass Index (BMI); Center for Epidemiologic Studies Depression Scale (CES-D); Experiences in Close Relationships Scale (ECR); Inventory of Interpersonal Problems (IIP-64); Patient Health Questionnaire 9 (PHQ-9); Rapid Response to Treatment: Self-Monitoring; Rosenberg Self Esteem Scale (RSES); Eating Disorder Diagnostic Scale (EDDS); Experiences in Close Relationships Scale Short Form (ECR-S); Therapeutic Factors Inventory (TFI); Outcome Rating Scale (ORS); Working Alliance Inventory Short (WAI-S); Eating Disorder Examination - Questionnaire (EDE-Q); Depression Anxiety and Stress Scales 21(DASS-21)
Starting date	November 2012
Contact information	Contact information is only displayed when the study is recruiting participants
Notes	

NCT01838226

Trial name or title	Randomized controlled trial of group prevention coaching
Methods	RCT
Participants	Adults aged 21 years and older with: • a diagnosis of inadequately controlled hypertension, as defined by an outpatient ICD-9 code of 401.x and a most recent blood pressure with either systolic > 140 mmHg or diastolic > 90 mmHg, or • inadequately controlled dyslipidemia, as defined by most recent total cholesterol > 200 mg/dL or HDL cholesterol < 35 mg/dL, or • current smoking, which can be identified using the CPRS Health Factor tied to the smoking clinical reminder.
Interventions	**Behavioral:** Problem Solving A group problem-solving intervention, with interval phone calls delivered to check in on goal progress and reinforce group learning. Groups will meet monthly for 6 months, and each patient will be called once between each group session. Each group will consist of 10 patients. Problem-solving teaches patients to overcome internal barriers to healthful behaviors. Problem solving will be combined, at all group sessions, with self-efficacy training, so that patients will be taught simultaneously to overcome both internal and external barriers. Participants will be asked to develop personal goals related to CVD-related behaviors (e.g., smoking and weight reduction).
Outcomes	**Primary outcome: r**isk of fatal coronary event or non-fatal MI

NCT01838226 *(Continued)*

	Secondary outcomes: International Physical Activity Questionnaire; Block Brief 2000 Food Frequency Questionnaire; Patient Activation Measure.
Starting date	August 2014
Contact information	Michael Owings, BS 716-862-8590 Michael.Owings2@va.gov David Edelman, MD MHS (919) 286-6936 david.edelman@va.gov
Notes	

NCT01866228

Trial name or title	Clinical trial of the impact of treatment consultation recordings on cancer patient outcomes
Methods	RCT
Participants	Adults aged 18 years and older presenting with a primary diagnosis of non-recurrent or metastatic brain, or neuroendocrine cancer
Interventions	**Consultation Recording.** The main goal of this study is to demonstrate the benefits of giving cancer patients an audio-recording of their first consultation with their cancer doctor. Patients will receive their recording immediately after their consultation, and will be able to listen to the recording at any time either alone, or with family and friends.
Outcomes	Primary outcomes: Control Preferences Scale; Patient Satisfaction with Cancer Care Scale; Prest-Man Satisfaction with Doctor Scale; Hospital Anxiety and Depression Scale; Perception of Being Informed Scale.
Starting date	June 2013
Contact information	Contact information is only displayed when the study is recruiting participants.
Notes	

NCT01992926

Trial name or title	Facilitating anemia treatment risk communication for patients with kidney disease: decision aid trial
Methods	Randomized controlled trial
Participants	Patients (over 18, under 80 years of age) with chronic kidney disease or end stage renal disease
Interventions	Interactive educational intervention:use of a concise, literacy-sensitive, physician-led, educational interaction with the patient.
Outcomes	**Primary outcome measures:** change in patient understanding of anemia and treatment options
Starting date	November 2013
Contact information	Contact information is only displayed when the study is recruiting participants

NCT01992926 *(Continued)*

Notes	The study is completed but results of the trial are not published yet

NCT02047929

Trial name or title	Comparing types of implementation of a shared decision making Intervention (ADAPT-NC)
Methods	RCT
Participants	1 Year and older Medicaid patients with the diagnosis of asthma
Interventions	Asthma Shared Decision Making (SDM) Toolkit Quote: "A potential solution to improving asthma outcomes is the use of patient-centered approaches like Shared Decision Making (SDM), identified by both the Institute of Medicine and the Patient-Centered Outcomes Research Institute as an important new means of improving patient outcomes. In the SDM process, patients and their health care providers are engaged jointly in making decisions about medical tests and treatments. The research team for this proposal was funded by the Agency for Health Care Research and Quality to build, disseminate and evaluate a novel Asthma SDM Toolkit - The Asthma Comparative Effectiveness Study. The Toolkit development was completed in 2010 and has been in evaluation for 2 years. Initial results show marked improvement in patient adherence to medications, decreases in utilization of the ED and hospital for asthma care. This study will continue to evaluate the Toolkit in a wide array of practices across North Carolina while testing a new method of dissemination."
Outcomes	**Primary outcome** Patient perception of shared decision making. **Secondary outcomes:** Asthma exacerbations, medication adherence.
Starting date	August 2013
Contact information	Contact information is only displayed when the study is recruiting participants
Notes	

NCT02063087

Trial name or title	Sharedd decision making in parents of children with head trauma: Head CT Choice (Head CT Choice)
Methods	RCT
Participants	Parents and their child, seeking care for a child who: • is < 18 years of age; • had blunt trauma above the eyebrows (not isolated to face or eyes); • is positive for at least 1 of the PECARN (Pediatric Emergency Care Applied Research Network) clinical prediction rule predictors.
Interventions	**Head CT Decision Aid** Quote: "The decision aid, Head CT Choice, educates parents regarding how the clinician determined the severity of their child's head trauma, their child's quantitative risk for a clinically-im-

NCT02063087 *(Continued)*

	portant TBI, the pros and cons of cranial CT compared to active observation, and what signs and symptoms parents should watch for in the next 24 hours that should prompt a return visit to the ED."
Outcomes	**Primary outcome:** assess parents' knowledge regarding their child's risk for a significant brain injury. **Secondary outcomes:** patient engagement in the decision-making process (OPTION); decisional conflict; trust in the physician; parental satisfaction; proportion of children who undergo head CT; healthcare utilization; rate of clinically important traumatic brain injury (ciTBI); fidelity.
Starting date	April 2014
Contact information	Erik Hess, MD, MSc; (507)284-7221; hess.erik@mayo.edu. Melissa Kuntz, BA; (507) 293-1239; kuntz.melissa@mayo.edu.
Notes	

NCT02136732

Trial name or title	Chronic care management for adults at federally qualified health centers
Methods	RCT
Participants	45 years of age or older, 2 or more chronic conditions, 2 or more emergency department visits or hospital admissions in previous 12 months.
Interventions	**Experimental:** active self-management intervention. Participants will receive home visits and phone calls from a registered nurse and social worker. The registered nurse and social worker will provide participants one on one coaching, education, support and referrals to community resources to help them manage their chronic conditions. **Active Comparator:** attention control phone calls. Participants will receive an initial visit and then a phone call every other month from a social services aide who can provide information about community resources that might be helpful.
Outcomes	**Primary outcome:** patient activation. **Secondary outcome:** acute care utilization. **Other outcome:** participant's health-related quality of life.
Starting date	October 2013
Contact information	Mike Wisor 509-444-8888; mwisor@chas.org. Kaleena Reynolds 509-444-888; kreynolds@chas.org
Notes	

NCT02138448

Trial name or title	Implementing personal health records to promote evidence-based cancer screening

NCT02138448 *(Continued)*

Methods	RCT
Participants	• Practices in a practice-based research network participating in our study that have an existing patient health record • Patients who attend these study practices (18 to 75 years)
Interventions	Intervention practices will implement an interactive preventive health record in addition to their standard personal health record functionality.
Outcomes	**Primary outcome:** percentage of patients who are up-to-date with recommended cancer screening tests in intervention versus control practices. **Secondary outcomes:** SDM outcomes (knowledge, communication, decisional conflict, and decision control) reported by patients in intervention versus control practices. To assess whether cancer screening rates differ for disadvantaged patients, defined as minorities and Medicaid beneficiaries. To assess whether SDM differ for disadvantaged patients, defined as minorities and Medicaid beneficiaries. To assess whether perceptions of the technology differ for disadvantaged patients, defined as minorities and Medicaid beneficiaries.
Starting date	February 2014
Contact information	Alexander H Krist, MD, MPH; 804-827-6750; ahkrist@vcu.edu. Rebecca A Aycock, PhD; 8048274121; raycock@vcu.edu.
Notes	

NCT02146573

Trial name or title	Pediatric Continuity Care Intensivist (CCI)
Methods	RCT
Participants	**CCI Provider** • Pediatric Intensive Care Unit Attending Physician who volunteers to serve in the role of CCI. Usual Care (UC) Provider • Any pediatric intensive care unit (PICU) attending physician who is not enrolled as a CCI. **Parent-Patient Dyads** • Parent/guardian of a child who has been admitted to a CHOP PICU for ≥7 days after onset of the study • Parent/guardian ≥ 18 years old • Parent/guardian is English-speaking • Child <18 years old at time of enrollment • Child has been admitted to the PICU at CHOP (Children's Hospital of Philadelphia) for ≥7 days following onset of study • Patients are also eligible if, at the time the study is initiated, they have been in the PICU for less than seven days
Interventions	**CCI Provider for Parent-patient dyad** Parents and patients are randomly assigned to a Continuity Care Intensivist (CCI) Provider who has received specialized communication training. The parent-patient dyad will receive standardized

NCT02146573 *(Continued)*

	care from the CCI throughout their time in the PICU in addition to being assigned a rotating physician of record.
Outcomes	**Primary outcome:** • Difference in patient length of stay in the PICU between usual care and intervention arm. **Secondary outcomes:** • Difference in number of new technological dependence patients acquire during hospitalization between usual care and intervention arms • Difference in patient hospital-acquired conditions between usual care and intervention arm • Difference in patient length of time on sedation medicines between usual care and intervention arm • Difference in patients' new or progressive multiple organ dysfunction syndrome between usual care and intervention arm • Difference in patient organ failure free days between usual care and intervention arm • Difference in patient ventilator free days between usual care and intervention arm • Difference in change in parent preferences for shared decision-making from baseline to patient discharge between usual care and intervention arm • Difference in change in parent preferences for control in decision-making from baseline to patient discharge between usual care and intervention arm • Affects of Parent attachment style on communication preferences • Difference in change in parental levels of anxiety and depression from baseline to patient discharge between usual care and intervention arm • Difference in change in parental levels of positive and negative affect from baseline to patient discharge between usual care and intervention arm • Difference in change in parental levels of anger from baseline to patient discharge between usual care and intervention arm • Difference in change in parental levels of hope from baseline to patient discharge between usual care and intervention arm • Difference in change in Parent/family satisfaction with decision-making from baseline to patient discharge between usual care and intervention arm • Difference in parent/family satisfaction with communication with their child's PICU physicians between usual care and intervention arm • Difference in change in parent self-report of medical communication competence from baseline to patient discharge between usual care and intervention arm • Difference in change in parent assessment of physician communication competency from baseline to patient discharge between usual care and intervention arm. The Communication Assessment Tool (CAT), a validated tool, will be used to measure parent perceptions of physician competence in interpersonal and communication skills • Comparison of physician burnout between intervention and control group from baseline up to 600 days • Physician satisfaction with the communication training and with the CCI experience • Evaluation of CCI provider experience in role of CCI and its feasibility of larger implementation • Comparison of physician comfort with end-of-life communication between intervention and control group from baseline up to 600 days • Difference in timing of patient's limitations of interventions to death between usual care and intervention arm • Frequency of palliative care consultation between usual care and intervention arm • Physician competency in communication with families via objective structured clinical examination (OSCE) evaluation • Comparison of physician self-reported communication competency between intervention and control group • Correlation between amount of CCI contact and parent and patient level outcomes

NCT02146573 *(Continued)*

Starting date	May 2014
Contact information	*Contact information is only displayed when the study is recruiting subjects.*
Notes	

NCT02165735

Trial name or title	Get Ready And Empowered About Treatment (GREAT)
Methods	RCT
Participants	**Inclusion criteria:** • age18 years or older, • confirmed HIV diagnosis, • receipt of care within a participating site. **Exclusion criteria:** • inability to provide informed consent, • limited English proficiency (Trainings and Personal Health Record are currently only available in English).
Interventions	**Experimental: patient empowerment** Participants will take part in six 90-minute sessions focused on development of basic information technology competency within a context that supports patient autonomy, competence and human relationships. **No Intervention: standard care** Participants will be followed through usual source of care, without receiving the empowerment training.
Outcomes	**Primary outcome :** patient empowerment based on changes in the Patient Activation Measure (PAM)
Starting date	June 2014
Contact information	Kevin A Fiscella, MD MPH, 585-271-1206 and Jonathan Tobin, PhD, 212-382-0699 ext 234, JNTobin@CDNetwork.org
Notes	

NCT02198690

Trial name or title	Trial of a mammography decision aid for women aged 75 and older
Methods	RCT
Participants	• English-speaking women • Aged 75 to 89 years • Scheduled for a routine visit or physical with their PCP in the next 4-12 weeks

NCT02198690 *(Continued)*

	• Women who have not had a mammogram in 6 months but have had one in 2 years
Interventions	**Experimental:** Mammography Decision Aid Quote: "Development and pilot testing of the decision aid (DA) has been described previously. In brief, the DA is written at a 6th grade reading level and includes information on 1) breast cancer risk factors for women >75 years; 2) health/life expectancy; 3) likely outcomes if screened and not screened with mammography; 4) competing mortality risks; 5) breast cancer treatments; and 6) a values clarification exercise. The last page asks users their intentions of being screened on a 15-point validated scale and invites users to share this information with their clinician. PCPs whose patients are randomized to receive the DA will be sent a copy of the DA via email and a link to an optional training on using the DA (5 informational slides and a 3-minute video)." **Placebo comparator:** Home safety pamphlet Quote:"To reduce response bias and to compensate for the time and attention required by the intervention group to read the DA, patients in the control arm will be provided a two page pamphlet on home safety for older adults developed by the American Geriatrics Society (AGS) Foundation for Health in Aging. PCPs whose patients are randomized to the receive the home safety pamphlet, will be sent an email informing them that their patient will be coming in early to read health educational materials for older adults as part of a study. We otherwise do not plan any intervention for control group PCPs because we do not want to change their usual behavior. However, if PCPs in the control arm request a copy of the educational materials then we will email them a copy of the home safety pamphlet."
Outcomes	**Primary outcome:** receipt of mammography screening. **Secondary outcomes:** screening intentions; knowledge of the pros and cons of mammography screening; Decisional Conflict Scale (DCS); **Decision-making role:** preparation for decision-making; acceptability; anxiety; home safety; screening discussions; home safety discussions.
Starting date	September 2014
Contact information	Mara A Schonberg, MD, MPH; 617-754-1414; mschonbe@bidmc.harvard.edu. Gianna Aliberti; 617-754-1435; galibert@bidmc.harvard.edu.
Notes	

NCT02278900

Trial name or title	Supporting doctor-patient communication in oncology
Methods	RCT
Participants	• Norwegian-speaking cancer patients at their first consultation at the outpatient clinic with newly diagnosed cancer or relapse of cancer • Age 18 and above who has given written informed consent to participate in the stud.
Interventions	**Communication aids** Quote: "Patients in the intervention group will receive the QPL at home in advance of the consultation along with information about the clinic.The consultations will be recorded in both the control and intervention group. The recording will be done on the computer, and the patients in the intervention group will be given the recording immediately after the consultation on a memory stick."
Outcomes	**Primary outcome:** difference in number of questions asked, and especially concerning prognosis.

NCT02278900 *(Continued)*

	Secondary outcome: difference in SDM. **Other outcomes:** hospital anxiety and depression scale (HADS) score; difference in satisfaction with the consultation and information retrieved; difference in health-related quality of life
Starting date	April 2014
Contact information	Contact information is only displayed when the study is recruiting participants.
Notes	

NCT02282722

Trial name or title	Improving informed consent for palliative chemotherapy
Methods	RCT
Participants	• Diagnosis of advanced colorectal cancer with metastasis, locally advanced pancreatic cancer, or metastatic pancreatic cancer • Is considering treatment with 1st line or 2nd line chemotherapy • Treating oncologist has recommended consideration of one or more of the regimens for which we have developed informed consent materials • Age ≥ 21 • English proficiency (reading and speaking
Interventions	**Experimental:** investigational informed consent Study participant will receive investigational informed consent for chemotherapy materials that were developed by the study team. **Active Comparator:** usual informed consent Study participant will receive usual, standard-of-care informed consent for chemotherapy materials.
Outcomes	**Primary outcome** Proportion of participants at 4 months who understand the benefits of palliative chemotherapy **Secondary outcomes** • Proportion of participants with core knowledge required for informed consent • Proportion of participants with decisional conflict • Proportion of patients achieving their desired role in decision-making
Starting date	December 2013
Contact information	Deborah Schrag, MD MPH; 617-582-8301; deb_schrag@dfci.harvard.edu. Andrea Enzinger, MD; 617-582-7335; andrea_enzinger@dfci.harvard.edu.
Notes	

NCT02285881

Trial name or title	Shared decision making between patients and GPs in the treatment of Type 2 diabetes in primary care
Methods	Cluster-randomized trial
Participants	Patients with type 2 diabetes mellitus aged 60 years to 80 years
Interventions	**Experimental: shared decision making** Quote: "In the intervention practices the SDM process is used. In the SDM process the patient and GP use a decision aid to discuss the pros and cons of two evidence based treatment possibilities, according to the Dutch College of General Practitioners (NHG) versus the ADDITION guideline, and the patients' preferences for either of these treatments. Together they choose one of these treatments, and set the five treatment targets (blood pressure, cholesterol, HbA1c, smoking status and weight) in order of priority. Subsequent treatment will take place according to the priorities of these OPTIMAL treatment targets. The priorities will be evaluated every 12 months." **No Intervention: control group** Quote: "Patients in the control practices will receive treatment-as-before, which means that the patients will not be offered the structured SDM process. So the GP will treat the former ADDITION patients as they were used during the period that followed after the ADDITION study (2009), either according to the national guidelines or to the ADDITION intensive treatment algorithm."
Outcomes	**Primary outcome** The between groups difference in the proportion of patients which achieve the treatment goals for HbA1c, blood pressure, and total cholesterol. **Secondary outcomes** • The difference between groups in the proportion of patients which achieved the five treatment goals for HbA1c, blood pressure, total cholesterol, body weight, and smoking. • Characteristics of success for the SDM process in the patients in the intervention group. • The difference in health related Quality of Life between both groups at 24 months as measured with the Audit of Diabetes Dependent Quality of Life and the European Quality of Life questionnaire. • The difference in health status between both groups at 24 months as measured with the Short Form-36. • The difference in well-being between baseline and 24 months within and between both groups as measured with the Well-Being Questionnaire. • The difference in well-being between baseline and 24 months within and between both groups as measured with the Well-Being Questionnaire. • The difference in coping style between baseline and 24 months within and between both groups as measured with the Diabetes Coping Measurement Questionnaire. **Other Outcome Measures** • Process evaluation of the SDM ability of the general practitioners by using the Shared Decision Making Questionnaire.
Starting date	March 2012
Contact information	Contact information is only displayed when the study is recruiting participants
Notes	The study is completed but not published yet

NCT02328326

Trial name or title	Caring Others Increasing EngageMent in PACT (CO-IMPACT)
Methods	RCT
Participants	**Patient inclusion criteria** • Provide signed and dated informed consent form • Willing to comply with all study procedures and plan to be available for the duration of the study • Male or female, age 30-70 years old • Plan to get most diabetes care at Ann Arbor VA (Veterans Affairs) over the subsequent 12 months • Able to use telephone to respond to bi-weekly automated Interactive Voice Response (IVR) calls • Be able to identify an adult family member or friend who is regularly involved in their health management or health care (involved with medications, managing sugars, coming to appointments, etc) • Have a diagnosis of diabetes and be at high-risk for diabetes complications, defined as: (1) a diagnosis of diabetes based on encounter diagnoses from 1 inpatient or 2 outpatient encounters (OR a diabetes medication (at least one > 3-month prescription from VA drug classes HS501 (insulin) or HS502, other than metformin), (2) have an assigned VAAAHS (VA Ann Arbor Healthcare System) primary care provider and at least 2 visits to VAAAHS primary care in the previous 12 months, (3) poor glycemic control (last HbA1C > 9 or HbA1C > 8 among patients < 55 years old) OR poor blood pressure control (last BP 160/100 or mean 6-month BP > 150/90) • Active Ann Arbor VA primary care patients - at least 2 visits in last 12 months **Care partner inclusion criteria** • Validated through completion of Care Partner study screener: • Between 21 and 75 years old • Fluent in English • Have continuous phone service (land line or mobile) or internet access • Live in the United States
Interventions	**Experimental: CO-IMPACT** Quote: "Patient and supporter (dyad) receive one coaching session on action planning, communicating with providers, navigation skills and support skills; preparation by phone before patients? primary care visits; after-visit summaries by mail; and biweekly automated phone calls to prompt action on new patient health concerns." **Active comparator: PACT** Quote: "Patient and their health supporter (dyad) will receive PACT care for high-risk diabetes, which includes (at primary care team discretion): nurse care manager visits, diabetes education classes, chronic disease self-management groups, telehealth, clinical pharmacist visits."
Outcomes	**Primary outcomes:** • patient activation, as measured by Patient Activation Measure - 13; • cardiac event 5-year risk score, as measured by UKPDS Risk Engine
Starting date	November 2016
Contact information	Shelley C Stoll, MPH; (734) 845-5085; Shelley.Stoll@va.gov. Ann-Marie Rosland, MD MS; (734) 222-7621; Ann-Marie.Rosland@va.gov.
Notes	

NCT02344576

Trial name or title	PCORI-1310-06998 Trial of a decision support intervention for Patients and Caregivers Offered Destination Therapy Heart Assist Device (DECIDE-LVAD)
Methods	RCT
Participants	**Inclusion criteria** • Adult patients who have advanced heart failure and are being evaluated for DT LVAD • Caregivers of patients who are being evaluated for DT LVAD **Exclusion criteria** • Under 18 years of age • Non-English Speaking • Unable to consent • Prisoner • Already implanted with DT LVAD
Interventions	**No intervention: control:** usual care Quote: "Patients and caregivers will receive the current usual education and consent process for DT LVAD at each hospital. This often means viewing consent forms and industry materials." **Experimental: DT LVAD Decision Support Intervention** Quote: "In the intervention phase of the study, patients and caregivers will receive the new decision support intervention, which consists primarily of decision aid materials about DT LVAD. The standard consent process will also still take place, but will be supplemented with additional decision support."
Outcomes	**Primary outcomes** • Reach of Intervention (proportion of the target population who participate in the intervention) • Effectiveness of Intervention (Knowledge: DT LVAD knowledge and Values: Concordance between patients' and caregivers' values and the treatment they choose according) • Adoption of Intervention (absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program) • Implementation of Intervention (extent to which the intervention is implemented as intended) • Maintenance of Intervention (whether sites decide at the conclusion of the study to maintain, modify, or discontinue the DT LVAD decision support intervention) **Secondary outcomes** • Changes in Decision Conflict (Decision Conflict Scale) • Changes in Decision Regret (Decision Regret Scale) • Changes in Stress, Anxiety and Depression (Perceived Stress Scale, Hospital Anxiety and Depression Scale) • Changes in Quality of life (EuroQol EQ5D (patients only) • Changes in Caregiver's Preparedness for Caregiving (Preparedness for Caregiving Scale (caregivers only) • Changes in Bereaved Caregiver Satisfaction with End-of-Life Care (Canadian Health Care Evaluation Project - Bereavement Questionnaire (bereaved caregivers only) • Changes in Preferences for Control of Medical Decisions (Control Preferences Scale (patients only) • Changes in Illness Acceptance (PEACE Illness Acceptance Measure (patients only) • Changes in Patient Satisfaction with Caregiver Involvement (Canadian Health Care Evaluation Project - Patient Questionnaire (patients only) • Changes in Family Satisfaction with Patient's Care (Family Satisfaction with Care (caregivers only)

NCT02344576 *(Continued)*

	• Changes in Cognition, literacy and numeracy (Short Portable Mental Status Questionnaire; REALM-R Literacy Assessment • Changes in Patient Health Status (Medical record review (patients only)
Starting date	May 2015
Contact information	Principal investigator: Larry Allen, MD, MHS, University of Colorado School of Medicine
Notes	No contact details provided

NCT02379078

Trial name or title	Impact of an interprofessional shared decision-making and goal-setting decision aid for patients with diabetes
Methods	RCT
Participants	**Inclusion criteria** • Diagnosis of Type 1 or Type 2 diabetes and • Have 2 or more other chronic comorbidities **Exclusion criteria** • Do not speak English • Have documented cognitive deficits • Unable to give informed consent • Have limited life expectancy (< 1 year) • Not available for follow-up • Seen primarily by a resident physician • Are pregnant or considering conception
Interventions	**Experimental: Shared decision-making aid** Quote:"At study start (step 1: provider-directed intervention phase): Online shared decision-making aid, 1-page provider enabler, provider training video made available to health care providers. At 6 months (step 2: provider- and patient-directed phase): Online shared decision-making aid, 1-page patient enabler, patient training video also made available to patients (in addition to health care providers). **Placebo Comparator: Generic hard-copy diabetes resources** Quote: "At study start (step 1: Provider-directed intervention phase): A hard copy of the executive summary of the CDA CPG and postcard outlining online resources made available to health care providers. At 6 months (step 2: provider- and patient-directed phase): A CDA patient education pamphlet regarding diabetes self-management also made available to patients. In addition, provider- and patient-directed guideline dissemination tools (not incorporating SDM) will also be publicly accessible from the CDA website."
Outcomes	**Primary outcome** • Decisional conflict assessed by Decisional Conflict Scale **Secondary outcomes** • Decisional conflict assessed by Decisional Conflict Scale • Diabetes distress assessed by Diabetes Distress Scale

NCT02379078 *(Continued)*

	• Quality of Life assessed by SF-36 • Chronic illness care assessed by patient-completed questionnaires (PACIC) Intention to engage in shared decision-making assessed by provider-completed questionnaires (Theory of Planned Behaviour Intention Questionnaire)
Starting date	March 2016
Contact information	Principal investigator: Catherine H Yu, MD FRCPC, St. Michael's Hospital, Toronto
Notes	No contact details provided

NCT02429115

Trial name or title	Peer-mentoring, quality of life and caregiver burden in patients with chronic kidney disease and their caregivers
Methods	RCT
Participants	**Inclusion criteria** • Diagnosed with stage 4 or 5 CKD by a physician / or caregiver to a patient with stage 4 or 5 CKD • At least 18 years of age • Able to read and write in English at the 8th grade level • Access to computer with internet and email capability **Exclusion criteria** • Inability to provide consent • Younger than 18 years of age • Prisoners
Interventions	**Experimental:** face-to-face peer mentoring Will receive 6 months of face-to-face peer mentoring by a trained peer mentor. **Experimental:** online peer mentoring Will receive 6 months of face-to-face peer mentoring by a trained peer mentor. **No Intervention:** control Will not receive peer mentoring.
Outcomes	**Primary outcome** • Quality of Life Survey Questionnaire **Secondary outcomes** • Patient Activation Measure • Zarit Caregiver Burden Interview
Starting date	February 2015
Contact information	Tabitha Rothenberger, 717-652-8123 ext 102, Tabitha@kfcp.org and Tara Liaghat, taraliaghat@yahoo.com

NCT02429115 *(Continued)*

Notes	

NCT02507349

Trial name or title	Person-centered versus measurement-based care in mental health (PCORI-SDM)
Methods	RCT
Participants	**Inclusion criteria** • Adults age 18 and older • Serious mental illness (schizophrenia, bipolar disorder, major depression) • Receiving services at one of the 15 participating community mental health centers • At least three claims for medication management services in past 12 months • Insured by Community Care Behavioral Health Organization **Exclusion criteria** • Assessed by clinicians as being too ill to be treated on an outpatient basis • Unable to speak, read, or understand English at the minimum required level
Interventions	**Active Comparator: Person-Centered Care** Quote: "Decision support center staffed by peers. Patient uses the CommonGround program prior to medication visit to prepare a personal report, with support from peer(s). The CommonGround report expresses goals for medication, how other strategies help with functioning, current problems, and medication side effects. Patient brings report into the medication visit. Prescriber and patient discuss medication options, and prescriber enters the shared decision into CommonGround during the visit." **Active comparator: Measurement-Based Care** Quote: "Clinic staff asks each patient to use a tablet computer to complete a brief assessment of symptoms and problems prior to medication visit. Prescriber views assessment results on office computer and discusses next steps in medication management with the patient."
Outcomes	**Primary outcomes** • Patient Experience of Medication Treatment (PEMM) • Shared Decision Making Questionnaire (SDM-Q-9) **Secondary outcomes** • Hope • Medication side effects • Patient Activation Measure (PAM) • Behavior and Symptom Identification Scale (BASIS-24) • Sheehan Disability Scale • Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (QLESQ-SF) **Other outcomes** • CollaboRATE • Intervention Fidelity
Starting date	August 2014

NCT02507349 *(Continued)*

Contact information	Principal investigators: Gregory J McHugo, PhD, Dartmouth Psychiatric Research Center, The Geisel School of Medicine at Dartmouth, Kim MacDonald-Wilson, ScD, CRC, CPRP, UPMC Center for High-Value Health Care, Patricia E Deegan, PhD, Pat Deegan, PhD & Associates, LLC
Notes	No contact details provided

NCT02592525

Trial name or title	Implementing shared decision making in interprofessional home care teams (IPSDM-SW)
Methods	RCT
Participants	**Inclusion criteria** Clients or caregivers of clients • Aged ≥ 65 years • Receiving care from the IP home care team of the enrolled CISSS/CIUSSS • Have made a decision about whether to stay at home or move to another location during the recruitment periods • Are able to read, understand and write French or English • Can give informed consent In the case clients are not able to provide informed consent, their caregiver will be eligible. **Exclusion criteria** • Clients who are not able to provide informed consent and who don't have a caregiver
Interventions	**Behavioral:** IP-SDM training for health professionals Quote: "Multifaceted SDM training program for providers: i) 1.5-hour online tutorial, ii) 3.5-hour skills building workshop; iii) video-clip demonstrating SDM in the context of an IP home care team with an aging adult making a decision about location of care (to be used with clients and providers as well); and iv) performance feedback to providers (role play during the workshop)."
Outcomes	**Primary outcome** • Assumed Role in decision making **Secondary outcomes** • Patient involvement in decision making assessed with the Dyadic-OPTION scale, a 12-item self-administered instrument that assesses 12 specific SDM behaviours during the decision-making process • Decisional Regret assessed with the Decisional Regret Scale • Decisional Conflict assessed with the Decisional Conflict Scale • Health-related quality of life assessed with two subscales (Social isolation and Emotional reactions) of the HR-QoL questionnaire from the Nottingham Health Profile, clients only • Burden of care assessed with the Zarit Burden Inventory Scale (ZBI), caregivers only • Preferred and chosen option (remain at home or move to another location) Questionnaire assessing the prefered and chosen option
Starting date	November 2015

NCT02592525 *(Continued)*

Contact information	Geneviève Painchaud Guérard, MSc, 418-525-4444 ext 52581, Genevieve.Painchaud-Guerard@crchudequebec.ulaval.ca and Hubert Robitaille, PhD, 418-525-4444 ext 52341, hubert.robitaille@crchudequebec.ulaval.ca
Notes	

NCT02611050

Trial name or title	Treatment decisions for multi-vessel CAD
Methods	RCT
Participants	**Inclusion criteria** • Stable multi-vessel coronary artery disease diagnosed by coronary angiography defined as left main disease (> 50% stenosis) or multi-vessel coronary artery disease (>70% stenosis in two or more coronary arteries) • At relative equipoise for at least two potential treatment options, in which the treating cardiologist or surgeon has determined the treatments are anatomically feasible and safe. **Exclusion criteria** • Prior coronary artery bypass grafting • Unable to read or write English • Not cognitively able to participate in the Option Grid as determined by clinician
Interventions	**Experimental:** Option Grid Quote: "Patients randomized to the Option Grid arm will receive the Multi-vessel Coronary Artery Disease Option Grid at the time of enrollment. The treating physician will then discuss the patient diagnosis and treatment choice reviewing the Option Grid within the conversation to facilitate patient understanding and shared decision making" **Usual Care:** Quote: "Patients randomized to usual care will discuss the patient diagnosis and treatment options typical to the physician's routine care.2
Outcomes	**Primary outcome** • Patient Decisional Conflict **Secondary outcomes** • CollaboRATE score • Treatment knowledge • Patient experience • Clinician experience • Treatment received
Starting date	December 2015
Contact information	Principal investigator: Elizabeth L Nichols, MS, The Dartmouth Institute
Notes	No contact details provided

NCT02623335	
Trial name or title	PCORI-1502-27462 Navigating high risk surgery: empowering older adults to ask questions that iInform decisions about surgical treatment
Methods	RCT
Participants	**Surgeons** **Inclusion criteria** • Consenting surgeons at participating hospital sites who practice vascular, cardiothoracic, hepatobiliary, colorectal, urologic, gynecologic, head and neck or neurosurgery • Regularly see patients preoperatively in the surgical clinic • Perform high risk operations on older patients with multiple comorbid conditions **Exclusion criteria** • Exclusively perform minimally invasive surgery (laparoscopy), endocrine or breast surgery as these procedures are not typically considered "high risk" • Patient panel is not generally comprised of older adults considering high risk procedures **Patients** **Inclusion criteria** • Age 60 and older • One or more chronic conditions from a list comprised of those included in the Charlson Comorbidity Index with 9 additional conditions included due to their saliency to surgical decision making • Have an upcoming outpatient consultation with an enrolled surgeon to discuss treatment for a vascular or oncologic problem that can be treated with a high-risk operation • English speaking and Spanish-speaking patients who require an interpreter will be included **Exclusion criteria** • Lack decision-making capacity • Deemed too physically or mentally ill to participate by their surgeon or clinic nurse • Self-report that their vision or literacy skills are too poor to read a newspaper • Cannot speak either English or Spanish with the fluency required to have a valid medical decision-making conversation as the QPL is currently only available in English and Spanish (Spanish speaking patients who require an interpreter to speak with their surgeon will be included) • Participating surgeons may also choose to exclude specific patients for study participation based on their own concerns about the patient participating in the study, for example patients who have urgent surgical needs or don't actually have a surgical problem **Family members** **Inclusion criteria** • Family member (patient participant) is enrolled in the study • Present at time of patient enrollment in study **Exclusion criteria** • Lack decision-making capacity • Self-report that their vision or literacy skills are too poor to read a newspaper • Cannot speak either English or Spanish with the fluency required to have a valid medical decision-making conversation as the QPL is currently only available in English and Spanish (Spanish speaking patients who require an interpreter to speak with the surgeon will be included)

NCT02623335 *(Continued)*

Interventions	**Experimental:** QPL (question prompt list) brochure Patients will be mailed the QPL (question prompt list) prior to their appointment with an enrolled surgeon. **No intervention:** usual care The investigators have observed that usual care includes informed consent and a surgeon-directed deliberative phase in which surgeons present their own evaluation of the trade-offs and goals of the proposed intervention.
Outcomes	**Primary outcome** • Patient engagement in decision making measured by clinic visit transcript coding for number of and types of questions raised • Change in illness-related stress measured by participant self-report on MYCaW (Measure Yourself Concerns and Wellbeing) instrument • Perceived self-efficacy in patient-physician interactions measured by participant self-report on the PEPPI-5 scale (Perceived Efficacy in Patient-Physician Interactions). • Interpersonal conflict explored through participant self-report during qualitative interview • Post-treatment regret measured by a specific participant self-report survey item: "Looking back, is there anything about your treatment that you would do differently?" **Secondary outcomes** • Participant autonomy support measured by self-report on the HCCQ instrument • Change in patient and family psychological well-being measured by self-report on the PROMIS scale • Patient treatment received measured by chart review • Physician engagement with patient measured by clinic visit transcript coding using OPTION coding system
Starting date	February 2016
Contact information	Principal investigators: Gretchen Schwarze, University of Wisconsin, Madison, Emily Finlayson, University of California, San Francisco, Zara Cooper, Brigham and Women's Hospital, Anne Mosenthal, Rutgers New Jersey Medical School, Ana Berlin, Rutgers New Jersey Medical School, Karen Brasel, Oregon Health and Science University
Notes	No contact details provided

NCT02631200

Trial name or title	Advance Care Planning with older patients who have End-stage Kidney Disease (ACREDiT)
Methods	RCT
Participants	**Inclusion criteria** • Attending the renal units taking part in the study • Receiving renal replacement therapy • Capacity to understand, retain, and weigh the necessary information and communicate their decisions • Identified by their consultant as having worsening symptoms, functional decline, and two or more co-morbidities. **Exclusion criteria**

NCT02631200 *(Continued)*

	• Expected to die in the next three months
Interventions	**Experimental:** Advance care plan Participants will be offered the opportunity to complete an advance care plan. **No Intervention:** usual care Participants will be offered usual care for 12 weeks (and only then be offered the opportunity to complete an advance care plan).
Outcomes	**Primary outcome** • Quality of life as measured by the Kidney Disease Quality of Life instrument - Short Form (KDQOL-36™) **Secondary outcomes** • Agreement between the patient and their nominated carer in terms of the patient's preferences, measured by asking the carer to make an independent assessment of the patient's preferences in relation to the key information covered by the ACP intervention, before taking part in the ACP • Degree of depression as measured by the Clinical Outcomes in Routine Evaluation measure (CORE 34) • The degree to which the patient felt that they had shared in decision-making about their care as measured by the Patient Experience of Shared Decision Making (SHARED) instrument
Starting date	December 2016
Contact information	Peter D O'Halloran, PhD, +44 (0) 289097 2490, p.ohalloran@qub.ac.uk and Helen Noble, PhD, +44 (0) 289097 2472, helen.noble@qub.ac.uk
Notes	

NCT02646423

Trial name or title	Effect of a patient-centered decision app on TOLAC (PROCEED)
Methods	RCT
Participants	**Inclusion criteria** • Women with exactly one prior Cesarean Delivery (CD) • Current singleton pregnancy • Gestational age, 16-24 weeks • English or Spanish speaker • Must be receiving prenatal care at one of the participating centers **Exclusion criteria** • Contraindications to vaginal delivery (e.g. placenta previa, prior classical cesarean, previous uterine rupture) • Prior VBAC (Vaginal delivery after Caesarean)
Interventions	**Experimental:** Prior CD Decision App (PCDDA) Quote: "Women who are randomized to PCDDA will be provided access to a tablet which they can use to view the Prior CD Decision App at their own pace. The research assistant will print a summary of the participant's predicted likelihood of a VBAC if she undergoes a trial of labor after Cae-

NCT02646423 *(Continued)*

	sarean (TOLAC), as well as her answers to the values clarification exercises, that she can review and share with whomever she chooses, including her provider." **No intervention:** Usual care - No App Quote "Women randomized to the Usual Care - No App group will simply continue with usual care."
Outcomes	**Primary outcome** • Delivery Approach - TOLAC or ERCD (elective repeat Caesarean delivery) **Secondary outcomes** • Actual Delivery - Vaginal or cesarean delivery among women who undergo TOLAC • Knowledge about TOLAC and ERCD: 8-item knowledge scale, adapted from Bernstein et al (2012), administered during telephone interview • Decisional Conflict: 16-item Decisional Conflict Scale, developed by O'Conner et al (1995), administered during telephone interview • Shared Decision Making: 9-item Shared Decision Making Scale, adapted from Kriston et al. (2010), administered during telephone interview • Decision Self-Efficacy: 11-item Decisional Self-Efficacy Scale, developed and modified by O'Conner et al. (1995, 2002), administered during telephone interview • Decision Satisfaction: 6-item Satisfaction with Decision Scale, developed by Holmes-Rovner et al (1996), administered during telephone interview
Starting date	January 2016
Contact information	Miriam Kuppermann, PhD, MPH, (415) 502-4089, miriam.kuppermann@ucsf.edu
Notes	

NCT02653170

Trial name or title	Michigan Stroke Transitions Trial (MISTT)
Methods	RCT
Participants	**Patient inclusion criteria** • A final confirmed hospital diagnosis of acute stroke (ischemic or hemorrhagic) • Patient living at home pre-stroke • Presence of stroke-related deficits at admission (defined as a National Institute of Health Stroke Severity score of >=1) • Presence of at least mild functional limitations at discharge (defined as a modified Rankin score [mRS] score of >=1), or therapy ordered • Discharged directly home (includes patient's residence or that of a family member) • Discharged to a rehabilitation facility (IRF or SNF) with the expectation of return to home within 4 weeks **Patient exclusion criteria** • Patients who live more than 50 miles from the hospital (for reasons related to the home visits) • Patients discharged to nursing home, hospice care or LTCH (Long-term care hospital) • Patients who have clinically documented cognitive deficits or stroke-related impairments including aphasia sufficient to impact the consent process and for whom a proxy respondent is not available

NCT02653170 *(Continued)*

- Patients who fail the 6-item cognitive screening (SIS-6) for cognitive impairment (score <=4) and for whom a proxy respondent is not available
- Patients enrolled in another acute stroke intervention trial that has a significant impact on the post-acute period (i.e. intensive data collection required of patient during follow-up)
- Limited life expectancy (< 6 months) or significant medical comorbidity likely to impact completion of the study (e.g., severe mental illness, drug or alcohol use or dependence, metastatic cancer)
- Neither the patient nor caregiver speaks English

Caregiver inclusion criteria

- Age 18 or over.
- Are identified by the stroke patient as the primary caregiver (individual who has primary responsibility for assisting with the patient's care).
- Speaks English.

Interventions

No intervention: usual care

Patients in this group will receive the hospitals' usual transitional care approach.

Experimental: SCM

One intervention is provided:

- SCM (Stroke Case manager): a trained social worker who provides in-home case management services.

Experimental: SCM and VSSP

Two interventions are provided:

- SCM (Stroke Case manager): a trained social worker who provides in-home case management services. Plus:
- VSSP (Virtual Stroke Support Portal): Access and training in the use of the VSSP: a purpose-built, online, patient-centered information and support resource.

Outcomes

Primary outcomes

- PROMIS-10 Global Quality of Life (Patient): Patient-centered questionnaire of 10 self-reported items addressing the 2 main quality-of-life domains of physical and mental health which include physical health, physical function, pain, fatigue, quality of life, mental health, satisfaction with social activities, and emotional problems.
- Bakas Caregiving Outcomes Scale (Caregiver): 15-item instrument designed to measure life changes in response to providing care to stroke survivors.

Secondary outcomes

- Patient Activation Measure (Patient): Patient questionnaire to assess self-efficacy and activation in managing one's own healthcare
- Depression symptoms (PHQ-9) (Caregiver): Validated 9-item questionnaire to identify depressive symptoms

Other outcomes

- NeuroQOL anxiety scale (Patient): Validated QOL scale measuring patient anxiety (administered by computer adaptive testing)
- Depression symptoms (PHQ-9) (Patient): Validated 9-item questionnaire to identify depressive symptoms
- Hospital readmission (Patient): Unscheduled hospital admissions
- Stroke recurrence (Patient): New onset acute stroke events requiring hospital admission
- Home Time (Patient): Total number of days spent at home since discharge back to home

NCT02653170 *(Continued)*

	• Oberst Caregiver Burden Scale (OCBS) (Caregiver): Validated 15-item questionnaire measuring caregiver burden in response to providing care to stroke survivors • Unhealthy days (Caregiver): Number of days in the past 30 days that the caregiver reported that their own physical or mental health had not been good • PROMIS emotional support scale (Caregiver): A validated 4-item questionnaire measuring emotional support • PROMIS informational support scale (Caregiver): A validated 4-item questionnaire measuring informational support
Starting date	January 2016
Contact information	Michele C Fritz, BSc, LVT, 517-353-8623 ext 209, mfritz@epi.msu.edu and Mathew J Reeves, BVSc, PhD, 517-353-8623 ext 130, reevesm@msu.edu
Notes	

NCT02663245

Trial name or title	INTEGRA Study: Primary care Intervention in Type 2 diabetes patients with poor glycaemic control
Methods	NRCT
Participants	**Inclusion criteria** • Diagnosis of Type 2 DM according to criteria of the World Health Organization of one or more years of disease duration • Age from 30 to 80 years • HbA1C ≥ 9% (DCCT) according to the last blood test carried out during the 12 months prior to inclusion in the study • No changes in the treatment that can influence the main variable during the 3 months prior inclusion in the study • Accepting to participate in the study and signing of the informed consent form **Exclusion criteria** • Patient refuses to participate and any other condition that prevents signing the informed consent form • Other types of diabetes: Type 1 DM, gestational diabetes and diabetes secondary to other diseases • Pharmacological treatments that interfere with carbohydrate metabolism, such as steroids • Life expectancy under 2 years • Current treatment for cancer other than basocellular or epidermoid skin cancer • Severe mental disease and dementia • Heart failure Class III or IV (NYHA). • Renal transplant or current treatment with dialysis • Alcohol and drug abuse • Pregnancy or intention to get pregnant • Breastfeeding • Chronic treatment with steroids; treatment with steroids during the 2 months prior inclusion in the study • Pharmacological treatment for weight loss during the 2 months prior to inclusion in the - study • Treatment with immunosuppressants • Haemoglobinopathies and chronic anemia • Body Mass Index > 45 mg/kg2 (1) • Participation in clinical trials for medicines.

NCT02663245 *(Continued)*

	• Patients with conditions that prevent follow up and completion of protocol.
Interventions	**Experimental:** intervention 1 Diabetes specific consultation + multicomponent intervention aimed at professionals and patients **Experimental:** intervention 2 Multicomponent intervention aimed at professionals and patients minus the diabetes specific consultation. **No Intervention:** control group No intervention. Data of the control groups will be retrieved from the SIDIAP.
Outcomes	**Primary outcome** • Glycaemic control measured by HbA1c **Secondary outcomes** • Lipid profile control as measured by the mean concentration of LDL-cholesterol, non-HDL cholesterol and triglycerides • Measurement of systolic blood pressure and of diastolic blood pressure • Control of chronic complications associated with type 2 diabetes according to the protocol of the CIH • Patient self-efficacy to implement changes in risk factors: Morisky-Green questionnaire • Direct health costs of type 2 diabetic patients • Evaluation of patient satisfaction using Spanish version of diabetes treatment satisfaction questionnaire (DTSQ) • Control of risk factors, smoking and exercise: Patient Activation Measure questionnaire • Evaluation of therapeutic inertia: specific questionnaire created by Redgedaps • Evaluation of quality of life using Spanish version of diabetes quality of life questionnaire (EsDQOL)
Starting date	December 2015
Contact information	Esther Rubinat, PhD, RN, 646186720, rubinatesther@gmail.com
Notes	

NCT02668900

Trial name or title	Decision support for adults facing implantable cardioverter-defibrillator pulse generator replacement
Methods	RCT
Participants	**Inclusion criteria** • ICD (implantable cardioverter-defibrillator) battery nearing depletion or at elective replacement indicator • Able to speak and read in English • Able to provide informed consent; or if incapable of providing informed consent, can be obtained by the patient's appointed substitute decision-maker or power of attorney for personal care. **Exclusion criteria**

NCT02668900 *(Continued)*

	• Participants and/or substitute decision maker unable to understand the patient decision aid or decision coaching session due to language barrier or visual impairment • Participants with cardiac resynchronization therapy (CRT) or participants eligible for an upgrade to CRT. • Participants with conduction system disease who are pacemaker dependent
Interventions	**Experimental:** decision support Quote: "The decision support intervention includes a patient decision and a decision coaching session. The patient decision aid includes a summary about the ICD's function, and the risks and benefits (including probabilities) associated with the option of replacing or not replacing the ICD. The decision coaching session will be led by a trained, non-directive decision coach who will provide support that aims to develop patients' skills in thinking about the options, assess their values associated with each option, and prepare them to discuss the decision in a consultation with their physician. The final decision, whether to replace or not replace the ICD, will be made with their treating physician (e.g., cardiologist, electrophysiologist)." **No intervention:** usual care Quote: "The control group will not receive the decision support intervention prior to consultation with the physician."
Outcomes	**Primary outcomes** • Participant referral/recruitment rate • Completion of decision support intervention • Key processes to the success **Secondary outcomes** • Knowledge • Decisional conflict • Values about ICD replacement • Preferred option • Perceptions of involvement in decision-making • The Medical Outcomes Trust Short Form (SF-36v2) • Acceptability and Usability of Decision Support **Other outcomes** • Actual choice • Survival
Starting date	April 2016
Contact information	Krystina B Lewis, RN, MN, kblewis@ottawaheart.ca and David Birnie, MD, 613 696 7269, dbirnie@ottawaheart.ca
Notes	

NCT02674360

Trial name or title	RCT regarding SDM online training andfFace-to-face SDM training
Methods	RCT
Participants	I**nclusion criteria**

NCT02674360 *(Continued)*

	• Oncologists or physicians treating a significant percentage of breast and/or colorectal cancer patients • Internet access **Exclusion criteria** • No exclusion criteria
Interventions	**Active comparator:** SDM Online Training Quote: "The intervention consists of a SDM training for oncologists, which is conducted in the form of a web-based SDM online Training (intervention group I). During training, the oncologists are guided to use decision aids for breast and colon cancer patients in their consultations, which were developed and evaluated in a previous project. The SDM training has the same duration (one session à 120 minutes) in both intervention groups. Doctors in the intervention group receive decision aids for breast cancer and colorectal cancer patients during training. The training contents are based on an already developed, evaluated and published SDM manual. The SDM online training works on the modeling principle." **Active comparator:** Face-to-Face SDM Training Quote: "The intervention consists of a SDM training for oncologists, which is conducted in the form of an individualized, context-based SDM individual face-to-face training at the workplace of the participants (intervention group II). During training, the oncologists are guided to use decision aids for breast and colon cancer patients in their consultations, which were developed and evaluated in a previous project. The SDM training has the same duration (one session à 120 minutes) in both intervention groups. Doctors in the intervention group receive decision aids for breast cancer and colorectal cancer patients during training. The training contents are based on an already developed, evaluated and published SDM manual. The individual training works on the coaching principle." **No intervention:** Control Group Quote: "The Control Group receives no SDM Training. All participants of the Control Group will be offered to participate in the SDM Online Training after T2."
Outcomes	**Primary outcome** • Change from baseline in SDM competence measured by an objective Rating (OPTION) **Secondary outcomes** • Change from baseline in SDM competence by subjective standardized patient rating (Dyadic Option) • Change from baseline in SDM competence by subjective standardized patient rating (Patient Perception Scale) • Change from baseline in SDM competence by subjective standardized patient rating (SDM-Q-9) • Change from baseline in SDM competence by subjective physician rating (Dyadic Option) • Change from baseline in SDM competence by subjective physician rating (Physician-Perception-Scale) • Change from baseline in SDM competence by subjective physician rating (SDM-Q-9) • Change from baseline in quality of doctor-patient-interaction by subjective Patient rating (Questionnaire on the Quality of physician-patient interaction) • Change from baseline in quality of doctor-patient-interaction by subjective Physician rating (Questionnaire on the Quality of physician-patient interaction)
Starting date	May 2016
Contact information	Kathrin M Gschwendtner, Dr, +49 6221/56-34587, kathrin.gschwendtner@med.uni-heidelberg.de

NCT02674360 *(Continued)*

Notes	

NCT02686775

Trial name or title	The PACO Project: A Clinical Study of a PAtient COach Program in vulnerable lung cancer patients (PACO)
Methods	RCT
Participants	**Inclusion criteria** • Diagnosed with non-small cell lung cancer or small cell lung cancer • Referred for further treatment at the oncology ward OR • Must either 1) Live alone (irrespective of education) or 2) Have no formal education beyond secondary school, or 3) Have one or more comorbidities, or 4) a performance status of 1-2, or 5) be more than 65 years old at time of inclusion. **Exclusion criteria** • Dementia • Being institutionalized • No proficiency of Danish
Interventions	**Experimental:** patient coach Standard care and patient coach. 5 face-to-face sessions of approximately 1-2 hours duration and 3 phone calls from inclusion to one month after end of first line treatment. Deviations from this schedule might depend on the treatment modules and on the wishes and needs of the patient. Several patients will continue directly into palliative care and the coach will thus support this transition. **Active Comparator:** standard treatment Standard care
Outcomes	**Primary outcome** • Receipt of first-line treatment according to clinical guidelines reported as a binary variable (yes/no) **Secondary outcomes** • Differences between groups in overall quality of life using the generic EORTC QLQ-C30 questionnaire (overall quality of life and functioning levels) and the lung cancer specific questionnaire QLQ-LC13 (symptoms) • Differences between groups in patient knowledge, skill, and confidence for self-management as assessed by the Patient Activation Measure (PAM) questionnaire • Differences between groups in patients beliefs in the ability to deal efficiently with a wide range of stressors as assessed by the General Self-Efficacy Scale questionnaire • Participation in self-management plans regarding smoking cessation reported as binary variable (yes/no) as assessed by a study specific questionnaire and medical records • Differences between groups in depression and anxiety as assessed by the Hospital Anxiety and Depression Scale (HADS)
Starting date	January 2016

NCT02686775 *(Continued)*

Contact information	Trille Kjaer, Postdoc, +4535257608, trille@cancer.dk and Susanne O Dalton, Senior researcher, sanne@cancer.dk
Notes	

NCT02721810

Trial name or title	Patient Engagement Initiative (PEI)
Methods	RCT
Participants	**Inclusion criteria** • Licensed physicians • At least 4 weeks of clinical work in an I.C.U. in the U.S.A. during the past 12 months **Exclusion criteria** • < 25 years old • Non-English speaking • Primarily practicing medicine outside the USA
Interventions	**No intervention:** control Prompts standard to rounds or electronic medical records **Experimental:** prompting Intervention Prompting consideration of 3-month functional outcome
Outcomes	**Primary outcome** • Presence of acceptable treatment option as assessed by a checklist completed by clinical colleges. **Secondary outcomes** • Level of conflict with proxy with a previously validated single question • Level of shared decision-making measured using CollaboRATE scale • Prevalence of communication skills for involving ICU proxies in treatment decisions assessed by a checklist completed by clinical colleges • Medical interactions assessed using the Roter Interaction Analysis System (RIAS) • Prevalence of the discussed option of stopping life support as assessed by blinded assessors • Prevalence of conveying prognosis as assessed by blinded assessors • Level of shared decision-making measured using CollaboRATE scale as assessed by blinded assessors • The Observer OPTIONS5 measure completed by blinded assessors • Consulting services requested by study participants
Starting date	October 2016
Contact information	Alison E Turnbull, DVM,MPH,PhD, (410)-955-2190, turnbull@jhmi.edu
Notes	

NCT02759939

Trial name or title	Right For Me: Birth control decisions made easier
Methods	RCT
Participants	**Inclusion criteria** • Completed a healthcare visit at a participating clinic • Assigned female sex at birth • Aged 15 to 49 years • Able to read and write English or Spanish • Not previously participated in the study **Exclusion criteria** • Not completed a healthcare visit at a participating clinic (including a patient's parent or a person acting as a patient's legal proxy) • Not assigned female sex at birth • Aged under 15 or over 49 years • Unable to read and write English or Spanish • Previously participated in the study
Interventions	**Experimental: Arm 1** Video + prompt card **Experimental: Arm 2** Decision aids + training **Experimental: Arm 3** Video + prompt card and decision aids + training
Outcomes	**Primary outcome measure** • Shared decision-making about contraceptive methods **Secondary outcome measures** • Conversation about contraception • Satisfaction with conversation about contraception • Intended contraceptive method(s) • Intention to use a highly effective contraceptive method • Values concordance of intended contraceptive method(s) • Decision regret about intended contraceptive method(s) • Contraceptive method(s) used • Adherence to contraceptive method(s) used • Satisfaction with contraceptive method(s) used • Unintended pregnancy (pregnancy timing preferences) • Unintended pregnancy (pregnancy seeking) • Unwelcome pregnancy **Other outcomes** • Exposure to video • Exposure to prompt card • Use of three questions

NCT02759939 *(Continued)*

	• Exposure to decision aid(s) • Acceptability of video • Acceptability of decision aid(s)
Starting date	July 2016
Contact information	Principal investigator: Rachel Thompson, PhD, Dartmouth College
Notes	No contact details provided

NCT02823262

Trial name or title	A breast cancer treatment decision aid for women aged 70 and older
Methods	RCT
Participants	**Inclusion criteria** • Phase I: Patient age ≥ 70 yrs. Female patient diagnosed with a first primary ER+, HER2-, LN-, 3 cm or less breast cancer > 6 months ago but < 2 years ago. Caregiver age >21 years. English speaking. • Phase II: Female patient age ≥ 70 yrs newly diagnosed with a first primary ER+, HER2-, LN-, 3cm or less breast cancer. Women newly diagnosed with breast cancer on the day of surgical consult. **Exclusion criteria** • Phase I: Patient Age < 70 years. Women diagnosed with Paget's disease, inflammatory breast cancer or a phyllodes tumor. Signs of Dementia. Score >10 on the Orientation-Memory-Concentration (OMC) test. Non-English Speaking; caregiver age < 21 years. Women who do not have capacity to participate. --- Before enrolling women in this study, possible participants will be asked 7 questions about the benefits and risks of the study. Women who answer 3 or more of these questions incorrectly will be excluded. • Phase II: Women with a history of breast cancer (invasive and non-invasive). Diagnosed with Paget's disease, inflammatory breast cancer or a phyllodes tumorSigns of Dementia Score > 10 on the OMC test (indicative of dementia). Women who do not have capacity to participate. --- Before enrolling women in this study, possible participants will be asked 7 questions about the benefits and risks of the study. Women who answer 3 or more of these questions incorrectly will be excluded.
Interventions	**Experimental: decision aid** **Post Initial Surgical Consultation** • Including background questionnaire and randomization into decision aid group or control group: • The Decision Aid Group (workbook and CD) explains each treatment including its benefits and risks.-- The DA asks women 10 questions about their health;the response to each question is associated with a point value and women are asked to tally their points. The DA groups women into 4 health categories based on their health score. • Assessment at one week after participants surgical consultation and five months after surgical consultation **Active Comparator: No decision aid** **Post Initial Surgical Consultation** • Including background questionnaire and randomization into decision aid group or control group: • Participant will receive usual care assistance when making treatment decisions.

NCT02823262 *(Continued)*

	• Assessment at one week after participants surgical consultation and five months after surgical consultation
Outcomes	**Primary outcome** • Change in Decisional Conflict Scale at 1 week **Secondary outcomes** • Knowledge score using our knowledge test • Change in Stage of decision-making at one week using one-item tool • Self-efficacy using 11-item scale • Values using importance scale 1-10 • Treatment preferences using two-item tool • Desired role in decision-making using one-item tool • Anxiety using 6-item Spielberger State-Trait Anxiety Inventory short-form • Quality of Life using the SF-12 physical and mental component scores • Preparation for decision-making using 10 items (1-5 scale) • Actual role in decision-making using one-item tool • Decision Regret using one-item tool • Satisfaction with treatment decision using 4-item tool • Satisfaction with the decision process using 4-item tool • Treatment received using chart abstraction • Acceptability using 0-3 scale
Starting date	July 2016
Contact information	Mara Schonberg, MD MPH, 617-754-1414
Notes	

NCT02842047

Trial name or title	The mediating effects of decentering on self-management of stress and end of life planning
Methods	RCT
Participants	**Inclusion criteria** • Caregivers of patients who have been diagnosed with Stage IV gastrointestinal (GI) or gynecological (GYN) cancer • Coming with the patient at the Seidman Comprehensive Cancer Center at University Hospitals Case Medical Center (UHCMC) • Have access to the internet and a computer, tablet, or smart phone • Speak and comprehend English **Exclusion criteria** • Currently practicing mindfulness-based interventions (yoga, meditation, deep breathing) • Require psychotherapy within the last three months • Have a history of dementia, major neurological illness • Pregnant • History of a medical condition or procedure that is contraindicated for functional magnetic resonance imaging (fMRI) scanning (i.e. cardiac pacemaker, sternal wires, or metal implants) • Claustrophobia requiring anxiolytics or sedation

NCT02842047 *(Continued)*

	• Expect to relocate from Northeast, Ohio within 2 months
Interventions	**Experimental:** End of Life Care with Meditation Quote: "The intervention has two content components: end of life planning education (using end of life planning videos) and strategies and kindness based meditation (using the Stop, Breathe & Think™ app). The activities comprising these components work together to improve both analytic neural processing (e.g. improving knowledge about goal setting and EOL (end-of-life) planning, learning self-monitoring of EOL values and goals of care, and self-regulation skills of monitoring symptoms of distress and anxiety) and emotional neural processing (e.g. teaching participants to experience the moment non-judgmentally and directing thoughts to think positive thoughts and feel positive feelings like kindness and compassion." **Active Comparator:** Meditation Only Quote: "This arm has the single content component of kindness based meditation delivered by using the Stop, Breathe & Think™ application. This group will also be instructed to view 3 caregiver wellness videos."
Outcomes	**Primary outcome** • Repeated Measures ANCOVA Model (F-Statistic) **Secondary outcomes** • Change in National Comprehensive Cancer Network (NCNN) Distress Thermometer Score • Change in Degner's Decisional Control Scale • Change in End of Life Value • Change in PROMIS-29 Scale • Change in O'Connor's Decisional Regret Scale • Change in FAMCARE (Family satisfaction with advanced cancer care) Scale
Starting date	July 2016
Contact information	Principal investigator: Sara Douglas, PhD, RN, Case Comprehensive Cancer Center
Notes	No contact details provided

NCT02866799

Trial name or title	Multi-PAP RCT: Improving prescription in primary care patients with multimorbidity and polypharmacy (Multi-PAP)
Methods	RCT
Participants	**Inclusion criteria** • Patients 65-74 years of age with multimorbidity (3 or more chronic diseases) and polypharmacy (5 or more drugs taken for at least three months) • Informed consent **Exclusion criteria** • Institutionalized patient at nursing homes or similar • Life expectancy < 12 months
Interventions	**Experimental:** multi-PAP intervention

NCT02866799 *(Continued)*

	Complex intervention with general practitioners and patients **Active comparator:** usual care Patients will receive the usual clinical care
Outcomes	**Primary outcome** • Medication Appropriateness Index (MAI) score **Secondary outcomes** • Medication Appropriateness Index (MAI) score • Morisky-Green questionnaire • Haynes-Sackett test • Euroqol 5D-5L questionnaire • Use of health services • Medication safety • Patient perception of shared decision-making
Starting date	November 2016
Contact information	Principal investigators: Alexandra Prados-Torres, MD, PhD, Instituto Aragonés de Ciencias de la Salud (IACS), Daniel Prados-Torres, MD, PhD, Servicio Andaluz de Salud (Andaluz Health Service), Isabel Del Cura-González, MD, PhD, Gerencia de Atención Primaria, Madrid
Notes	No contact details provided

NCT02868983

Trial name or title	Integrating Behavioral Health and Primary Care for comorbid behavioral and medical problems (IBHPC)
Methods	RCT

Participants	**Inclusion criteria**
	
	• Over 18 years of age
	• At least one target chronic medical condition:
	  * arthritis
	  * asthma
	  * chronic obstructive lung disease
	  * diabetes
	  * heart failure
	  * or hypertension.
	• Evidence of a behavioral problem or need
	• Diagnosis of:
	  * anxiety
	  * chronic pain including headache
	  * depression
	  * fibromyalgia
	  * insomnia
	  * irritable bowel syndrome
	  * problem drinking
	  * substance use disorder

NCT02868983 *(Continued)*

	• OR persistent use of certain medications used for behavioral concerns:
	  * antidepressants
	  * anxiolytics
	  * opioids
	  * antineuropathy agents
	• OR persistent failure to attain physiologic control of a medical problem:
	  * blood pressure>165 while on 3 or more medications
	  * A1C > 9% for 6 months)
	  * OR the presence of three or more of the target chronic medical conditions.
	
	Exclusion criteria
	
	No exclusions apply.

Interventions	**Experimental:** Integration The intervention consists of training for practice leaders, BHCs, PCPs, and office staff, a Protocolized Redesign Process support for practice redesign, and a toolkit of suggested tactics for implementing Tasks A through D: A. Identification B. Assessment C. Treatment D. Surveillance No Intervention: Co-Location A Behavioral Health Clinician (BHC) such as a psychologist or counselor is housed in or near the primary care practice.
Outcomes	**Primary outcome** • PROMIS-29 v2 (Change in general health) **Secondary outcomes** • CAHPS 12-Month PCMH Adult Questionnaire 2.0 • Consultation and Relational Empathy measure • Patient Activation Measure-13 • Modified Self-reported Medication-taking Scale • Patient Report of Utilization • Restricted Activity Days • Duke Activity Status Index • Hgb A1C • 30-day use • Global Appraisal of Individual Needs - Short Screener • Systolic blood pressure • Asthma Symptom Utility Index
Starting date	April 2016
Contact information	Principal investigator: Benjamin Littenberg, MD, University of Vermont
Notes	No contact details provided

NCT02890615

Trial name or title	CanDirect: Effectiveness of a telephone-supported Depression Self-care Intervention for Cancer Survivors (CanDirect)

NCT02890615 *(Continued)*

Methods	RCT
Participants	**Inclusion criteria** • Completed primary cancer treatment (surgery, radiation and/or chemotherapy) for any type of cancer (NB: patients receiving adjuvant therapies will be eligible) • Between 1-10 years post-diagnosis (as suggested by clinicians collaborating on the project) • With moderate depressive symptoms (PHQ-9 score of 8-19) **Exclusion criteria** • Metastatic disease • Suicidal • Moderate-severe cognitive impairment • Unable to speak and read in English or French • Only non-melanoma skin cancer (without any other single primary cancer) • Receiving ongoing psychological treatment at baseline (because of recent finding that this treatment may negatively modify the effectiveness of the coaching component of the intervention). NB: those who begin psychological treatment during follow-up will not be withdrawn • Dose of antidepressant medication changed within last 6 weeks at baseline. NB: those who change dose or treatment during follow-up will not be withdrawn
Interventions	**Experimental:** Depression Self-care Intervention (SCI) Quote: "Intervention group participants will receive the Depression Self-Care Toolkit for Cancer Survivors and will be supported by telephone by a coach who will help to activate them, guide them through the materials, help in selecting appropriate tools, and provide positive reinforcement. Coach contacts will be made every week for 3 months followed by 3 monthly contacts, up to a maximum of 15 contacts, lasting 10-20 minutes each. The coach uses a stepped approach (i.e. educate about depression, initiate mood monitoring, determine participant's goals with respect to reducing depressive symptoms, and help with the use of specific tools). A suggested script is provided for the coach as a framework for each call. Tailoring of the SCI to different participants will be based on problems, depressive symptoms (from the PHQ-9), or concerns a participant may raise during the call." **No Intervention:** Control group Quote: "Members of both groups will continue to receive "usual care" for their depression. We will not interfere with usual care beyond recommending that participants discuss their depressive symptoms with their doctor. If participants consent, a short progress report will be send to their treating physician at the end of the study. At each follow-up, we will ask participants about specific treatment they have received for depression since entering the study (antidepressant medication initiation, discontinuation, change of dose, or psychotherapy) and use of community resources. The Intervention group will receive the Depression SCI. The Control group will receive only usual care for 6 months after randomization; they will be given the Toolkit with a single coaching call upon completion of the final interview, to ensure their access to depression treatment."
Outcomes	**Primary outcome** • Change in severity of depression symptoms: Centre for Epidemiologic Studies Depression Scale (CES-D) **Secondary outcome measures** • Change in severity of anxiety symptoms: Hospital Anxiety and Depression Scale - Anxiety subscale (HADS-Anxiety) • Change in mental and physical health-related quality of life: Short Form health survey (SF-12) • Change in activation: Patient Activation Measure (PAM)

NCT02890615 *(Continued)*

	• Change in depression diagnosis: Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders - IV Disorders (SCID) • Change in use of health services: doctor office and clinic visits, emergency room visits, hospitalizations, psychosocial treatment or support group participation, changes in cancer diagnosis or treatment
Starting date	July 2016
Contact information	Manon de Raad, 514-345-3511 ext 3074, manon.deraad@ssss.gouv.qc.ca
Notes	

NCT02905032

Trial name or title	SDM for stroke prevention in atrial fibrillation (SDM4Afib)
Methods	RCT
Participants	**Clinician inclusion criteria** • All clinicians (MDs, NP/PAs, PharmDs) that are responsible for the modality of anticoagulation in eligible AF patients at participating sites, without exclusion **Patient inclusion criteria** • ≥ 18 years of age • Chronic nonvalvular atrial fibrillation deemed at high risk of thromboembolic strokes (CHA2D2-VASc Score ≥ 1, or 2 in women) • Able to read and understand (despite cognitive, sensorial, hearing or language challenges) the informed consent document as determined by the study co-ordinator during consent **Patient exclusion criteria** • Clinician indicates that patient is not a candidate for a discussion about anticoagulation medication
Interventions	**No intervention:** standard care Observations in clinical encounter via video, audio or observational notes. **Active comparator:** standard care + decision aid Observation of clinical encounter using the decision aid via video, audio, or observational notes.
Outcomes	**Primary outcome** • SDM Quality - knowledge transfer, knowledge of risk, collaborative agreement, patient decision satisfaction, quality of communication, patient satisfaction with encounter, clinician satisfaction. **Secondary outcomes** • SDM processes • Anticoagulation use
Starting date	September 2016
Contact information	Principal investigator: Peter A Noseworthy, Mayo Clinic

NCT02905032 *(Continued)*

Notes	No contact details provided

NCT02917603

Trial name or title	Shared decision making to improve palliative care in the nursing home
Methods	RCT
Participants	**Inclusion criteria** • Residents: residents of The Bluffs nursing home, Columbia Missouri, over the age of 65, have at least one family member who agrees to participate, and have a serious life-limiting illness. Residents enrolled in hospice or admitted to post hospital short-term nursing home stay are excluded from participation. • Family Members: identified family member by a resident or nursing home staff at The Bluffs, over the age of 18, without cognitive impairment, and with access to a computer, tablet, or smart phone device. **Exclusion criteria** • Residents enrolled in hospice can not participate.
Interventions	**Experimental: i**ntervention These family members and residents will use web conferencing technology to attend their quarterly care conferences **No Intervention:** control These families and residents will receive usual care
Outcomes	**Primary outcome measure** • Patient Health Questionaire 9 **Secondary outcomes** • Zarit Burden Interview • Nursing Facility Family Satisfaction • Minimum Data Set 3.0 Pain • Patient Perceived Involvement in Care Survey • Leeds Attitude to Concordance • Generalized Anxiety- 7 • Caregiver quality of life
Starting date	September 2016
Contact information	Debra Oliver, PhD, 573-884-5301, oliverdr@health.missouri.edu and Karla Washington, PhD, (573) 884-2119, washingtonkar@health.missouri.edu
Notes	

NCT02920086

Trial name or title	Improving partnerships with family members of ICU patients (IMPACT)
Methods	RCT
Participants	**Inclusion criteria for patients** • Have a projected duration of mechanical ventilation of >72 hours from time of screening • Have a family member who meets the following criteria **Inclusion criteria for family member** • 18 years of age or older • Present and expected to visit regularly (minimum about 3 times a week) while the patient is in hospital • The nominated or legally appointed substitute decision-maker • Able to communicate in English (verbally and in writing). **Exclusion criteria** • Patients who are not expected to remain alive in ICU for 72 hours after initial screening (physician judgment) or for whom life-sustaining treatments are expected to be withdrawn in the subsequent 72 hours (as sufficient time will be required for implementation of the study interventions) • Uncomplicated elective surgical patients (regardless of age) • Patients receiving long-term tube feeding pre-admission or those who are not anticipated to resume oral intake because of pre-existing swallowing problems (severe dysphagia, stroke, etc.) as they may not benefit from the nutritional intervention • Patients who have received organ transplantation during this hospitalization
Interventions	**Experimental:** Nutrition Education Program Nutrition education for family members of an elderly critically ill patient **Experimental:** Decision Support Program Decision support education for family members of an elderly critically ill patient **No Intervention:** usual care No intervention
Outcomes	**Primary outcomes** • Nutritional adequacy during the ICU stay • Consumption of Oral Nutritional Supplements • Intake on hospital wards (3-day calorie count) • Hand grip strength • Use of shared-decision making (OPTION tool) • Change in decisional conflict (10-item Decisional Conflict Scale) • Family satisfaction with decision-making • Overall family satisfaction with ICU
Starting date	January 2017
Contact information	Daren Heyland, MD, 613-549-6666 ext 3339, dkh2@queensu.ca
Notes	

NCT02935920

Trial name or title	A study on optimizing follow-up for postmenopausal women with breast cancer treated with adjuvant endocrine therapy
Methods	RCT
Participants	**Inclusion criteria** • Postmenopausal at the time of diagnosis (menostasis > 12 months. Bilateral salpingo-oophorectomy) • Complete disease remission after primary operation • Histologically-confirmed hormone-receptor positive breast cancer, 1% or more of the tumor cells express hormone receptors • High-risk profile with a 10-year recurrence of more than 10% • Planned adjuvant endocrine therapy regardless of other adjuvant therapy to be initiated within 1 month or initiated within the last 9 months. • Written and verbally informed consent • Able to read and speak Danish • Access to a computer and an email-account **Exclusion criteria** • Patient followed regularly as part of a research protocol • Women postmenopausal due to surgery on the ovaries/uterus age < 50 • Prognostic low-grade risk of recurrence (tumor size 10 mm or less, lymph node negative, ductal carcinoma grade 1 and lobular carcinoma grade 1 or 2)
Interventions	**Experimental**: individual, tailored follow-up Patient symptoms are evaluated by the use of PRO-data to uncover the needs of a consultation. The outcome of the questionnaire is used to customize the follow-up program to the individual patient. **No intervention:** standard follow-up Scheduled clinical examination every six months throughout the course of adjuvant treatment, performed by a doctor or nurse.
Outcomes	**Primary outcome** • The difference in PREM (patient reported experience measure) as reported by patients in the individualized and standard follow-up groups, respectively
Starting date	April 2016
Contact information	Cathrine L. Riis, MD, cathrine.lundgaard.riis@rsyd.dk and Karina D. Steffensen, MD, PhD, karina.dahl.steffensen@rsyd.dk
Notes	

NCT02971163

Trial name or title	Syncope Decision Aid for emergency care (SynDA)
Methods	RCT

NCT02971163 *(Continued)*

Participants	**Inclusion criteria** • Emergency department patient • Age 40 years or above • Chief complaint of syncope • Capacity to make medical decisions • Speak and read English • Working phone number and fixed address **Exclusion criteria** • Altered mental status • Cognitive impairment • Serious acute diagnosis:(e.g. clinically significant cardiac dysrhythmia, structural heart disease, gastrointestinal hemorrhage, myocardial infarction, pulmonary embolism, pneumonia, arterial dissection, serious infection, ectopic pregnancy, subarachnoid hemorrhage, or stroke.) • Hemodynamic instability • Inability to read or speak English • Major communication barrier • Lack of phone number or fixed address • Too high risk as per physician judgment
Interventions	**Experimental:** SynDA The research coordinator will print the appropriate version of the SynDA based on the patient's individualized risk score and the corresponding estimated probability of a serious medical event within 30 days. **No Intervention:** Control Patients in the control arm will receive usual emergency care pertaining to syncope.
Outcomes	**Primary outcome** • Number of participants at end of study **Secondary outcomes** • Patient knowledge and satisfaction • Decisional conflict scale • Admission rate • Repeat visits to the ED • Clinical diagnosis • Incidence of diagnostic testing • OPTION scale
Starting date	January 2017
Contact information	Marc Probst, MD, MS, 212-824-8094, marc.probst@mssm.edu
Notes	

NCT02987608

Trial name or title	A feasibility trial of power up

NCT02987608 *(Continued)*

Methods	NRCT
Participants	**Inclusion criteria** • Recently been referred to CAMHS (Centre for Addiction and Mental Health) (pre - first appointment) • Presenting with emotional difficulties • Clinician will have confirmed that the young person does not have any vulnerability which would make taking part in the study inappropriate to their context
Interventions	**No Intervention:** control phase (No Power Up) 60 young people will receive CAMHS treatment as usual. Measures of empowerment, activation, and symptoms will be completed by participants soon after their referral to the service. The same measures plus shared decision making questionnaires will be administered three months later. **Experimental:** intervention phase (Power Up) 60 young people use Power Up alongside CAMHS treatment as usual. Measures of empowerment, activation, and symptoms will be completed by participants soon after their referral to the service. The same measures plus shared decision making questionnaires and a Power Up feedback form will be administered three months later.
Outcomes	**Primary outcomes** • Shared Decision Making Questionnaire - 9 (SDM Q-9) • CollaboRATE • Experience of Service Questionnaire (ESQ) • Dyadic OPTION scale **Secondary Outcomes** • Patient Activation Measure - Mental Health (PAM - MH) • Strengths and Difficulties questionnaire (SDQ) • Youth Efficacy / Empowerment Scale - Mental Health (YES - MH) • Client Receipt of Services Inventory (CSRI) - Children's Version. **Other Outcomes** • Did Not Attends (DNAs) • Number of sessions attended • Type of therapy / intervention received
Starting date	September 2016
Contact information	Louise N Chapman, 020 7443 2205, louise.chapman@annafreud.org and Julian Edbrooke - Childs, 020 7443 2275, julian.edbrooke-childs@annafreud.org
Notes	

NCT02988661

Trial name or title	Women Empowered to Live With Lupus Study (WELL)
Methods	NRCT
Participants	**Inclusion criteria**

NCT02988661 *(Continued)*

	• Currently participating in the GOAL study **Exclusion criteria** • Participation in the Chronic Disease Self-Management Program (CDSMP) in the past five years • Significant cognitive impairment
Interventions	**Active comparator:** Chronic Disease Self-management Program (CDSMP) A random sample of African American women with SLE selected from the Georgians Organized Against Lupus (GOAL) parent cohort will be used to recruit participants into the CDSMP. This group will be identified as the WELL Cohort. **No intervention:** usual care African American women consented into the parent Georgians Organized Against Lupus (GOAL) cohort who have not been selected to be enrolled in the intervention will comprise the usual care group. This group will continue their longitudinal assessments as part or the GOAL cohort data collection efforts.
Outcomes	**Primary outcomes:** • Change in Communication with Physicians assessed by the Stanford 3Q Scale • Change in Self-efficacy for Managing Medications assessed by the PROMIS SF8a score • Change in Global Health assessed by the PROMIS Global Health score • Change in Physical Function assessed by the PROMIS SF10b score • Change in Pain Interference assessed by the PROMIS SF8a score • Change in Fatigue assessed by the PROMIS SF8a score • Change in Sleep Disturbance assessed by the PROMIS SF8a score • Change in Anxiety Level assessed by the PROMIS SF8a score • Change in Ability to Participate in Social Roles and Activities assessed by the PROMIS SF8a score **Secondary outcomes:** • Change in the Patient Activation Measure (PAM SF 10) score • Change in Self-Efficacy assessed by the PROMIS SF4a score • Change in Angry Mood assessed by the PROMIS SF5 score • Change in Perceived Stress Scale (PSS) Score • Hospitalization Rate • Emergency Department Visit Rate
Starting date	January 2017
Contact information	Charmayne M Dunlop-Thomas, MS, MPH, 404-251-8898, cmdunlo@emory.edu
Notes	

NCT03012087

Trial name or title	Using m-health tools to reduce the misuse of opioid pain relievers
Methods	Randomized controlled trial
Participants	Patients (18 years and older) visiting emergency department for an injury- or pain-related chief complaint

NCT03012087 *(Continued)*

Interventions	**Intervention group:** MyHealthyChoices. Quote:"My Healthy Choices explains what opioid pain medications are, assesses and explains the patient's risk factors related to taking opioids, assesses patient preferences about pain medications, and produces a tailored patient report based on the answers. The patient is encouraged to show the report to the treating ED clinician so they can discuss medication options for treating the patient's pain. Following discharge from the ED, intervention group participants discharged with a prescription pain reliever receive messages about safe medication use, storage, and disposal and access to an educational web portal that contains more information on prescription pain medications and safety." **Control group:** Health Risk Assessment. Quote: "The WellSource health risk assessment content focuses on general health promotion, and the participant's overall health and wellness. A summary report based on the participants' answers is sent to their email address."
Outcomes	**Primary outcome**: Change in self-reported preference for opioid pain reliever **Secondary outcomes:** Change in knowledge about prescription pain medication side effects and safe practices for taking, storing and disposing prescription pain medications.
Starting date	September 2016
Contact information	Contact information is only displayed when the study is recruiting participants
Notes	The study is completed but results of the trial are not published yet

NCT03037112

Trial name or title	Resetting the default: improving provider-patient communication to reduce antibiotic misuse
Methods	RCT
Participants	**Inclusion criteria** • Parent or guardian of a child 1-5 years of age with suspected respiratory tract infection who are English or Spanish speaking **Exclusion criteria** • Parents of children who require hospitalization • Received antibiotics in the last 30 days • Have concurrent bacterial infection, an immune compromising condition or chronic medical condition
Interventions	**Active comparator: education** Quote: "All providers will receive identical training on the appropriate prescribing of antibiotics for ARTIs in a 20 minute presentation. Follow up refresher video clips will also be available for all providers to view at their convenience throughout the study. Parents in both arms will receive identical high quality education on the pros and cons of antibiotics and tips for communicating with their provider." **Active comparator:** Communication skills

NCT03037112 *(Continued)*

	Quote: "Providers randomized to the communication intervention will receive additional training on communication skills in a 40 minute communication skills training session. This training session will include good and bad communication examples, training on positive and negative behavioral framing, and education regarding key drivers of patient satisfaction."
Outcomes	**Primary outcomes** • Shared decision-making • Parent satisfaction with visit **Secondary outcomes** • Antibiotic use • Revisits • Adverse drug reactions
Starting date	March 2017
Contact information	Emily Hurley, PhD, 816-302-0251, eahurley@cmh.edu and Areli Ramphal, MSW, 314-747-5128, aramphal@cmh.edu
Notes	

NCT03084159

Trial name or title	Multi-disciplinary participatory design of a process to deliver a CKD diagnosis in primary care
Methods	NRCT
Participants	**Inclusion criteria** • 18 years old or older • Have an estimated glomerular filtration rate (eGFR) of less than 60 ml/min/1.73 m2 • Able to read and understand English without an interpreter • Diagnosed with chronic kidney disease on record **Exclusion criteria** • Patients with renal transplant or on dialysis • Patients who have documented or provider known cognitive impairment or vision impairment that will prohibit meaningful interaction with education activation worksheet • Patients who are not aware of their CKD diagnosis
Interventions	**Experimental:** participatory design and intervention Quote: "Patients in this arm will receive the intervention of using an education worksheet during their appointment with their provider. They will be asked to complete post intervention surveys. Providers and staff at this site have been involved in the design of the intervention process, to make it streamlined and efficient for application in practice." **Experimental:** intervention only Quote: "A future arm will include patients at another site that will also receive the intervention of using an education worksheet during their appointment and fill out post intervention surveys. Providers/staff have not been involved in the initial design of the intervention process but will use it as part of the intervention delivery." **No Intervention:** usual care

NCT03084159 *(Continued)*

	Quote: "A third site will include usual care, which does not include the intervention. Participants will be given post visit surveys similar to those in the two other study / intervention arms. This site will serve as a usual care comparison."
Outcomes	**Primary outcomes** • Level of objective understanding of CKD as measured by the Kidney Knowledge Survey (KiKS) • Level of perceived understanding of CKD as measured by the Perceived Kidney Knowledge Survey (PiKS) **Secondary outcomes** • Level of positive perception of patient-provider communication as measured by the Patient Communication Assessment Tool (CAT) • Level of mental anxiety/stress related to condition as measured by the adapted NDBCSS scale • Level of energy/fatigue and emotional well-being as measured by the SF-36 mental health component **Other outcome** • Level of positive assessment of care as measured by the Patient Assessment of Care for Chronic Conditions (PACIC) scale
Starting date	June 2017
Contact information	Emily Chen, MA, 734-232-4508, emilypc@med.umich.edu
Notes	

NCT03109145

Trial name or title	MyHealtheVet to enable shared decision making regarding menopausal in postmenopausal women veterans (MEANS)
Methods	NRCT
Participants	**Inclusion criteria** • Women Veterans, age 45-60 • Receive primary care at the Miami Veterans Affairs Healthcare System • Able to communicate in English • Already or willing to register and become authenticated in the patient health portal, MyHealtheVet. • Able to use read, understand, and respond to secure messages using patient health portal. **Exclusion criteria** • Not willing to register and become authenticated for patient health portal. • Not willing to receive educational secure messages from patient health portal.
Interventions	**Experimental:** menopause educational secure messaging Secure messages that provide information about menopause and treatment option for menopause symptoms. **No intervention:** usual care: control

NCT03109145 *(Continued)*

	Control group of eligible women patients between 45-60 years who do not receive the intervention at the West Palm Beach and Orlando Veterans Healthcare System. Usual care participants did not receive the educational secure messages.
Outcomes	**Primary outcomes** • Menopause knowledge • Feasibility of patient portal use for educating and tracking women regarding menopause and menopause related symptoms. **Secondary outcomes** • Shared decision making • Menopause-related diagnosis • Focus group • Patient portal registration and authentication
Starting date	October 2014
Contact information	Stuti Dang, MD, MPH, 305-575-7000 ext 3388, stuti.dang@va.gov
Notes	

NCT03134092

Trial name or title	The Life STORRIED Study
Methods	RCT
Participants	**Inclusion criteria** • Age 18 years to 70 years old. • Experiencing back pain or renal colic. • Text messaging and internet access including email capabilities or access to a smart phone - anticipated discharge within 12 hours. **Exclusion criteria** • Patients who take opioids for chronic pain or cancer treatments. • Patients who have taken opioids in the last month. • Patients who are pregnant, in police custody, intoxicated, cognitively impaired, or otherwise unable to fully consent and participate. • Patients who are hemodynamically compromised, in respiratory distress, or in severe emotional or physical distress. • Patients older than 70 or younger than 18. • Patients who will be admitted to hospital or deemed to have a critical illness • Patients who are cognitively impaired • Patients who are suicidal or homicidal ideation by chart review and clinician assessment • Patients who have evidence of current drug abuse, as measured by a DAST-10105 score of 2 or greater • Patients with evidence of aberrant behavior based on clinical assessment. • Patients who do not have a phone, text messaging OR email address • Patients under police arrest at ED visit • Patients who are non-English or Spanish speaking • Patients previously enrolled

NCT03134092 *(Continued)*

	• Patient with any current contraindications for NSAIDs or opioid medications including allergies, chronic kidney disease (GFR90, if measured).
Interventions	**No Intervention**: Generalized Risk Communication (GRC) **Active Comparator**: Probabilistic Risk Communication (PRT) **Experimental:** Narrative Enhanced Risk Tool (NERT)
Outcomes	**Primary outcome** • Risk awareness and recall **Secondary outcomes** • Patient reported use of opioid medication • Reported use of non opioid pain medication • Functional ability/return to usual activities • Patient-reported shared decision making • Satisfaction with pain treatment • Trust in provider • Patient preference for treatment plan • Treatment plan agreement between patient preference and provider decision
Starting date	June 2017
Contact information	Erica B Goldberg, MSW, 215-573-2944, erica.goldberg@uphs.upenn.edu and Camille Lin, BA, 215-746-5608, camille.lin@uphs.upenn.edu
Notes	

NCT03136367

Trial name or title	What matters most: choosing the right breast cancer surgery for you
Methods	RCT
Participants	**Inclusion criteria** • Assigned female at birth • Between 18 and 74 years of age • Confirmed diagnosis (via biopsy) of early stage breast cancer (stages I-IIIA) • Eligible for both breast-conserving surgery and mastectomy • Spoken English, Spanish, or Mandarin Chinese **Exclusion criteria** • Transgender men and women • Women who have undergone prophylactic mastectomy • Women >74 years of age • Women with visual impairment • Women with a diagnosis of psychosis or severe dementia • Women with recurrent breast cancer or inflammatory breast carcinoma
Interventions	**Experimental: Arm 1:** Option Grid

NCT03136367 *(Continued)*

	Quote: "Patients in this arm will receive the Option Grid for breast cancer surgery, an encounter decision aid, when they first meet with the breast surgeon to discuss their surgical options for breast cancer treatment." **Experimental: Arm 2:** Picture Option Grid Quote: "Patients in this arm will receive the Picture Option Grid for breast cancer surgery, an encounter decision aid, when they first meet with the breast surgeon to discuss their surgical options for breast cancer treatment."
Outcomes	**Primary outcome** • Change in decision quality **Secondary outcomes** • Health literacy measured using Chew's 1-item health literacy screening (Chew et al. 2008) • Treatment choice, or which surgical or treatment option the patient chose • Quality of life reported by the patient measured using the validated 6-item EQ-5D-5L measure (Herdman et al., 2011; Pickard et al. 2007) • Knowledge of surgical options, measured using the validated 5-item knowledge sub-scale on the Decision Quality Worksheet (Sepucha et al. 2012) • Anxiety, measured using the validated 8-item PROMIS anxiety short form (Pilkonis et al, 2011) • Self-reported shared decision-making about breast cancer surgical options measured using the validated 3-item CollaboRATE measure (Barr et al., 2014; Elwyn et al., 2013) • Shared decision-making observed during the surgical consultation, measured using the validated observer-rated OPTION5 (Barr et al., 2015) • Patient-reported feelings of decision regret, measured using the validated 5-item decision regret scale (Brehaut et al. 2003) • Patient-reported measure of integration of healthcare delivery, measured using IntegRATE (Elwyn et al. 2015) • Patient-reported measure of financial toxicity, or financial distress, as a result of their cancer diagnosis, measured by 4 items from COST (de Souza et al., 2014; de Souza et al, 2017) and self-reported out-of-pocket expenses incurred as a result of the patient's cancer diagnosis • Intervention's pattern of use • Exploration of strategies that promote the interventions' sustained use and dissemination
Starting date	September 2017
Contact information	Marie-Anne Durand, MSc, PhD, 603-653-0851, marie-anne.durand@dartmouth.edu and Renata Yen, MPH, 603-650-1494, renata.west.yen@dartmouth.edu
Notes	

NCT03216109

Trial name or title	Improving supportive care for patients with thoracic malignancies
Methods	RCT
Participants	**Inclusion criteria** • All patients with stage III and IV lung cancer treated at VA Palo Alto. This includes all newly diagnosed patients and those under follow-up care. **Exclusion criteria**

NCT03216109 *(Continued)*

	• Patients who do not anticipate receiving oncology care at the VA Palo Alto Health Care System. • Patients who are unable to consent.
Interventions	**Experimental:** Weekly telephone symptom assessment Quote: "Each patient who is enrolled in the intervention will receive a weekly phone call from the Research Assistant for a total of 9 months to assess symptoms using the Edmonton Symptom Assessment Scale. Results of the symptom assessments will be provided to the clinic staff (RN and MD) for review each week. Symptom assessments will be documented into an encrypted, HIPAA compliant digital platform which provides longitudinal symptom data management and also provides symptom assessment tools for the clinical team in their intervention strategies. In addition, patients will complete symptom and quality of life surveys at 0, 3, 6 and 9 months." **No intervention:** control arm Quote: "Patients randomized to usual clinical care will receive standard of care for thoracic malignancies as provided by the VA Palo Alto Health Care System. Patients will complete outcome surveys at 0, 3, 6, and 9 months."
Outcomes	**Primary outcome:** • Symptom documentation **Secondary outcomes** • Emergency Department (ED) Visit (Chart Review • Hospitalizations (Chart Review) • Change in Quality of Life using the Functional Assessment of Cancer Therapy - Lung survey • Change in patient satisfaction with decision-making using the Satisfaction with Decision Survey • Change in Patient Activation using the validated Patient Activation Measure • Change in symptoms using the validated Edmonton Symptom Assessment Scale
Starting date	May 2017
Contact information	Manali Patel, MD, MPH, 650-498-6000, manalip@stanford.edu and Evan Hall, MD, MPhil, 650-498-6000, ethall@stanford.edu
Notes	

NCT03221556

Trial name or title	Improving outcomes for low-income mothers With depression
Methods	RCT
Participants	**Inclusion criteria** • Woman is pregnant and receives prenatal care at Boston Medical Center; or is biological mother of 0 to 18-month-old child receiving care at BMC pediatric primary care clinic • Woman has EPDS score ≥ 10 • Woman receives Medicaid insurance • Woman comfortable speaking and receiving information in English or Spanish • Woman has no current source of mental health care **Exclusion criteria** • Woman under 18 years of age

NCT03221556 *(Continued)*

	• Woman endorses suicidality • Woman exhibits signs of psychosis or is cognitively limited*As part of the informed consent process, we will administer the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), which has been validated in populations of depressed and schizophrenic adults
Interventions	**Active comparator:** Engagement-Focused Care Coordination Quote: "The brief intervention in Engagement-Focused Care Coordination is the Engagement Interview. In this model, providers meet one to two times with mothers who screen positive for depression, and use techniques of shared decision-making to help mothers process the results of the screen; explore treatment options; and connect with formal mental health services. Engagement-Focused Care Coordination emphasizes referral to formal mental health services." **Active comparator:** Problem Solving Education (PSE) Quote: "The brief Problem Solving Education (PSE) is a six-session cognitive-behavioral program. PSE offers immediate intervention in the PCMH, followed by referral to further treatment if symptoms persist."
Outcomes	**Primary outcome** • Quick Inventory of Depressive Symptoms (QIDS SR-16) **Secondary outcomes** • Beck Anxiety Inventory • Patient Activation Measure • Coping Self-Efficacy Scale • Parenting Stress Index - Short Form • Child Behavior Checklist (CBCL-1.5/5) • Collaborative Psychiatric Epidemiology Survey
Starting date	September 2017
Contact information	Michael Silverstein, MD MPH, (617) 414-7903, misilve@bu.edu and Winta Z Haile, 617-414-3638, whaile@bu.edu
Notes	

NCT03228615

Trial name or title	IBD shared decision making intervention
Methods	RCT
Participants	**Inclusion criteria** • Clinician anticipates discussing TNFai (tumor necrosis factor alpha inhibitor) treatment at clinic visit; parent and patient willing to have visit video-recorded **Exclusion criteria** • patient over age 17; prior use of TNFai; unable to read and speak English; clinic visit not conducted in English; previous participation in this study; known major mental illness in parent or adolescent patient; medical instability at scheduled visit; patient's gastroenterologist is a study investigator
Interventions	**Experimental:** Shared Decision Making Intervention

NCT03228615 *(Continued)*

	No Intervention: usual care group
Outcomes	**Primary outcomes** • Acceptability of multi-component intervention: OPTION scale • Feasibility of multi-component intervention: Receipt of intervention components • Feasibility of multi-component intervention: Length of clinic visit
Starting date	July 2017
Contact information	Ellen A Lipstein, MD, MPH, 513-803-1626, ellen.lipstein@cchmc.org, Cassandra M Dodds, MA, CCRP, 513-803-3144, cassandra.dodds@cchmc.org
Notes	

NCT03234322

Trial name or title	The impact of a diabetes risk prediction model in primary care
Methods	RCT
Participants	**Inclusion criteria for participation of medical practitioners** • general practitioners, medical practitioners and internists working as general practitioners with and without further training in diabetology according to German Diabetes Association standards • provide the routine health check **Exclusion criteria for participation of medical practitioners** • treat exclusively patients with private insurance • treat exclusively diabetes patients in a specialized medical practice **Inclusion criteria for participation of participants** • appointment for the routine health check • insured in statutory health insurance • age > 35 years • Body Mass Index (BMI) of ≥ 27 kg/m2 **Exclusion criteria for participation of participants** • type 1 or type 2 diabetes diagnosis or already abnormal blood glucose level (fasting glucose ≥ 126 mg/dl or 2 hours oral glucose tolerance test (oGTT) ≥ 200mg/dl or glycated hemoglobin (HbA1c) ≥6,5%) before the routine health check • no sufficient German language skills to fill in the questionnaires • presence of an incurable disease with a prognosis of less than one year • severe mental illness or dementia • severe underlying disease, which largely impairs physical activity • pregnancy • participation in another clinical study 30 days before study inclusion
Interventions	**Experimental:** intervention group In the intervention group the routine health check is expanded by usage of a non-invasive diabetes risk score. **No intervention:** control group

NCT03234322 *(Continued)*

	In the control group the routine health check is conducted.
Outcomes	**Primary outcome** • Difference of participant's physical activity at twelve months after the routine health check between the groups. **Secondary outcomes** • Improvement in the counseling process assessed by PCPs • Improvement in the counseling process assessed by participants • Improvement of shared decision making, assessed by participants • Improvement of shared decision making, assessed by PCPs • Improved motivation to change lifestyle, assessed by participants • Change in Body-Mass-Index (BMI) • Change in participant's quality of life • Change in participant's level of depression and anxiety • Change of participant's perceived risk of developing diabetes • Acceptance of PCPs according to the application of a diabetes risk score for routine use in clinical practice • Acceptance of participants according to the application of a diabetes risk score for routine use in clinical practice. **Other outcome** • Change on participant's individual diabetes risk
Starting date	September 2017
Contact information	Principal investigator: Wolfgang Rathmann, Dr, German Diabetes Center
Notes	No contact details provided

NTR4554

Trial name or title	Prostate Cancer Patient-centered Care (PCPCC): impact of a treatment decision aid in a pragmatic, cluster randomized controlled trial
Methods	RCT
Participants	**Inclusion criteria** • Men that are newly diagnosed with early stage prostate cancer • Tumour stage T1 or T2 • Maximum PSA-score of 20 • Maximum Gleason-score of 7 • Patients who are eligible for at least two treatment options • Patients (in the intervention arm) have to be able to make use of a computer with internet-access in order make use of the web-based decision aid. • Patients have to be able to read and understand Dutch language. **Exclusion criteria** • Patients with advanced cancer • If the urologist judges the patient is not in the right condition to participate

NTR4554 *(Continued)*

	• In the case of a second opinion when the other involved hospital also uses a decision aid from this or an other study
Interventions	The control group will receive usual care; information provision and provided decisional support will be given according to the hospital standards. In addition to usual care, the intervention group will be granted access to an online decision aid, providing patients with structured information on the risks and benefits of the different treatment options and offer value-clarification tasks. A summary is obtained to discuss with their physician during the following consultation.
Outcomes	**Primary outcomes** • Decisional conflict (short term) • Decisional regret • Treatment satisfaction (long term). **Secondary outcomes** • Decision-making role • Knowledge about prostate cancer • Satisfaction with information • Preparation for decision making • Health-related quality of life • Personality (anxiety, depression, optimism) and skills measures (self-efficacy, health literacy, numeracy)
Starting date	May 2014
Contact information	M. Cuypers, +31 13 466 28 55, M.Cuypers@uvt.nl
Notes	

NTR4879

Trial name or title	Implementation of shared decision making in a clinical setting; how to make it fit in the daily workflow?
Methods	Non-randomised, single arm intervention
Participants	**Inclusion criteria** • Patients diagnosed with stage I or II breast cancer, provided the two treatment options, mastectomy or breast conserving surgery with radiotherapy, are applicable. Eligible patient should speak and understand the Dutch language. **Exclusion criteria** • Men diagnosed with breast cancer • Women not eligible to decide between having a mastectomy or lumpectomy with radiation.
Interventions	Implementing shared decision making (SDM) using a patient decision aid
Outcomes	**Primary outcomes** • Knowledge on treatment • Perceived shared decision making • Decisional conflict

NTR4879 *(Continued)*

	Secondary outcomes • Patients and caregivers experiences with implementation of shared decision making and the patient decision aid
Starting date	October 2014
Contact information	W. Savelberg, 043-3882336, wilma.savelberg@maastrichtuniversity.nl
Notes	

NTR5177

Trial name or title	(Cost-)effectiveness and implementation of a decision aid for patients with localized prostate cancer and their partners: study protocol of a stepped wedge cluster randomized controlled trial
Methods	RCT
Participants	**Inclusion criteria** • Newly diagnosed adult patients with localized prostate cancer (and their partners) who have made a decision for a curable treatment option for prostate cancer, but have not undergone this treatment yet. **Exclusion criteria** • Patients (and their partners) younger than 18 years, patients (and their partners) who are not able to understand the Dutch language in speech and in writing, patients who do not have a choice for multiple treatment options for localized prostate cancer.
Interventions	**Control group:** patients with prostate cancer (and their partners), who have a choice for a curative treatment option and who receive care as usual by health care providers in participating centers. **Intervention group:** patients with prostate cancer (and their partners), who have a choice for a curative treatment option and who additionally to care as usual by health care providers in participating centers, will receive the PDA.
Outcomes	**Primary outcomes** • Decisional conflict (patients) • Effect of prostate cancer in the relationship (partners) • Communication between patient and partner and interaction with HCPs • Social contacts and support: Active Engagement Scale (AES) **Secondary outcomes** **Patients** • Quality of life (EORTC QLQ-C30 and PR25) • Treatment preferences • Experienced participation and approach to decision making • Expectations of the treatment (SETS pre-treatment) • Outcome of the treatment (SETS post-treatment) • Subjective and objective knowledge about prostate cancer • Communication between patient and partner • Need for supportive care (SCNS SF-34 and prostate module) • Decision regret (DRS)

NTR5177 *(Continued)*

Cost-evaluation

- Quality of life for the benefit of cost analysis (EQ5D)
- Registration of aftercare (TiC-P)
- Productivity Costs (PRODISQ)

Satisfaction with intervention

- Use of the PDA
- Appreciation for the PDA
- Satisfaction with the use of the PDA (SCIP-B)
- Preparation for decision making (Prep-DM)
- Promoting and impeding factors using the PDA

Partners

- Quality of life of partners (SF-12)
- Treatment preferences
- Experienced participation and approach to decision making
- Role as caregiver (CSI)

Satisfaction with intervention

- Use of the PDA (study-specific questionnaire)
- Appreciation for the PDA (study-specific questionnaire)
- Promoting and impeding factors using the PDA

Moderating factors patients and partners

- Socio-demographic questionnaire with clinical variables Monitoring and blunting coping styles

Implementation

- Implementation rate number of participating hospitals and proportion participating HCPs per hospital as a proportion of total number of all HCPs treating prostate cancer patients, and approximate proportion of patients provided with the PDAs as a proportion of total number of eligible patients per participating hospital (retrieved from the Netherlands Cancer Registry)
- Measurement instrument for determinants of innovation (MIDI) among HCPs

Starting date	February 2014
Contact information	Dr. André Vis, +31 20 444 0261, a.vis@vumc.nl
Notes	

NTR5262

Trial name or title	Shared decision making in mental health with Routine Outcome Monitoring (ROM) as an information source
Methods	RCT
Participants	**Inclusion criteria** • Teams which are participating in the Dutch Breakthrough ROM network (project) • Inclusion of clients which are receiving treatment (through the participating teams/pPractitioners) and will give informed consent

NTR5262 *(Continued)*

	Exclusion criteria • Clients who are not able to speak and read Dutch • Clients who don't agree with participating in the study (no informed consent)
Interventions	Appliance of Routine Outcome monitoring in Shared Decision Making about treatment options between client and practitioner. Breakthrough, intervention teams, receive training in SDM & ROM model, support and coaching in the implementation.
Outcomes	**Primary outcome** • The client's perception of shared decision making **Secondary outcomes** • Client-practitioner relationship • Client's commitment to the treatment • Reduction of symptoms, the improvement of functioning in the society or quality of live
Starting date	August 2015
Contact information	Drs. Metz Margot, 06 51 43 72 69, mmetz@trimbos.nl
Notes	

NTR5489

Trial name or title	CHOICE: CHOosing treatment together In Cancer at the End of life
Methods	RCT
Participants	**Inclusion criteria** **Patients** • Diagnosed with metastasized or locally irresectable cancer • Not eligible for treatment with curative intent • Median life expectancy of <1 year without systemic treatment, and a median survival benefit of systemic treatment of < 6 months. • Scheduled for a consultation with a participating medical oncologist in which decisions about the start, (dis)continuation or adjustment of palliative systemic treatment will be made. **Oncologists** • Eligible are all medical oncologists (in training) treating the eligible patient population with an appointment of at least 1 year after the start of the trial **Exclusion criteria** **Patients** • Insufficient mastery of Dutch, i.e. inability to understand the 'Gesprekswijzer' as well as the questionnaires as judged by either the physician or the researcher • Cognitive disabilities or a psychiatric disorder that hinder understanding of the 'Gesprekswijzer' as well as the questionnaires as judged by either the physician or the researcher • Not enough time (< 2 days) to make sure the Gesprekswijzer is received before the consultation in which decisions are made • A primary brain tumor or brain metastasizes which significantly hinder cognitive functioning

NTR5489 *(Continued)*

	• Being not, or no longer, eligible for (an additional line of) palliative systemic treatment (standard or experimental) **Oncologist** • Excluded will be oncologists involved in the design of the content of the interventions.
Interventions	Quote: "The oncologist skills training is based on a four-step model of SDM and on techniques known from behavior change theories. The training is provided in small groups (n=3-5) by a professional trainer and actor. It consists of a reader, two half days of training making use of modelling videos and role play, a booster session and a consultation room tool. The 'Gesprekswijzer' consists of a Question Prompt List and Value Clarification Exercises, i.e., two known methods to empower patients in communication and decision making. The booklet comprises (1) an explanation that, when cure is no longer an option, treatment decisions are highly dependent on individual preferences, (2) example question patients may wish to pose in the upcoming consultation with the oncologist and (3) questions to help patients think about their values."
Outcomes	**Primary outcome** • Observed SDM in the audio-recorded consultation as assessed with a validated scoring instrument (OPTION) as well as a study-specific adaptation of that instrument. **Secondary outcomes** • Observed SDM in a simulated patient encounter (effect training only) • Patients' perceived efficacy in communication • Patient and oncologist satisfaction with communication and decision making • Congruence between patients' preferred and perceived role in decision making • Patients' attitudes towards striving for quantity (length) or quality of life • Patients' evaluation of the decision made • Patients' quality of life • The treatment decision made • Patients' trust in the oncologist • Patients' anxiety • Patients' fighting spirit • Consultation time • Patients'use and evaluation of the 'Gesprekswijzer'
Starting date	December 2015
Contact information	Dr. Inge Henselmans, 020-5668735, I.Henselmans@amc.uva.nl
Notes	

NTR5677

Trial name or title	Empowerment in mental health care using e-health in a redesigned intake process: a cluster randomised controlled trial
Methods	RCT
Participants	**Inclusion criteria** • Patients who are referred to one of the participating centers treating depression, anxiety and personality disorders, for whom a full intake is planned and who have sufficient command of the Dutch language, are eligible for participation and will be asked for written informed consent.

NTR5677 *(Continued)*

	Exclusion criteria • Patients who do not get a full intake because of a come back in treatment and patients who do not speak and read Dutch.
Interventions	The intake-teams randomized to the intervention group implement e-health interventions in a re-designed intake process. To implement this new way of working, the clinicians of the intervention teams follow a training aiming to gain insight, knowledge and skills in the application of recovery supported care, shared decision making and e-health with the purpose to motivate and empower patients in gaining an active role in their recovery and stimulating an equivalent interplay between patients and clinicians.
Outcomes	**Primary outcome** • Degree in patient motivation for treatment and patient activation in mental health (treatment) **Secondary outcomes** • Quality of the patient-clinician relationship • Process of shared decision making • Patients' adherence to treatment and clinical outcome
Starting date	September 2016
Contact information	Margot Metz, 06-51437269, m.metz@ggzbreburg.nl
Notes	

NTR6106

Trial name or title	A decision aid for the treatment of Benign Prostatic Hyperplasia: a prospective cohort study to investigate the effect
Methods	Prospective cohort study
Participants	**Inclusion criteria** • New patient with a LUTS caused by benign prostatic hyperplasia who have the choice between: • waiting OR start medication • continue (other) medication OR operation **Exclusion criteria** • Absolute operation indication (example: persistent urinary retention) • Speak not good enough dutch to understand the DA or questionnary • Cannot use a computer
Interventions	Using a BPH decision aid
Outcomes	**Primary outcomes** • Value congruence and regret **Secondary outcomes** • Decisional conflict • SCIP-B • SDM-Q-9

NTR6106 *(Continued)*

	• EORTC-info-25 • Knowledge
Starting date	September 2016
Contact information	Fieke van der Wijden, f.vanderwijden@etz.nl
Notes	

NTR6227

Trial name or title	Secondary manifestations of arterial disease - influence of cardiovascular prognosis and treatment effect predictions on patient and physician decision-making: a three-armed, blinded, randomized controlled trial
Methods	RCT
Participants	**Inclusion criteria** • Inclusion in the SMART study (NL45885.041.13) • Clinically manifest cardiovascular disease, such as a confirmed diagnosis or strong clinical suspicion of one of the following: coronary artery disease, cerebrovascular disease, peripheral artery disease. • Use of statin medication at baseline • Between 18 and 80 years of age • Rankin Scale < 3 **Exclusion criteria** • Pregnancy • Terminal malignancy or short life-expectancy • No follow-up possible • Inability to effectively communicate in Dutch • No informed consent (IC) signed • Baseline questionnaire not returned
Interventions	The three-arms of this trial are: **Standard-communication practices only (Control Group)** **Standard- communication practices plus personalized information on:** • prediction passport: 10-year risk of recurrent event and change in absolute risk associated with statin therapy; • educational videos; • telephone conversation. **Standard-communication practices plus personalized information on:** • prediction passport: recurrent cardiovascular event-free life expectancy and change in recurrent cardiovascular event-free life-expectancy associated with statin therapy; • educational videos; • telephone conversation.
Outcomes	**Primary outcome** • Patient experience with decision-making, measured using the Decisional Conflict Scale (DCS)

NTR6227 *(Continued)*

	Secondary outcomes • Prolonged Improved Patient Decision-Making measured with Decisional Conflict Scale (DCS) • Self-reported medication adherence • Patients' illness perceptions • Understanding of therapy-effects • General practitioners' assessment of the intervention • Patient Activation • Patient Reported Shared Decision-Making • Patient Perception of Statin Efficacy • Quality of Life questionnaire • Serum LDL-c (mmol/L) levels
Starting date	March 2017
Contact information	Nicole N. M. Jaspers, +31 88 75 556 50, N.E.M.Jaspers@umcutrecht.nl
Notes	

NTR6379

Trial name or title	Shared decision making in patients with Castration-Resistant Prostate Cancer - the impact of implementation of a treatment decision aid in CRPC patients
Methods	RCT
Participants	**Inclusion criteria** • Men who are newly diagnosed with CRPC. CRPC is defined as any cancer progression under maximal hormonal treatment with anti-androgens and/or LHRH agonist or antagonist (when three consecutive rises of PSA are observed at castrate serum levels of testosterone (< 50 ng/dL or <1.7 nmol/L) and/or progression of osseous lesions is shown)) • Patients are eligible for at least two treatment options • Patients have to be able to make use of a computer with internet-access in order to make use of the web-based decision aid • Patients have to be able to complete a Dutch questionnaire **Exclusion criteria** • In the case of a second opinion the patient will not be included if the first opinion was obtained in one of the other involved hospitals and vice versa • Patients who do not have sufficient knowledge of the Dutch language
Interventions	Decision aid with value clarification exercise
Outcomes	**Primary outcomes** • Objective knowledge • Informed choice **Secondary outcomes** • Correlation between G8 score and treatment decision • Correlation between TUG-test and treatment decision • Quality of life • Anxiety

NTR6379 *(Continued)*

- Value clarification
- Satisfaction with decision making, information and treatment
- Preparation for decision making
- Healthcare providers' evaluation of decision aid
- Partner involvement in SDM
- Treatment outcome (e.g. dose reductions, treatment delays, treatment discontinuation, treatment switch, and death)

Starting date	September 2016
Contact information	Prof. Dr. J. J. M. Takkenberg, +31 (0)10 7035413, j.j.m.takkenberg@erasmusmc.nl
Notes	

NTR6487

Trial name or title	A multicentre stepped-wedge cluster-randomised trial studying the level of shared decision-making during vascular surgical consultation before and after the introduction of decision support tools
Methods	RCT
Participants	**Inclusion criteria** • Age ≥ 18 years • Newly diagnosed patients with an asymptomatic abdominal aortic aneurism and which has grown to 5.5 cm or more. • Newly diagnosed patients with a symptomatic carotid artery stenosis of >70% or >50% in men, that are diagnosed within 6 months or 12 weeks, respectively, since the onset of symptoms.20 • Newly diagnosed patients with invalidating intermittent claudication (Fontaine IIb) • Varicose veins for which the patient is considering treatment • Eligible for more than one treatment option • Written informed consent **Exclusion criteria** • Insufficient understanding of the Dutch language or cognitively unable to complete Dutch questionnaires. • Life expectancy less than 1 year • Patients requiring emergency surgery • ASA IV patients (with severe systemic disease that is a constant threat to life)
Interventions	**Decision support tools:** decision aids, decision tables, decision cards, training
Outcomes	**Primary outcome** • Level of SDM during the doctor-patient consultations in which a treatment decision is to be made **Secondary outcomes** • Level of disease-specific knowledge in patients • Quality of life in patients • Level of SDM as perceived by patients • Decisional conflict in patients • Level of SDM as perceived by physicians

NTR6487 *(Continued)*

	• The (chosen) treatment • The successful introduction of DSTs • Process measures of implementation
Starting date	August 2017
Contact information	Sylvana de Mik, +31 (0)20 566 2971, s.m.demik@amc.nl
Notes	

Simmons ongoing

Trial name or title	Skills training for shared decision making: a randomized pilot study
Methods	Randomized pilot study
Participants	Physicians from Partners HealthCare System (PHS) in Boston, MA
Interventions	The study randomly assigned participants to watch a webinar (developed by investigators and featuring demonstrations of SDM skills) or review video decision aids (DAs), and to receive individual feedback on their SPI or not.
Outcomes	Presence/absence of 9 key elements of SDM using the Braddock's Informed Decision Making (IDM) framework, confidence in SDM skills, satisfaction with the skills training and completion of the assigned training arm
Starting date	
Contact information	Leigh Simmons, MD; 617-726-2368
Notes	

Steele Gray 2016

Trial name or title	Supporting goal-oriented primary health care for seniors with complex care needs Using mobile technology: evaluation and implementation of the Health System Performance Research Network, Bridgepoint Electronic Patient Reported Outcome Tool
Methods	RCT
Participants	**Inclusion criteria** • Need to be rostered at family health teams recruited to participate • Over age 65 • Have two or more chronic conditions • Have had 10 or more visits to their primary health care provider within the last 12 months
Interventions	Use of the electronic patient reported outcomes (ePRO) tool. The ePRO mobile app and portal offers an innovative approach to creating and monitoring goal-oriented patient-care plans to improve patient self-management and shared decision-making between patients and healthcare providers. The ePRO tool also supports proactive patient monitoring by the patient, caregiver(s), and healthcare provider.

Steele Gray 2016 *(Continued)*

Outcomes	**Primary outcome** • Health-related quality of life measured by the AQoL-4D **Secondary outcomes** Patient self-management using the 13-item patient activation measure (PAM) Efficiency using a cost-effectiveness analysis
Starting date	Unknown
Contact information	Carolyn Steele Gray, Bridgepoint Collaboratory , Lunenfeld-Tanenbaum Research Institute, Sinai Health System, 1 Bridgepoint Drive, AM.37, Toronto, ON M4M 2B5, Canada, Phone: 1 416 461 8252 ext 2908, Fax: 1 416 461 0656, Email: ac.metsyshtlaehianis@yargeleets.nylorac
Notes	The expected completion date of the study is November 2019

Thompson 2017

Trial name or title	Should I continue taking my acid reflux medication? Design of a pilot before/after study evaluating a patient decision aid
Methods	Before/after study
Participants	**Inclusion criteria** • ≥18 years of age • Taking a proton pump inhibitor (PPI) for mild/moderate upper GI symptoms (mild or moderate gastroesophageal reflux disease (GERD)/esophagitis Los Angeles Grade A or B) for at least 4 weeks with resolution of symptoms • Currently asymptomatic **Exclusion criteria** • Severe GERD or upper GI symptoms, esophagitis Los Angeles Grade C or D at baseline • Taking PPI for gastroprotection (at moderate or high risk of GI bleeding) • History of Barrett's esophagus • History of bleeding peptic ulcer • Taking PPI for treatment of current ulcer not healed
Interventions	Patients will have an appointment with a pharmacist to go through a patient decision aid to discuss the decision (probabilities of benefit and harm, individual values and preferences). Following the appointment, patients can follow up with their family physician should they wish to pursue deprescribing or can receive instructions from the pharmacist.
Outcomes	• Decisional conflict/confidence measured with the SURE test • Patient knowledge and realistic expectations • Preferred option (continue PPI, stop and use on demand/use a lower dose, or unsure) • Congruence between patients' choice • Perception that shared decision-making took place using the control preferences scale (patient and pharmacist) • Agreement between patient and pharmacist ratings • Proportion of patients continuing on PPIs at their pre-PtDA dose after 8 weeks

Thompson 2017 *(Continued)*

Starting date	Unknown
Contact information	wthomp01@gmail.com
Notes	

UMIN000009239

Trial name or title	Comparison of Shared Decision Making (SDM) and routine care for University students in psychiatric outpatient clinic. A Randomized controlled trial
Methods	Randomized controlled trial
Participants	Patient (20 years and older) at first visit to psychiatric clinic at Waseda University Health Support Center
Interventions	Shared decision making intervention
Outcomes	• patient satisfaction with routine care and SDM • patient satisfaction, clinic visits, medication adherence, and depression every 2 weeks until 24 weeks after decision making
Starting date	November 2012
Contact information	
Notes	Recrutment completed but results not published

UMIN000022832

Trial name or title	A shared decision making communication training program for clinicians treating: a pilot clustered randomised controlled trial
Methods	RCT
Participants	**Inclusion criteria** Eligible therapists: • informed and asked for participation • stroke Eligible patients: • informed and asked for participation • be in the charge of eligible therapists **Exclusion criteria** Eligible therapists: • assigned to this study group Eligible patients:

UMIN000022832 *(Continued)*	• assigned to either the group as the object of the study • cannot be taken communicate • be determined to be inappropriate
Interventions	Education program (communication) Education program (stroke)
Outcomes	**Primary outcome** • 9-item SDM Questionnaire **Secondary outcomes** • Autonomy Preference Index • Patient Satisfaction Questionnaire • Functional Independent Measurement • Fugl-Meyer Assessment • The General Health Questionnaire
Starting date	July 2016
Contact information	Noriko Kon, 03-5307-5151, nobinobi.00.nontan.sc@gmail.com
Notes	

ARI: Acute respiratory infection; **ARTI:** Acute respiratory tract infection; **BHC:** Behavioural health clinician; **CAHPS:** Consumer Assessment of Healthcare Providers and Systems; **CANSAS-P:** Camberwell Assessment of Need, Short Appraisal Schedule - Patient; **CHA2D2-VASc**–Congestive heart failure/Hypertension/Age - Diabetes mellitis - Vascular disease/Age/Sex category [clinical prediction rule]; **CI:** Co-investigators; **CRCS:** Colorectal cancer screening; **CSI:** Caregiver Strain Index; **CVR:** Cardiovascular risk; **DECIMS**: Decision coaching in multiple sclerosis; **DST:** Decision support tools; **ED:** Emergency department; **EORTC:** European Organisation for Research and Treatment of Cancer; **EPDS:** Edinburgh Postnatal Depression Scale; **EQ5D:** EuroQol 5 Dimensions (self-rated health); **EUROHIS:** European Health Inverview Surveys; **HAS-P:** Helping Alliance Scale - Patient;**HIPAA:** Health Insurance Portability and Accountability Act; **HRA:** Health Risk Assessment; **IBD:** Inflammatory bowel disease;**IDAF**: Index of Dental Anxiety and Fear; M**APPIN'SDM:** Multifocal approach to sharing in shared decision making; **MARS:** Medication Adherence Rating Scale; **NYHA:** New York Heart Association; **OHIP:** Oral Health Impact Profile; **PACT**: Patient-Aligned Care Team; **PCMH:** Patient-centered medical home; **PCORI:** Patient-Centered Outcomes Research Institute; **PEP:** Patient empowerment program; **PEPPI**: Perceived Efficacy in Patient-Physician Interactions; **PHQ:** Patient Health Questionnaire; **PREP-DM**: Preparation for Decision Making scale; **PRODISQ:** Productivity and Disease Questionnaire; **PROMIS:** Patient-Reported Outcomes Measurement Information System; **PSA:** Prostate-specific antigen; **PtDA:** Patient decision aid; **QoL:** Quality of life/QOL; **QPL:** Question prompt list; **QPS**: Question prompt sheets; **QQPPI:** Questionnaire on the Quality of Physician-Patient Interaction; **RA:** Rheumatoid arthritis; **SAS:** Statistical Analysis System; **SCIP**: Satisfaction with Cancer Information Profile;**SCNS**: Supportive Care Needs Survey; **SDM-Q9:** Shared Decision Making Questionnaire (9-item); **SDM:** Shared decision making; **SDMI:** Shared decision making intervention; **SES:** Socioeconomic status; **SETS:** Stanford Expectations of Treatment Scale; **SF:** Short-form; **SURE [screening test]:** Sure of myself; Understand information; Risk-benefit ratio; Encouragement; **TAS:** Treatment Alliance Scale;**TiC-P:** Trimbos/iMTA questionnaire for costs associated with psychiatric illness; **TTE:** Time to event; **TTO:** Time trade-off; **UC:** Usual care; **USH:** Unguided self-help; **VA:** Veteran Affairs; **VBAC:** Vaginal birth after caesarean;**VOICE:** Values and Options in Cancer Care (VOICE); **VOICE:** Valuing Opinions, Individual Communication and Experience; **ZUF:** Fragebogen zur Patientenzufriedenheit [questionnaire on patient satisfaction].

DATA AND ANALYSES

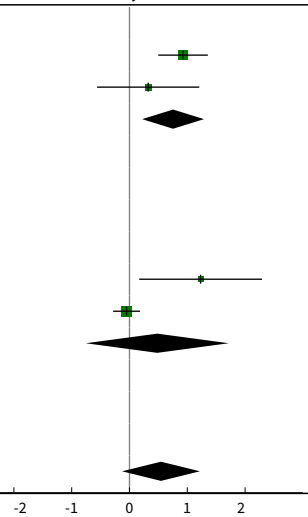
Comparison 1. Group 1: Interventions targeting patients compared to usual care

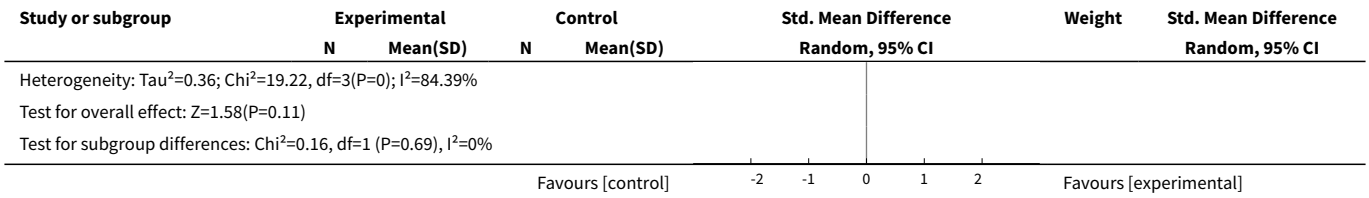
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Shared decision making (OBOM, continuous)	4	424	Std. Mean Difference (IV, Random, 95% CI)	0.54 [-0.13, 1.22]
1.1 Cluster RCT	2	116	Std. Mean Difference (IV, Random, 95% CI)	0.75 [0.22, 1.29]
1.2 Individual RCT	2	308	Std. Mean Difference (IV, Random, 95% CI)	0.48 [-0.76, 1.72]
2 Shared decision making (PROM, continuous)	9	1386	Std. Mean Difference (IV, Random, 95% CI)	0.32 [0.16, 0.48]
2.1 Cluster RCT	2	303	Std. Mean Difference (IV, Random, 95% CI)	0.40 [0.18, 0.63]
2.2 Individual RCT	7	1083	Std. Mean Difference (IV, Random, 95% CI)	0.29 [0.10, 0.49]
3 Shared decision making (PROM, continuous) - NRCT	1	303	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.21, 0.25]
4 Shared decision making (PROM, categorical)	6	754	Risk Difference (M-H, Random, 95% CI)	-0.09 [-0.19, 0.01]
5 Knowledge	3	565	Std. Mean Difference (IV, Random, 95% CI)	0.38 [0.16, 0.61]
6 Knowledge (categorical)	2	312	Risk Difference (M-H, Random, 95% CI)	0.17 [0.05, 0.29]
7 Satisfaction	1	107	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.24, 0.52]
8 Decisional conflict	3	367	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-0.68, 0.09]
9 Decision regret	1	212	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.39, 0.19]
10 Patient-physician communication (number of topics raised by patients)	1	100	Std. Mean Difference (IV, Random, 95% CI)	0.26 [-0.13, 0.65]
11 Patient-physician communication (patient raised discussion)	1	157	Risk Difference (M-H, Random, 95% CI)	0.29 [0.14, 0.44]
12 Patient-physician communication (patient participation in discussion)	1	157	Risk Difference (M-H, Random, 95% CI)	0.27 [0.13, 0.42]
13 Decision self-efficacy	2	274	Std. Mean Difference (IV, Random, 95% CI)	0.16 [-0.08, 0.40]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
14 Empowerment	1	342	Std. Mean Difference (IV, Random, 95% CI)	0.26 [0.05, 0.48]
15 Empowerment (categorical)	1	262	Risk Difference (M-H, Random, 95% CI)	0.18 [0.09, 0.27]
16 Adherence	2	598	Risk Difference (M-H, Random, 95% CI)	-0.03 [-0.07, 0.02]
17 Health-related quality of life (physical)	1	116	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.36, 0.36]
18 Health-related quality of life (mental)	1	116	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.26, 0.46]
19 Anxiety	2	419	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.33, 0.37]
20 Anxiety (categorical)	1	127	Risk Difference (M-H, Random, 95% CI)	0.04 [-0.07, 0.15]
21 Depression	1	127	Risk Difference (M-H, Random, 95% CI)	0.16 [0.05, 0.28]
22 Consultation length	2	224	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.39, 0.58]
23 Cost	1	105	Std. Mean Difference (IV, Random, 95% CI)	0.82 [0.42, 1.22]

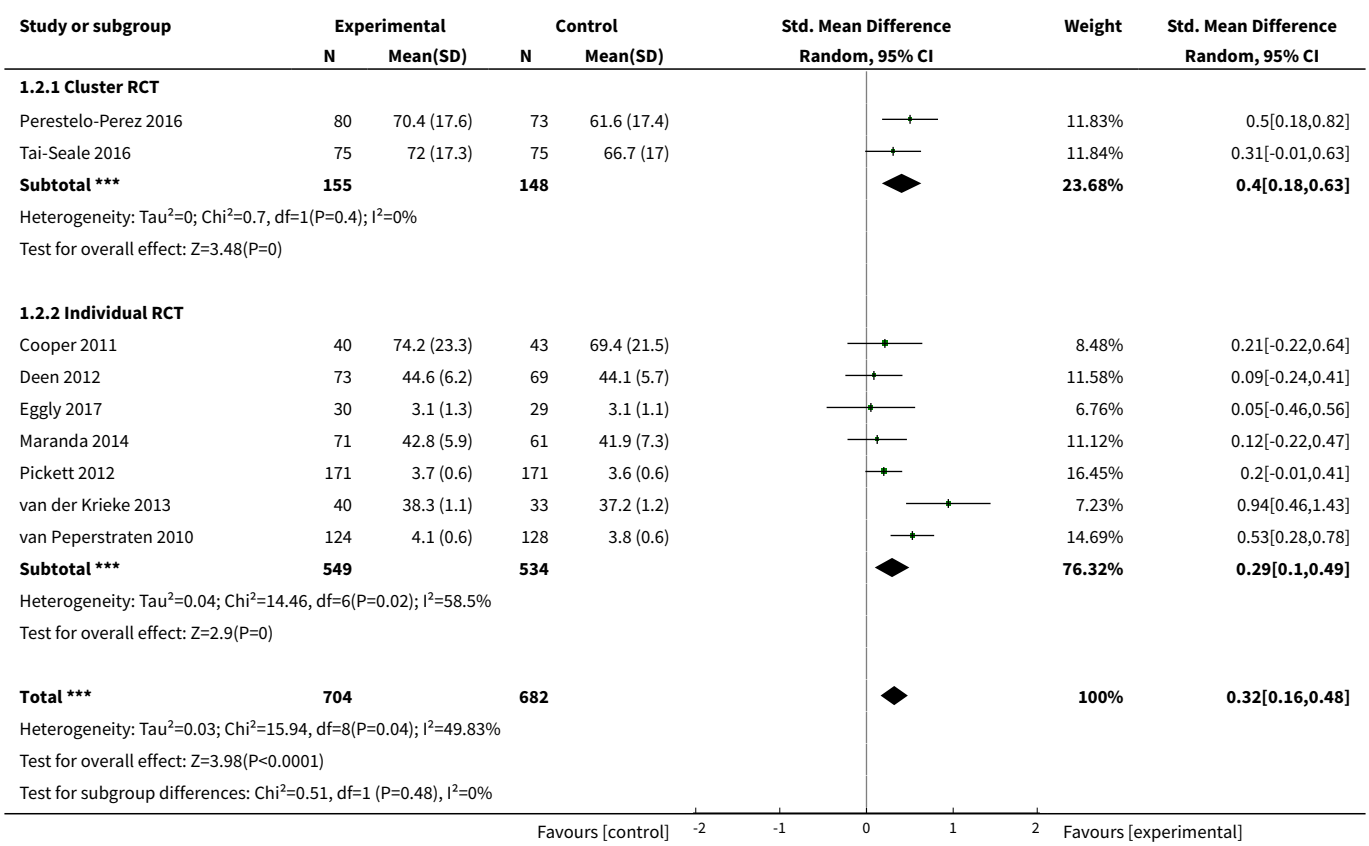
Analysis 1.1. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 1 Shared decision making (OBOM, continuous).

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
1.1.1 Cluster RCT							
LeBlanc 2015a	57	46.6 (16.4)	39	32.5 (12.9)		29.1%	0.93[0.5,1.36]
Tai-Seale 2016	10	28.8 (16.8)	10	23.9 (11.8)		21.04%	0.32[-0.56,1.21]
Subtotal ***	**67**		**49**			**50.14%**	**0.75[0.22,1.29]**
Heterogeneity: Tau^2=0.06; Chi^2=1.45, df=1(P=0.23); I^2=31.11%							
Test for overall effect: Z=2.76(P=0.01)							
1.1.2 Individual RCT							
LeBlanc 2015b	13	57 (12.9)	6	41.8 (8.7)		18.12%	1.23[0.17,2.29]
Maclachlan 2016	160	0.9 (1.4)	129	1 (1.4)		31.74%	-0.05[-0.28,0.18]
Subtotal ***	**173**		**135**			**49.86%**	**0.48[-0.76,1.72]**
Heterogeneity: Tau^2=0.67; Chi^2=5.33, df=1(P=0.02); I^2=81.24%							
Test for overall effect: Z=0.76(P=0.45)							
Total ***	**240**		**184**			**100%**	**0.54[-0.13,1.22]**

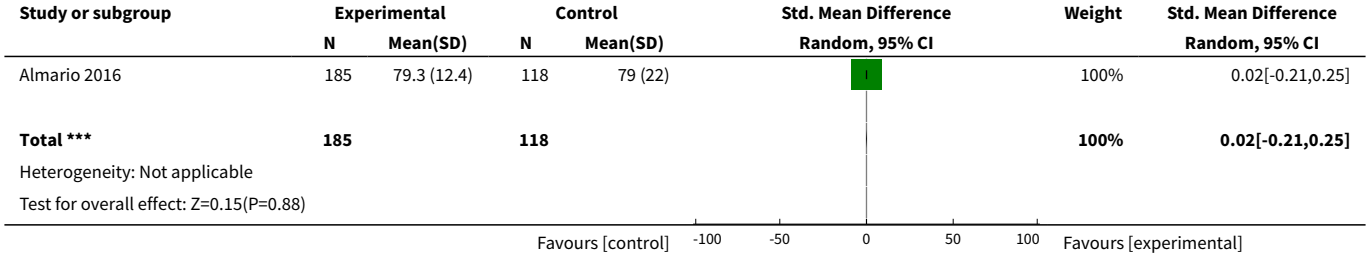




Analysis 1.2. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 2 Shared decision making (PROM, continuous).

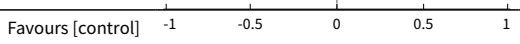


Analysis 1.3. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 3 Shared decision making (PROM, continuous) - NRCT.



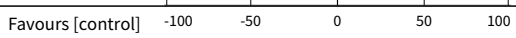
Analysis 1.4. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 4 Shared decision making (PROM, categorical).

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Krist 2007	63/174	23/63		20.92%	-0[-0.14,0.14]
Landrey 2012	29/74	33/78		18.86%	-0.03[-0.19,0.12]
Murray 2001	34/57	42/48		18.65%	-0.28[-0.44,-0.12]
Sheridan 2014	37/69	32/45		16.63%	-0.17[-0.35,0]
Vestala 2013	6/18	7/21		8.5%	0[-0.3,0.3]
Vodermaier 2009	35/53	36/54		16.44%	-0.01[-0.19,0.17]
Total (95% CI)	**445**	**309**		**100%**	**-0.09[-0.19,0.01]**
Total events: 204 (Experimental), 173 (Control)					
Heterogeneity: Tau^2=0.01; Chi^2=9.69, df=5(P=0.08); I^2=48.39%					
Test for overall effect: Z=1.75(P=0.08)					



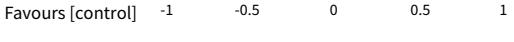
Analysis 1.5. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 5 Knowledge.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Landrey 2012	71	3.5 (1.5)	77	3.3 (1.4)		29.8%	0.14[-0.19,0.46]
Perestelo-Perez 2016	80	2.4 (1.3)	75	1.8 (1.4)		30.24%	0.45[0.13,0.77]
van Peperstraten 2010	127	7.7 (0.6)	135	7.2 (1.2)		39.96%	0.52[0.27,0.77]
Total ***	**278**		**287**			**100%**	**0.38[0.16,0.61]**
Heterogeneity: Tau^2=0.02; Chi^2=3.55, df=2(P=0.17); I^2=43.6%							
Test for overall effect: Z=3.33(P=0)							



Analysis 1.6. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 6 Knowledge (categorical).

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Krist 2007	135/196	40/75		86.23%	0.16[0.03,0.29]
LeBlanc 2015b	20/29	5/12		13.77%	0.27[-0.05,0.6]
Total (95% CI)	**225**	**87**		**100%**	**0.17[0.05,0.29]**
Total events: 155 (Experimental), 45 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.43, df=1(P=0.51); I^2=0%					
Test for overall effect: Z=2.78(P=0.01)					



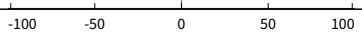
Analysis 1.7. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 7 Satisfaction.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Vodermaier 2009	53	29.1 (3)	54	28.7 (2.9)		100%	0.14[-0.24,0.52]
Total ***	**53**		**54**			**100%**	**0.14[-0.24,0.52]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.72(P=0.47)							

Favours [control] Favours [experimental]

Analysis 1.8. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 8 Decisional conflict.

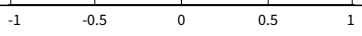
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Murray 2001	57	2.3 (0.4)	48	2.6 (0.5)		31.64%	-0.66[-1.06,-0.27]
Perestelo-Perez 2016	78	23.9 (16.8)	77	23.8 (14.8)		35.97%	0.01[-0.31,0.32]
Vodermaier 2009	53	1.8 (0.6)	54	2 (0.6)		32.38%	-0.28[-0.66,0.1]
Total ***	**188**		**179**			**100%**	**-0.3[-0.68,0.09]**
Heterogeneity: Tau^2=0.08; Chi^2=6.81, df=2(P=0.03); I^2=70.63%							
Test for overall effect: Z=1.51(P=0.13)							



Favours [control] Favours [experimental]

Analysis 1.9. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 9 Decision regret.

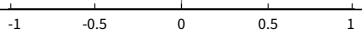
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
van Tol-Geerdink 2016	146	14.2 (14.9)	66	15.7 (15.3)		100%	-0.1[-0.39,0.19]
Total ***	**146**		**66**			**100%**	**-0.1[-0.39,0.19]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.67(P=0.5)							



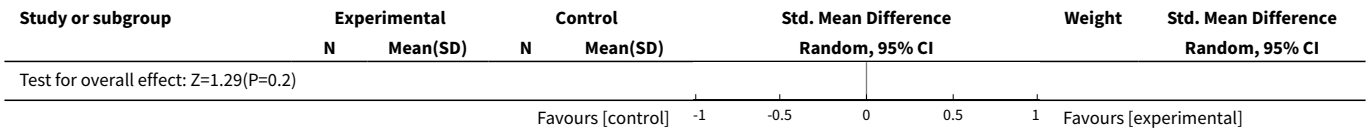
Favours [control] Favours [experimental]

Analysis 1.10. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 10 Patient-physician communication (number of topics raised by patients).

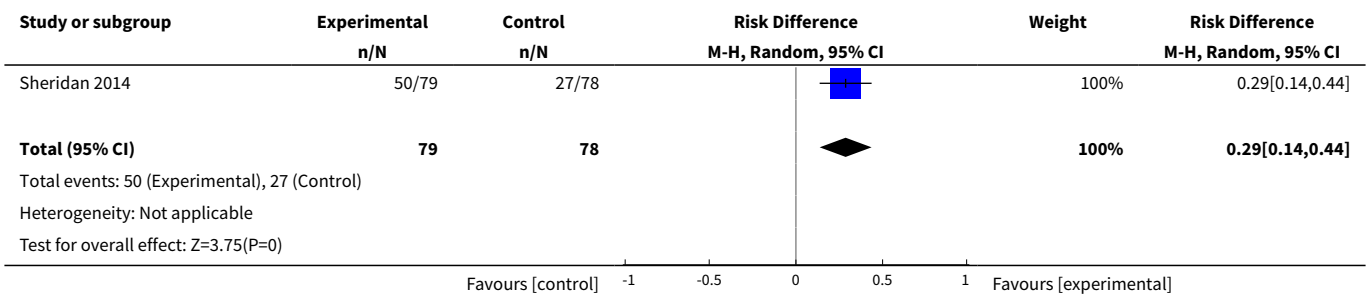
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Hamann 2014	51	3.5 (2.3)	49	2.9 (2.3)		100%	0.26[-0.13,0.65]
Total ***	**51**		**49**			**100%**	**0.26[-0.13,0.65]**
Heterogeneity: Not applicable							



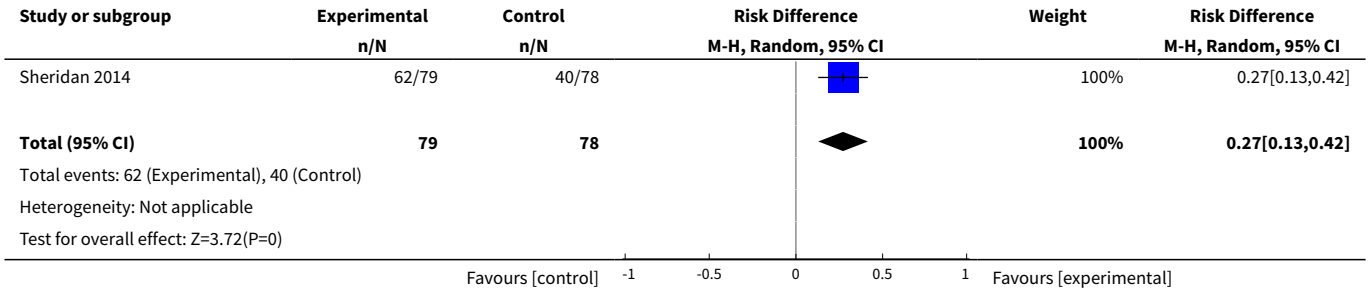
Favours [control] Favours [experimental]



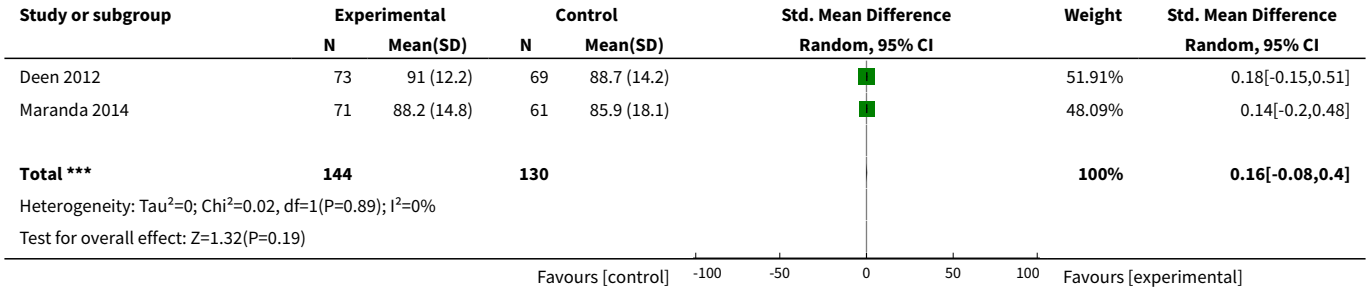
Analysis 1.11. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 11 Patient-physician communication (patient raised discussion).



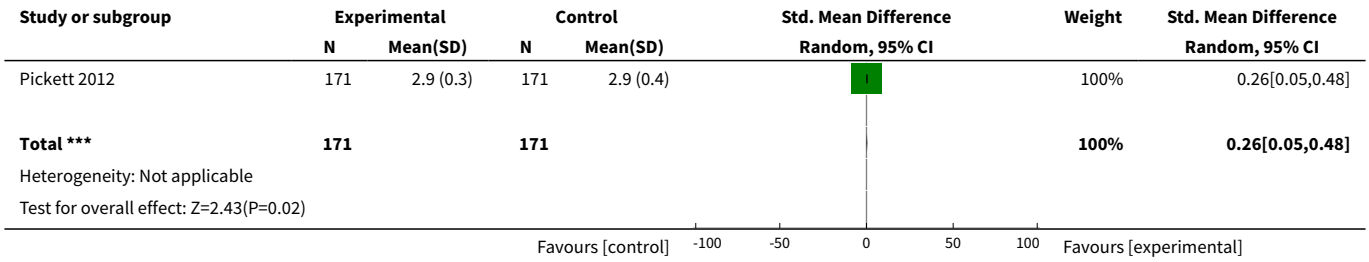
Analysis 1.12. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 12 Patient-physician communication (patient participation in discussion).



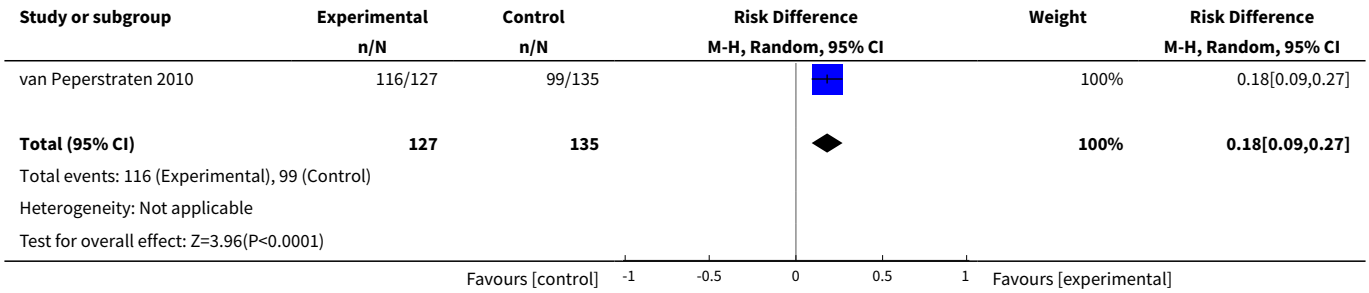
Analysis 1.13. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 13 Decision self-efficacy.



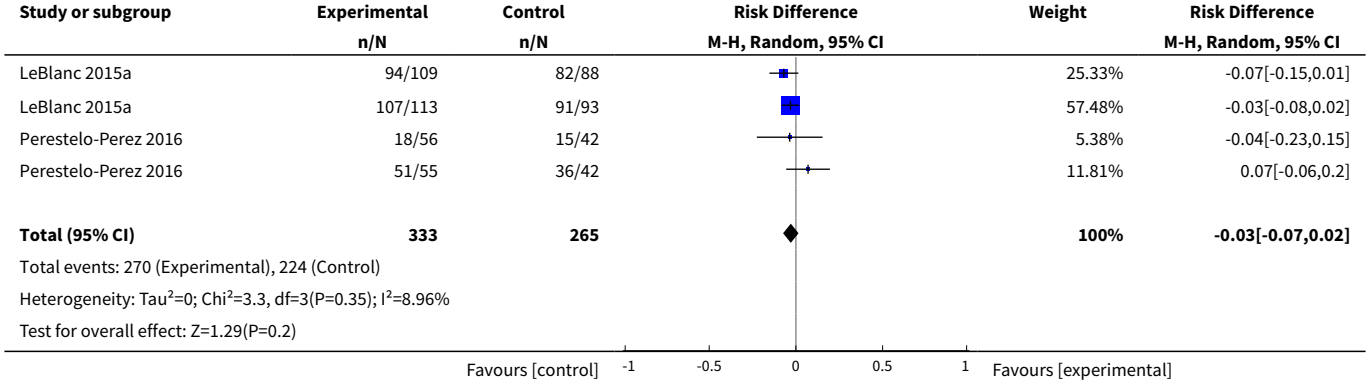
Analysis 1.14. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 14 Empowerment.



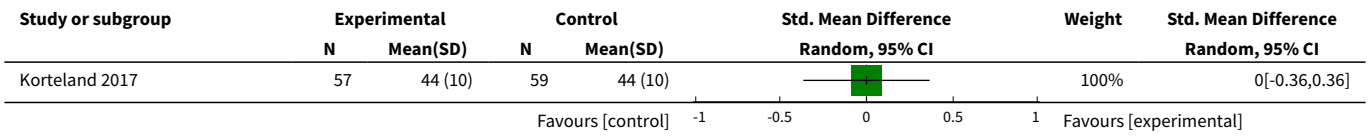
Analysis 1.15. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 15 Empowerment (categorical).

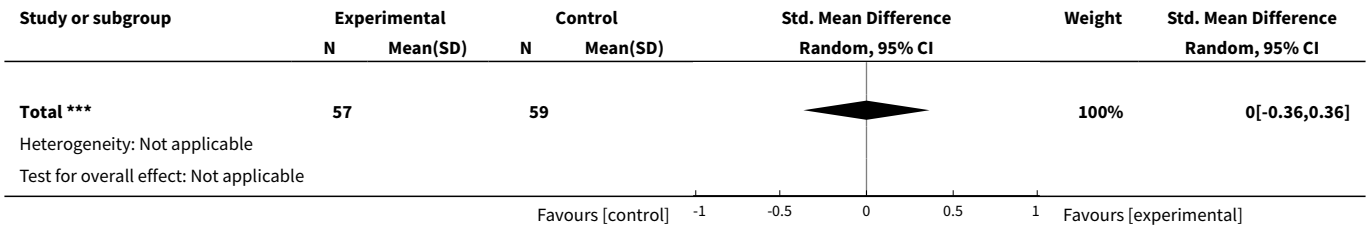


Analysis 1.16. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 16 Adherence.

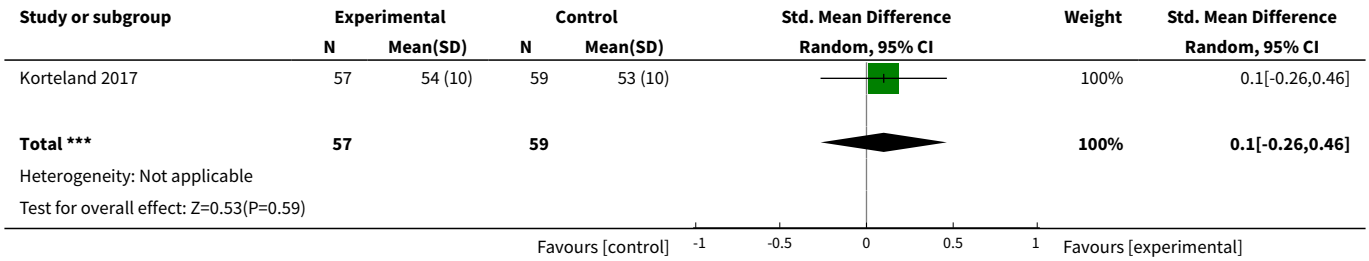


Analysis 1.17. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 17 Health-related quality of life (physical).

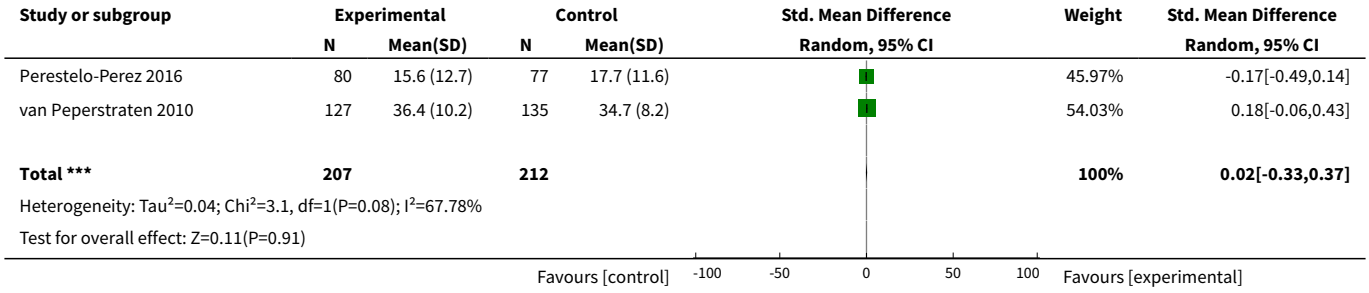




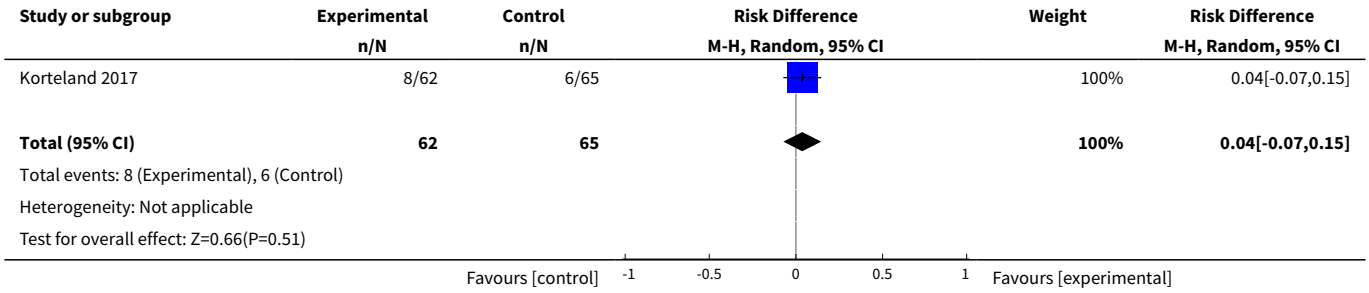
Analysis 1.18. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 18 Health-related quality of life (mental).



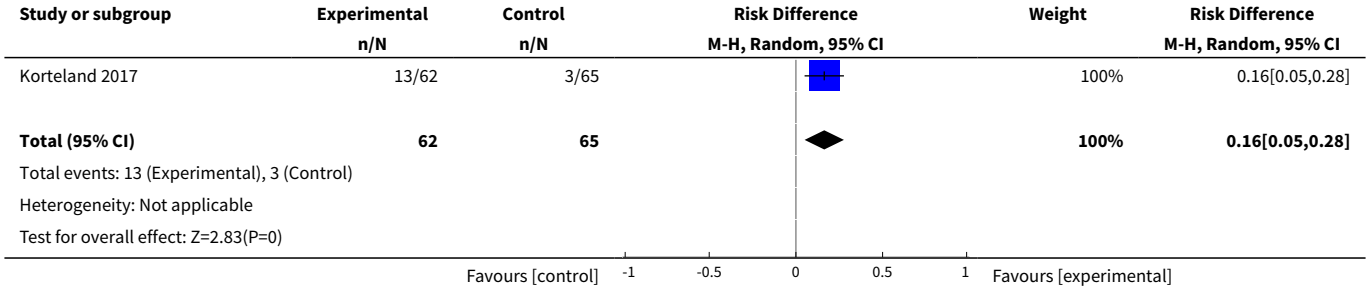
Analysis 1.19. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 19 Anxiety.



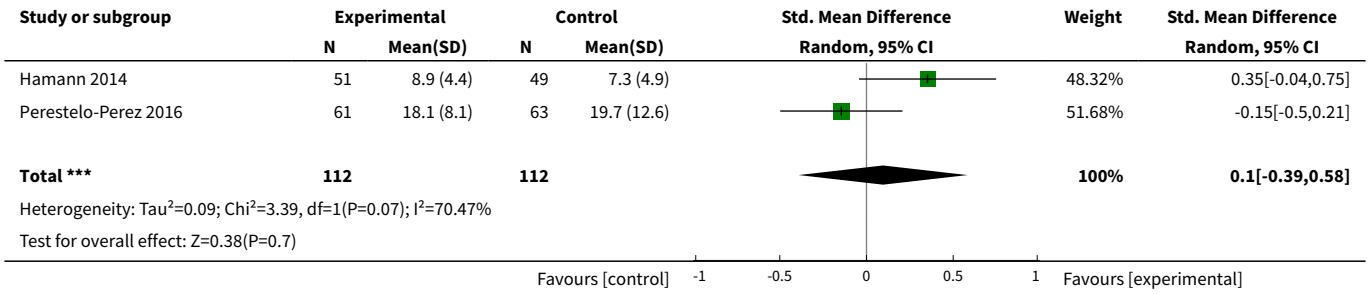
Analysis 1.20. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 20 Anxiety (categorical).



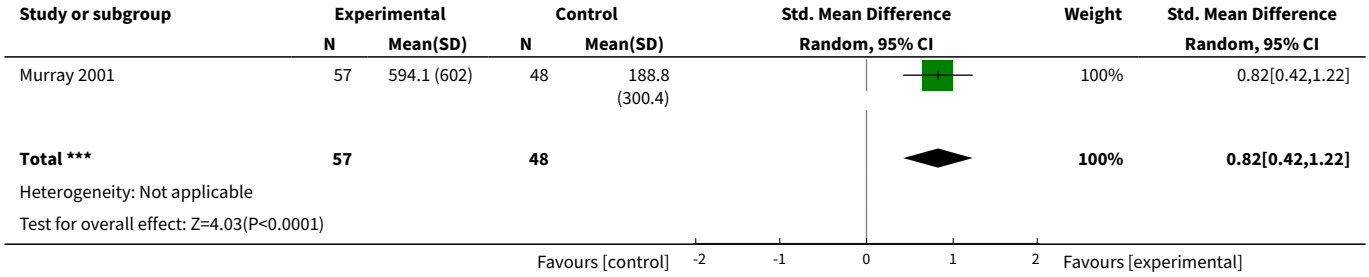
Analysis 1.21. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 21 Depression.



Analysis 1.22. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 22 Consultation length.



Analysis 1.23. Comparison 1 Group 1: Interventions targeting patients compared to usual care, Outcome 23 Cost.



Comparison 2. Group 2: Interventions targeting healthcare professionals compared to usual care

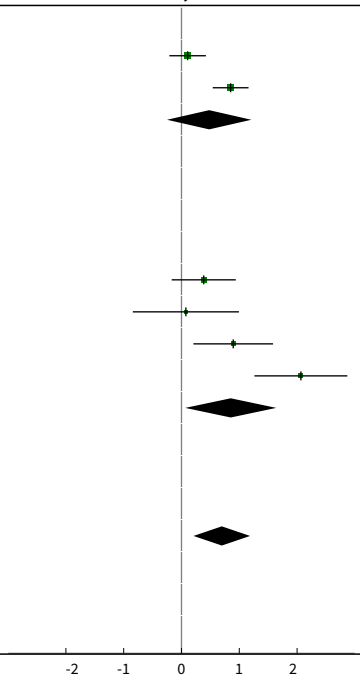
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Shared decision making (OBOM, continuous)	6	479	Std. Mean Difference (IV, Random, 95% CI)	0.70 [0.21, 1.19]
1.1 Cluster RCT	2	329	Std. Mean Difference (IV, Random, 95% CI)	0.48 [-0.25, 1.21]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.2 Individual RCT	4	150	Std. Mean Difference (IV, Random, 95% CI)	0.85 [0.06, 1.64]
2 Shared decision making (OBOM, continuous) - CBAs	1	21	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.96, 0.76]
3 Shared decision making (PROM, continuous)	5	5772	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.15, 0.20]
3.1 Cluster RCT	4	5678	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.17, 0.20]
3.2 Individual RCT	1	94	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.30, 0.51]
4 Shared decision making (PROM, categorical)	2	6303	Risk Difference (M-H, Random, 95% CI)	0.01 [-0.03, 0.06]
5 Knowledge	2	969	Std. Mean Difference (IV, Random, 95% CI)	0.26 [-0.16, 0.69]
6 Knowledge (categorical)	1	80	Risk Difference (M-H, Random, 95% CI)	-0.13 [-0.36, 0.10]
7 Satisfaction with consultation	1	479	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.18, 0.18]
8 Satisfaction with information	1	1492	Risk Difference (M-H, Random, 95% CI)	0.02 [-0.02, 0.07]
9 Satisfaction with decision making process	1	1488	Risk Difference (M-H, Random, 95% CI)	-0.03 [-0.07, 0.02]
10 Satisfaction with discussion	1	1483	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.05, 0.05]
11 Decision regret	1	326	Std. Mean Difference (IV, Random, 95% CI)	0.29 [0.07, 0.51]
12 Self-efficacy	1	4475	Std. Mean Difference (IV, Random, 95% CI)	-0.03 [-0.09, 0.03]
13 Adherence	1	827	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.21, 0.06]
14 General health	1	4056	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.04, 0.08]
15 Psychological well-being	1	4052	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.06, 0.06]
16 Health-related quality of life (physical)	1	359	Std. Mean Difference (IV, Random, 95% CI)	0.16 [-0.05, 0.36]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
17 Health-related quality of life (mental)	1	359	Std. Mean Difference (IV, Random, 95% CI)	0.28 [0.07, 0.49]
18 Health-related quality of life	1	4449	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.06, 0.06]
19 Anxiety	1	3003	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.02, 0.02]
20 Consultation length	1	175	Std. Mean Difference (IV, Random, 95% CI)	0.51 [0.21, 0.81]
21 Consultation length (10-20 min)	1	479	Risk Difference (M-H, Random, 95% CI)	-0.04 [-0.13, 0.05]
22 Safety	1	154	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.32, 0.32]

Analysis 2.1. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 1 Shared decision making (OBOM, continuous).

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
2.1.1 Cluster RCT							
Cox 2017	78	4.4 (4.2)	76	4 (3.2)		20.38%	0.11[-0.21,0.42]
Sanders 2017	86	1.7 (1)	89	0.9 (1)		20.45%	0.85[0.54,1.16]
Subtotal ***	**164**		**165**			**40.82%**	**0.48[-0.25,1.21]**
Heterogeneity: Tau^2=0.25; Chi^2=10.86, df=1(P=0); I^2=90.79%							
Test for overall effect: Z=1.29(P=0.2)							
2.1.2 Individual RCT							
Fossli 2011	26	63.6 (12)	25	58.9 (12.2)		17.32%	0.38[-0.17,0.94]
LeBlanc 2015b	19	42.9 (15.1)	6	41.8 (8.7)		12.49%	0.08[-0.84,0.99]
Shepherd 2011	18	36.6 (12.6)	18	25 (12.7)		15.45%	0.9[0.21,1.58]
Stacey 2006	18	0.8 (0.2)	20	0.4 (0.2)		13.91%	2.07[1.26,2.87]
Subtotal ***	**81**		**69**			**59.18%**	**0.85[0.06,1.64]**
Heterogeneity: Tau^2=0.5; Chi^2=14.14, df=3(P=0); I^2=78.78%							
Test for overall effect: Z=2.12(P=0.03)							
Total ***	**245**		**234**			**100%**	**0.7[0.21,1.19]**
Heterogeneity: Tau^2=0.28; Chi^2=27.11, df=5(P<0.0001); I^2=81.55%							
Test for overall effect: Z=2.79(P=0.01)							
Test for subgroup differences: Chi^2=0.46, df=1 (P=0.5), I^2=0%							



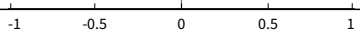
Analysis 2.2. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 2 Shared decision making (OBOM, continuous) - CBAs.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Ampe 2017	11	38.8 (14)	10	40.1 (9.5)		100%	-0.1[-0.96,0.76]
Total ***	**11**		**10**			**100%**	**-0.1[-0.96,0.76]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=0.23(P=0.82)							

Favours [control] Favours [experimental]

Analysis 2.3. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 3 Shared decision making (PROM, continuous).

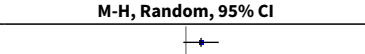
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
2.3.1 Cluster RCT							
Kennedy 2013	1626	67.7 (27.7)	2379	69.1 (26.3)		25.89%	-0.05[-0.12,0.01]
Koerner 2014	199	57 (25.9)	264	59 (25.2)		20.47%	-0.08[-0.26,0.11]
Tinsel 2013	363	73 (19.5)	368	66.6 (21.3)		22.45%	0.32[0.17,0.46]
Wilkes 2013	188	11.4 (3)	291	11.8 (3)		20.5%	-0.13[-0.32,0.05]
Subtotal ***	**2376**		**3302**			**89.32%**	**0.02[-0.17,0.2]**
Heterogeneity: Tau^2=0.03; Chi^2=23.17, df=3(P<0.0001); I^2=87.05%							
Test for overall effect: Z=0.16(P=0.87)							
2.3.2 Individual RCT							
Cooper 2011	51	71.6 (19.9)	43	69.4 (21.5)		10.68%	0.11[-0.3,0.51]
Subtotal ***	**51**		**43**			**10.68%**	**0.11[-0.3,0.51]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.51(P=0.61)							
Total ***	**2427**		**3345**			**100%**	**0.03[-0.15,0.2]**
Heterogeneity: Tau^2=0.03; Chi^2=23.49, df=4(P=0); I^2=82.97%							
Test for overall effect: Z=0.29(P=0.77)							
Test for subgroup differences: Chi^2=0.15, df=1 (P=0.7), I^2=0%							



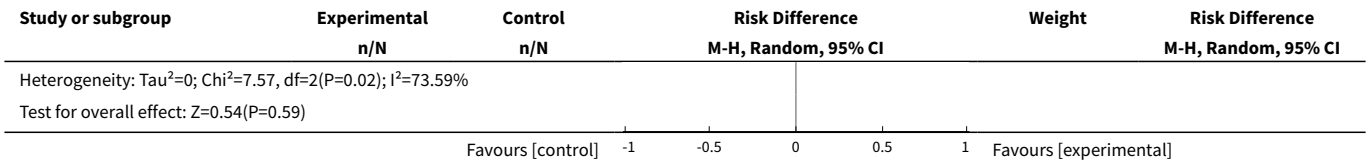
Favours [controll] Favours [experimental]

Analysis 2.4. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 4 Shared decision making (PROM, categorical).

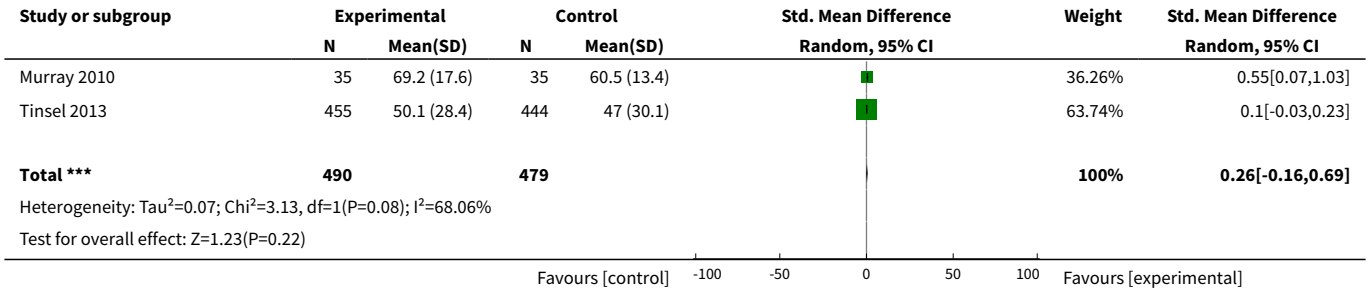
Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Légaré 2012	79/176	64/177		14.74%	0.09[-0.01,0.19]
O'Cathain 2002	263/1531	235/1206		42.52%	-0.02[-0.05,0.01]
O'Cathain 2002	354/1515	358/1698		42.74%	0.02[-0.01,0.05]
Total (95% CI)	**3222**	**3081**		**100%**	**0.01[-0.03,0.06]**
Total events: 696 (Experimental), 657 (Control)					



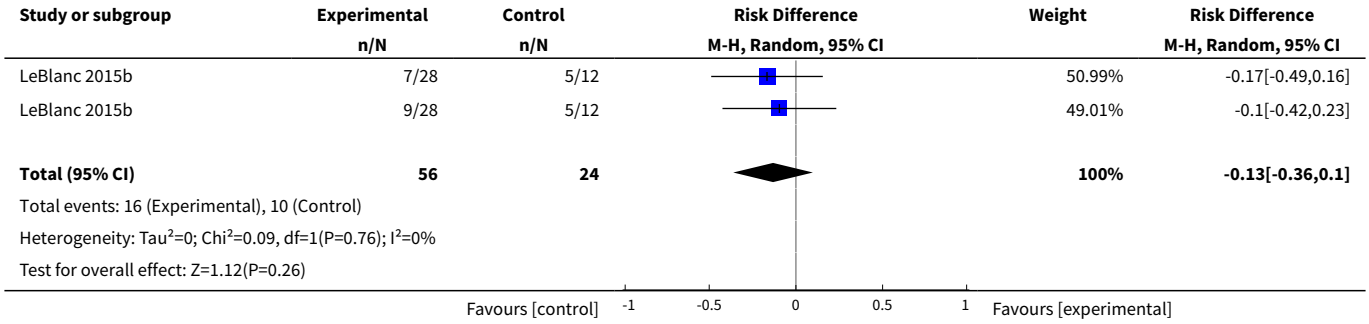
Favours [control] Favours [experimental]



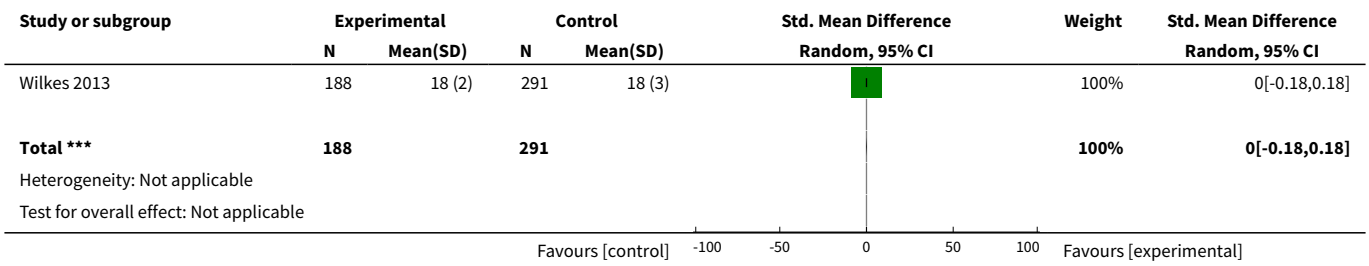
Analysis 2.5. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 5 Knowledge.



Analysis 2.6. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 6 Knowledge (categorical).

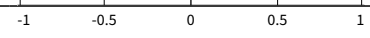


Analysis 2.7. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 7 Satisfaction with consultation.



Analysis 2.8. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 8 Satisfaction with information.

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
O'Cathain 2002	635/855	458/637		100%	0.02[-0.02,0.07]
Total (95% CI)	**855**	**637**		**100%**	**0.02[-0.02,0.07]**
Total events: 635 (Experimental), 458 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%					
Test for overall effect: Z=1.02(P=0.31)					



Analysis 2.9. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 9 Satisfaction with decision making process.

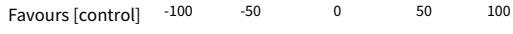
Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
O'Cathain 2002	656/855	502/633		100%	-0.03[-0.07,0.02]
Total (95% CI)	**855**	**633**		**100%**	**-0.03[-0.07,0.02]**
Total events: 656 (Experimental), 502 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.19(P=0.23)					

Analysis 2.10. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 10 Satisfaction with discussion.

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
O'Cathain 2002	548/847	414/636		100%	-0[-0.05,0.05]
Total (95% CI)	**847**	**636**		**100%**	**-0[-0.05,0.05]**
Total events: 548 (Experimental), 414 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.16(P=0.87)					

Analysis 2.11. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 11 Decision regret.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Légaré 2012	162	12.4 (19.1)	164	7.6 (13.7)		100%	0.29[0.07,0.51]
Total ***	**162**		**164**			**100%**	**0.29[0.07,0.51]**



Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Heterogeneity: Not applicable							
Test for overall effect: Z=2.59(P=0.01)							

Favours [control] -100 -50 0 50 100 Favours [experimental]

Analysis 2.12. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 12 Self-efficacy.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Kennedy 2013	1816	70.4 (23.1)	2659	71.1 (22.5)		100%	-0.03[-0.09,0.03]
Total ***	**1816**		**2659**			**100%**	**-0.03[-0.09,0.03]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=1.01(P=0.31)							

Favours [control] -100 -50 0 50 100 Favours [experimental]

Analysis 2.13. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 13 Adherence.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Tinsel 2013	419	95.4 (8.8)	408	96 (6.3)		100%	-0.08[-0.21,0.06]
Total ***	**419**		**408**			**100%**	**-0.08[-0.21,0.06]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.12(P=0.26)							

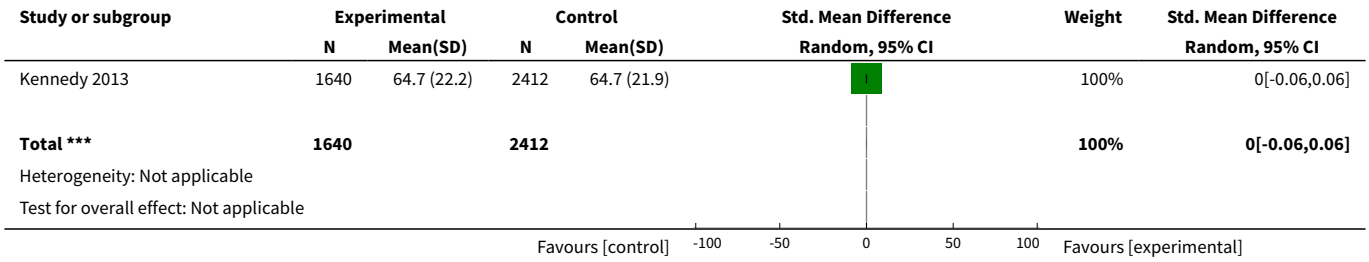
Favours [control] -100 -50 0 50 100 Favours [experimental]

Analysis 2.14. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 14 General health.

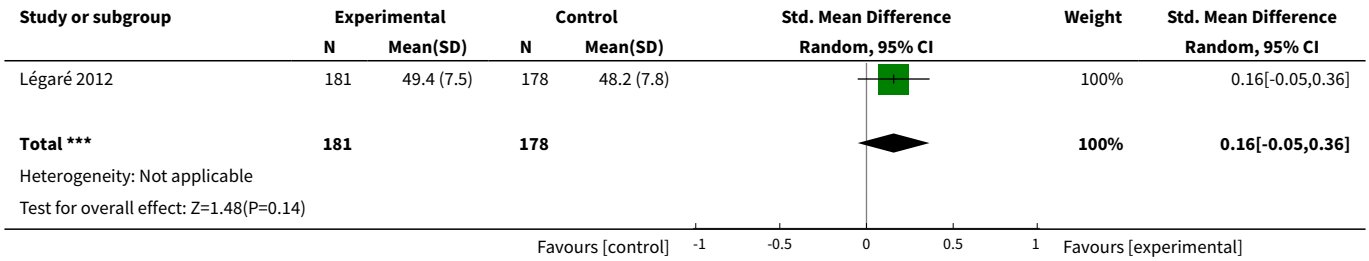
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Kennedy 2013	1643	42.2 (25.8)	2413	41.7 (24.8)		100%	0.02[-0.04,0.08]
Total ***	**1643**		**2413**			**100%**	**0.02[-0.04,0.08]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.62(P=0.54)							

Favours [control] -100 -50 0 50 100 Favours [experimental]

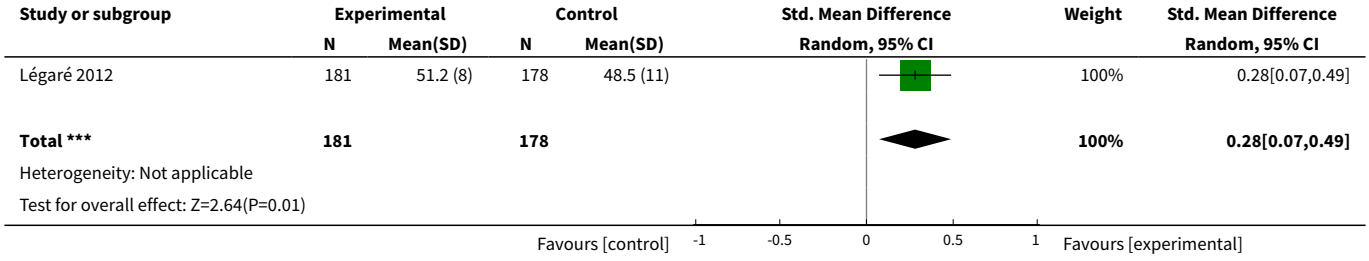
Analysis 2.15. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 15 Psychological well-being.



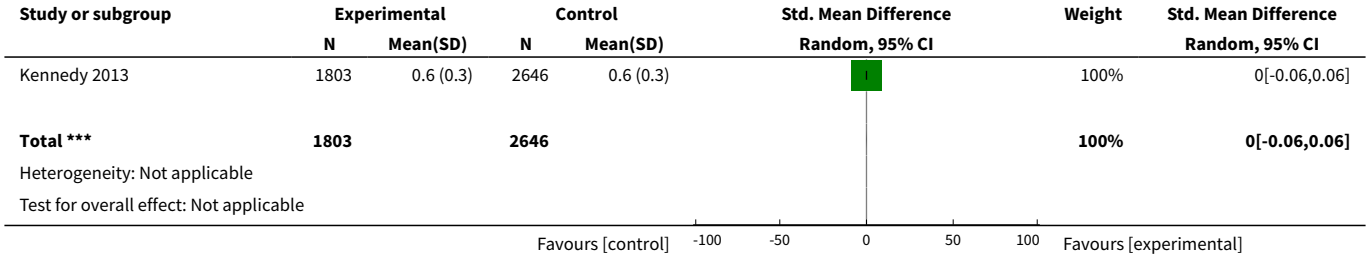
Analysis 2.16. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 16 Health-related quality of life (physical).



Analysis 2.17. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 17 Health-related quality of life (mental).

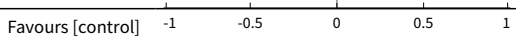


Analysis 2.18. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 18 Health-related quality of life.



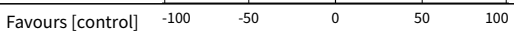
Analysis 2.19. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 19 Anxiety.

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
O'Cathain 2002	86/846	64/630		52.29%	0[-0.03,0.03]
O'Cathain 2002	96/803	87/724		47.71%	-0[-0.03,0.03]
Total (95% CI)	**1649**	**1354**		**100%**	**-0[-0.02,0.02]**
Total events: 182 (Experimental), 151 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0, df=1(P=0.98); I^2=0%					
Test for overall effect: Z=0.02(P=0.98)					



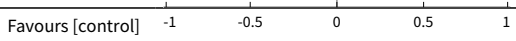
Analysis 2.20. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 20 Consultation length.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Sanders 2017	86	15.8 (6)	89	13.1 (4.5)		100%	0.51[0.21,0.81]
Total ***	**86**		**89**			**100%**	**0.51[0.21,0.81]**
Heterogeneity: Not applicable							
Test for overall effect: Z=3.31(P=0)							



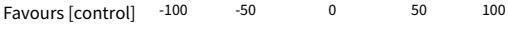
Analysis 2.21. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 21 Consultation length (10-20 min).

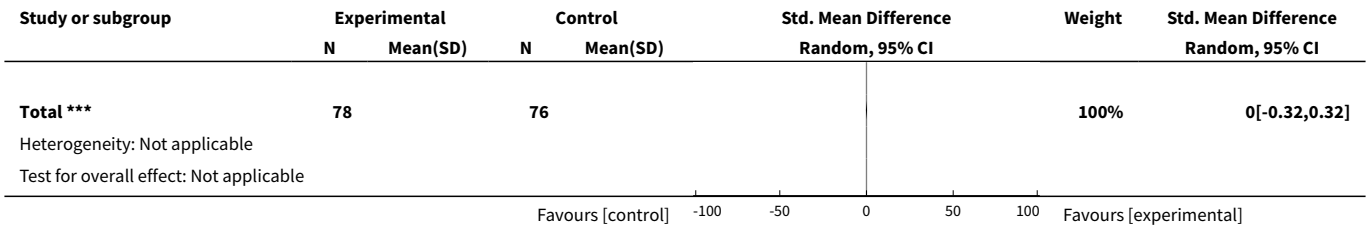
Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Wilkes 2013	103/188	172/291		100%	-0.04[-0.13,0.05]
Total (95% CI)	**188**	**291**		**100%**	**-0.04[-0.13,0.05]**
Total events: 103 (Experimental), 172 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.93(P=0.35)					



Analysis 2.22. Comparison 2 Group 2: Interventions targeting healthcare professionals compared to usual care, Outcome 22 Safety.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Cox 2017	78	4.1 (0.7)	76	4.1 (0.7)		100%	0[-0.32,0.32]





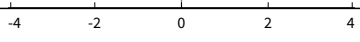
Comparison 3. Group 3: Interventions targeting both patients and healthcare professionals compared to usual care

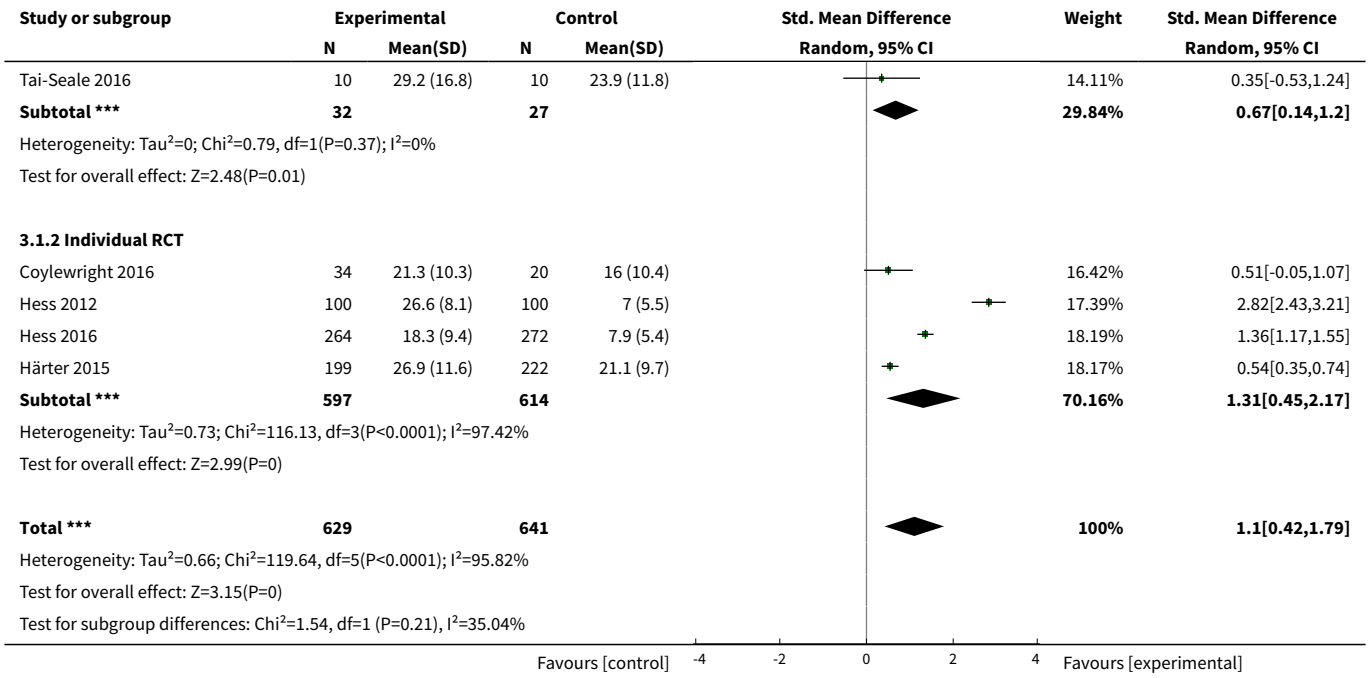
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Shared decision making (OBOM, continuous)	6	1270	Std. Mean Difference (IV, Random, 95% CI)	1.10 [0.42, 1.79]
1.1 Cluster RCT	2	59	Std. Mean Difference (IV, Random, 95% CI)	0.67 [0.14, 1.20]
1.2 Individual RCT	4	1211	Std. Mean Difference (IV, Random, 95% CI)	1.31 [0.45, 2.17]
2 Shared decision making (PROM, continuous)	7	1479	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.02, 0.28]
2.1 Cluster RCT	4	890	Std. Mean Difference (IV, Random, 95% CI)	0.20 [-0.01, 0.41]
2.2 Individual RCT	3	589	Std. Mean Difference (IV, Random, 95% CI)	-0.01 [-0.17, 0.16]
3 Shared decision making (PROM, categorical)	2	266	Risk Difference (M-H, Random, 95% CI)	-0.01 [-0.20, 0.19]
3.1 Cluster RCT	1	169	Risk Difference (M-H, Random, 95% CI)	-0.09 [-0.23, 0.05]
3.2 Individual RCT	1	97	Risk Difference (M-H, Random, 95% CI)	0.11 [-0.10, 0.31]
4 Knowledge	2	1004	Std. Mean Difference (IV, Random, 95% CI)	0.41 [0.28, 0.53]
5 Knowledge (categorical)	4	1260	Risk Difference (M-H, Random, 95% CI)	0.28 [0.05, 0.51]
6 Satisfaction with care	2	362	Std. Mean Difference (IV, Random, 95% CI)	0.51 [-0.34, 1.36]
7 Satisfaction with decision	1	424	Std. Mean Difference (IV, Random, 95% CI)	0.24 [0.05, 0.43]
8 Satisfaction with consultation	1	393	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.23, 0.23]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9 Decisional conflict	2	1065	Std. Mean Difference (IV, Random, 95% CI)	-0.35 [-0.71, 0.01]
10 Confidence in decision	1	414	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.17, 0.22]
11 Decision regret	1	369	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.08, 0.33]
12 Patient-physician communication (patient-centered communication)	1	265	Std. Mean Difference (IV, Random, 95% CI)	0.23 [-0.01, 0.47]
13 Match between preferred and actual level of participation in decision making	2	185	Risk Difference (M-H, Random, 95% CI)	-0.03 [-0.16, 0.10]
14 Adherence	1	489	Std. Mean Difference (IV, Random, 95% CI)	0.60 [0.36, 0.83]
15 Adherence (categorical)	2	145	Risk Difference (M-H, Random, 95% CI)	0.00 [-0.15, 0.15]
16 Health-related quality of life	1	265	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.16, 0.33]
17 Health-related quality of life (physical)	1	75	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.37, 0.54]
18 Health-related quality of life (mental)	1	75	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.44, 0.46]
19 Anxiety	1	419	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.31, 0.08]
20 Depression	1	418	Std. Mean Difference (IV, Random, 95% CI)	-0.14 [-0.33, 0.05]
21 Consultation length	1	536	Std. Mean Difference (IV, Random, 95% CI)	3.72 [3.44, 4.01]
22 Safety	1	898	Risk Difference (M-H, Random, 95% CI)	0.0 [-0.00, 0.00]

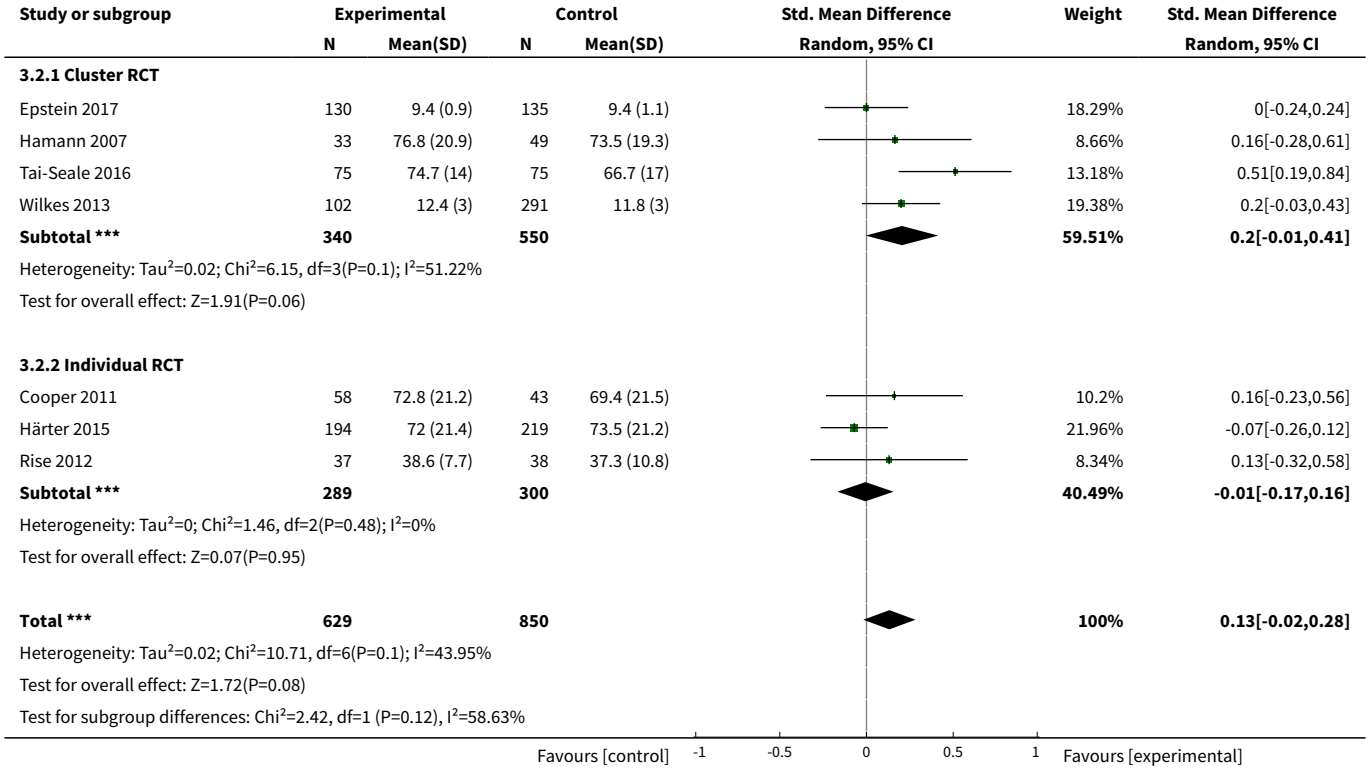
Analysis 3.1. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 1 Shared decision making (OBOM, continuous).

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
3.1.1 Cluster RCT							
Branda 2013	22	49.7 (21.7)	17	28.3 (27.9)		15.73%	0.85[0.19,1.52]



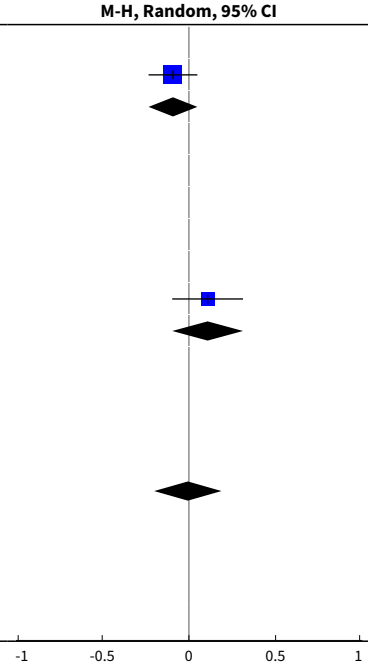


Analysis 3.2. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 2 Shared decision making (PROM, continuous).



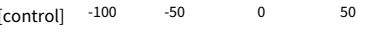
Analysis 3.3. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 3 Shared decision making (PROM, categorical).

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
3.3.1 Cluster RCT					
Mathers 2012	25/92	28/77		57.09%	-0.09[-0.23,0.05]
Subtotal (95% CI)	**92**	**77**		**57.09%**	**-0.09[-0.23,0.05]**
Total events: 25 (Experimental), 28 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.28(P=0.2)					
3.3.2 Individual RCT					
Härter 2015	21/36	29/61		42.91%	0.11[-0.1,0.31]
Subtotal (95% CI)	**36**	**61**		**42.91%**	**0.11[-0.1,0.31]**
Total events: 21 (Experimental), 29 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.04(P=0.3)					
Total (95% CI)	**128**	**138**		**100%**	**-0.01[-0.2,0.19]**
Total events: 46 (Experimental), 57 (Control)					
Heterogeneity: Tau^2=0.01; Chi^2=2.51, df=1(P=0.11); I^2=60.08%					
Test for overall effect: Z=0.06(P=0.95)					
Test for subgroup differences: Chi^2=2.5, df=1 (P=0.11), I^2=59.94%					



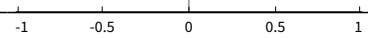
Analysis 3.4. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 4 Knowledge.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Coylewright 2016	58	63.3 (48.9)	48	39.6 (48.6)		10.38%	0.48[0.09,0.87]
Hess 2016	451	4.2 (1.5)	447	3.6 (1.5)		89.62%	0.4[0.27,0.53]
Total ***	**509**		**495**			**100%**	**0.41[0.28,0.53]**
Heterogeneity: Tau^2=0; Chi^2=0.16, df=1(P=0.69); I^2=0%							
Test for overall effect: Z=6.4(P<0.0001)							

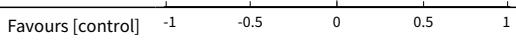


Analysis 3.5. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 5 Knowledge (categorical).

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Branda 2013	14/23	12/36		21.12%	0.28[0.02,0.53]
Hess 2016	293/451	81/447		27.84%	0.47[0.41,0.53]
Mathers 2012	29/95	23/80		25.78%	0.02[-0.12,0.15]
Sheridan 2012	27/58	9/70		25.26%	0.34[0.19,0.49]

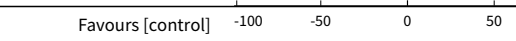


Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Total (95% CI)	**627**	**633**		**100%**	**0.28[0.05,0.51]**
Total events: 363 (Experimental), 125 (Control)					
Heterogeneity: Tau^2=0.05; Chi^2=37.6, df=3(P<0.0001); I^2=92.02%					
Test for overall effect: Z=2.37(P=0.02)					



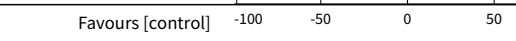
Analysis 3.6. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 6 Satisfaction with care.

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Loh 2007	191	29.8 (2.7)	96	27 (3.6)		52.4%	0.92[0.67,1.18]
Rise 2012	37	24.4 (5)	38	24.2 (4)		47.6%	0.05[-0.4,0.51]
Total ***	**228**		**134**			**100%**	**0.51[-0.34,1.36]**
Heterogeneity: Tau^2=0.34; Chi^2=10.71, df=1(P=0); I^2=90.67%							
Test for overall effect: Z=1.17(P=0.24)							



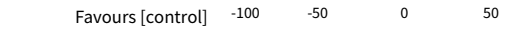
Analysis 3.7. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 7 Satisfaction with decision.

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Härter 2015	201	85.6 (14.1)	223	82 (15.7)		100%	0.24[0.05,0.43]
Total ***	**201**		**223**			**100%**	**0.24[0.05,0.43]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=2.46(P=0.01)							



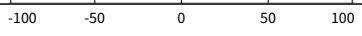
Analysis 3.8. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 8 Satisfaction with consultation.

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Wilkes 2013	102	18 (3)	291	18 (3)		100%	0[-0.23,0.23]
Total ***	**102**		**291**			**100%**	**0[-0.23,0.23]**
Heterogeneity: Not applicable							
Test for overall effect: Not applicable							



Analysis 3.9. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 9 Decisional conflict.

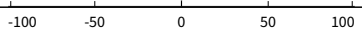
Study or subgroup	Experimental		Control		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Hess 2016	451	43.5 (15.3)	447	46.4 (14.8)		57.37%	-0.19[-0.32,-0.06]
Mathers 2012	89	17.4 (12.6)	78	25.2 (14.9)		42.63%	-0.57[-0.88,-0.26]
Total ***	**540**		**525**			**100%**	**-0.35[-0.71,0.01]**
Heterogeneity: Tau^2=0.05; Chi^2=4.72, df=1(P=0.03); I^2=78.83%							
Test for overall effect: Z=1.9(P=0.06)							



Favours [control] Favours [experimental]

Analysis 3.10. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 10 Confidence in decision.

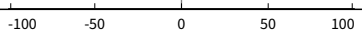
Study or subgroup	Experimental		Control		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Härter 2015	190	81.5 (17.4)	224	81 (18.4)		100%	0.03[-0.17,0.22]
Total ***	**190**		**224**			**100%**	**0.03[-0.17,0.22]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.28(P=0.78)							



Favours [control] Favours [experimental]

Analysis 3.11. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 11 Decision regret.

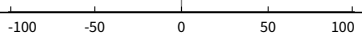
Study or subgroup	Experimental		Control		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Härter 2015	186	13.6 (16.2)	183	11.6 (15)		100%	0.13[-0.08,0.33]
Total ***	**186**		**183**			**100%**	**0.13[-0.08,0.33]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.23(P=0.22)							



Favours [control] Favours [experimental]

Analysis 3.12. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 12 Patient-physician communication (patient-centered communication).

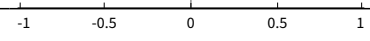
Study or subgroup	Experimental		Control		Std. Mean Difference	Weight	Std. Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI		Random, 95% CI
Epstein 2017	130	0.2 (0.8)	135	-0 (0.7)		100%	0.23[-0.01,0.47]
Total ***	**130**		**135**			**100%**	**0.23[-0.01,0.47]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.86(P=0.06)							



Favours [control] Favours [experimental]

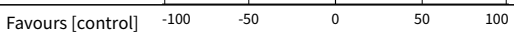
Analysis 3.13. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 13 Match between preferred and actual level of participation in decision making.

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Härter 2015	25/35	44/61		49.49%	-0.01[-0.19,0.18]
Sheridan 2012	27/38	39/51		50.51%	-0.05[-0.24,0.13]
Total (95% CI)	**73**	**112**		**100%**	**-0.03[-0.16,0.1]**
Total events: 52 (Experimental), 83 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.12, df=1(P=0.73); I^2=0%					
Test for overall effect: Z=0.46(P=0.65)					



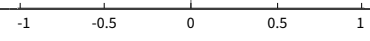
Analysis 3.14. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 14 Adherence.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Loh 2007	191	4.8 (0.6)	96	4.3 (1.1)		85.54%	0.62[0.37,0.87]
Loh 2007	191	4.3 (0.9)	11	3.9 (1)		14.46%	0.44[-0.17,1.05]
Total ***	**382**		**107**			**100%**	**0.6[0.36,0.83]**
Heterogeneity: Tau^2=0; Chi^2=0.29, df=1(P=0.59); I^2=0%							
Test for overall effect: Z=5.04(P<0.0001)							



Analysis 3.15. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 15 Adherence (categorical).

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Branda 2013	38/49	22/28		60.11%	-0.01[-0.2,0.18]
Hamann 2007	18/30	22/38		39.89%	0.02[-0.21,0.26]
Total (95% CI)	**79**	**66**		**100%**	**0[-0.15,0.15]**
Total events: 56 (Experimental), 44 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.04, df=1(P=0.84); I^2=0%					
Test for overall effect: Z=0.03(P=0.98)					

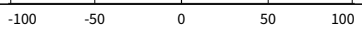


Analysis 3.16. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 16 Health-related quality of life.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Epstein 2017	130	-0 (0.7)	135	-0.1 (0.8)		100%	0.08[-0.16,0.33]
Total ***	**130**		**135**			**100%**	**0.08[-0.16,0.33]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.69(P=0.49)							

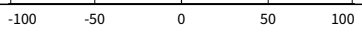
Analysis 3.17. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 17 Health-related quality of life (physical).

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Rise 2012	37	49.1 (8.9)	38	48.4 (8.7)		100%	0.08[-0.37,0.54]
Total ***	**37**		**38**			**100%**	**0.08[-0.37,0.54]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.37(P=0.72)							



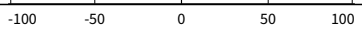
Analysis 3.18. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 18 Health-related quality of life (mental).

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Rise 2012	37	40.6 (9.2)	38	40.6 (7.9)		100%	0.01[-0.44,0.46]
Total ***	**37**		**38**			**100%**	**0.01[-0.44,0.46]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.04(P=0.97)							



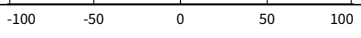
Analysis 3.19. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 19 Anxiety.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Härter 2015	201	7.9 (4.2)	218	8.4 (4.4)		100%	-0.12[-0.31,0.08]
Total ***	**201**		**218**			**100%**	**-0.12[-0.31,0.08]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.18(P=0.24)							



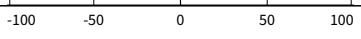
Analysis 3.20. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 20 Depression.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Härter 2015	202	5.8 (4.3)	216	6.4 (4.3)		100%	-0.14[-0.33,0.05]
Total ***	**202**		**216**			**100%**	**-0.14[-0.33,0.05]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.42(P=0.16)							



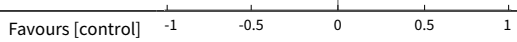
Analysis 3.21. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 21 Consultation length.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Hess 2016	264	4.4 (0.4)	272	3.1 (0.3)		100%	3.72[3.44,4.01]
Total ***	**264**		**272**			**100%**	**3.72[3.44,4.01]**
Heterogeneity: Not applicable							
Test for overall effect: Z=26.01(P<0.0001)							



Analysis 3.22. Comparison 3 Group 3: Interventions targeting both patients and healthcare professionals compared to usual care, Outcome 22 Safety.

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Hess 2016	0/451	0/447		100%	0[-0,0]
Total (95% CI)	**451**	**447**		**100%**	**0[-0,0]**
Total events: 0 (Experimental), 0 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					



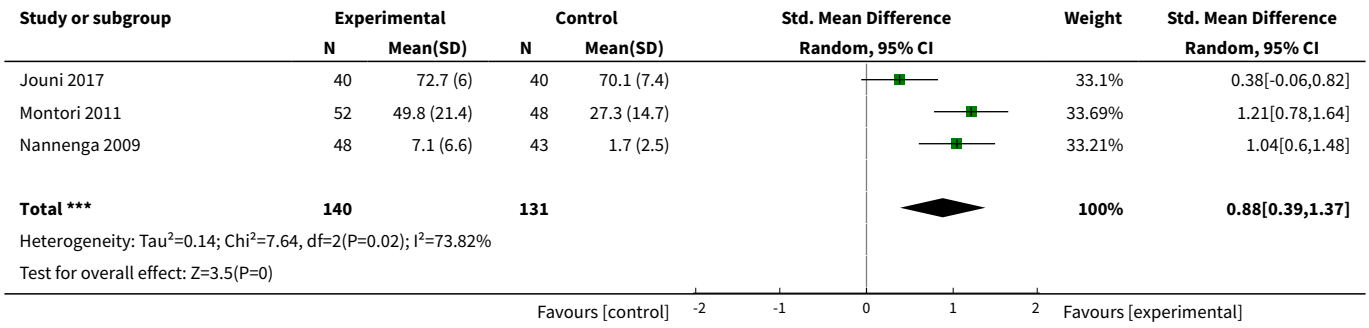
Comparison 4. Group 4: Inteventions targeting patients compared to other interventions targeting patients

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Shared decision making (OBOM, continuous)	3	271	Std. Mean Difference (IV, Random, 95% CI)	0.88 [0.39, 1.37]

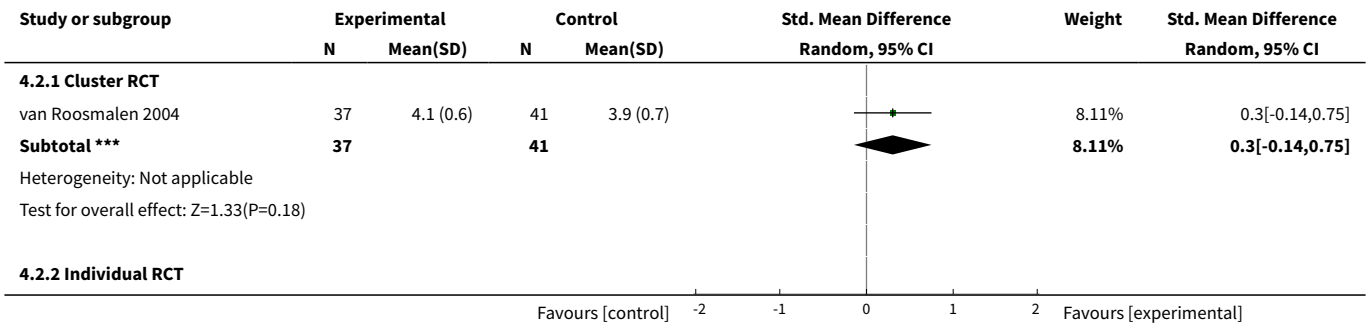
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Shared decision making (PROM, continuous)	11	1906	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.18, 0.24]
2.1 Cluster RCT	1	78	Std. Mean Difference (IV, Random, 95% CI)	0.30 [-0.14, 0.75]
2.2 Individual RCT	10	1828	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.22, 0.23]
3 Shared decision making (PROM, continuous) comp1 - NRCT	1	97	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.61, 0.19]
4 Shared decision making (PROM, continuous) comp2 - NRCT	1	110	Std. Mean Difference (IV, Random, 95% CI)	-0.19 [-0.56, 0.19]
5 Shared decision making (PROM, continuous) comp3 - NRCT	1	99	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.37, 0.43]
6 Shared decision making (PROM, categorical)	10	2272	Risk Difference (M-H, Random, 95% CI)	0.03 [-0.02, 0.08]
7 Knowledge	1	596	Std. Mean Difference (IV, Random, 95% CI)	0.30 [0.13, 0.47]
8 Knowledge (categorical)	3	706	Risk Difference (M-H, Random, 95% CI)	0.16 [-0.10, 0.42]
9 Satisfaction with decision	1	596	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.10, 0.24]
10 Satisfaction with treatment	2	267	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.34, 0.16]
11 Satisfaction with consultation	1	207	Std. Mean Difference (IV, Random, 95% CI)	-0.14 [-0.42, 0.13]
12 Satisfaction with information provided	1	39	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.52, 0.73]
13 Decisional conflict	5	1088	Std. Mean Difference (IV, Random, 95% CI)	-0.20 [-0.48, 0.08]
14 Decision uncertainty	1	80	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.65, 0.23]
15 Decision self-efficacy	2	100	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.41, 0.37]
16 Match between preferred and actual level of participation in decision making	4	1206	Risk Difference (M-H, Random, 95% CI)	-0.10 [-0.16, -0.05]

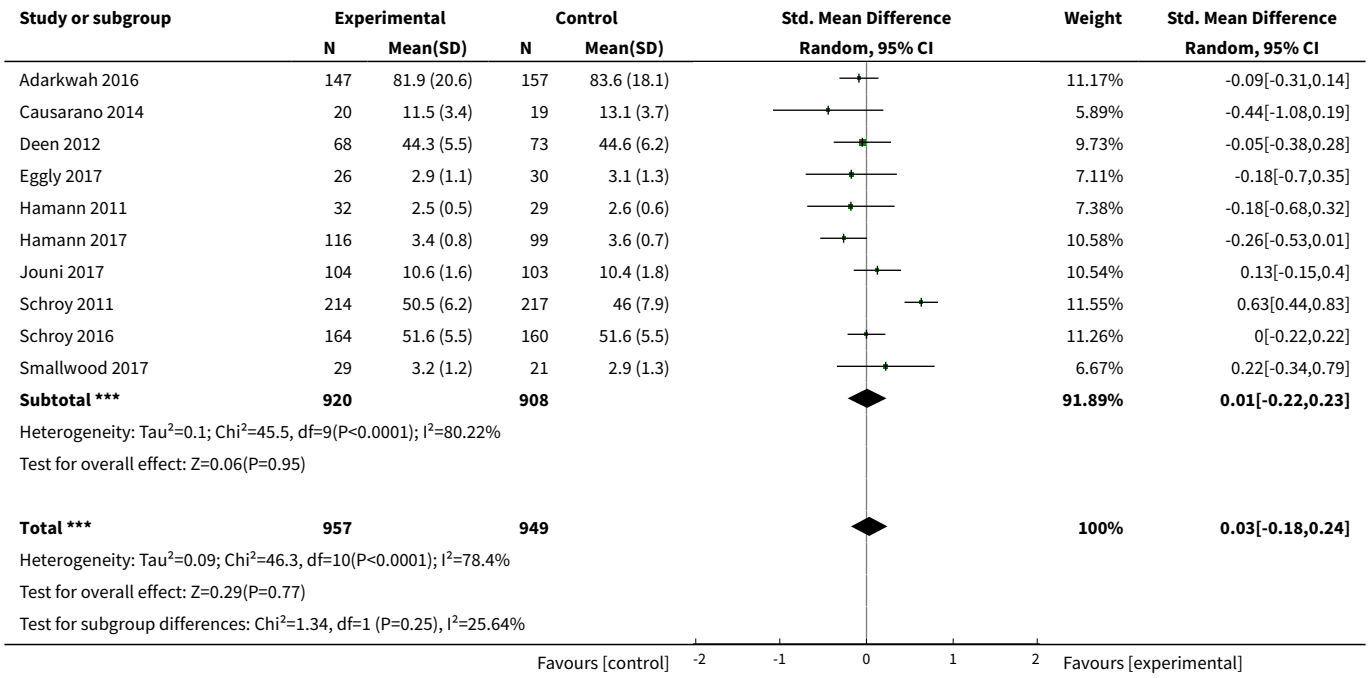
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
17 Match between preferred option and decision made	2	363	Risk Difference (M-H, Random, 95% CI)	-0.20 [-0.60, 0.20]
18 Adherence	1	100	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.35, 0.44]
19 Adherence (categorical)	3	301	Risk Difference (M-H, Random, 95% CI)	0.01 [-0.10, 0.12]
20 General health	1	88	Std. Mean Difference (IV, Random, 95% CI)	-0.19 [-0.61, 0.23]
21 Anxiety	2	682	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.27, 0.05]
22 Depression	1	86	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.69, 0.16]
23 Consultation length	1	39	Std. Mean Difference (IV, Random, 95% CI)	-0.65 [-1.29, -0.00]

Analysis 4.1. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 1 Shared decision making (OBOM, continuous).

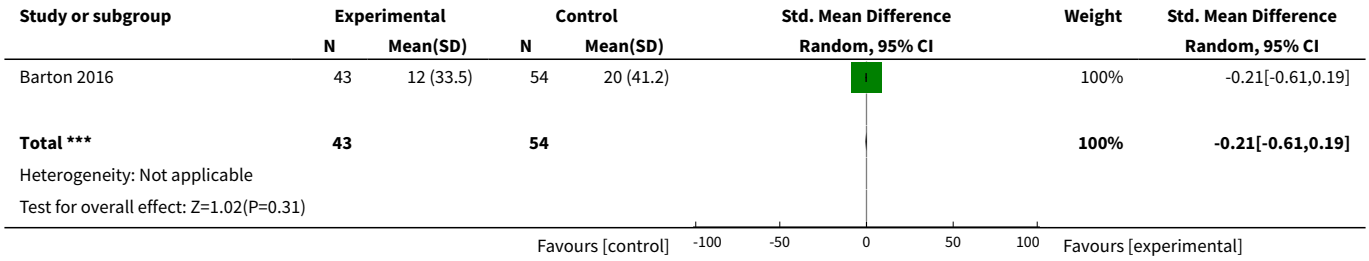


Analysis 4.2. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 2 Shared decision making (PROM, continuous).

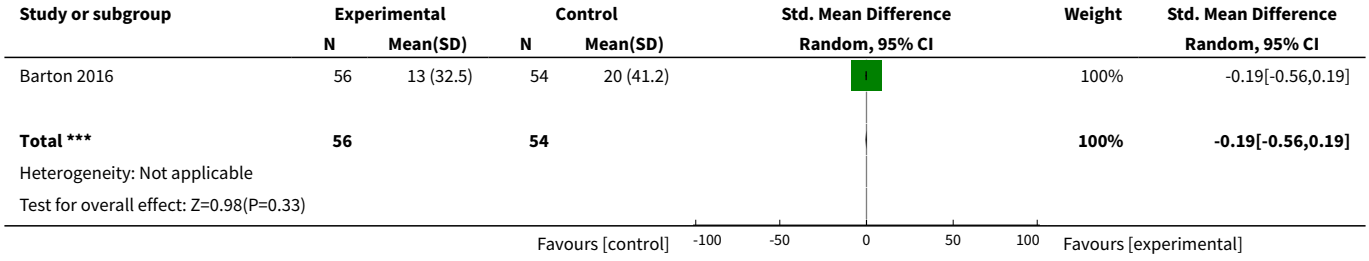




Analysis 4.3. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 3 Shared decision making (PROM, continuous) comp1 - NRCT.

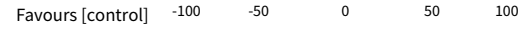


Analysis 4.4. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 4 Shared decision making (PROM, continuous) comp2 - NRCT.



Analysis 4.5. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 5 Shared decision making (PROM, continuous) comp3 - NRCT.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Barton 2016	56	13 (32.5)	43	12 (33.5)		100%	0.03[-0.37,0.43]
Total ***	**56**		**43**			**100%**	**0.03[-0.37,0.43]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.15(P=0.88)							



Analysis 4.6. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 6 Shared decision making (PROM, categorical).

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Butow 2004	22/69	17/62		8.24%	0.04[-0.11,0.2]
Davison 1997	10/30	15/30		3.88%	-0.17[-0.41,0.08]
Davison 2002	159/367	153/367		20.63%	0.02[-0.06,0.09]
Deschamps 2004	24/42	22/48		5.3%	0.11[-0.09,0.32]
Dolan 2002	27/43	22/43		5.2%	0.12[-0.09,0.32]
Kasper 2008	55/136	53/142		12.7%	0.03[-0.08,0.15]
Krist 2007	71/198	63/174		15.32%	-0[-0.1,0.09]
Raynes-Greenow 2010	39/176	31/175		18.03%	0.04[-0.04,0.13]
Stiggelbout 2008	16/31	24/33		4.29%	-0.21[-0.44,0.02]
Thomson 2007	35/51	25/55		6.42%	0.23[0.05,0.41]
Total (95% CI)	**1143**	**1129**		**100%**	**0.03[-0.02,0.08]**
Total events: 458 (Experimental), 425 (Control)					
Heterogeneity: Tau^2=0; Chi^2=13.28, df=9(P=0.15); I^2=32.21%					
Test for overall effect: Z=1.14(P=0.26)					

Analysis 4.7. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 7 Knowledge.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Raynes-Greenow 2010	395	65.1 (29.5)	201	56.5 (27.4)		100%	0.3[0.13,0.47]
Total ***	**395**		**201**			**100%**	**0.3[0.13,0.47]**
Heterogeneity: Not applicable							
Test for overall effect: Z=3.42(P=0)							

Analysis 4.8. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 8 Knowledge (categorical).

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Barton 2016	30/48	31/58		30.92%	0.09[-0.1,0.28]
Krist 2007	156/226	135/196		35.46%	0[-0.09,0.09]
Köpke 2014	57/88	23/90		33.62%	0.39[0.26,0.53]
Total (95% CI)	**362**	**344**		**100%**	**0.16[-0.1,0.42]**
Total events: 243 (Experimental), 189 (Control)					
Heterogeneity: Tau^2=0.05; Chi^2=22.71, df=2(P<0.0001); I^2=91.19%					
Test for overall effect: Z=1.22(P=0.22)					

Analysis 4.9. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 9 Satisfaction with decision.

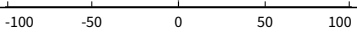
Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Raynes-Greenow 2010	395	81.5 (10.3)	201	80.7 (11.7)		100%	0.07[-0.1,0.24]
Total ***	**395**		**201**			**100%**	**0.07[-0.1,0.24]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.85(P=0.39)							

Analysis 4.10. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 10 Satisfaction with treatment.

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Hamann 2011	32	25.5 (4.1)	29	26.7 (3.2)		23.62%	-0.32[-0.83,0.19]
Hamann 2017	109	25.7 (4.2)	97	25.8 (5.2)		76.38%	-0.02[-0.29,0.25]
Total ***	**141**		**126**			**100%**	**-0.09[-0.34,0.16]**
Heterogeneity: Tau^2=0; Chi^2=1.04, df=1(P=0.31); I^2=3.64%							
Test for overall effect: Z=0.72(P=0.47)							

Analysis 4.11. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 11 Satisfaction with consultation.

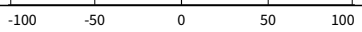
Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Jouni 2017	104	6 (0.2)	103	6 (0.1)		100%	-0.14[-0.42,0.13]



Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Total ***	**104**		**103**			**100%**	**-0.14[-0.42,0.13]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.03(P=0.31)							

Analysis 4.12. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 12 Satisfaction with information provided.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Causarano 2014	20	69.9 (12.6)	19	68.4 (15)		100%	0.11[-0.52,0.73]
Total ***	**20**		**19**			**100%**	**0.11[-0.52,0.73]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.33(P=0.74)							

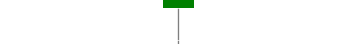


Analysis 4.13. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 13 Decisional conflict.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Adarkwah 2016	147	15.4 (14)	157	14.8 (12.4)		26.26%	0.05[-0.18,0.27]
Dolan 2002	45	1.8 (0.5)	43	2 (0.8)		18.52%	-0.29[-0.71,0.13]
Lalonde 2006	26	2.4 (0.3)	24	2.3 (0.3)		14.17%	0.1[-0.46,0.65]
Raynes-Greenow 2010	395	23.9 (10.6)	201	24.9 (12.9)		28.3%	-0.09[-0.26,0.08]
Smallwood 2017	29	17.8 (17.3)	21	47.1 (33.1)		12.75%	-1.15[-1.76,-0.54]
Total ***	**642**		**446**			**100%**	**-0.2[-0.48,0.08]**
Heterogeneity: Tau^2=0.07; Chi^2=14.33, df=4(P=0.01); I^2=72.1%							
Test for overall effect: Z=1.39(P=0.17)							

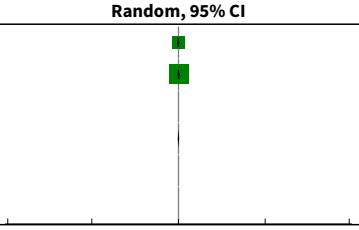
Analysis 4.14. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 14 Decision uncertainty.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
van Roosmalen 2004	38	2.1 (0.9)	42	2.3 (1)		100%	-0.21[-0.65,0.23]
Total ***	**38**		**42**			**100%**	**-0.21[-0.65,0.23]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=0.92(P=0.36)							



Analysis 4.15. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 15 Decision self-efficacy.

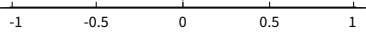
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Causarano 2014	20	89.9 (12.9)	19	91.4 (11.5)		39%	-0.12[-0.75,0.51]
Hamann 2011	32	56.7 (8.4)	29	56.3 (9.5)		61%	0.04[-0.46,0.55]
Total ***	**52**		**48**			**100%**	**-0.02[-0.41,0.37]**
Heterogeneity: Tau^2=0; Chi^2=0.16, df=1(P=0.69); I^2=0%							
Test for overall effect: Z=0.1(P=0.92)							



Favours [control] Favours [experimental]

Analysis 4.16. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 16 Match between preferred and actual level of participation in decision making.

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Bernhard 2011	21/50	32/58		9.24%	-0.13[-0.32,0.06]
Davison 2002	241/367	292/367		49.45%	-0.14[-0.2,-0.08]
Dolan 2002	13/43	11/43		9.06%	0.05[-0.14,0.24]
Kasper 2008	18/136	31/142		32.26%	-0.09[-0.17,0]
Total (95% CI)	**596**	**610**		**100%**	**-0.1[-0.16,-0.05]**
Total events: 293 (Experimental), 366 (Control)					
Heterogeneity: Tau^2=0; Chi^2=3.76, df=3(P=0.29); I^2=20.19%					
Test for overall effect: Z=3.45(P=0)					



Favours [control] Favours [experimental]

Analysis 4.17. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 17 Match between preferred option and decision made.

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Causarano 2014	1/8	8/14		41.4%	-0.45[-0.79,-0.1]
Schroy 2016	147/173	148/168		58.6%	-0.03[-0.1,0.04]
Total (95% CI)	**181**	**182**		**100%**	**-0.2[-0.6,0.2]**
Total events: 148 (Experimental), 156 (Control)					
Heterogeneity: Tau^2=0.07; Chi^2=5.33, df=1(P=0.02); I^2=81.23%					
Test for overall effect: Z=0.99(P=0.32)					

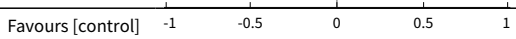
Favours [control] Favours [experimental]

Analysis 4.18. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 18 Adherence.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Hamann 2017	54	2.6 (2.1)	46	2.5 (2.2)		100%	0.05[-0.35,0.44]
Total ***	**54**		**46**			**100%**	**0.05[-0.35,0.44]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.23(P=0.82)							

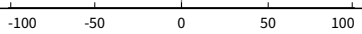
Analysis 4.19. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 19 Adherence (categorical).

Study or subgroup	Experimental n/N	Control n/N	Risk Difference M-H, Random, 95% CI	Weight	Risk Difference M-H, Random, 95% CI
Barton 2016	31/52	20/40		29.83%	0.1[-0.11,0.3]
Hamann 2017	51/91	49/82		57.54%	-0.04[-0.18,0.11]
Montori 2011	11/17	12/19		12.64%	0.02[-0.3,0.33]
Total (95% CI)	**160**	**141**		**100%**	**0.01[-0.1,0.12]**
Total events: 93 (Experimental), 81 (Control)					
Heterogeneity: Tau^2=0; Chi^2=1.08, df=2(P=0.58); I^2=0%					
Test for overall effect: Z=0.16(P=0.87)					



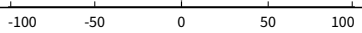
Analysis 4.20. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 20 General health.

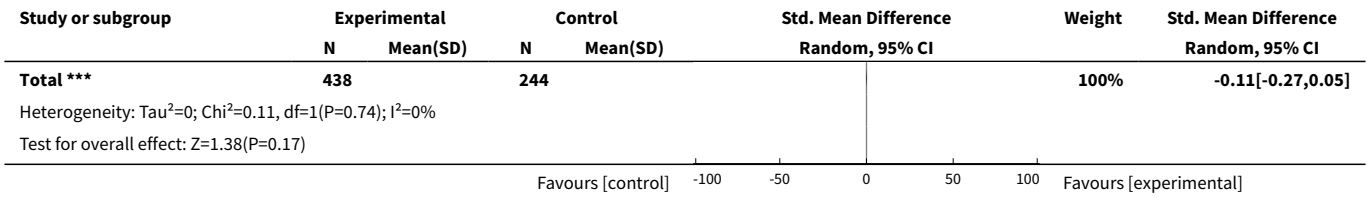
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
van Roosmalen 2004	40	7.6 (1.9)	48	7.9 (1.3)		100%	-0.19[-0.61,0.23]
Total ***	**40**		**48**			**100%**	**-0.19[-0.61,0.23]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=0.87(P=0.39)							



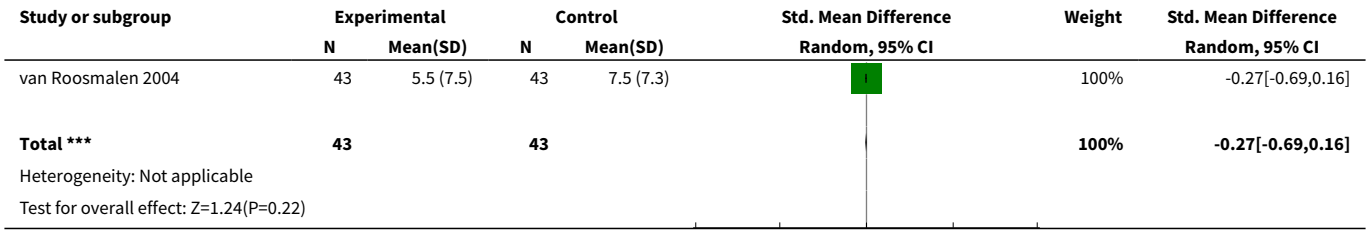
Analysis 4.21. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 21 Anxiety.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Raynes-Greenow 2010	395	33.3 (9.3)	201	34.3 (11)		86.14%	-0.1[-0.27,0.07]
van Roosmalen 2004	43	35.4 (11.7)	43	37.4 (10.7)		13.86%	-0.18[-0.6,0.25]

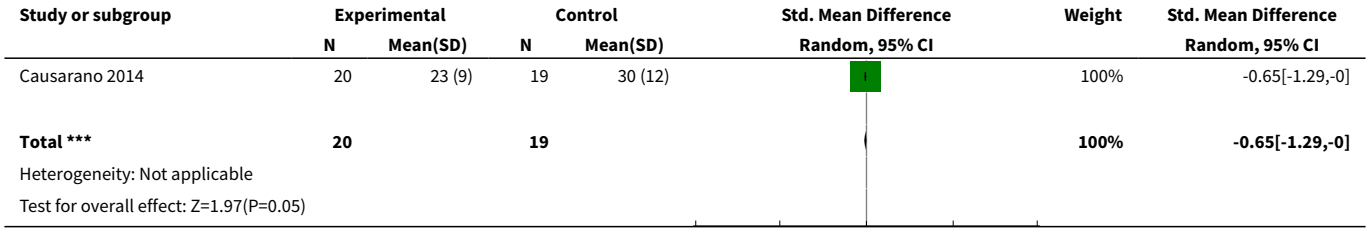




Analysis 4.22. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 22 Depression.



Analysis 4.23. Comparison 4 Group 4: Inteventions targeting patients compared to other interventions targeting patients, Outcome 23 Consultation length.

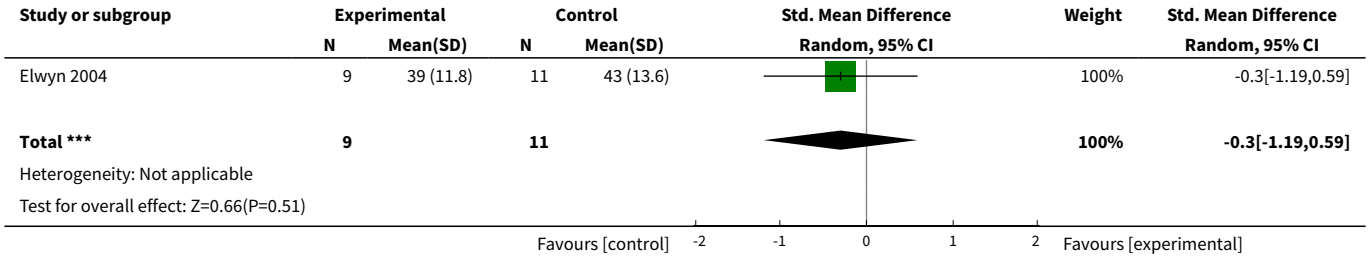


Comparison 5. Group 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals

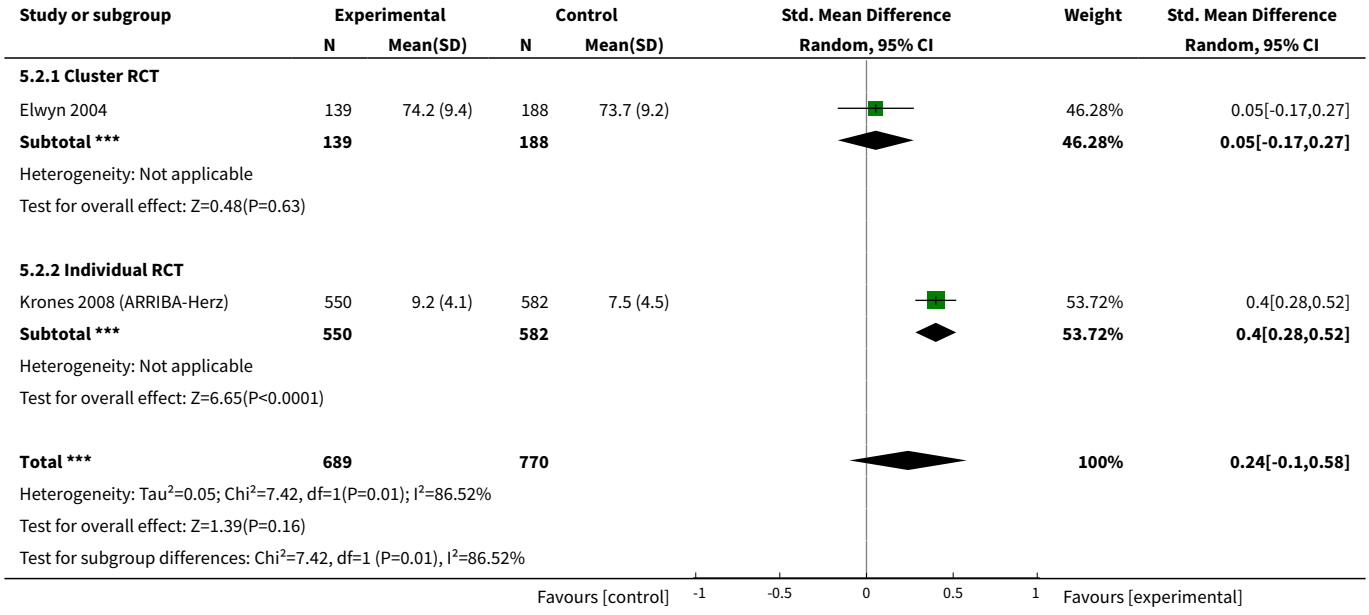
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Shared decision making (OBOM, continuous)	1	20	Std. Mean Difference (IV, Random, 95% CI)	-0.30 [-1.19, 0.59]
2 Shared decision making (PROM, continuous)	2	1459	Std. Mean Difference (IV, Random, 95% CI)	0.24 [-0.10, 0.58]
2.1 Cluster RCT	1	327	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.17, 0.27]
2.2 Individual RCT	1	1132	Std. Mean Difference (IV, Random, 95% CI)	0.40 [0.28, 0.52]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Health status (mental)	1	295	Std. Mean Difference (IV, Random, 95% CI)	0.24 [0.01, 0.47]
4 Health status (physical)	1	295	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.19, 0.28]
5 Anxiety	1	843	Std. Mean Difference (IV, Random, 95% CI)	0.14 [0.00, 0.28]

Analysis 5.1. Comparison 5 Group 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals, Outcome 1 Shared decision making (OBOM, continuous).



Analysis 5.2. Comparison 5 Group 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals, Outcome 2 Shared decision making (PROM, continuous).

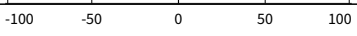


Analysis 5.3. Comparison 5 Group 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals, Outcome 3 Health status (mental).

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Elwyn 2004	171	50.4 (10.9)	124	47.8 (11.2)		100%	0.24[0.01,0.47]
Total ***	**171**		**124**			**100%**	**0.24[0.01,0.47]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=2.02(P=0.04)							

Analysis 5.4. Comparison 5 Group 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals, Outcome 4 Health status (physical).

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Elwyn 2004	171	42.5 (11.8)	124	41.9 (13.1)		100%	0.05[-0.19,0.28]
Total ***	**171**		**124**			**100%**	**0.05[-0.19,0.28]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.39(P=0.7)							



Analysis 5.5. Comparison 5 Group 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals, Outcome 5 Anxiety.

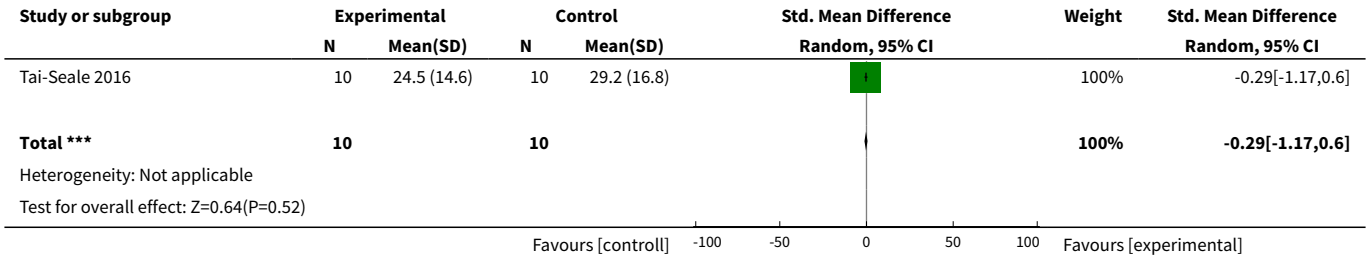
Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Elwyn 2004	138	10 (3.6)	187	9.9 (3.8)		38.74%	0.04[-0.18,0.26]
Elwyn 2004	117	11.3 (4.3)	164	10.2 (3.8)		33.06%	0.25[0.02,0.49]
Elwyn 2004	101	10.5 (3.9)	136	10 (3.2)		28.21%	0.15[-0.11,0.4]
Total ***	**356**		**487**			**100%**	**0.14[0,0.28]**
Heterogeneity: Tau^2=0; Chi^2=1.71, df=2(P=0.42); I^2=0%							
Test for overall effect: Z=2(P=0.05)							

Comparison 6. Group 6: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals

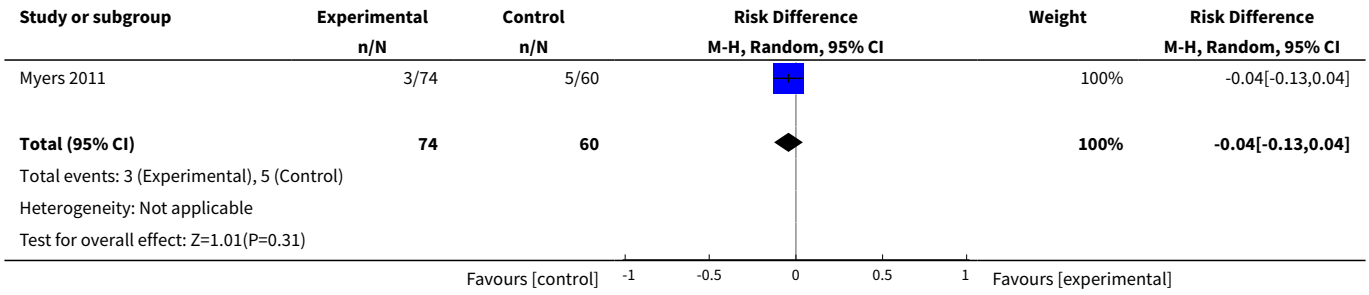
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Shared decision making (OBOM, continuous)	1	20	Std. Mean Difference (IV, Random, 95% CI)	-0.29 [-1.17, 0.60]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Shared decision making (OBOM, categorical)	1	134	Risk Difference (M-H, Random, 95% CI)	-0.04 [-0.13, 0.04]
3 Shared decision making (PROM, continuous)	1	150	Std. Mean Difference (IV, Random, 95% CI)	0.0 [-0.32, 0.32]
4 Decisional conflict	1	286	Std. Mean Difference (IV, Random, 95% CI)	-0.07 [-0.30, 0.16]

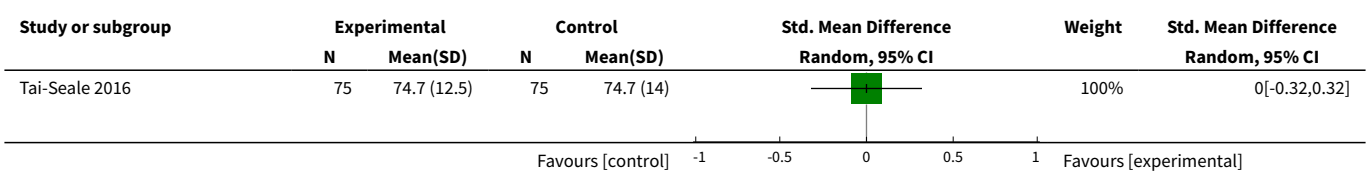
Analysis 6.1. Comparison 6 Group 6: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals, Outcome 1 Shared decision making (OBOM, continuous).

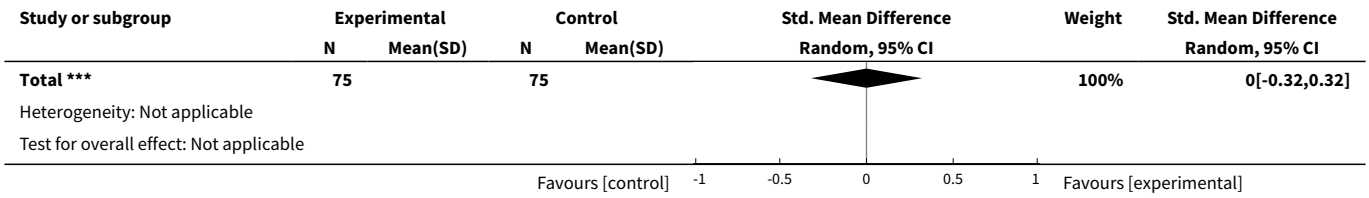


Analysis 6.2. Comparison 6 Group 6: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals, Outcome 2 Shared decision making (OBOM, categorical).

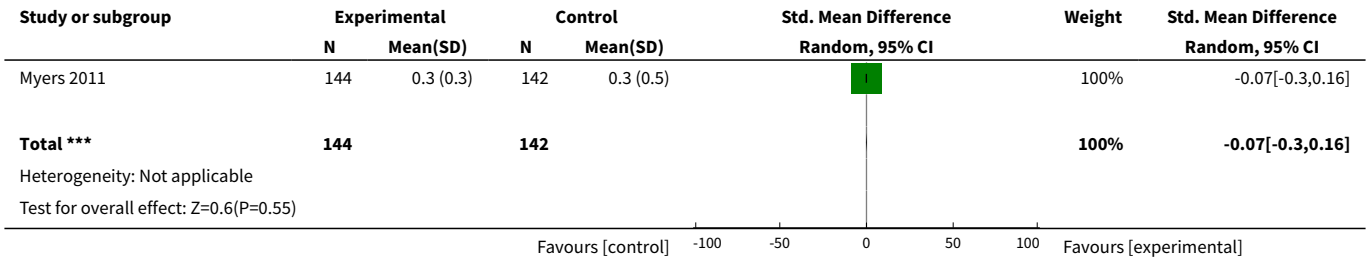


Analysis 6.3. Comparison 6 Group 6: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals, Outcome 3 Shared decision making (PROM, continuous).





Analysis 6.4. Comparison 6 Group 6: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals, Outcome 4 Decisional conflict.



ADDITIONAL TABLES

Table 1. Effect of intervention on primary outcome: interventions targeting patients compared to usual care

Observer-based outcome measure - Continous data								Meta-analysis
Study	**Intervention**	**Control**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
LeBlanc 2015a	Patient-mediated intervention (decision aid)	Usual care	OPTION	96	0.93 (0.50 to 1.36)	0.54 (-0.13 to 1.22)	84%	X
Maclachlan 2016	Patient-mediated intervention (educational meeting for patient)	Usual care	RIAS for patients (Patient activation and engagement)	289	-0.05 (-0.28 to 0.18)			X
LeBlanc 2015b	Patient-mediated intervention (decision aid)	Usual care	OPTION (/100)	19	1.23 (0.17 to 2.29)			x
Tai-Seale 2016	Patient-mediated intervention (one-page ASK handout)	Usual care	OPTION5 (/100)	20	0.32 (-0.56 to 1.21)			x
Observer-based outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Control**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
No study								
Observer-based outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Control**	**Outcome**	**Direct quote**				
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care	Who made the decision in today's consultation	Intervention: Median (2) - Range (1-4); Control: Median (2) - Range (1-4) - No difference				na
Haskard 2008	Patient-mediated intervention	Usual care	Physician informative and participatory	Unit of error analysis				na
Haskard 2008	Patient-mediated intervention	Usual care	Patient active	Unit of error analysis				na
Haskard 2008	Patient-mediated intervention	Usual care	Physician-patient interaction	Unit of error analysis				na

Table 1. Effect of intervention on primary outcome: interventions targeting patients compared to usual care *(Continued)*

Patient-reported outcome measure - Continous data								
Study	**Intervention**	**Control**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	**Meta-analysis**
Deen 2012	Patient-mediated intervention (decision aid)	Usual care	Patient Activation Measure (PAM)	138	-0.07 (-0.40 to 0.26)	0.28 (0.13 to 0.44)	57%	
Deen 2012	Patient-mediated intervention (Patient Activation)	Usual care	Patient Activation Measure (PAM)	142	0.09 (-0.24 to 0.41)			X
Deen 2012	Patient-mediated intervention (decision aid + Patient Activation)	Usual care	Patient Activation Measure (PAM)	137	0.04 (-0.29 to 0.38)			
Maranda 2014	Patient-mediated intervention (patient activated intervention)	Usual care	Patient Activation Measure (PAM)	132	0.12 (-0.22 to 0.47)			x
Pickett 2012	Patient-mediated intervention (training for patients)	Usual care	Patient self-advocacy (immediately after)	Pre: 428; Post: 342	0.20 (-0.01 to 0.41)			x
Pickett 2012	Patient-mediated intervention (training for patients)	Usual care	Patient self-advocacy (6 months after)	Pre: 428; Post: 318	0.02 (-0.20 to 0.24)			
van der Krieke 2013	Patient-mediated intervention (web-based information and decision tool)	Usual care	COMRADE (communication)	73	0.94 (0.46 to 1.43)			x
van Peperstraten 2010	Patient-mediated intervention (decision aid + support call)	Usual care	Decision Evaluation scale	252	0.53 (0.28 to 0.78)			x
Cooper 2011	Patient-mediated intervention	Usual care	Participatory Decision making (PDM)	83	0.21 (-0.22 to 0.64)			x
Perestelo-Perez 2016	Patient-mediated intervention (decision aid)	Usual care	Satisfaction with Decision making process (SDMP)	153	0.50 (0.18 to 0.82)			X
Tai-Seale 2016	Patient-mediated intervention (one-page ASK handout)	Usual care	CollaboRATE (%)	150	0.31 (-0.01 to 0.63)			X

Table 1. Effect of intervention on primary outcome: interventions targeting patients compared to usual care *(Continued)*

Almario 2016	Patient-mediated intervention (GI PROMIS)	Usual care	SDMQ-9	303	0.02 (-0.22 to 0.25)			X
Eggly 2017	Patient-mediated intervention (QPL-only)	Usual care	Patient role in treatment decision	59	0.05 (-0.46 to 0.56)			x
Eggly 2017	Patient-mediated intervention (QPL-plus-Coach)	Usual care	Patient role in treatment decision	55	-0.14 (-0.67 to 0.39)			
Patient-reported outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Control**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
Krist 2007	Patient-mediated intervention (decision aid brochure)	Usual care	Modified Control Preference Scale	237	0.00 (-0.14 to 0.14)	-0.09 (-0.19 to 0.01)	48%	x
Krist 2007	Patient-mediated intervention (decision aid web)	Usual care	Modified Control Preference Scale	261	-0.01 (-0.14 to 0.13)			
Landrey 2012	Patient-mediated intervention (mailed flyer)	Usual care	Modified Control Preference Scale	152	-0.03 (-0.19 to 0.12)			x
Murray 2001	Patient-mediated intervention (decision aid)	Usual care	Modified Control Preference Scale	105	-0.28 (-0.44 to -0.12)			x
Sheridan 2014	Patient-mediated intervention (decision aid)	Usual care	Shared decision	114	-0.17 (-0.35 to 0.002)			x
Vestala 2013	Patient-mediated intervention (patient participation in nursing documentation)	Usual care	Modified Control Preference Scale	39	0.00 (-0.30 to 0.30)			x
Vodermaier 2009	Patient-mediated intervention (decision aid)	Usual care	Modified Control Preference Scale	107	-0.01 (-0.19 to 0.17)			x
Patient-reported outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Control**	**Outcome**	**Direct quote**				
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care	Who made the decision in today's consultation	Intervention: Median (3) - Range (1-5); Control: Median (3) - Range (1-5) - No difference				na

Table 1. Effect of intervention on primary outcome: interventions targeting patients compared to usual care *(Continued)*

van der Krieke 2013	Patient-mediated intervention (web-based information and decision tool)	Usual care	COMRADE (confidence)	COMRADE confidence in decision: F(1.67) = 0.086. P=0.77. see also Table 3	na
Vodermaier 2009	Patient-mediated intervention (decision aid)	Usual care	Man-Son-Hing Instrument	No data	na
van Tol-Geerdink 2016	Patient-mediated intervention (decision aid)	Usual care	Patient participation	"At t2, 95% of the patients in the decision aid group indicated that they actually had been involved in the decision, compared to 83% in the usual care group (P = 0.002). As such, the decision aid had the expected effect on patient participation."Page 466	na
Wolderslund 2017	Patient-mediated intervention (question prompt list) + other (digital audio recording)	Usual care	Involvement in decision making	"Intention-to-treat analyses of the participants' perception of the consultation showed that on average, 4.5% more patients (range: 4.0-5.5), regardless of intervention group, rated their satisfaction with the treatment, confidence in and relationship with the health professional, and involvement in decision making in the highest reply category compared with patients in the control group. This increase was significant (p = 0.001) except for decision making (p = 0.044)." Page 247	na
Wolderslund 2017	Other (digital audio recording)	Usual care	Involvement in decision making	"Intention-to-treat analyses of the participants' perception of the consultation showed that on average, 4.5% more patients (range: 4.0-5.5), regardless of intervention group, rated their satisfaction with the treatment, confidence in and relationship with the health professional, and involvement in decision making in the highest reply category compared with patients in the control group. This increase was significant (p = 0.001) except for decision making (p = 0.044)." Page 247	na
Korteland 2017	Patient-mediated intervention (decision aid)	Usual care	Involvement in decision making	There was no difference between intervention and control group regarding those who "totally agree" that the doctor has involved them in the decision (37.3% vs 39.1%; fig 2)	na

ASK: Ask Share Know; CI: confidence interval; COMRADE: Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness; GI PROMIS: gastrointestinal Patient Reported Outcomes Measurement Information System; N: sample size; na: not applicable; OPTION: observing patient involvement; QPL: question prompt list; RD: risk difference; SDM: shared decision making; SMD: standardized mean difference.

Table 2. Effect of interventions on primary outcome: interventions targeting healthcare professionals compared to usual care

Observer-based outcome measure - Continous data	**Meta-analysis**

Table 2. Effect of interventions on primary outcome: interventions targeting healthcare professionals compared to usual care *(Continued)*

Study	Intervention	Intervention	Outcome	N	SMD	SMD (95% CI)	I^2	
Fossli 2011	Educational meeting + audit and feedback + distribution of educational material	Usual care	Fours Habits Coding Scheme (4HCS)	51	0.38 (-0.17 to 0.94)	0.60 (0.15 to 1.06)	80%	x
Shepherd 2011	Educational outreach visit	Usual care	Assessing Communication about Evidence and Patient Preferences (ACEPP)	36	1.25 (0.53 to 1.97)			
Shepherd 2011	Educational outreach visit	Usual care	OPTION	36	0.90 (0.21 to 1.58)			x
Stacey 2006	Distribution of educational materials + educational meeting + audit and feedback and barriers assessment	Usual care	Decision Support Analysis Tool (DSAT)	38	2.07 (1.26 to 2.87)			x
Sanders 2017	Educational meeting + Audit feedback	Usual care	OPTION	175	0.93 (0.62 to 1.25)			
Sanders 2017	Educational meeting + Audit feedback	Usual care	Level of autonomy (CPS) (2=SDM)	175	0.85 (0.54 to 1.16)			x
Ampe 2017	Educational meetings (Training)	usual care	OPTION (/100)	21	-0.10 (-0.96 to 0.76)			x
Cox 2017	Educational meeting + Distribution of educational material	Usual care	Family engagement	Pre: 144 post: 154	0.11 (-0.21 to 0.42)			x
LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	usual care	OPTION (/100)	25	0.08 (-0.84 to 0.99)			x

Observer-based outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
No study								

Table 2. Effect of interventions on primary outcome: interventions targeting healthcare professionals compared to usual care *(Continued)*

Observer-based outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Direct quote	Meta-analysis
Bernhard 2011	Educational meeting + audit and feedback	Usual care	SDM framework (DAS-O subscale) (SGA)	There was no effect for this variable for SGA doctors (estimated population mean difference = 0.52, SE = 1.39, ES = 0.04, P = 0.71)	na
Bernhard 2011	Educational meeting + audit and feedback	Usual care	SDM framework (DAS-O subscale) (ANZ)	"In the ANZ cohort, the estimated population mean of the difference for establishing the SDM framework (subscale 1 of the DAS-O) was statistically significant, indicating that after the training workshop, doctors in the experimental group within the ANZ cohort displayed more behaviours designed to establish the SDM framework than doctors in the control group (estimated population mean difference = 3.42, SE = 1.50, ES = 0.30, P = 0.03). However, the ES was small." Page 2578	na
Murray 2010	Educational meeting + audit and feedback + distribution of educational materials + educational outreach + barriers assessment	Usual care	Decision Support Analysis Tool (DSAT)	"The mean score change from baseline in the intervention group 3.75 (95% CI 2.46 to 5.03) was significantly greater than the mean score change in the control group -0.667 (95% CI -1.57 to 0.24) using the two sided t-test (P < 0.0001)" Page 116	na

Patient-reported outcome measure - Continous data

Study	Intervention	Intervention	Outcome	N	SMD	SMD (95% IC)	I^2	Meta-analysis
Cooper 2011	Educational meeting	Usual care	Participatory Decision making (PDM)	94	0.11 (-0.30 to 0.51)	0.03 (-0.15 to 0.20)	83%	x
Kennedy 2013	Educational meeting	Usual care	Shared decision making (short-form healthcare climate questionnaire) - 12 month vs baseline	4005	-0.05 (-0.12 to 0.01)			x
Koerner 2014	Educational meeting	Usual care	SDM-Q-9 (post-intervention)	Pre: 402; Post: 463	-0.08 (-0.26 to 0.11)			x
Koerner 2014	Educational meeting	Usual care	SDM-Q-9 (Six-months after)	Pre: 402; Post: 461	-0.03 (-0.22 to 0.16)			

Table 2. Effect of interventions on primary outcome: interventions targeting healthcare professionals compared to usual care *(Continued)*

Tinsel 2013	Distribution of educational material + educational meeting	Usual care	SDM-Q-9 (6 months)	Pre: 940; Post: 731	0.32 (0.17 to 0.46)			x
Tinsel 2013	Distribution of educational material + educational meeting	Usual care	SDM-Q-9 (12 months)	Pre: 940; Post: 628	0.16 (0.00 to 0.32)			
Tinsel 2013	Distribution of educational material + educational meeting	Usual care	SDM-Q-9 (18 months)	Pre: 940; Post: 570	0.25 (0.08 to 0.41)			
Wilkes 2013	Distribution of educational material	Usual care	Overall PSA SDM perception	479	-0.13 (-0.32 to 0.05)			x
Patient-reported outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
Légaré 2012	Educational meeting and distribution of educational material	Usual care	Modified Control Preference Scale	Pre: 353; Post: 353	0.09 (-0.01 to 0.19)	0.01 (-0.03 to 0.06)	74%	x
O'Cathain 2002	Educational meeting and distribution of educational material	Usual care	Modified Control Preference Scale (antenatal sample)	Pre: 2745; Post: 2737	-0.02 (-0.05 to 0.01)			x
O'Cathain 2002	Educational meeting and distribution of educational material	Usual care	Modified Control Preference Scale (postnatal sample)	Pre: 3156; Post 3213	0.02 (-0.01 to 0.05)			x
Patient-reported outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
Bernhard 2011	Educational meeting + audit and feedback + distribution of educational material	Usual care	Patient involvement preference and actual involvement	"There was considerable variation in patient outcomes between the SGA and ANZ cohorts and no substantial training effect." Page 6				na
Légaré 2012	Educational meeting and distribution of educational material	Usual care	D-OPTION	359	Pre: -0.48 (-0.69 to -0.27)			na

ANZ: Australia, New Zealand; CI: confidence interval; CPS: control preference scale; DAS-O: Decision Analysis System for Oncology; N: sample size; na: not applicable; OPTION: observing patient involvement; PSA: prostatic specific antigen; RD: risk difference; SE: standard error; SGA: Switzerland, Germany and Austria; SDM: shared decision making; SMD: standardized mean difference.

Table 3. Effect of interventions on primary outcome: interventions targeting both patients and healthcare professionals compared to usual care

Observer-based outcome measure - Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Branda 2013	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Level of patient engagement (OPTION)	39	0.85 (0.19 to 1.52)	1.10 (0.42 to 1.79)	96%	x
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	OPTION	421	0.54 (0.35 to 0.74)			x
Hess 2012	Patient-mediated intervention + educational meeting	Usual care	OPTION	200	2.83 (2.43 to 3.21)			x
Coylewright 2016	Patient-mediated intervention + Educational meeting	Usual care	OPTION (/100)	54	0.51 (-0.05 to 1.07)			x
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care	OPTION (/100)	536	1.36 (1.17 to 1.55)			X
Tai-Seale 2016	Educational material (video) + patient mediated intervention (booklet) + educational meeting (coaching session for providers)	Usual care	OPTION5 (/100)	20	0.35 (-0.53 to 1.24)			x
Tai-Seale 2016	[Educational material (video) + patient mediated intervention (booklet) + educational meeting (coaching session for providers)] + Patient mediated intervention (one-page ASK handout)	Usual care	OPTION5 (/100)	20	0.04 (-0.83 to 0.92)			
Observer-based outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	

Table 3. Effect of interventions on primary outcome: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

No study

Observer-based outcome measure - Qualitative statement								Meta-analysis
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
Haskard 2008	Patient-mediated intervention + Distribution of educational material + education meeting	Usual care	Physician informative and participatory	Unit of error analysis				na
Haskard 2008	Patient-mediated intervention + Distribution of educational material + education meeting	Usual care	Patient active	Unit of error analysis				na
Haskard 2008	Patient-mediated intervention + Distribution of educational material + education meeting	Usual care	Physician-patient interaction	Unit of error analysis				na
Patient-reported outcome measure - Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Cooper 2011	Patient-mediated intervention + Educational meeting	Usual care	Participatory Decision making (PDM)	101	0.16 (-0.23 to 0.56)	0.13 (-0.02 to 0.28)	44%	x
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	SDM-Q-9	413	-0.07 (-0.26 to 0.12)			x
Hamann 2007	Patient-mediated intervention (decision aid) + Educational meeting	Usual care	COMRADE	82	0.16 (-0.28 to 0.61)			x
Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Treatment Alliance Scale (TAS)	75	0.07 (-0.38 to 0.52)			
Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Patient Activation Measure (PAM)	75	0.13 (-0.32 to 0.58)			x

Table 3. Effect of interventions on primary outcome: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Patient participation (PP)	75	-0.09 (-0.55 to 0.36)	
Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Treatment Alliance Scale (TAS) - 6 months	64	0.00 (-0.49 to 0.49)	
Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Patient Activation Measure (PAM) - 6 months	64	0.12 (-0.37 to 0.61)	
Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Patient participation (PP) - 6 months	64	0.09 (-0.40 to 0.58)	
Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Treatment Alliance Scale (TAS) - 12 months	63	0.16 (-0.34 to 0.65)	
Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Patient Activation Measure (PAM) - 12 months	63	0.21 (-0.28 to 0.71)	
Rise 2012	Patient-mediated intervention (use of PCOMS) + Educational meeting	Usual care	Patient participation (PP) - 12 months	63	0.28 (-0.22 to 0.78)	
Wilkes 2013	Patient mediated intervention (web-based educational program for patients) + Distribution of educational material	Usual care	Overall PSA SDM perception	393	0.20 (-0.03 to 0.43)	x
Tai-Seale 2016	Educational material (video) + patient mediated intervention (booklet) + educational meeting (coaching session for providers)	Usual care	CollaboRATE (/100)	150	0.51 (0.19 to 0.84)	x
Tai-Seale 2016	[Educational material (video) + patient mediated intervention (booklet) + educational meeting (coaching session for	Usual care	CollaboRATE (/100)	150	0.53 (0.21 to 0.86)	

Table 3. Effect of interventions on primary outcome: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

	providers)] + Patient mediated intervention (one-page ASK handout)							
Epstein 2017	Patient-mediated intervention (patients & caregivers coaching session + question prompt list) + Educational meeting	Usual care	Health Care Climate Questionnaire (HCCQ)	265	0.00 (-0.24 to 0.24)			x
Patient-reported outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
Mathers 2012	Patient-mediated intervention (decision aid) + Educational meeting	Usual care	Modified Control Preference Scale	169	-0.09 (-0.23; 0.05)	-0.01 (-0.20 to 0.19)	60%	x
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Patient perception scale (PPS)	97	0.11 (-0.10 to 0.31)			x
Patient-reported outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
Leighl 2011	Patient-mediated intervention + educational meeting	Usual care	Modified Control Preference Scale	There was no difference after the intervention: the mean score of the item on the CPS scale in the intervention group was: 2.86 (0.92), it was 2.87 (1.04) in the control group. See Figure 4, page 2082. Data are from the authors.				na
Loh 2007	Patient-mediated intervention + educational meeting	Usual care	PPS (Man-Son-Hing)	"In the intervention group, significantly higher patient participation from pre- to post-intervention was found for … the Man-Son-Hing patient participation scale." P = 0.10. Page 329				na
Wetzels 2005	Patient-mediated Intervention (leaflet) + educational outreach visit	Usual care	COMRADE - 4 items	Unable to calculate. No differences between groups were detected.				na

CI: confidence interval; COMRADE: Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness; N: sample size; na: not applicable; OPTION: observing patient involvement; PCOMS: Partners for Change Outcome Management System; PSA: prostatic specific antigen; RD: risk difference; SDM: shared decision making; SMD: standardized mean difference.

Table 4. Effect of interventions on primary outcome: interventions targeting patients compared to other interventions targeting patients

Observer-based outcome measure - Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (usual care and booklet)	OPTION	100	1.21 (0.78 to 1.64)	0.88 (0.39. to1.37)	74%	x
Nannenga 2009	Patient-mediated intervention (decision aid)	Patient-mediated intervention (pamphlet)	OPTION	91	1.04 (0.60 to 1.48)			x
Jouni 2017	Patient-mediated intervention (conventional risk and genetic risk information + decision aid)	Patient-mediated intervention (conventional risk information + decision aid)	OPTION5 (/100)	80	0.38 (-0.06 to 0.82)			x
Observer-based outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
No study								
Observer-based outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
No study								
Patient reported outcome measure - Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Causarano 2014	Patient-mediated intervention (Routine education + educational meeting to patient)	Patient-mediated intervention (Routine education)	Decision making subscale (M-PICS)	39	-0.44 (-1.08 to 0.19)	0.03 (-0.16 to 0.23)	76%	x
Deen 2012	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Patient Activation)	Patient Activation Measure (PAM)	142	-0.15 (-0.48 to 0.18)			

Table 4. Effect of interventions on primary outcome: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Deen 2012	Patient-mediated intervention (decision aid + Patient Activation)	Patient-mediated intervention (Patient Activation)	Patient Activation Measure (PAM)	141	-0.05 (-0.38 to 0.28)	x
Deen 2012	Patient-mediated intervention (decision aid + Patient Activation)	Patient-mediated intervention (decision aid)	Patient Activation Measure (PAM)	137	0.11 (-0.22 to 0.45)	
Hamann 2011	Patient-mediated intervention (SDM training)	Patient-mediated intervention (cognitive training)	Who makes important decisions about your medical treatment? (postintervention)	61	-0.18 (-0.68 to 0.32)	x
Hamann 2011	Patient-mediated intervention (SDM training)	Patient-mediated intervention (cognitive training)	Who makes important decisions about your medical treatment? (at 6 months)	48	-1.09 (-1.70 to -0.48)	
Schroy 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Educational material)	Satisfaction with the decision making process	422	0.66 (0.46 to 0.85)	
Schroy 2011	Patient-mediated intervention (decision aid + YDR)	Patient-mediated intervention (Educational material)	Satisfaction with the decision making process	431	0.63 (0.44 to 0.83)	x
Schroy 2011	Patient-mediated intervention (decision aid + YDR)	Patient-mediated intervention (decision aid)	Satisfaction with the decision making process	419	-0.03 (-0.22 to 0.16)	
van Roosmalen 2004	Patient-mediated intervention (Shared decision making intervention +decision aid)	Patient-mediated intervention (decision aid)	Perceived participation in DM (T4)	78	0.30 (-0.14 to 0.75)	x
van Roosmalen 2004	Patient-mediated intervention (Shared decision making intervention +decision aid)	Patient-mediated intervention (decision aid)	Perceived participation in DM (T5)	71	0.15 (-0.31 to 0.62)	

Table 4. Effect of interventions on primary outcome: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Schroy 2016	Patient-mediated intervention (decision aid + risk assessment tool)	Patient-mediated intervention (decision aid)	Satisfaction with Decision making process (SDMP)	324	0.00 (-0.22 to 0.22)	x
Adarkwah 2016	Patient-mediated intervention (Computerised decision aid (Time-to-event))	Patient-mediated intervention (Computerised decision aid (emoticon)	PEF-FB-9 (SDM-Q9)	304	-0.09 (-0.31 to 0.14)	x
Barton 2016	Patient-mediated intervention (adapted guide)	Patient-mediated intervention (Existing medication guide)	The Interpersonal Processes of Care (IPC) measure (which includes a 2-item decision-making subscale) (in %)	97	-0.21 (-0.61 to 0.19)	
Barton 2016	Patient-mediated intervention (adapted guide + decision aid)	Patient-mediated intervention (Existing medication guide)	The Interpersonal Processes of Care (IPC) measure (which includes a 2-item decision-making subscale) (in %)	110	-0.19 (-0.56 to 0.19)	
Barton 2016	Patient-mediated intervention (adapted guide + decision aid)	Patient-mediated intervention (adapted guide)	The Interpersonal Processes of Care (IPC) measure (which includes a 2-item decision-making subscale) (in %)	99	0.03 (-0.37 to 0.43)	x
Eggly 2017	Patient mediated intervention (QPL-plus-Coach)	Patient-mediated intervention (QPL-only)	Patient role in treatment decision	56	-0.18 (-0.70 to 0.35)	x
Hamann 2017	Patient-mediated intervention (SDM Training for patients)	Patient-mediated intervention (Cognitive training for patient - control group)	Who makes important decision about your medical treatment ?	215	-0.26 (-0.53 to 0.01)	x
Jouni 2017	Patient-mediated intervention (conventional risk and	Patient-mediated intervention (conven-	SDM-Q (0-11)	207	0.13 (-0.15 to 0.40)	x

Table 4. Effect of interventions on primary outcome: interventions targeting patients compared to other interventions targeting patients *(Continued)*

	genetic risk information + decision aid)	tional risk information + decision aid)						
Smallwood 2017	Patient-mediated intervention (decision aid)	Patient-mediated intervention (web-based information)	Shared decision Making	50	0.22 (-0.34 to 0.79)			x
Patient-reported outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
Butow 2004	Patient-mediated intervention (booklet + brochure + question prompt sheet)	Patient-mediated intervention (booklet)	Modified Control Preference Scale	131	0.04 (-0.11 to 0.20)	0.03 (-0.02 to 0.08)	32%	x
Davison 1997	Patient-mediated intervention (individual empowerment sessions)	Patient-mediated intervention (information package)	Modified Control Preference Scale	60	-0.17 (-0.41 to 0.08)			x
Deschamps 2004	Patient-mediated intervention (pharmacist consultation, patient-specific information and a 40-minute consultation with pharmacist)	Patient-mediated intervention (decision aid)	Modified Control Preference Scale	90	0.11 (-0.09 to 0.32)			x
Dolan 2002	Patient-mediated intervention (preliminary phase + decision aid)	Patient-mediated intervention (preliminary phase + educational phase)	Modified Control Preference Scale	86	0.12 (-0.09 to 0.32)			x
Kasper 2008	Patient-mediated intervention	Patient-mediated intervention	Modified Control Preference Scale	278	0.03 (-0.08 to 0.15)			x
Krist 2007	Patient-mediated intervention (decision aid web)	Patient-mediated intervention (decision aid brochure)	Modified Control Preference Scale	372	0.00 (-0.10 to 0.09)			x
Raynes-Greenow 2010	Patient-mediated intervention (decision aid (Audio))	Patient-mediated intervention (Pamphlet)	Modified Control Preference Scale - First Follow-up	351	0.04 (-0.04 to 0.13)			x

Table 4. Effect of interventions on primary outcome: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Raynes-Greenow 2010	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Pamphlet)	Modified Control Preference Scale - First Follow-up	343	0.04 (-0.04 to 0.13)	
Raynes-Greenow 2010	Patient-mediated intervention (decision aid (Audio))	Patient-mediated intervention (Pamphlet)	Modified Control Preference Scale - Second Follow-up	277	0.04 (-0.04 to 0.13)	
Raynes-Greenow 2010	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Pamphlet)	Modified Control Preference Scale - Second Follow-up	286	0.07 (-0.02 to 0.13)	
Stiggelbout 2008	Patient-mediated intervention (individualized brochure)	Patient-mediated intervention (general brochure)	Modified Control Preference Scale	64	-0.21 (-0.44 to 0.02)	x
Thomson 2007	Patient-mediated intervention (Computerised decision aid)	Patient-mediated intervention (Guidelines)	DM role experienced (patient more important in DM)	106	0.23 (0.05; 0.41)	x
Davison 2002	Patient-mediated intervention (computer)	Patient-mediated intervention (discussion with research nurse)	Modified Control Preference Scale	734	0.02 (-0.06 to 0.09)	x

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Direct quote	Meta-analysis
Köpke 2014	Patient-mediated intervention (interactive-4h education program)	Patient-mediated intervention (4h MS-specific stress management program.)	Decision autonomy (at 12 months)	"Overall, 70 (IG) and 72 (CG) decisions on DMDs were reported during the 12 months of follow-up. In both groups, most decisions were reported to be solely of mostly driven by the patient or were shared between patients and physicians with no differences between groups." Page 414	na
Lalonde 2006	Patient-mediated intervention (decision aid + personal risk profile)	Patient-mediated intervention (decision aid + personal risk profile + personal risk assessment)	Decision satisfaction inventory	No statistically significant differences in patient satisfaction with the decision-making process were detected between the study groups. Page 55	na

Table 4. Effect of interventions on primary outcome: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Street 1995	Patient-mediated intervention (Interactive multimedia program (decision aid))	Patient-mediated intervention (brochure (decision aid)	Perceived Decision Control Instrument	"The experimental manipulation (computer program versus brochure) had very little effect on the dependent variables." Page 2280	na
Butow 2004	Patient-mediated intervention (booklet + brochure + question prompt sheet)	Patient-mediated intervention (booklet)	Physician behaviours facilitating patient involvement	"On average, oncologists demonstrated about 7.5 of the 12 behaviours, with no significant differences between the groups (cancer consultation preparation package (CCPP) versus control booklet)." Page 4406	na
Wolderslund 2017	Patient-mediated intervention (question prompt list) + other (digital audio recording)	Other (digital audio recording)	Involvement in decision making	"Intention-to-treat analyses of the participants' perception of the consultation showed that on average, 4.5% more patients (range: 4.0-5.5), regardless of intervention group, rated their satisfaction with the treatment, confidence in and relationship with the health professional, and involvement in decision making in the highest reply category compared with patients in the control group. This increase was significant (p = 0.001) except for decision making (p = 0.044)." Page 247	na

CG: control group; CI: confidence interval; DM: decision making; IG: intervention group; M-PICS: modified perceived involvement in care scale; N: sample size; na: not applicable; OPTION: observing patient involvement; QPL: question prompt list; RD: risk difference; SDM: shared decision making; SMD: standardized mean difference; YDR: Web-based ''Your Disease Risk'' colorectal cancer risk assessment tool.

Table 5. Effect of interventions on primary outcome: interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals

Observer-based outcome measure - Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Elwyn 2004	Educational Meeting + audit and feedback	Educational Meeting + audit and feedback	OPTION	20	-0.30 (-1.19 to 0.59)	-0.30 (-1.19 to 0.59)		na
Observer-based outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
No study								

Table 5. Effect of interventions on primary outcome: interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals *(Continued)*

Observer-based outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
Feng 2013	Distribution of educational material (Intervention A)	Distribution of educational material (Brochure + control)	Prostate Cancer Screening Abstraction Tool	P-value < 0.05				na
Patient-reported outcome measure - Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Elwyn 2004	Educational meeting + audit and feedback	Educational Meeting + audit and feedback	COMRADE (communication) - Time 1	Pre: 187; Post: 327	-0.07 (-0.29 to 0.15)	0.24 (-0.10 to 0.58)	87%	
Elwyn 2004	Educational meeting + audit and feedback	Educational Meeting + audit and feedback	COMRADE (communication) - Time 2	Pre: 163; Post: 290	-0.11 (-0.34 to 0.13)			
Elwyn 2004	Educational meeting + audit and feedback	Educational Meeting + audit and feedback	COMRADE (confidence) - Time 1	Pre: 187; Post: 327	0.05 (-0.17 to 0.27)			x
Elwyn 2004	Educational meeting + audit and feedback	Educational Meeting + audit and feedback	COMRADE (confidence) - Time 2	Pre: 163; Post: 290	-0.18 (-0.42 to 0.05)			
Krones 2008 (ARRIBA-Herz)	Educational meeting + audit and feedback + educational material + educational outreach visit	Educational Meeting	PPS (Man Son-Hing): I made the decision jointly (Score inversé pour respecter le sens de l'échelle)	1132	0.48 (0.36 to 0.60)			
Krones 2008 (ARRIBA-Herz)	Educational meeting + audit and feedback + educational material + educational outreach visit	Educational Meeting	SDM-Q	1132	0.40 (0.28 to 0.52)			x

Table 5. Effect of interventions on primary outcome: interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals *(Continued)*

Krones 2008 (ARRI-BA-Herz)	Educational meeting + audit and feedback + educational material + educational outreach visit	Educational Meeting	PPS (Man-Son-Hing)	1052	6.11 (5.82 to 6.40)			
Patient-reported outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
No study								
Patient-reported outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
No study								

CI: confidence interval; COMRADE: Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness; N: sample size; na: not applicable; OPTION: observing patient involvement; PPS: patient participation scale; RD: risk difference; SDM: shared decision making; SMD: standardized mean difference.

Table 6. Effect of interventions on primary outcome: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals

Observer-based outcome measure - Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Tai-Seale 2016	[Educational material (video) + patient mediated intervention (booklet) + educational meeting (coaching session for providers)] + Patient mediated intervention (one-page ASK handout)	Educational material (video) + patient mediated intervention (booklet) + educational meeting (coaching session for providers)	OPTION5 (/100)	20	-0.29 (-1.17 to 0.60)	-0.29 (-1.17 to 0.60)		na
Observer-based outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	

Table 6. Effect of interventions on primary outcome: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals *(Continued)*

Myers 2011	Patient-mediated intervention (pamphlet and counseling) + reminders	Patient-mediated intervention (pamphlet) + reminders	Informed decision making scale (IDM)	134	-0.04 (-0.13 to 0.04)	-0.04 (-0.13 to 0.04)		na
Observer-based outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
No study								
Patient-reported outcome measure - Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Tai-Seale 2016	[Educational material (video) + patient mediated intervention (booklet) + educational meeting (coaching session for providers)] + Patient mediated intervention (one-page ASK handout)	Educational material (video) + patient mediated intervention (booklet) + educational meeting (coaching session for providers)	CollaboRATE (/100)	150	0.00 (-0.32 to 0.32)	0.00 (-0.32 to 0.32)		na
Patient-reported outcome measure - Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
No study								
Patient-reported outcome measure - Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
Cooper 2013	Patient-mediated intervention + educational outreach visit + distribution of educational material + audit and feedback (patient-centered group)	Patient-mediated intervention + educational outreach visit + distribution of educational material (Standard group)	Patient Rating of their clinicians participatory decision-making skills (from baseline to 12 months)	OR = 0.7 (IC 95% 0.3-1.9) - No significant				na

Table 6. Effect of interventions on primary outcome: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals *(Continued)*

Cooper 2013	Patient-mediated intervention + educational outreach visit + distribution of educational material + audit and feedback (Patient-centered group)	Patient-mediated intervention + educational outreach visit + distribution of educational material (Standard group)	Patient Rating of their clinicians participatory decision-making skills (from baseline to 18 months)	OR = 0.6 (IC 95% 0.2-1.8) - No significant	na

ASK: Ask Share Know; CI: confidence interval; N: sample size; na: not applicable; OPTION: observing patient involvement; OR: odds ratio; RD: risk difference; SMD: standardized mean difference.

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care

Continous Data								**Meta-analysis**
Study	**Intervention**	**Control**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Landrey 2012	Patient-mediated intervention (mailed flyer)	Usual care	Knowledge/knowledge not addressed in decision aid	148	0.14 (-0.19 to 0.46)	0.38 (0.16 to 0.61)	44%	x
van Peperstraten 2010	Patient-mediated intervention (decision aid + support call)	Usual care		Pre: 304 Post: 262	0.52 (0.27 to 0.77)			x
van Peperstraten 2010	Patient-mediated intervention (decision aid + support call)	Usual care		262	0.81 (0.55 to 1.06)			
Perestelo-Perez 2016	Patient-mediated intervention (decision aid)	Usual care		Pre: 167; Post: 155	0.45 (0.13 to 0.77)			x
Perestelo-Perez 2016	Patient-mediated intervention (decision aid)	Usual care	Knowledge (items addressed in decision aid)	Pre: 164; Post: 152	0.77 (0.44 to 1.10)	0.77 (0.44 to 1.10)	na	na
Vodermaier 2009	Patient mediated intervention (decision aid)	Usual care	Satisfaction with de-	107	0.14 (-0.24 to 0.52)	0.14 (-0.24 to 0.52)	na	na

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

			cision and treatment					
Murray 2001	Patient-mediated intervention (decision aid)	Usual care	Decisional conflict	105	-0.66 (-1.06 to -0.27]	-0.30 (-0.68 to 0.09)	71%	x
Vodermaier 2009	Patient-mediated intervention (decision aid)	Usual care		107	-0.28 (-0.66 to 0.10)			x
Perestelo-Perez 2016	Patient-mediated intervention (decision aid)	Usual care		155	0.01 (-0.31 to 0.32)			x
van Tol-Geerdink 2016	Patient-mediated intervention (decision aid)	Usual care	Decision regret (6 months)	212	-0.10 (-0.39 to 0.19)	-0.10 (-0.39 to 0.19)	na	na
van Tol-Geerdink 2016	Patient-mediated intervention (decision aid)	Usual care	Decision regret (12 months)	201	-0.20 (-0.50 to 0.10)	-0.20 (-0.50 to 0.10)		
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care	Patient-physician communication (number of topics raised by the patient)	100	0.26 (-0.13 to 0.65)	0.26 (-0.13 to 0.65)	na	x
Deen 2012	Patient-mediated intervention (decision aid)	Usual care	Decision self-efficacy	137	0.07 (-0.26 to 0.41)	0.16 (-0.08 to 0.40)	0%	
Deen 2012	Patient-mediated intervention (Patient Activation)	Usual care		142	0.18 (-0.15 to 0.51)			x
Deen 2012	Patient-mediated intervention (decision aid + Patient Activation)	Usual care		135	0.08 (-0.25 to 0.42)			
Maranda 2014	Patient mediated intervention	Usual care		132	0.14 (-0.20 to 0.48)			x

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

Pickett 2012	Patient-mediated intervention (training for patients)	Usual care	Empowerment (time 2)	Pre: 428; Post: 342	0.26 (0.05 to 0.48)	0.26 (0.05 to 0.48)	na	na
Pickett 2012	Patient-mediated intervention (training for patients)	Usual care	Empowerment (time 3)	Pre: 428; Post: 318	0.17 (-0.05 to 0.39)	0.17 (-0.05 to 0.39)		
Korteland 2017	Patient-mediated intervention (decision aid)	Usual care	Health-related QoL (physical)	Pre: 133; Post: 116	0.00 (-0.36 to 0.36)	0.00 (-0.36 to 0.36)	na	x
Korteland 2017	Patient-mediated intervention (decision aid)	Usual care	Health-related QoL (mental)	Pre: 133; Post: 116	0.10 (-0.26 to 0.46)	0.10 (-0.26 to 0.46)	na	x
van Peperstraten 2010	Patient-mediated intervention (decision aid + support call)	Usual care	Anxiety (20-80)	Pre: 304 Post: 262	-0.17 (-0.49 to 0.14)	-0.17 (-0.49 to 0.14)	na	na
Perestelo-Perez 2016	Patient-mediated intervention (decision aid)	Usual care	Anxiety (state)	Pre: 166; Post: 157	0.18 (-0.06 to 0.43)	0.18 (-0.06 to 0.43)	na	na
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care	Consultation length (min: sec)	100	0.35 (-0.04 to 0.75)	0.10 (-0.39 to 0.58)	70%	x
Perestelo-Perez 2016	Patient-mediated intervention (decision aid)	Usual care	Consultation length	124	-0.15 (-0.50 to 0.21)			x
Murray 2001	Patient mediated intervention (decision aid)	Usual care	Cost (excluding intervention)	105	0.25 (-0.14 to 0.63)	0.25 (-0.14 to 0.63)	na	na
Murray 2001	Patient mediated intervention (decision aid)	Usual care	Cost (including intervention)	105	0.82 (0.42 to 1.22)	0.82 (0.42 to 1.22)		

Categorical data								**Meta-analysis**
Study	**Intervention**	**Control**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

LeBlanc 2015b	Patient-mediated intervention (decision aid)	Usual care	Overall knowledge/Knowledge of risk without medication	41	0.27 (-0.05 to 0.60)	0.17 (0.05 to 0.29)	0%	x
LeBlanc 2015b	Patient-mediated intervention (decision aid)	Usual care		41	0.38 (0.06 to 0.69)			
Krist 2007	Patient-mediated intervention (decision aid brochure)	Usual care		271	0.16 (0.03 to 0.29)			x
Krist 2007	Patient-mediated intervention (decision aid web)	Usual care		301	0.16 (0.03 to 0.28)			
Sheridan 2014	Patient-mediated intervention (decision aid)	Usual care	Patient-physician communication (patient raised discussion)	157	0.29 (0.14 to 0.44)	0.29 (0.14 to 0.44)	na	x
Sheridan 2014	Patient mediated intervention (decision aid)	Usual care	Patient-physician communication (patient participation in discussion)	157	0.27 (0.13 to 0.42)	0.27 (0.13 to 0.42)	na	x
van Peperstraten 2010	Patient-mediated intervention (decision aid + support call)	Usual care	Empowerment (number of fully empowered couples)	Pre: 304 Post: 262	0.18 (0.09 to 0.27)	0.18 (0.09 to 0.27)	na	na
LeBlanc 2015a	Patient-mediated intervention (decision aid)	Usual care	Adherence (% of patients who filled their prescription within 30 days)	197	-0.07 (-0.15 to 0.01)	-0.07 (-0.15 to 0.01)	na	na
LeBlanc 2015a	Patient-mediated intervention (decision aid)	Usual care	Adherence (% of pa-	206	-0.03 (-0.08 to 0.02)	-0.03 (-0.08 to 0.02)	na	na

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

			tients with a PDC > 80%)					
Pereste-lo-Perez 2016	Patient-mediated interven-tion (decision aid)	Usual care	Adherence to medica-tion (some-times forget take choles-terol medi-cine)	98	-0.04 (-0.23 to 0.15)	-0.04 (-0.23 to 0.15)	na	na
Pereste-lo-Perez 2016	Patient-mediated interven-tion (decision aid)	Usual care	Adherence to medica-tion (did not miss a dose last week)	97	0.07 (-0.06 to 0.20)	0.07 (-0.06 to 0.20)	na	na
Korteland 2017	Patient-mediated interven-tion (decision aid)	Usual care	Anxiety (mild, mod-erate and severe)	Pre: 138; Post: 127	0.04 (-0.07 to 0.15)	0.04 (-0.07 to 0.15)	na	na
Korteland 2017	Patient-mediated interven-tion (decision aid)	Usual care	Depression (mild, mod-erate and severe)	Pre: 138; Post: 127	0.16 (0.05 to 0.28)	0.16 (0.05 to 0.28)	na	na

Qualitative statement					**Meta-analy-sis**
Study	**Intervention**	**Control**	**Outcome**	**Direct quotes**	
LeBlanc 2015b	Patient-mediated interven-tion (decision aid)	Usual care	Knowledge (overall: generic and tailored)	No significant differences between groups (table 2, page 9 of the publication and table 2 of the supplementary material)	na
LeBlanc 2015a	Patient-mediated interven-tion (decision aid)	Usual care		Significant difference in favor of the intervention group (p=0.03) (table 2; page 1767)	na
Korteland 2017	Patient-mediated interven-tion (decision aid)	Usual care		"Intervention patients ... had a better knowledge of prosthetic valves (85% versus 68%; P=0.004)" Page 1	na
Sheridan 2014	Patient-mediated interven-tion (decision aid)	Usual care		Results reported only for the intervention group	na

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

LeBlanc 2015a	Patient-mediated intervention (decision aid)	Usual care	Knowledge : Generic	No differences between groups (p=0.65) (table 2; page 1767)	na
LeBlanc 2015b	Patient-mediated intervention (decision aid)	Usual care		No significant differences betwwen groups (table 2, page 9 of the publication and table 2 of the supplementary material)	na
LeBlanc 2015a	Patient-mediated intervention (decision aid)	Usual care	Knowledge : Tailored to information in the decision aid	Significant difference in favour of the intervention group (p<0.001) (table 2; page 1767)	na
LeBlanc 2015b	Patient-mediated intervention (decision aid)	Usual care		Significant differences between groups (table 2, page 9 of the publication and table 2 of the supplementary material)	na
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care	Satisfaction with the consultation	Intervention group (median; range) 5.0 (4–5) vs control group 5.0 (3–5) (p-value=0.27). Page 231 (table 2)	na
Almario 2016	Patient-mediated intervention (GI PROMIS)	Usual care		"Table 3 presents the CG-CAHPS provider rating scores for the GI PROMIS and control arms in the intention-to-treat analysis. After adjusting for confounders, we found no difference in provider rating between groups." Page 7	na
Haskard 2008	Patient-mediated intervention	Usual care	Satisfaction with care	"There were no significant main effects of patient training on patient satisfaction questionnaire items." Page 518	na
van der Krieke 2013	Patient-mediated intervention (web-based information and decision tool)	Usual care		"Patients also did not differ in self-reported satisfaction with care (CSQ) (F1,70=0.014, P=.91)." (no page number, in the resuts section)	na
Landrey 2012	Patient-mediated intervention (mailed flyer)	Usual care	Satisfaction with the intervention	“Among patients who reported receiving the flyer, 86.4% felt the content was clearly presented, 86.4% felt it contained about the right amount of information, 45.5% felt the information was completely balanced, and 43.2% viewed it as biased against PSA testing; 88.6% would recommend it to others.” Page 71	na
Murray 2001	Patient-mediated intervention (decision aid)	Usual care		“Patients reacted positively to the decision aid (table 3)” Page 5	na
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care		"Fifteen patients rated the QPS as not helpful, while 16 rated it as somewhat helpful and 20 patients as helpful." Page 230	na
LeBlanc 2015a	Patient mediated intervention (decision aid)	Usual care		"After the encounters with their clinicians, patients in the decision aid arm ... were more … satisfied (ranging from risk ratio [RR], 1.25 [P = .81] to RR, 2.40 [P = .002]) compared with patients in the control arm (Table 2)." Page 1765	na

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

van der Krieke 2013	Patient-mediated intervention (web-based information and decision tool)	Usual care		"They agreed or completely agreed with the following statements: “I have been well informed about the treatment options offered by Friesland Mental Health Care Service by the decision aid” (22/29, 76%), “The advice presented by the decision aid has helped me to reflect on what I want” (22/29, 76%), “The decision aid was easy to use” (20/28, 71%), “I would recommend the decision aid to others” (20/27, 74%) and “The decision aid helped me to get a clearer view on what my problem areas or points of interest are” (17/28, 61%). Patients were divided on whether the decision aid helped them to better prepare the evaluation meeting with their clinicians, 44% (12/27) said it did help; 56% (15/27) were neutral or said it did not help. " (no page number, in the result section)	na
Eggly 2017	Patient-mediated intervention (question prompt list)	Usual care		"The mean patient response across the eight questions about the QPL booklet was 2.80 (SD = 0.23). T-tests showed no significant differences between the two intervention arms on any of these questions (p’s > 0.05). The mean response across the five questions about coaching was 2.83 (SD = 0.29) (Table 3)." Page 823	na
Eggly 2017	Patient-mediated intervention (question prompt list + communication coach)	Usual care		"The mean patient response across the eight questions about the QPL booklet was 2.80 (SD = 0.23). T-tests showed no significant differences between the two intervention arms on any of these questions (p’s > 0.05). The mean response across the five questions about coaching was 2.83 (SD = 0.29) (Table 3)." Page 823	na
Krist 2007	Patient-mediated intervention (decision aid brochure)	Usual care	Decisional conflict	"DCS scores among all 3 groups were equally low and did not differ signifi cantly (control, 1.58; brochure, 1.54; and Web site, 1.55)." Page 115	na
Krist 2007	Patient-mediated intervention (decision aid web)	Usual care		"DCS scores among all 3 groups were equally low and did not differ significantly (control, 1.58; brochure, 1.54; and website, 1.55)." Page 115	na
Sheridan 2014	Patient-mediated intervention (decision aid)	Usual care		Results reported only for the intervention group	na
Korteland 2017	Patient-mediated intervention (decision aid)	Usual care		No differences between groups (p>0.05). Page 5; table 2	na
LeBlanc 2015b	Patient-mediated intervention (decision aid)	Usual care		"Decision conflict was low for both groups, and was lower in the Decision Aid arm, but no significant difference was found in the overall scale or in its subscales across arms (Table 2)." Page 8	na
LeBlanc 2015a	Patient-mediated intervention (decision aid)	Usual care	Decisional conflict (0 =	"After the encounters with their clinicians, patients in the decision aid arm reported significantly higher comfort with the decision (mean difference [MD], 5.3 out of 100; 95% CI, 1.1-9.5; P = .01)" Page 1765	na

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

			conflict, 100 = comfort)		
Korteland 2017	Patient-mediated intervention (decision aid)	Usual care	Decision regret (3 months post-operative)	"Three months postoperative regret with regard to prosthetic valve choice ranged from 0 to 55, with no statistical difference between the intervention and control groups. The majority of patients in the intervention and control groups did not experience any regret (70% versus 64%, respectively; P=0.513)." Page 4	na
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care	Patient-physician communication (Dominant behaviour of physician)	There was more dominant behaviour in the control group compared to the intervention group (Median, range: intervention group 2.0 (0–4) control group 3.0 (0–4); p= 0.03) (table 2)	na
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care	Patient-physician communication (Dominant behaviour of patient)	There no difference between groups (Median, range: intervention group 1.0 (0–4) control group 1.0 (0–4); p= 0.46) (table 2)	na
Hamann 2014	Patient-mediated intervention (question prompt sheet)	Usual care	Patient-physician communication (Patient shows interest, raises questions)	There no difference between groups (Median, range: intervention group 2.0 (0–4) control group 1.0 (0–3); p= 0.31) (table 2)	na
Sheridan 2014	Patient-mediated intervention (decision aid)	Usual care	Patient-physician communication (Patients' perceptions of discussions and	"Intervention participants also tended to report better interactions with their provider, with improvements for the following 3 of 6 items from the Healthcare Climate questionnaire: "My provider provided me with choices and options about lowering my chances of heart disease" (+15 percentage points; adjusted p = .02); "My provider listened to how I would like to do things" (+21 percentage points; adjusted p < .01); and "My provider tried to understand how I see things before suggesting new ways to lower my chances of heart disease" (+15 percentage points; adjusted p = .05)." Page 5	na

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

			the health care visit)		
Vestala 2013	Patient-mediated intervention (patient participation in nursing documentation)	Usual care	Empowerment	"No statistical difference was identified between the intervention and control group with regards to empowerment." page 70	na
Krist 2007	Patient-mediated intervention (decision aid brochure)	Usual care	Match between preferred and actual level of participation in decision making	"Concordance did not differ between the 3 study groups (P1 = .41)." Page 117	na
Krist 2007	Patient-mediated intervention (decision aid web)	Usual care		"Concordance did not differ between the 3 study groups (P1 = .41)." Page 117	na
Cooper 2011	Patient-mediated intervention	Usual care	Adherence to medication	“Changes in patient-reported adherence to medications at 12 months did not differ for any of the intervention groups compared to the patient+physician minimal intervention group.” Page 1300	na
LeBlanc 2015b	Patient-mediated intervention (decision aid)	Differents forms of usual care [Reminder (copy of patient's estimated risk of fracture as computed by the FRAX) OR usual care]		"No difference was found in adherence to the medication that was prescribed for both, those who filled their initial prescription [PDC Median 46.7%, IQR (30, 62) for Decision Aid arm vs. 85%, IQR (55.3, 92.6) for FRAX/Usual Care arm, Table 3] or for all that were prescribed bisphosphonates [PDC Median (IQR) 46.7%, (7.8, 46.7) for Decision Aid arm vs. 0%, (0, 72.5) for FRAX/Usual Care arm]. Only one patient in the Decision Aid arm and 3 in the FRAX/Usual Care arm had PDC >80%." page 8	na
Murray 2001	Patient-mediated intervention (decision aid)	Usual care	Health status and physical function	"We found no difference between the two groups in the trends over time in the EQ5D responses nor in the SF36 scores." Page 5	na
Murray 2001	Patient-mediated intervention (decision aid)	Usual care	Health states and valuation of health states	"We found no difference between the two groups in the trends over time in the EQ5D responses nor in the SF36 scores." Page 5	na

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

LeBlanc 2015b	Patient-mediated intervention (decision aid)	Usual care	Health-related QoL	"We found no difference between the FRAX and usual care arms, nor were overall results significantly impacted by analyses comparing the three arms versus only two arms (Decision aid arm vs. FRAX/usual care arms together, see Tables A, B, C, D, and E in S1 File. Therefore, the results comparing the FRAX arm and the Usual Care arm were combined and all subsequent results are presented as Decision Aid vs. FRAX/Usual Care arm (i.e. different forms of usual care)." page 7 There were no difference between group regarding quality of life [Median (IQR); Decision aid: 85 (80 to 95) FRAX/UC: 85 (73 to 90); p=0.19 (table 4)]	na
Murray 2001	Patient-mediated intervention (decision aid)	Usual care	Anxiety	"The Spielberger scores were similar at the final assessment in the two groups (MannWhitney U test). " page 5	na
van Peperstraten 2010	Patient-mediated intervention (decision aid + support call)	Usual care	Depression (number with subclinical depression)	"At uptake of in vitro fertilisation the frequency of subclinical depression did not differ between the intervention and control group: 11% (16/147) v 9% (113/151). After patients received the empowerment strategy, however, this frequency was higher in the intervention group (13% (16/126) v 4% (5/136); P=0.01); this difference diminished after embryo transfer, however (14% (17/123) v 14% (17/120); P=0.94)." Page 5	na
LeBlanc 2015a	Patient-mediated intervention (decision aid)	Usual care	Depression (symptoms) - 3 months	"There was no observed difference across arms in control of depression symptoms (mean PHQ-9 score), remission rate (PHQ-9 score <5), or responsiveness (>50% PHQ-9 improvement) at 3 and 6 months" Pages 1765-1766	na
LeBlanc 2015a	Patient-mediated intervention (decision aid)	Usual care	Depression (symptoms) - 6 months	"There was no observed difference across arms in control of depression symptoms (mean PHQ-9 score), remission rate (PHQ-9 score <5), or responsiveness (>50% PHQ-9 improvement) at 3 and 6 months" Pages 1765-1766	na
Vestala 2013	Patient-mediated intervention (patient participation in nursing documentation)	Usual care	Depression	Not reported	na
Perestelo-Perez 2016	Patient-mediated intervention (decision aid)	Usual care	Stress (diabete related)	No difference between groups (page 298; table 2)	na
Krist 2007	Patient-mediated intervention (decision aid brochure)	Usual care	Consultation length	“These [discussion times] patient-physician differences did not differ significantly across the control, brochure, and Web groups.” Page 116	na
Krist 2007	Patient-mediated intervention (decision aid web)	Usual care		“These [discussion times] patient-physician differences did not differ significantly across the control, brochure, and Web groups.” Page 116	na

Table 7. Effect of interventions on secondary outcomes: interventions targeting patients compared with usual care *(Continued)*

Vodermaier 2009	Patient-mediated intervention (decision aid)	Usual care		"No time differences emerged in the length of the treatment decision consultation with the physicians on patient self-reports. The mean time for the treatment decision making appointment was about 15 minutes" Page 593	na
Eggly 2017	Patient-mediated intervention (question prompt list)	Usual care		"There were no significant differences in interaction length between either of the two intervention arms and the usual care arm (Arm 2 vs. Arm 1, p = 0.21); Arm 3 vs. Arm 1, p = 0.11)." Page 823	na
Eggly 2017	Patient-mediated intervention (question prompt list + communication coach)	Usual care		"There were no significant differences in interaction length between either of the two intervention arms and the usual care arm (Arm 2 vs. Arm 1, p = 0.21); Arm 3 vs. Arm 1, p = 0.11)." Page 823	na
LeBlanc 2015b	Patient-mediated intervention (decision aid)	usual care]		"Encounter duration in the FRAX/Usual Care arm had a median of 10.7 minutes and a range of 2.5 to 54.9 minutes, where encounters in the Decision Aid arm had a median duration of 11.5 with a range of 5.4 to 21.4 minutes (median difference 0.8 minutes, range -33.6 to 3.0)." Page 10	na
Maclachlan 2016	Patient-mediated intervention (educational meeting for patient)	Usual care		"The overall average length of consultations was 5.58 minutes, 5.78 minutes in the trained group and 5.37 minutes in the untrained group." Page 5	na
van Peperstraten 2010	Patient-mediated intervention (decision aid + support call)	Usual care	Cost	"The mean total savings in the intervention group were calculated to be EURO169.75 per couple included from the waiting list for in vitro fertilisation" Page 5	na

CI: confidence interval; CSQ: Client Satisfaction Questionnaire; DA: decision aid; DCS: Decisional Conflict Scale; GI PROMIS: gastrointestinal Patient Reported Outcomes Measurement Information System; N: sample size; na: not applicable; PDC: percentage of days covered; PHQ-9: Patient Health questionnaire for depression; PSA: Prostatic Specific Antigen; QPL: question prompt list; QPS: question prompt sheet; QoL: quality of life; RD: risk difference; RR: relative risk; SD: standard deviation; SMD: standardized mean difference.

Table 8. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to usual care

Continous Data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Murray 2010	Educational meeting + audit and feedback + distribution of educational material + educa-	Usual care	Knowledge	70	0.55 (0.07 to 1.03)	0.26 (-0.16 to 0.69)	68%	x

Table 8. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to usual care *(Continued)*

	tional outreach visit + barriers assessement							
Tinsel 2013	Distribution of educational material + educational meeting	Usual care	Knowledge (time 1)	Pre: 1083; Post: 899	0.10 (-0.03 to 0.23)			x
Tinsel 2013	Distribution of educational material + educational meeting	Usual care	Knowledge (time 2)	Pre: 1083; Post: 794	0.09 (-0.05 to 0.23)			
Tinsel 2013	Distribution of educational material + educational meeting	Usual care	Knowledge (time 3)	Pre: 1083; Post: 714	0.17 (0.02 to 0.31)			
Wilkes 2013	Distribution of educational material	Usual care	Satisfaction with consultation	479	0.00 (-0.18 to 0.18)	0.00 (-0.18 to 0.18)	na	na
Légaré 2012	Educational meeting and distribution of Educational material	Usual care	Decision regret (2 weeks)	Pre: 329 Post: 326	0.29 (0.07 to 0.51)	0.29 (0.07 to 0.51)	na	na
Kennedy 2013	Educational meeting	Usual care	Self-efficacy (6 months)	Pre: 5599; Post: 4475	-0.03 (-0.09 to 0.03)	-0.03 (-0.09 to 0.03)	na	na
Kennedy 2013	Educational meeting	Usual care	Self-efficacy (12 months)	Pre: 5599; Post: 4005	-0.04 (-0.10 to 0.03)	-0.04 (-0.10 to 0.03)	na	na
Tinsel 2013	Distribution of educational material + educational meeting	Usual care	Adherence to medication (time 1)	Pre: 1070; Post: 827	-0.08 (-0.21 to 0.06)	-0.08 (-0.21 to 0.06)	na	na
Tinsel 2013	Distribution of educational material + educational meeting	Usual care	Adherence to medication (time 2)	Pre: 1070; Post: 744	-0.01 (-0.16 to 0.13)	-0.01 (-0.16 to 0.13)	na	na
Tinsel 2013	Distribution of educational material + educational meeting	Usual care	Adherence to medication (time 3)	Pre: 1070; Post: 675	0.10 (-0.05 to 0.25)	0.10 (-0.05 to 0.25)	na	na
Kennedy 2013	Educational meeting	Usual care	General health	Pre: 5599; Post: 4056	0.02 (-0.04 to 0.08)	0.02 (-0.04 to 0.08)	na	na

Table 8. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to usual care *(Continued)*

Kennedy 2013	Educational meeting	Usual care	Psychological well-being	4052	0.00 (-0.06 to 0.06)	0.00 (-0.06 to 0.06)	na	na
Légaré 2012	educational meeting and distribution of educational material	Usual care	Health-related QoL (physical)	359	0.16 (-0.05 to 0.36)	0.16 (-0.05 to 0.36)	na	na
Légaré 2012	Educational meeting and distribution of Educational material	Usual care	Health-related QoL (mental)	359	0.28 (0.07 to 0.49)	0.28 (0.07 to 0.49)	na	na
Kennedy 2013	Educational meeting	Usual care	Health-related QoL (6 months)	Pre: 5598; Post: 4449	0.00 (-0.06 to 0.06)	0.00 (-0.06 to 0.06)	na	na
Kennedy 2013	Educational meeting	Usual care	Health-related QoL (12 months)	Pre: 5598; Post: 3991	0.00 (-0.06 to 0.06)	0.00 (-0.06 to 0.06)		
Sanders 2017	Educational meeting + audit and feed-back	Usual care	Consultation length (minutes)	175	0.51 (0.21 to 0.81)	0.51 (0.21 to 0.81)	na	na
Cox 2017	Distribution of educatuonal material (FCR checklist) + Educational meeting	Usual care	Safety (parent perception of hospital safety)	Pre: 144; Post: 154	0.00 (-0.32 to 0.32)	0.00 (-0.32 to 0.32)	na	na
Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	Usual care	Knowledge of risk without medication	40	-0.10 (-0.42 to) 0.23]	-0.10 (-0.42 to 0.23)	na	na
LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	Usual care	Knowledge of risk risk post-treatment	40	-0.17 (-0.49 to 0.16)	-0.17 (-0.49 to 0.16)	na	na
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Satisfaction with amount of information	Pre: 1671 Post: 1492	0.02 (-0.02 to 0.07)	0.02 (-0.02 to 0.07)	na	na

Table 8. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to usual care *(Continued)*

			(postnatal period)					
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Satisfaction with the decision making process (how choice had been made) (postnatal period)	Pre: 1666 Post: 1488	-0.03 (-0.07 to 0.02)	-0.03 (-0.07 to 0.02)	na	na
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Satisfaction with discussion with HCP (View of whether they had had sufficient discussion with HCP) (postnatal period)	Pre: 1657 Post: 1483	-0.00 (-0.05 to 0.05)	-0.00 (-0.05 to 0.05)	na	na
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Anxiety (more anxious) - antenatal period	Pre: 1195 Post: 1527	-0.00 (-0.03 to 0.03)	-0.00 (-0.02 to 0.02)	0%	x
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Anxiety (more anxious) - postnatal period	Pre: 1651 Post: 1476	0.00 (-0.03 to 0.03)			x
Wilkes 2013	Distribution of Educational material	Usual care	Consultation length (10-20 minutes)	479	-0.04 (-0.13 to 0.05)	-0.04 (-0.13 to 0.05)	na	na

Qualitative statement					**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**	
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Knowldege (antenatal period)	Adjusted mean difference 95%CI : 0.20 (-0.09 to 0.49) (Page 3, table 3)	na

Table 8. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to usual care *(Continued)*

O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Knowldege (postnatal period)	Adjusted mean difference 95%CI : 0.20 (-0.05 to 0.44) (Page 3, table 3)	na
Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Knowledge	"Although there were some tendencies in the expected direction, there was no overall effect by the training in the secondary patient outcomes in either language cohort." Pages 1269-1270	na
LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	Usual care	Knowledge (overall)	No differences between group (table 2; supplementary material)	na
LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	Usual care	Knowledge (Items not addressed in DA) (4 items)	No differences between group (table 2; supplementary material)	na
LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	Usual care	Knowledge (Items addressed in DA) (9 items)	Significant differences between group (table 2; supplementary material)	na
Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Satisfaction with consultation	"There was higher satisfaction with doctor's consultation skills for patients in ANZ than for patients in SGA, and all cohorts showed improved satisfaction with doctor's consultation skills except for the ANZ control group (Figure 3c), although not statistically significant (p = 0.08 for SGA and p = 0.26 for ANZ)." Page 1270	na
Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Satisfaction with decision (2 weeks)	"Overall, patients were satisfied with their treatment decision (Figure 3a). Although there were some tendencies in the expected direction, there was no overall effect by the training in the secondary patient outcomes in either language cohort." Pages 1269-1270	na
Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Satisfaction with decision (4 months)	"Although there were some tendencies in the expected direction, there was no overall effect by the training in the secondary patient outcomes in either language cohort." Pages 1269-1270	na
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Satisfaction with the decision making process (how choice had been made)	No difference between groups (Page 3; table 2)	na

Table 8. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to usual care *(Continued)*

			(antenatal period)		
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Satisfaction with discussion with HCP (View of whether they had had sufficient discussion with HCP) (antenatal period)	No difference between groups (Page 3; table 2)	na
Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Satisfaction with doctor communication	"Although there were some tendencies in the expected direction, there was no overall effect by the training in the secondary patient outcomes in either language cohort." Pages 1269-1270	na
Fossli 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Satisfaction (Patient global satisfaction)	"The duration of encounters (min:sec) did not change significantly (1:03 (p = 0.69, 95% CI 6:13; 4:07)) from pre to post, and neither did patient global satisfaction (0.3 (p = 0.38, 95% CI 0.3; 0.8))." Page 166	na
Murray 2010	Educational meeting + audit and feedback + distribution of Educational material + Educational outreach visit + barriers assessement	Usual care	Satisfaction with the intervention (acceptability and utility of intervention components)	All the intervention group members who logged to the autotutorial and completed the satisfaction survey (n=8), rated the tutorial as excellent to very good, seven indicated that the tutorial was helpful, and six reported that it was very easy to complete. "In all, 37 members of the intervention group (97%) commented on the acceptability of the skills building workshop. Most (n=35 (94%)) said they would recommend the workshop to others, and 26 (68%) gave it an overall rating of excellent. Workshop participants rated the workshop very good at helping them to understand and use decision support…" Overall, the POC PtDA was rated as acceptable and clinically usefull by the 38 participants who provided data...31(81%) agreed that the PtDA would be acceptable to patients, while 24 (63%) agreed that it would be acceptable to practitioners." Page 117 "All 36 who participated in the Educational outreach call indicated an interested in using the POC PtDa and express frustration that it was not available for use in their clinical practice setting." Page 118	na
O'Cathain 2002	Educational meeting + distribution of Educational material	Usual care	Satisfaction with amount of information (antenatal period)	Difference between groups: adjusted OR 1.40 (1.05 to 1.88) (Page 3; table 2)	na

Table 8. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to usual care *(Continued)*

LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	Usual care	Decisional conflict	"Decision conflict was low for both groups, and was lower in the Decision Aid arm, but no significant difference was found in the overall scale or in its subscales across arms (Table 2)." page 8	na
Légaré 2012	Educational meeting + distribution of Educational material	Usual care		"The training had no statistically significant effect on decisional conflict,…" Page E731	na
Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care		"Overall, patients in the SGA cohort reported higher conflict scores than those in the ANZ cohort… Post-randomisation, although there was no change in conflict in the SGA cohort, in the ANZ cohort there was an increased level of conflict in the control group (estimate = 0.28; ES = 0.17: p = 0.003). This change exceeded the improvement in the training group (estimate = 0.14; ES = 0.09; p = 0.13). In summary, the training appeared to have no overall effect on decisional conflict in either language cohort." Pages 1268-1269	na
Légaré 2012	Educational meeting + distribution of Educational material	Usual care	Adherence to decision	No differences between group (page E733; table 4)	na
Cooper 2011	Educational meeting	Usual care	Adherence to medication	Changes in patient-reported adherence to medications at 12 months did not differ for any of the intervention groups compared to the patient+physician minimal intervention group."Page 1300	na
Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Health-related QoL	"The quality of life indicators showed similar findings (data not shown)." Page 1270	na
LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	Usual care		"We found no difference between the FRAX and usual care arms, nor were overall results significantly impacted by analyses comparing the three arms versus only two arms (Decision aid arm vs. FRAX/usual care arms together, see Tables A, B, C, D, and E in S1 File. Therefore, the results comparing the FRAX arm and the Usual Care arm were combined and all subsequent results are presented as Decision Aid vs. FRAX/Usual Care arm (i.e. different forms of usual care)." Page 7 There were no difference between group regarding quality of life [Median (IQR); Decision aid: 85 (80, 95) FRAX/UC: 85 (73, 90); p=0.19 (table 4)]	na
Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Anxiety (state) - 2 weeks	"Anxiety slightly decreased over time for all cohorts. Patients in the SGA (Figure 4a) and ANZ (Figure 4b) cohorts reported comparable anxiety levels at each time point." Page 1270	na

Table 8. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to usual care *(Continued)*

Bernhard 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Anxiety (state) - 4 months	"Anxiety slightly decreased over time for all cohorts. Patients in the SGA (Figure 4a) and ANZ (Figure 4b) cohorts reported comparable anxiety levels at each time point." Page 1270	na
Fossli 2011	Educational meeting + audit and feedback + distribution of Educational material	Usual care	Consultation length	"The duration of encounters (min:sec) did not change significantly (1:03 (p = 0.69, 95% CI 6:13; 4:07)) from pre to post, and neither did patient global satisfaction (0.3 (p = 0.38, 95% CI 0.3; 0.8))." Page 166	na
Murray 2010	Educational meeting + audit and feedback + distribution of Educational material + Educational outreach visit + barriers assessement	Usual care		"At baseline there was no significant difference. However, in the post-calls, the mean call duration was longer in the intervention group at 13,47 minutes (95% confidence interval 11.8;14.21), than in the control group at 10.29 minutes (95% CI 8.79 to 11.79 P = 0.004)" Page 117	na
Shepherd 2011	Educational outreach visit	Usual care		"These effects occurred without any significant difference in consultation length, mean consultation lengths were 26 minutes for control and intervention visits." Page 381	na
LeBlanc 2015b	Reminder (copy of patient's estimated risk of fracture as computed by the FRAX)	Usual care		"We found no difference between the FRAX and usual care arms, nor were overall results significantly impacted by analyses comparing the three arms versus only two arms (Decision aid arm vs. FRAX/usual care arms together, see Tables A, B, C, D, and E in S1 File..." Page 7	na

ANZ: Australia, New Zealand; CI: confidence interval; DA: decision aid; DCS: Decisional Conflict Scale; ES: effect size; HCP: healthcare professional; IQR: interquartile range; N: sample size; na: not applicable; POC: place-of-care; PtDA: patient decision aid; QoL: quality of life; OR: odds ratio; RD: risk difference; SGA: Switzerland, Germany and Austria; SMD: standardized mean difference.

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care

Continous Data								Meta-analysis
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Coylewright 2016	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Knowledge	107	0.98 (0.57 to 1.38)	0.41 (0.28 to 0.53)	0%	
Coylewright 2016	Patient-mediated intervention (decision aid) + educational meeting	Usual care		106	0.48 (0.09 to 0.87)			x

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care		898	0.40 (0.27 to 0.53)			x
Loh 2007	Patient-mediated intervention + educational meeting	Usual care	Satisfaction with care (overall)	287	0.92 (0.67 to 1.18)	0.51 (-0.34 to 1.36)	91%	x
Rise 2012	Patient-mediated intervention (use of PCOMS) + educational meeting	Usual care	Satisfaction with care (6 weeks)	75	0.05 (-0.40, 0.51)			x
Rise 2012	Patient-mediated intervention (use of PCOMS) + educational meeting	Usual care	Satisfaction with care (6 months)	64	0.00 (-0.49 to 0.49)			
Rise 2012	Patient-mediated intervention (use of PCOMS) + educational meeting	Usual care	Satisfaction with care (12 months)	63	0.21 (-0.28 to 0.71)			
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Satisfaction with decision (post-consultation)	424	0.24 (0.05 to 0.43)	0.24 (0.05 to 0.43)	na	na
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Satisfaction with decision (3 months)	366	-0.47 (-0.67 to -0.26)	-0.47 (-0.67 to -0.26)	na	na
Wilkes 2013	Patient-mediated intervention (web-based educational program for patients) + distribution of educational material	Usual care	Satisfaction with consultation	393	0.00 (-0.23 to 0.23)	0.00 (-0.23 to 0.23)	na	na
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Decisional conflict (confidence in decision) (post-consultation)	414	0.03 (-0.17 to 0.22)	0.03 (-0.17 to 0.22)	na	na
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Decisional conflict (confidence	371	-0.32 (-0.53 to -0.12)	-0.32 (-0.53 to -0.12)	na	na

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

			in decision) (3 months)					
Mathers 2012	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Decisional conflict	167	-0.19 (-0.32 to -0.06)	-0.35 (-0.71 to 0.01)	79%	x
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care		898	-0.57 (-0.88 to -0.26)			x
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Decision regret (3 months)	369	0.13 (-0.08 to 0.33)	0.13 (-0.08 to 0.33)	na	na
Epstein 2017	Patient-mediated intervention (patients & caregivers coaching session + question prompt list) + educational meeting	Usual care	Patient-physician communication (patient-centred communication)	Pre: 118; Post: 265	0.23 (-0.01 to 0.47)	0.23 (-0.01 to 0.47)	na	na
Loh 2007	Patient-mediated intervention + educational meeting	Usual care	adherence to medcation (patient's assessment)	287	0.44 (-0.17 to 1.05)	0.44 (-0.17 to 1.05)	na	na
Loh 2007	Patient-mediated intervention + educational meeting	Usual care	adherence to medication (physician's assessment)	287	0.62 (0.37 to 0.87)	0.62 (0.37 to 0.87)	na	na
Epstein 2017	Patient-mediated intervention (patients & caregivers coaching session + question prompt list) + educational meeting	Usual care	Health-related QoL	265	0.08 (-0.16 to 0.33)	0.08 (-0.16 to 0.33)	na	na
Rise 2012	Patient-mediated intervention + educational meeting	Usual care	Health-related QoL (physical)-6 weeks	Pre: 75; Post: 75	0.08 (-0.37 to 0.54)	0.08 (-0.37 to 0.54)	na	na
Rise 2012	Patient-mediated intervention + educational meeting	Usual care	Health-related QoL (physical)-6 months	Pre:75; Post: 64	-0.09 (-0.58 to 0.40)	-0.09 (-0.58 to 0.40)	na	na

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

Rise 2012	Patient- mediated intervention + educational meeting	Usual care	Health-related QoL (physical)- 12 months	Pre: 75; Post: 63	0.11 (-0.39 to 0.60)	0.11 (-0.39 to 0.60)	na	na
Rise 2012	Patient-mediated intervention + educational meeting	Usual care	Health-related QoL (mental)- 6 weeks	Pre: 75; Post: 75	0.01 (-0.44 to 0.46)	0.01 (-0.44 to 0.46)	na	na
Rise 2012	Patient-mediated intervention + educational meeting	Usual care	Health-related QoL (mental)- 6 months	Pre:75; Post: 64	0.24 (-0.25 to 0.74)	0.24 (-0.25 to 0.74)	na	na
Rise 2012	Patient-mediated intervention + educational meeting	Usual care	Health-related QoL (mental)- 12 months	Pre: 75; Post: 63	0.15 (-0.34 to 0.65)	0.15 (-0.34 to 0.65)	na	na
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Anxiety - post-consultation	419	-0.12 (-0.31 to 0.08)	-0.12 (-0.31 to 0.08)	na	na
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Anxiety - 3 months	367	-0.85 (-1.06 to -0.63)	-0.85 (-1.06 to -0.63)	na	na
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Depression - post-consultation	418	-0.14 (-0.33 to 0.05)	-0.14 (-0.33 to 0.05)	na	na
Härter 2015	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Depression - 3 months	364	-0.59 (-0.80 to -0.38)	-0.59 (-0.80 to -0.38)	na	na
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care	Consultation length (minutes)	536	3.72 (3.44 to 4.01)	3.72 (3.44 to 4.01)	na	na

Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
Sheridan 2012	Patient-mediated intervention (video + coahcing session) + educational meeting	Usual care	Knowledge	128	0.34 (0.19 to 0.49)	0.28 (0.05 to 0.51)	92%	x

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

Branda 2013	Patient-mediated intervention (decision aid) + educational meeting	Usual care		59	0.08 (-0.18 to 0.34)			
Branda 2013	Patient mediated intervention (decision aid) + educational meeting	Usual care		59	0.28 (0.02 to 0.53)			x
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care		898	0.02 (0.00 to 0.03)			
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care		898	0.47 (0.41 to 0.53)			x
Mathers 2012	Patient-mediated intervention (decision aid) + educational meeting	Usual care		175	0.23 (0.09 to 0.37)			
Mathers 2012	Patient-mediated intervention (decision aid) + educational meeting	Usual care		175	0.02 (-0.12 to 0.15)			x
Härter 2015	Patient-mediated intervention + educational meeting	Usual care	Match between preferred and actual level of participation in decision making	96	-0.01 (-0.19 to 0.18)	-0.03 (-0.16 to 0.10)	0%	x
Sheridan 2012	Patient-mediated intervention (video + coahcing session) + educational meeting	Usual care		89	-0.05 (-0.24 to 0.13)			x
Hamann 2007	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Adherence (good) (6 months)	86	-0.14 (-0.35 to 0.07	0.00 (-0.15 to 0.15)	0%	x
Hamann 2007	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Adherence (good) (12 months)	68	0.02 (-0.21 to 0.26)			
Branda 2013	Patient-mediated intervention decision aid) + educational meeting	Usual care	Adherence to medication (% of patients with ≥ 80% of days covered)	77	-0.01 (-0.20 to 0.18)			x
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care	Safety (whether a patient experienced a major	898	0.00 (-0.00 to 0.01)	0.00 (-0.00 to 0.01)	na	na

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

			adverse cardiac event): MACE within 30 days				
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care	Safety (whether a patient experienced a major adverse cardiac event): Acute myocardial infarction	898	0.01 (-0.00 to 0.02)	0.01 (-0.00 to 0.02)	na	na
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care	Safety (whether a patient experienced a major adverse cardiac event): Death of cardiac or unknown cause	898	0.00 (-0.00 to 0.00)	0.00 (-0.00 to 0.00)	na	na

Qualitative statement

Study	Intervention	Intervention	Outcome	Direct quote	Meta-analysis
Hamann 2007	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Knowledge	"Patients in the intervention group knew significantly more about their disease and treatment at the time of discharge." Page 270 (Hamann 2006)	na
Hess 2012	Patient-mediated intervention + educational meeting	Usual care	Knowledge	"Patients randomized to the shared decision-making arm answered a greater number of questions in the knowledge questionnaire correctly (Table 2)." page 255 "They also had greater knowledge regarding their exact pretest probability of ACS within 45 days (25% versus 1%; mean difference, 24%; 95% CI, 22%–26%)." Page 255	na
Branda 2013	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Knowledge (baseline)	Decision aid use significantly increased knowledge transfer at baseline (Table 3).	na
Branda 2013	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Knowledge (3 months)	No difference between group (page 6; table 3)	na
Branda 2013	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Knowledge (6 months)	No difference between group (page 6; table 3)	na

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

Leighl 2011	Patient-mediated intervention + educational meeting	Usual care	Satisfaction with decision (4 weeks)	"Decision satisfaction and decisional conflict scores were similar in both arms. There were also no differences in decisional conflict subscale scores between arms. Other outcomes were similar between groups (Table 3)." Page 2080	na
Hess 2012	Patient-mediated intervention + educational meeting	Usual care	Satisfaction with the decision making process	"Patients who used the decision aid reported greater satisfaction with the decision making process (strongly agree, 61% versus 40%; absolute difference, 21%; 95% CI, 7%–33%)." Page 255	na
Leighl 2011	Patient-mediated intervention + educational meeting	Usual care	Satisfaction with consultation (post visit)	"Decision satisfaction and decisional conflict scores were similar in both arms. There were also no differences in decisional conflict subscale scores between arms. Other outcomes were similar between groups (Table 3)." Page 2080	na
Wetzels 2005	Patient-mediated Intervention (leaflet) + educational outreach visit	Usual care	Satisfaction with care	"Finally, patients were very satisfied with the way their GP behaved during the consultation. No differences between intervention and control group were detected." Page 290	na
Hamann 2007	Patient-mediated intervention (decision aid) + educational meeting	Usual care		"Patients in the intervention group did not differ from the patients in the control group in regard to overall satisfaction with treatment (ZUF 8)…" Page 270 (Hamann 2006)	na
Haskard 2008	Patient-mediated intervention + distribution of educational material + educational meeting	Usual care		"The following significant (p < .05) effects emerged: physician training improved patients' satisfaction with information and overall care" (page 513). "Physician training improved patient satisfaction with "overall care" (the linear time physician training interaction)" Page 518	na
Hess 2012	Patient-mediated intervention + educational meeting	Usual care	Satisfaction with the intervention	"The decision aid was acceptable, clear, and helpful to patients and clinicians (Table 2)." Page 255	na
Leighl 2011	Patient-mediated intervention + educational meeting	Usual care		"Ninety percent of those who received the DA reported that it was helpful or very helpful in making their treatment decision." Page 2081	na
Branda 2013	Patient-mediated intervention (decision aid) + educational meeting	Usual care		"Patients were similarly satisfied with usual care and the decision aid; 71% of decision aid patients found the information provided helpful compared to 53% of patients in the usual care arm (p=.17) (Table 4)." Page 4	na
Mathers 2012	Patient-mediated intervention (decision aid) + educational meeting	Usual care		"Most of the PDA users found the PDA useful. When asked about their opinion of the PDA, 83.2% (n=88), 86.3% (n=89), 86.3% (n=89) and 88.4% (n=90) thought that the PDA had helped them	na

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

				to recognise that a decision needs to be made; know that the decision depends on what matters most to them; think about how involved they wanted to be in the decision; and prepare to talk to the nurse or doctor about what mattered most to them',respectively." Pages 7-8	
Hess 2016	Patient-mediated intervention (decision aid) + reminder (quantitative pretest probability web tool)	Usual care		"Patients randomized to the decision aid found the information discussed to be of greater clarity, and a greater proportion (decision aid, 88.0% v usual care, 79.9%; absolute difference 8.1%, P=0.004) would recommend the way they discussed management options with their clinician to others." page 6	na
Leighl 2011	Patient-mediated intervention + educational meeting	Usual care	Decisional conflict	"There were also no differences in decisional conflict subscale scores between arms. (Table 3)." Page 2080	na
Branda 2013	Patient-mediated intervention (decision aid + educational meeting	Usual care		"Patient decisional comfort was similarly high in both trial arms." Page 5	na
Coylewright 2016	Patient-mediated intervention (decision aid) + educational meeting	Usual care		"The decision aid significantly improved the degree to which patients felt informed regarding their choices (decisional conflict score in decision aid arm: 15.4 versus UC: 21.9; P=0.043); overall decisional conflict was not different between the 2 arms." Page 773	na
Hess 2012	Patient-mediated intervention + educational meeting	Usual care		"Patients who used the decision aid also experienced less decisional conflict when engaging in management decisions regarding their care." Page 255	na
Mathers 2012	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Decision regret (6 months)	"Table 9 shows that there was no difference at 6 months in the Regret Scale" Page 7	na
Epstein 2017	Patient-mediated intervention (patients & caregivers coaching session + question prompt list) + educational meeting	Usual care	Self-efficacy	"There were no statistically significant effects of the intervention on the PEPPI..." Page 96	na
Leighl 2011	Patient-mediated intervention + educational meeting	Usual care	Match between preferred and actual level of participation in decision making	"After arriving at a treatment decision, 32% of those who received the DA and 35% in the standard arm reported perceiving a role in decision making that matched their preference. Most perceived playing a greater role than initially preferred (DA arm, 38%; standard arm, 41%). There were no significant differences between study arms." Page 2081	na

Table 9. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to usual care *(Continued)*

Cooper 2011	Patient-mediated intervention + educational meeting	Usual care	Adherence to medication	“Changes in patient-reported adherence to medications at 12 months did not differ for any of the intervention groups compared to the patient+physician minimal intervention group.” Page 1300	na
Mathers 2012	Patient-mediated intervention (decision aid) + educational meeting	Usual care	Persistence with the chosen option	"Patients in the intervention group were rather more likely to persist with their chosen option." Page 7 [68.1% vs 56.3%; adjusted OR (95% CI): 1.17 (1.00 to 1.36); p= 0.041]	na
Leighl 2011	Patient-mediated intervention + educational meeting	Usual care	Anxiety	"Patient anxiety was low to moderate at all time points, with a minor decrease over time. There was no difference between study arms, demonstrating no adverse impact of the DA (Fig 3)." Page 2080	na
Loh 2007	Patient-mediated intervention + educational meeting	Usual care	Depression	No difference between group (page 329; table 2)	na
Loh 2007	Patient-mediated intervention + educational meeting	Usual care	Consultation length (minutes)	"No differences were found between study groups for length of consultation." Page 329	na
Wetzels 2005	Patient-mediated intervention (leaflet) + educational outreach visit	Usual care		There were no differences between intervention and control group regarding consultation length (page 292, table 3)	na

ACS: acute coronary syndrom; CI: confidence interval; DA: decision aid; MACE: major averse cardiac events; N: sample size; na: not applicable; PCOMS: Partners for Change Outcome Management System; PEPPI: Perceived Efficacy in Patient-Physician Interactions; PDA: patient decision aid; QoL: quality of life; OR: odds ratio; RD: risk difference; SMD: standardized mean difference.

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients

Continous data								Meta-analysis
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Raynes-Greenow 2010	Patient-mediated intervention (audio + non-audio decision aid)	Patient-mediated intervention (Pamphlet)	Knowledge	596	0.30 (0.13 to 0.47)	0.30 (0.13 to 0.47)	na	na
Raynes-Greenow 2010	Patient-mediated intervention (audio + non-audio decision aid)	Patient-mediated intervention (Pamphlet)	Satisfaction with decision (first follow-up)	596	0.07 (-0.10 to 0.24)	0.07 (-0.10 to 0.24)	na	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Raynes-Greenow 2010	Patient-mediated intervention (audio + non-audio decision aid)	Patient-mediated intervention (Pamphlet)	Satisfaction with decision (second follow-up)	596	0.11 (-0.06 to 0.28)	0.11 (-0.06 to 0.28)	na	na
Hamann 2011	Patient-mediated intervention (SDM training)	Patient-mediated intervention (cognitive training)	Satisfaction with treatment	61	-0.32 (-0.83 to 0.19)	-0.09 (-0.34 to 0.16)	4%	x
Hamann 2017	Patient-mediated intervention (training for patient-SDM training)	Patient-mediated intervention (training for patient- cognitive training)		206	-0.02 (-0.29 to 0.25)			x
Jouni 2017	Patient-mediated intervention (conventional risk and genetic risk information + decision aid)	Patient-mediated intervention (conventional risk information + decision aid)	Satisfaction with consultation	207	-0.14 (-0.42 to 0.13)	-0.14 (-0.42 to 0.13)	na	na
Causarano 2014	Patient-mediated intervention (Routine education + educational meeting to patient)	Patient-mediated intervention (Routine education)	Satisfaction with the information provided	39	0.11 (-0.52 to 0.73)	0.11 (-0.52 to 0.73)	na	na
Dolan 2002	Patient-mediated intervention (preliminary phase + decision aid)	Patient-mediated intervention (preliminary phase + educational phase)	Decisional conflict	88	-0.29 (-0.71 to 0.13)	-0.20 (-0.48 to 0.08)	72%	x
Lalonde 2006	Patient-mediated intervention (decision aid + four-step decision making strategy)	Patient-mediated intervention (decision aid)	Decisional conflict	50	0.10 (-0.46 to 0.65)			x
Raynes-Greenow 2010	Patient-mediated intervention (audio + non-audio decision aid)	Patient-mediated intervention (Pamphlet)	Decisional conflict (primary follow-up)	596	-0.09 (-0.26 to 0.08)			x
Raynes-Greenow 2010	Patient-mediated intervention (audio + non-audio decision aid)	Patient-mediated intervention (Pamphlet)	Decisional conflict (second follow-up)	596	-0.02 (-0.19 to 0.15)			

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Adarkwah 2016	Patient-mediated intervention (decision aid-Emoticon group)	Patient-mediated intervention (decision aid-TTE group)	Decisional conflict	304	0.05 (-0.18 to 0.27)			x
Smallwood 2017	Patient-mediated intervention (decision aid)	Patient-mediated intervention (web-based information)	Decisional conflict (post-intervention)	50	-1.15 (-1.76 to -0.54)			x
Smallwood 2017	Patient-mediated intervention (decision aid)	Patient-mediated intervention (web-based information)	Decisional conflict (3 months)	50	-0.51 (-1.08 to 0.06)			
van Roosmalen 2004	Patient-mediated intervention (shared decision making intervention+decision aid)	Patient-mediated intervention (decision aid)	Decision uncertainty - time 4	80	-0.21 (-0.65 to 0.23)	-0.21 (-0.65 to 0.23)	na	na
van Roosmalen 2004	Patient-mediated intervention (shared decision making intervention+decision aid)	Patient-mediated intervention (decision aid)	Decision uncertainty - time 5	71	-0.42 (-0.89 to 0.05)	-0.42 (-0.89 to 0.05)	na	na
Causarano 2014	Patient-mediated intervention (routine education + educational meeting to patient)	Patient-mediated intervention (Routine education)	Decision self-efficacy	39	-0.12 (-0.75 to 0.51)	-0.02 (-0.41 to 0.37)	0%	x
Hamann 2011	Patient-mediated intervention (SDM training)	Patient-mediated intervention (cognitive training)		61	0.04 (-0.46 to 0.55)			x
Hamann 2017	Patient-mediated intervention training for patient-SDM training)	Patient-mediated intervention (training for patient- cognitive training)	Adherence to medication - 6 months after discharge	100	0.05 (-0.35 to 0.44)	0.05 (-0.35 to 0.44)	na	na
Hamann 2017	Patient-mediated intervention training for patient-SDM training)	Patient-mediated intervention (training for patient- cognitive training)	Adherence to medication - 12 months	85	-0.18 (-0.61 to 0.25)	-0.18 (-0.61 to 0.25)	na	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

			after discharge					
van Roosmalen 2004	Patient-mediated intervention (shared decision making intervention+decision aid)	Patient-mediated intervention (decision aid)	General health (t4)	88	-0.19 (-0.61 to 0.23)	-0.19 (-0.61 to 0.23)	na	na
van Roosmalen 2004	Patient-mediated intervention (shared decision making intervention+decision aid)	Patient-mediated intervention (decision aid)	General health (t5)	82	0.53 (0.09 to 0.97)	0.53 (0.09 to 0.97)	na	na
Raynes-Greenow 2010	Patient-mediated intervention (Audio + non-audio decision aid)	Patient-mediated intervention (Pamphlet)	Anxiety (State) - 1st follow-up	596	-0.10 (-0.27 to 0.07)	-0.11 (-0.27 to 0.05)	0%	x
Raynes-Greenow 2010	Patient-mediated intervention (Audio + non-audio decision aid)	Patient-mediated intervention (Pamphlet)	Anxiety (State) - 2nd follow-up	596	0.05 (-0.12 to 0.21)			
van Roosmalen 2004	Patient-mediated intervention (shared decision making intervention+decision aid)	Patient-mediated intervention (decision aid)	Anxiety (State) - time 4	86	-0.18 (-0.60 to 0.25)			x
van Roosmalen 2004	Patient-mediated intervention (shared decision making intervention+decision aid)	Patient-mediated intervention (decision aid)	Anxiety (State) - time 5	87	-0.36 (-0.78, 0.07)			
van Roosmalen 2004	Patient-mediated intervention (shared decision making intervention+decision aid)	Patient-mediated intervention (decision aid)	Depression - time 4	86	-0.27 (-0.69 to 0.16)	-0.27 (-0.69 to 0.16)	na	na
van Roosmalen 2004	Patient-mediated intervention (shared decision making intervention+decision aid)	Patient-mediated intervention (decision aid)	Depression - time 5	87	-0.39 (-0.82 to 0.03)	-0.39 (-0.82 to 0.03)	na	na
Causarano 2014	Patient-mediated intervention (Routine education +	Patient-mediated intervention (Routine education)	Consultation length (minutes)	39	-0.65 (-1.29 to -0.00)	-0.65 (-1.29 to -0.00)	na	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

educational meeting to patient)

Categorical data								Meta-analysis
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
Barton 2016	Patient-mediated intervention (Low literacy medication guide)	Patient-mediated intervention (Existing medication guide)	Knowledge	106	0.09 (-0.10 to 0.28)	0.16 (-0.10 to 0.42)	91%	x
Barton 2016	Patient-mediated intervention (decision aid + low literacy medication guide)	Patient-mediated intervention (Existing medication guide)		118	0.25 (0.08 to 0.41)			
Barton 2016	Patient-mediated intervention (decision aid + low literacy medication guide)	Patient-mediated intervention (Low literacy medication guide)		108	0.16 (-0.01 to 0.33)			
Köpke 2014	Patient-mediated intervention (interactive-4h education programme)	Patient-mediated intervention (4h MS-specific stress management programme)		Pre: 192; Post: 178	0.39 (0.26 to 0.53)			x
Krist 2007	Patient-mediated intervention (decision aid web)	Patient-mediated intervention (decision aid brochure)		422	0.00 (-0.09 to 0.09)			x
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Concordance between preferred and assumed role in decision making	131	-0.13 (-0.32 to 0.06)	-0.10 (-0.16 to -0.05)	20%	x
Dolan 2002	Patient-mediated intervention (preliminary phase + decision aid)	Patient-mediated intervention (preliminary phase + educational phase)		86	0.05 (-0.14 to 0.24)			x
Kasper 2008	Patient-mediated intervention (decision aid + information booklet about immunotherapy)	Patient-mediated intervention (decision aid + standard information package)		278	-0.09 (-0.17 to 0.00)			x

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Davison 2002	Patient-mediated intervention (computer generated information and decision preference profiles + computer generated prompt sheet)	Patient-mediated intervention (discussion with research nurse)		734	-0.14 (-0.20 to -0.08)			x
Schroy 2016	Patient-mediated intervention (decision aid + electronic risk assessment tool)	Patient-mediated intervention (decision aid)	Concordance between preferred and chosen option	341	-0.03 (-0.10 to 0.04)	-0.20 (-0.60 to 0.20)	81%	x
Causarano 2014	Patient-mediated intervention (Routine education + educational meeting to patient)	Patient-mediated intervention (Routine education)		22	-0.45 (-0.79 to -0.10)			x
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)	Adherence to medication (self-report): did not miss a dose in last week	36	0.02 (-0.30 to 0.33)	0.01 (-0.10 to 0.12)	0%	x
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)	Adherence to medication (pharmacy record): > 80% d covered	42	0.26 (0.06 to 0.47)			
Barton 2016	Patient-mediated intervention (Low literacy medication guide)	Patient-mediated intervention (Existing medication guide)	Adherence to medication: did not miss dose in past week	81	-0.23 (-0.44 to -0.03)			
Barton 2016	Patient-mediated intervention (decision aid + low literacy medication guide)	Patient-mediated intervention (Existing medication guide)	Adherence to medication: did not miss dose in past week	93	-0.14 (-0.33 to 0.05)			

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Barton 2016	Patient-mediated intervention (decision aid + low literacy medication guide)	Patient-mediated intervention (Low literacy medication guide)	Adherence to medication: did not miss dose in past week	92	0.10 (-0.11 to 0.30)			x
Hamann 2017	Patient-mediated intervention training for patient-SDM training)	Patient-mediated intervention (training for patient- cognitive training)	Adherence to medication and outpatient visits (good adherence)	173	-0.04 (-0.18 to 0.11)			x
Köpke 2014	Patient-mediated intervention (interactive-4h education programme)	Patient-mediated intervention (4h MS-specific stress management programme)	Adherence to medication (DMD discontinuation)	86	-0.14 (-0.31 to 0.02)	-0.14 (-0.31 to 0.02)	na	na

Qualitative statement

Study	Intervention	Intervention	Outcome	Direct quote	Meta-analysis
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)	Knowledge (DA specific)	Knowledge DA specific (P = 0.001) Table 2, page 553	na
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)	Knowledge (Not in the DA)	Knowledge not in the DA (P = 0.35) Table 2, page 553	na
Köpke 2014	Patient-mediated intervention (interactive-4h education programme)	Patient-mediated intervention (4h MS-specific stress management programme)	Knowledge	Significant difference between groups (p < 0.001) (Page 415; table 3)	na
Schroy 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (educational material)		"Mean [standard deviation] cumulative pretest knowledge scores were comparable (P = 0.91) for the 3 groups (decision aid plus YDR, 7.6 [2.8]; decision aid alone, 7.7 [2.9]; control, 7.5 [2.7]). Cumulative posttest scores, however, were significantly higher (P < 0.001) for the 2 intervention groups (decision aid plus YDR, 10.7 [1.8]; decision aid alone, 10.9 [1.6]) compared with the control group (8.6 [2.7]), with differences corresponding to large effect sizes of d = 1.15 and	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

				d = 1.27 for the decision aid plus YDR group and decision aid alone group versus control, respectively." Pages 7 and 8	
Schroy 2011	Patient-mediated intervention (decision aid + YDR)	Patient-mediated intervention (educational material)		"Mean [standard deviation] cumulative pretest knowledge scores were comparable (P = 0.91) for the 3 groups (decision aid plus YDR, 7.6 [2.8]; decision aid alone, 7.7 [2.9]; control, 7.5 [2.7]). Cumulative posttest scores, however, were significantly higher (P < 0.001) for the 2 intervention groups (decision aid plus YDR, 10.7 [1.8]; decision aid alone, 10.9 [1.6]) compared with the control group (8.6 [2.7]), with differences corresponding to large effect sizes of d = 1.15 and d = 1.27 for the decision aid plus YDR group and decision aid alone group versus control, respectively." Pages 7 and 8	na
Lalonde 2006	Patient-mediated intervention (decision aid + four-step decision making strategy)	Patient-mediated intervention (decision aid)		"Since similar CVD knowledge and risk perception before and after the intervention were observed in DA and PRP groups, the participants in both groups were combined." page 54 ...” However, knowledge of the estimated benefits of treatment tended to improve after the intervention (29% versus 58%; P = 0.06)“ Page 55	na
Nannenga 2009	Patient-mediated intervention (decision aid)	Patient-mediated intervention (pamphlet)		"Use of the decision aid resulted in higher knowledge scores (mean difference 1.6, 95% CI: 0.7, 2.5)..." Page 42	na
Street 1995	Patient-mediated intervention (Interactive multimedia program decision aid)	Patient-mediated intervention (brochure decision aid)		“The effect for method of communication approached significance (F = 3.30, P = 0.07) as patients in the computer group tended to learn more (mean, 75.5%; SD13.64%) than did patients in the brochure group (mean, 71.4%; SD, 15.7%)” Page 2279	na
Street 1995	Patient-mediated intervention (Interactive multimedia program decision aid)	Patient-mediated intervention (brochure decision aid)		“The effect for method of communication approached significance (F = 3.30, P = 0.07) as patients in the computer group tended to learn more (mean, 75.5%; SD13.64%) than did patients in the brochure group (mean, 71.4%; SD, 15.7%)” Page 2279	na
Thomson 2007	Patient-mediated intervention (Computerised decision aid)	Patient-mediated intervention (Guidelines)		"Although the overall knowledge scores improved slightly post-clinic, by three months they were back to pre-clinic levels; there was no difference between decision aid and guidelines groups at any point." Page 220	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Satisfaction with consultation	“No significant differences were found between the groups in satisfaction with either the consultation or treatment decision” Page 4407	na
Davison 2002	Patient-mediated intervention (computer generated information and decision	Patient-mediated intervention (discus-		"The 14-item satisfaction questionnaire was found to be reliable (Cronbach’s Alpha = .885) (see Figure 3 for items included in the questionnaire). Women did not significantly differ on any of the	

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

	preference profiles + computer generated prompt sheet)	sion with research nurse)		items, and both groups were satisfied with their clinic visits. The overall mean score for this scale was 1.64 (SD = .54)." (no page number, in the results section)	
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Satisfaction with decision (treatment)	"No significant differences were found between the groups in satisfaction with either the consultation or treatment decision" Page 4407	na
Deschamps 2004	Patient-mediated intervention (pharmacist consultation + patient specific information + letter)	Patient-mediated intervention (decision aid)		"Women in the pharmacist and decision-aid groups had mean SWD scores of 4.3 and 4.4 respectively (scale range: 1 to 5) with no significant differences being reported between groups. Page 26	na
Köpke 2014	Patient-mediated intervention (interactive-4h education programme)	Patient-mediated intervention (4h MS-specific stress management programme)		"In both groups, almost all decisions were reported as satisfactorily (data not shown)." Page 414	na
Kasper 2008	Patient-mediated intervention (decision aid + information booklet about immunotherapy)	Patient-mediated intervention (decision aid + standard information package)	Satisfaction with the intervention	"Patients in the IG rated the value of the received information for the decision-making process significantly higher than did those in the CG ($P < 0.001$). This result refers to the IG patients feeling of being better informed ($P < 0.001$), getting important questions more adequately answered ($P < 0.01$), and being better supported in finding their preferred role ($P < 0.05$), compared to patients in the CG." Pages 1349-1350	na
Lalonde 2006	Patient-mediated intervention (decision aid + four-step decision making strategy)	Patient-mediated intervention (decision aid)		"As reported in table 2, comparison of the acceptability of each educational tool revealed no satistically significant differences." Page 54	na
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)		"Patients receiving the decision aid were satisfied with this mode of information transfer to the same extent as patients in usual care encounters (Table 2)." Page 553	na
Raynes-Greenow 2010	Patient-mediated intervention (Audio + non-audio decision aid)	Patient-mediated intervention (Pamphlet)		"Equally both groups would recommend the intervention they received to a pregnant friend (decision aid group 94% compared to pamphlet group 93%, chi-square, df=1, P = 0.57)" Page 7	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)		"No significant differences were found between groups in terms of reported anxiety provoked, perceived utility, or ease of understanding of the materials." Page 4405	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Barton 2016	Patient-mediated intervention (low literacy medication guide)	Patient-mediated intervention (Existing medication guide)		"The acceptability scale completed by patients immediately postvisit did not differ significantly across the 3 trial arms (P50.24)." Page 894	na
Barton 2016	Patient-mediated intervention (decision aid + low literacy medication guide)	Patient-mediated intervention (Existing medication guide)		"The acceptability scale completed by patients immediately postvisit did not differ significantly across the 3 trial arms (P50.24)." Page 895	na
Barton 2016	Patient-mediated intervention (decision aid + low literacy medication guide)	Patient-mediated intervention (Low literacy medication guide)		"The acceptability scale completed by patients immediately postvisit did not differ significantly across the 3 trial arms (P50.24)." Page 896	na
Hamann 2017	Patient-mediated intervention training for patient-SDM training)	Patient-mediated intervention (training for patient- cognitive training)		"Overall patients enjoyed visiting both, the intervention and the control group. However, their ratings were more positive regarding the specific content of the intervention group and more patients in the intervention group planned to play a more active role in future consultations compared with the control group (Table 2)." Page 178	na
Warner 2015	Patient-mediated intervention (decision aid + patient education brochure) + education meeting	Patient-mediated intervention (patient education brochure)	Satisfaction with discussion	"The measure of satisfaction with the smoking discussion assessed on the morning of surgery was significantly higher in patients receiving the decision aid (81 [24] and 90 [19] for the usual care and decision aid groups, respectively; P = 0.02). However, these differences did not persist; by 30 days after surgery, satisfaction was not different between groups (84 [21] and 84 [24] for the usual care and the decision aid groups, respectively, at day 30; P = 0.90)." Page 23	na
Warner 2015	Patient-mediated intervention (decision aid + patient education brochure) + education meeting	Patient-mediated intervention (patient education brochure)	Satisfaction with information provided	"However, clarity of information and helpfulness were rated significantly higher by patients receiving the decision aid, whereas willingness to recommend to others and assessment of the amount of information presented did not differ significantly (table 3)" Page 23	na
Barton 2016	Patient-mediated intervention (Low literacy medication guide)	Patient-mediated intervention (Existing medication guide)	Decisional conflict	No significant differences between groups (page 895; table 2)	na
Barton 2016	Patient-mediated intervention (decision aid + low literacy medication guide)	Patient-mediated intervention (Existing medication guide)		Significant difference between groups (page 895; table 2)	na
Causarano 2014	Patient-mediated intervention (Routine education +	Patient-mediated intervention (Routine education)		"The decrease in decisional conflict was greater in the intervention group (−37.7, SD=22.5) compared to routine education (−24.3,	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

	educational meeting to patient)			SD=16.0). The Cohen's d effect size of 0.69 (95 % CI= 0.02–1.42) suggested a moderate to large effect size." (page 1371)	
Krist 2007	Patient-mediated intervention (decision aid web)	Patient-mediated intervention (decision aid brochure)		"DCS scores among all 3 groups were equally low and did not differ signifi cantly (control, 1.58; brochure, 1.54; and Web site, 1.55)." Page 115	na
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)		No difference between groups (p=0.725) (table 2)	na
Deschamps 2004	Patient-mediated intervention (pharmacist consultation + patient specific information + letter)	Patient-mediated intervention (decision aid)		The differences between groups were non-significant (Table 2), Page 25	na
Nannenga 2009	Patient-mediated intervention (decision aid)	Patient-mediated intervention (pamphlet)		"use of the decision aid resulted in higher knowledge scores (mean difference 1.6, 95% CI: 0.7, 2.5) and less decisional conflict (mean difference -9.8, 95% CI: -14.2, -5.4)." Page 42	na
Thomson 2007	Patient-mediated intervention (Computerised decision aid)	Patient-mediated intervention (Guidelines)		"For the decision conflict scale (the primary outcome measure), the difference in total scores between groups (maximum score 5 for high decision conflict) was estimated on each occasion. The mean (95% CI) differences for decision aid group versus the guideline group were 0.02 (20.22 to 0.26), 20.18 (20.34 to 20.01) and 20.15 (20.37 to 0.06) at pre-clinic, post-clinic and three month follow-up respectively with a negative difference representing a lower decision conflict. While decision conflict fell in both groups post-clinic compared to pre-clinic, the difference between groups post-clinic was significant at the 5% level (t=2.12, df=107, p=0.036)." Page 219	na
Köpke 2014	Patient-mediated intervention (interactive-4h education programme)	Patient-mediated intervention (4h MS-specific stress management programme)		"Decisional conflict scores were low for all subgroup categories with no differences between groups neither before the intervention nor after 12 months (data not shown). Overall, values further decreased during the study for both groups." Page 415	na
Stiggelbout 2008	Patient-mediated intervention (individualized brochure)	Patient-mediated intervention (general brochure)	Patient-clinician communication (understanding)	"The only difference that was seen for the items related to understanding was a difference in favor of the IB group in the stated understanding of the issues that were important in the treatment decision: 84% (n=32) of the IB group felt that due to the brochure they had better understanding, v. 62% (n=21) of the GB group (chi-square test P =0:04)." Page 756	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Stiggelbout 2008	Patient-mediated intervention (individualized brochure)	Patient-mediated intervention (general brochure)	Patient-clinician communication (consultation with surgeon)	"A main difference between the 2 groups was seen in satisfaction with the duration of the consultation. Whereas 89% of the IB group was (rather) satisfied, all patients (100%) in the GB group were satisfied with the duration of the consultation (chi-square test P =0:04). For patients' impression whether the surgeon perceived them more as a medical problem than as a person with a problem, an interaction effect was observed, F(1, 68)=4.31, P =0:04. Further analysis showed that in the IB group from 1st to 2nd consultation, the feeling increased that the surgeon perceived them more as a medical problem than as a person with a problem (mean increased from 1.9, s 1.3, to 2.3, s 1.4), whereas for the GB group this feeling decreased (from 2.0, s 1.3, to 1.7, s 1.2)." Page 757	na
Krist 2007	Patient-mediated intervention (decision aid web)	Patient-mediated intervention (decision aid brochure)	Concordance between preferred and assumed role in decision making	"Concordance did not differ between the 3 study groups (P1 = .41)." (figure 2, page 117)	na
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)	Adherence to medication (pharmacy record): % of days covered	No difference between groups (p=0.09) (table 5)	na
Deschamps 2004	Patient-mediated intervention (pharmacist consultation + patient specific information + letter)	Patient-mediated intervention (decision aid)	Adherence to medication (HRT)	"There was no statistically significant difference in adherence between the study groups" Page 26	na
Thomson 2007	Patient-mediated intervention (Computerised decision aid)	Patient-mediated intervention (Guidelines)	Adherence to initial decision	"Fitting first a difference between groups, participants in the decision aid group were less likely to make a definite decision to start or continue warfarin than participants in the guidelines arm (OR=0.33, 95% CI 0.12 to 0.95)." Page 220	na
Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)	Persistence (pharmacy record): Number of	No difference between group (p=0.38) (table 5)	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

			days covered		
Stiggelbout 2008	Patient-mediated intervention (individualized brochure)	Patient-mediated intervention (general brochure)	Health-related QoL	“Patients’ quality of life was stable over time, in both groups. No effects were observed in the repeated measures for the anxiety and depression scales of the HADS, nor on the quality of life scales” Page 757	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Anxiety (State) - before consultation	"Before the consultation, patients who had received the CCPP were significantly more anxious than those who received the control booklet (mean, 42 v 38, respectively; t 2.0; P .04)." Page 4406	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Anxiety (State) - after consultation	"In both groups, anxiety decreased by 3 points after the consultation, and there was no significant difference between the groups immediately after the consultation and 1 month later." Page 4407	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Anxiety (State) - 1 month	"In both groups, anxiety decreased by 3 points after the consultation, and there was no significant difference between the groups immediately after the consultation and 1 month later." Page 4407	na
Stiggelbout 2008	Patient-mediated intervention (individualized brochure)	Patient-mediated intervention (general brochure)	Anxiety	“Patients’ quality of life was stable over time, in both groups. No effects were observed in the repeated measures for the anxiety and depression scales of the HADS, nor on the quality of life scales” Page 757	na
Thomson 2007	Patient-mediated intervention (Computerised decision aid)	Patient-mediated intervention (Guidelines)		"There was a significant fall in anxiety immediately after the clinic (mean change pre-clinic to post-clinic of 24.57 (95% CI 26.30 to 22.84)) but no evidence that this reduction varied between the two groups (F1,95=0.001; p=0.98)." Page 220	na
Köpke 2014	Patient-mediated intervention (interactive-4h education programme)	Patient-mediated intervention (4h MS-specific stress management programme)		"Mean scores of anxiety and depression were low and no significant differences between groups and between measurement points were found for Hospital Anxiety and Depression Scale assessments. At baseline, results were 7±3.6 (IG) and 7±3.7 (CG) for anxiety and 4.1±3.8 (IG) and 4.8±4.1 (CG) for depression. After 12 months, results were 6.6±3.6 (IG) and 6.8±4.1 (CG) for anxiety and 3.8±3.4 (IG) and 4.5±4.1 (CG) for depression, indicating that neither intervention had an influence on participants’ anxiety and depression levels." Page 415	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Davison 1997	Patient-mediated intervention (individual empowerment sessions)	Patient-mediated intervention (information package)	Anxiety (trait)	“There was no evidence trait scores were different among groups, among measurement times, or between groups and measurement times” Page 195	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Depression - before consultation	"The groups’ depression levels were similar at baseline; both were in the low range (mean, 16.25)." Page 4406	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Depression - after consultation	"No significant differences between groups were observed in raw or change scores on depression immediately after the consultation or 1 month later." Page 4407	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Depression - 1 month	"No significant differences between groups were observed in raw or change scores on depression immediately after the consultation or 1 month later." Page 4407	na
Davison 1997	Patient-mediated intervention (individual empowerment sessions)	Patient-mediated intervention (information package)	Depression	“No significant differences in mean depression scores were found among the groups, among measurement times, or between groups and measurement times” Page 196	na
Stiggelbout 2008	Patient-mediated intervention (individualized brochure)	Patient-mediated intervention (general brochure)	Depression	“Patients’ quality of life was stable over time, in both groups. No effects were observed in the repeated measures for the anxiety and depression scales of the HADS, nor on the quality of life scales” Page 757	na
Köpke 2014	Patient-mediated intervention (interactive-4h education programme)	Patient-mediated intervention (4h MS-specific stress management programme)	Depression	"Mean scores of anxiety and depression were low and no significant differences between groups and between measurement points were found for Hospital Anxiety and Depression Scale assessments. At baseline, results were 7±3.6 (IG) and 7±3.7 (CG) for anxiety and 4.1±3.8 (IG) and 4.8±4.1 (CG) for depression. After 12 months, results were 6.6±3.6 (IG) and 6.8±4.1 (CG) for anxiety and 3.8±3.4 (IG) and 4.5±4.1 (CG) for depression, indicating that neither intervention had an influence on participants’ anxiety and depression levels." Page 415	na
Butow 2004	Patient-mediated intervention (consultation preparation package)	Patient-mediated intervention (booklet)	Consultation length (minutes)	"Consultation length was similar between groups—on average, 36 minutes per consultation." Pages 4406-4407	na
Krist 2007	Patient-mediated intervention (decision aid web)	Patient-mediated intervention (decision aid brochure)	Consultation length	“These [discussion times] patient-physician differences did not differ significantly across the control, brochure, and Web groups.” Page 116	na

Table 10. Effect of interventions on secondary outcomes: interventions targeting patients compared to other interventions targeting patients *(Continued)*

Montori 2011	Patient-mediated intervention (decision aid)	Patient-mediated intervention (Usual care and booklet)	Consultation length (minutes)	"The median (range)duration of osteoporosis discussions was 12.4 minutes (2.3-27.4) in the decision aid arm compared with 9.4 minutes (2.1-58) in the usual care arm (P .045)" Pages 552-553	na
Nannenga 2009	Patient-mediated intervention (decision aid)	Patient-mediated intervention (pamphlet)	Consultation length (minutes)	"We found no significant difference in face-to-face consultation duration with the staff endocrinologist (mean difference 3.8 min longer with the decision aid, 95% CI - 2.9 to 10.5)." Page 42	na

CCPP: cancer consultation preparation package; CG: control group; CI: confidence interval; CVD: cardiovascular diseases; DA; decision aid; DCS: Decisional Conflict Scale; df: degrees of freedom; DMD: disease modifying drug; GB: general brochure; HADS: Hospital Anxiety and Depression Scale; HRT: Hormone Replacement Therapy; IB: individualized brochure; IG: intervention group; MS: Multiple Sclerosis; N: sample size; na: not applicable; OR: odds ratio; QoL: quality of life; RD: risk difference; SD: standard deviation; SDM: shared decision making; SMD: standardized mean difference; SWD: Satisfaction With Decision; TTE: time-to-event; YDR: Web-based ''Your Disease Risk'' colorectal cancer risk assessment tool.

Table 11. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals

Continous data								Meta-analysis
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I²**	
Elwyn 2004	Educational meeting + audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Health status (mental) time 1	Pre: 169 Post: 295	0.24 (0.01 to 0.47)	0.24 (0.01 to 0.47)	na	na
Elwyn 2004	Educational meeting + audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Health status (mental) time 2	Pre: 147 Post: 257	0.17 (-0.07 to 0.42)	0.17 (-0.07 to 0.42)	na	na
Elwyn 2004	Educational meeting + audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Health status (physical) time 1	Pre: 169 Post: 295	0.05 (-0.19 to 0.28)	0.05 (-0.19 to 0.28)	na	na
Elwyn 2004	Educational meeting + audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Health status (physical) time 2	Pre: 147 Post: 257	-0.01 (-0.26 to 0.24)	-0.01 (-0.26 to 0.24)	na	na
Elwyn 2004	Educational meeting + audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Anxiety - time 1	Pre: 186 Post: 325	0.04 (-0.18 to 0.26)	0.04 (-0.18 to 0.26)	na	na

Table 11. Effect of interventions on secondary outcomes: interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals *(Continued)*

Elwyn 2004	Educational meeting + audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Anxiety - time 2	Pre: 165 Post: 281	0.25 (0.02 to 0.49)	0.25 (0.02 to 0.49)	na	na
Elwyn 2004	Educational meeting + audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Anxiety - time 3	Pre: 136 Post: 237	0.15 (-0.11 to 0.40)	0.15 (-0.11 to 0.40)	na	na

Categorical data

Study	Intervention	Intervention	Outcome	N	RD	RD (95% CI)	I^2	Meta-analysis
No study								

Qualitative statement

Study	Intervention	Intervention	Outcome	Direct quote	Meta-analysis
Krones 2008 (ARRIBA-Herz)	Educational meeting + audit and feedback + educational material and Educational outreach visit	Educational meeting	Knowledge	"Knowledge did not improve through intervention." Page 223. Difference intervention - control (95% CI): 0.11 (-0.01 to 0.24); p=0.07 (table 4)	na
Elwyn 2004	Educational meeting and audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Satisfaction with information provided	”No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes“ Page 351	na
Elwyn 2004	Educational meeting and audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Satisfaction with decision	”No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes“ Page 351	na
Krones 2008 (ARRIBA-Herz)	Educational meeting + audit and feedback + Educational material and Educational outreach visit	Educational meeting	Decision regret (6 months)	"After 6 months, patients who could remember the decision and had completed the decisional regret scale (385 interventions, 377 controls), reported less decisional regret in the intervention arm. " Page 223. Difference intervention - control (95% CI): -3.39 (-6.26 to -0.53); p=0.02 (table 4)	na
Elwyn 2004	Educational meeting and audit and feedback (SDM skills)	Educational meeting + audit and feedback (risk communication skills)	Consultation length (minutes)	“There was no difference in the mean consultation lengths at baseline, phase 1 and phase 2 (overall consultation mean duration was 12.5 minutes)” Page 342	na

CI: confidence interval; N: sample size; na: not applicable; RD: risk difference; SDM: shared decision making; SMD: standardized mean difference.

Table 12. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals

Continous data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**SMD**	**SMD (95% CI)**	**I^2**	
Myers 2011	Patient-mediated intervention (pamphlet+counselling) + reminders (prompting)	Patient-mediated intervention + reminders (prompting)	Decisional conflict	286	-0.07 (-0.30 to 0.16)	-0.07 (-0.30 to 0.16)	na	na
Categorical data								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**N**	**RD**	**RD (95% CI)**	**I^2**	
No study								
Qualitative statement								**Meta-analysis**
Study	**Intervention**	**Intervention**	**Outcome**	**Direct quote**				
Cooper 2013	Patient-mediated intervention, educational outreach visit + distribution of educational material + audit and feedback (Patient-centred group)	Patient-mediated intervention + educational outreach visit + distribution of educational material (Standard group)	Satisfaction with the intervention (helpfulness of the Depression Case Manager)	"At 12 months, compared with patients in the standard group, patients in the patient-centred group had statistically significantly higher odds of rating their DCM as extremely helpful at identifying concerns (OR, 3.00; 95 percent CI, 1.23, 7.30) and improving adherence to treatment (OR, 2.60; 95 percent CI, 1.11, 6.08). Similar patterns were present, but not statistically significant, for other ratings of the DCMs (data not shown)." Page 166				na
Cooper 2013	Patient-mediated intervention, educational outreach visit + distribution of educational material + audit and feedback (Patient-centred group)	Patient-mediated intervention + educational outreach visit + distribution of educational material (Standard group)	Depression (symptom reduction)	"Both groups experienced statistically highly significant reductions in mean depression severity score over time that are clinically meaningful. However, none of the adjusted between-group differences in CES-D over the follow-up period were statistically significant (at 6 months, 1.8 points, 95 percent CI -3.4, 6.9; at 12 months, 2.4 points, 95 percent CI -7.7, 2.9; and at 18 months, 2.9 points, 95 percent CI, -8.2, 2.4)." Page 164				na
Cooper 2013	Patient-mediated intervention, educational outreach visit + distribution of educa-	Patient-mediated intervention + educational outreach	Depression (remission)	"At 12 months, 33 percent of the patient-centred group and 42 percent of the standard group achieved remission from depression (as mea-				na

Table 12. Effect of interventions on secondary outcomes: interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals *(Continued)*

	tional material + audit and feedback (Patient-centred group)	visit + distribution of educational material (Standard group)	sured by the CIDI); this difference was not statistically significant (adjusted OR 0.97; 95 percent CI, 0.34, 2.80)." Page 165

CES-D: centre for Epidemiological Studies Depression Scale; CI: confidence interval; CIDI: Composite International Diagnostic Interview; DCM: depression case manager; N: sample size; na: not applicable; OR: odds ratio; RD: risk difference; SDM: shared decision making; SMD: standardized mean difference.

APPENDICES

Appendix 1. Search strategies

PubMed

Search date: 15 June 2017

No.	Search terms	Results
#1	(shared decision*[tiab] or sharing decision*[tiab] or informed decision*[tiab] or informed choice*[tiab] or decision aid*[tiab] or ((share*[ti] or sharing*[ti] or informed*[ti]) and (decision*[ti] or deciding*[ti] or choice*[ti])))	14116
#2	(decision making[mh:noexp] or decision support techniques[mh:noexp] or decision support systems, clinical[mh] or choice behaviour[mh:noexp] or decision making*[tiab] or decision support*[tiab] or choice behaviour*[tiab] or ((decision*[ti] or choice*[ti]) and (making*[ti] or support*[ti] or behaviour*[ti])))	195864
#3	(patient participation[mh] or patient participation*[tiab] or consumer participation*[tiab] or patient involvement*[tiab] or consumer involvement*[tiab] or ((patient*[ti] or consumer*[ti]) and (involvement*[ti] or involving*[ti] or participation*[ti] or participating*[ti])))	29921
#4	(professional-patient relations[mh] or ((nurses[mh] or physicians[mh] or nurse*[ti] or physician*[ti] or clinician*[ti] or doctor*[ti] or general practitioner*[ti] or gps[ti] or health care professional*[ti] or healthcare professional*[ti] or health care provider*[ti] or healthcare provider*[ti] or resident*[ti]) and (patients[mh] or patient*[ti] or consumer*[ti] or people*[ti])))	160812
#5	(clinical trial[pt:noexp] or randomized controlled trial[pt] or controlled clinical trial[pt] or evaluation studies[pt] or comparative study[pt] or intervention studies[mh] or Evaluation Studies as Topic[mh:noexp] or program evaluation[mh:noexp] or random allocation[mh] or random*[tiab] or double blind*[tiab] or controlled trial*[tiab] or clinical trial*[tiab] or pretest*[tiab] or pre test*[tiab] or posttest*[tiab] or post test*[tiab] or prepost*[tiab] or pre post*[tiab] or controlled before*[tiab] or "before and after"[tiab] or interrupted time*[tiab] or time serie*[tiab] or intervention*[tiab])	4001044
#6	((#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)) AND #5)	8177
#7	((#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)) AND #5) Filters: Publication date from 2015/01/01 to 2017/12/31	1760

Embase (OVID)

Embase database used: Embase <1974 to 2017 June 14>

Search date: 15 June 2017

No.	Search terms	Results

(Continued)

1	(shared decision or sharing decision or informed decision or informed choice or decision aid).ti,ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti.	12773
2	exp clinical decision making/ or exp decision making/ or exp decision support system/ or exp ethical decision making/ or exp family decision making/ or exp medical decision making/ or exp patient decision making/ or (decision making or decision support or choice behaviour).ti,ab. or ((decision* or choice*) and (making* or support* or behaviour*)).ti.	355815
3	exp patient participation/ or (patient participation or consumer participation or patient involvement or consumer involvement).ti,ab. or ((patient* or consumer*) and (involvement* or involving* or participation* or participating*)).ti.	33527
4	exp doctor patient relation/ or exp nurse patient relationship/ or ((exp nurse/ or exp physician/ or (nurse* or physician* or clinician* or doctor* or general practitioners or gps or health care professionals or healthcare professionals or health care providers or healthcare providers or resident*)).ti. and (exp patient/ or (patient* or consumer* or people*).ti.))	412940
5	1 or (2 and 3) or (2 and 4) or (3 and 4)	46996
6	exp clinical trial/ or exp randomized controlled trial/ or exp controlled clinical trial/ or exp controlled trial/ or exp pretest posttest control group design/ or exp comparative study/ or exp evaluation research/ or exp intervention study/ or exp randomization/ or (random* or double blind or controlled trial or clinical trial or pretest* or pre test or pre tests or posttest* or post test or post tests or prepost* or pre post or controlled before or "before and after" or interruped time or time serie? or intervention*).ti,ab.	8427337
7	(2015* or 2016* or 2017*).yr.	3508644
8	5 and 6 and 7	4460
9	limit 8 to embase	2206

The Cochrane Library (Wiley)
Search date: 15 June 2017

No.	Search terms	Results
#1	((shar* or inform*) near/3 (decision* or aid* or deciding* or choice*)):ti,ab,kw	2463
#2	((decision* or choice*) near/3 (making* or support* or behaviour*)):ti,ab,kw	11115
#3	((patient* or consumer*) near/3 (involvement* or involving* or participation* or participating*)):ti,ab,kw	8416
#4	((nurse* or physician* or clinician* or doctor* or general practitioner* or gps or health care professional* or healthcare professional* or health care provider* or healthcare provider* or resident*) near/3 (patient* or consumer* or people*)):ti,ab,kw	15782
#5	#1 or (#2 and #3) or (#2 and #4) or (#3 and #4)	4248

(Continued)

#6	#1 or (#2 and #3) or (#2 and #4) or (#3 and #4) Publication Year from 2015 to 2017	1360

Cinahl (EBSCO)
Search date: 15 June 2017

No.	Search terms	Results
S1	AB Shared Decision* OR TI Shared Decision* OR AB Sharing Decision* OR TI Sharing Decision* OR AB Informed Decision* OR TI Informed Decision* OR AB Informed Choice* OR TI Informed Choice* OR AB Decision Aid* OR TI Decision Aid* OR ((TI Share* OR TI Sharing OR TI Informed*) AND (TI Decision* OR TI Deciding* OR TI Choice*))	7,369
S2	MH "Decision Making+" OR MW Decision Support OR AB Decision Making* OR TI Decision Making* OR AB Decision Support* OR TI Decision Support* OR AB Choice Behaviour* OR TI Choice Behaviour* OR ((TI Decision* OR TI Choice*) AND (TI Making* OR TI Support* OR TI Behaviour*))	85,579
S3	MH Consumer Participation OR AB Patient Participation* OR TI Patient Participation* OR AB Consumer Participation* OR TI Consumer Participation* OR AB Patient Involvement* OR TI Patient Involvement* OR AB Consumer Involvement* OR TI Consumer Involvement* OR ((TI Patient* OR TI Consumer*) AND (TI Participating* OR TI Participation* OR TI Involving* OR TI Involvement*))	17,733
S4	MH Professional Patient Relations OR MH Nurse Patient Relations OR MH Physician Patient Relations OR ((MH Nurses+ OR MH Physicians+ OR TI Nurse* OR TI Physician* OR TI Clinician* OR TI Doctor* OR TI General Practitioner* OR TI GPs OR TI Health Care Professional* OR TI Healthcare Professional* OR TI Health Care Provider* OR TI Healthcare Provider* OR TI Resident*) AND (MH Patients+ OR TI Patient* OR TI Consumer* OR TI People*))	47,297
S5	MH Experimental Studies+ OR MH Quasi-Experimental Studies OR MH Comparative Studies OR MH Evaluation Research OR AB Random* OR TI Random* OR AB Double Blind* OR TI Double Blind* OR AB Controlled Trial* OR TI Controlled Trial* OR AB Clinical Trial* OR TI Clinical Trial* OR AB Pretest* OR TI Prestest* OR AB Pre Test* OR TI Pre Test* OR AB Posttest* OR TI Posttest* OR AB Post Test* OR TI Post Test* OR AB Prepost* OR TI Prepost* OR AB Pre Post* OR TI Pre Post* OR AB Controlled Before* OR TI Controlled Before* OR AB "Before and After*" OR TI "Before and After*" OR AB Interruped Time* OR TI Interrupted Time* OR AB Time Serie* OR TI Time Serie* OR AB Intervention* OR TI Intervention*	521,147
S6	(S1 OR (S2 AND S3) OR (S2 AND S4) OR (S3 AND S4)) AND S5	3,439
S7	S6 Limiters - Published Date: 20150101-20171231; Exclude MEDLINE records	341

PsycINFO (OVID)
PsycINFO database used:PsycINFO <1967 to June Week 1 2017>

Search date: 15 June 2017

No.	Search terms	Results
1	(shared decision or sharing decision or informed decision or informed choice or decision aid).ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti.	3799
2	(decision making or decision support or choice behaviour).ab. or ((decision* or choice*) and (making* or support* or behaviour)).hw.	98574
3	client participation.hw. or (consumer participation or consumer involvement or patient participation or patient involvement).ab. or ((patient* or consumer*) and (participating* or participation* or involving* or involvement*)).hw.	3741
4	therapeutic processes.hw. or (((nurses or physicians or general practitioners or gynecologists or internists or neurologists or obstetricians or pathologists or pediatricians or psychiatrists or surgeons).hw. or (nurse* or physician* or clinician* or doctor* or general practitioner or gps or health care professional or healthcare professional or health care provider* or healthcare provider).ti.) and ((patients or outpatients).hw. or (patient* or consumer* or people* or outpatient*).ti.))	33440
5	1 or (2 and 3) or (2 and 4) or (3 and 4)	6170
6	(2015* or 2016* or 2017*).yr.	441961
7	5 and 6	1124
8	(clinical trial or empirical study or experimental replication or followup study or longitudinal study or prospective study or quantitative study or treatment outcome).md.	2121872
9	experimental design/	10194
10	between groups design/	107
11	quantitative methods/	2763
12	quasi experimental methods/	141
13	(randomised or randomized or randomly or controlled or control group? or evaluat* or time series or time point or time points or quasi experiment* or quasiexperiment* or (before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or multicenter study or multicentre study or multi center study or multi centre study or repeated measur*).ti,ab.	680691
14	(trial or effect? or impact? or intervention?).ti.	390327
15	exp clinical trial/	10376
16	((clinical or control*) adj3 trial*).ti,ab.	58915
17	((singl* or doubl* or trebl* or tripl*) adj5 (blind* or mask*)).ti,ab.	23288
18	(volunteer* or control group or controls).ti,ab.	208831
19	placebo/ or placebo*.ti,ab.	35733

(Continued)

20	pretesting/	229
21	posttesting/	135
22	repeated measures/	625
23	time series/	1783
24	or/8-23	2459274
25	7 and 24	828

ClinicalTrials.gov

Search date: 4 August 2017

Search terms	Results
"informed choice"	101
"decision making"	435
"decision support"	295
"informed decision"	85
"decision aid"	297
"sharing decision"	141
"shared decision"	122
	1,476

WHO International Clinical Trials Registry Platform

Search date: 4 August 2017

"informed choice"	16
"decision making"	672
"decision support"	317
"informed decision"	33
"decision aid"	269
"sharing decision"	0

(Continued)

"shared decision"	153
	1,460

Appendix 2. International Shared Decision Making Conference 2013, 2015, 2017 (ISDM)

[Search in ISDM proceedings]	[Results]
References	**700**

Appendix 3. Society for Medical Decision Making 2012, 2013, 2014, 2015, 2016 (SMDM)

[Search in SMDM proceedings]	[Results]
References	**1607**

Appendix 4. Reference lists of systematic reviews

[Reference lists of systematic reviews]	[Results]
Reference	**587**

Appendix 5. Reference lists of primary studies included

[Reference list of primary studies]	[Results]
Reference	**976**

Appendix 6. Impact of studies not included in the quantitative synthesis on the pooled results (for the randomized trials)

Comparison 1: Interventions targeting patients compared with usual care		
Observer-based outcome measure - continuous data		The study not included in the quantitative synthesis supported the pooled result
Studies included in the quantitative synthesis (n = 424)	**SMD (95% IC)**	

(Continued)

LeBlanc 2015a	0.54 (-0.13 to 1.22)	
Maclachlan 2016		
LeBlanc 2015b		
Tai-Seale 2016		
Observer-based outcome measure - continuous data		
Studies not included in the quantitative synthesis	**Results**	
Hamann 2014	n= 100, no difference between the study groups, unclear risk of bias	
Haskard 2008	Unit of error analysis	
Patient reported outcome measure - continuous data		It is unlikely that the study not included in the quantitative synthesis would change the direction of the effect size estimate given that its sample size is not very large
Studies included in the quantitative synthesis (n = 1386)	**SMD (95% IC)**	
Deen 2012	0.32 (0.16 to 0.48)	
Maranda 2014		
Pickett 2012		
van der Krieke 2013		
van Peperstraten 2010		
Cooper 2011		
Perestelo-Perez 2016		
Tai-Seale 2016		
Eggly 2017		
Patient-reported outcome measure - continuous data		
Studies not included in the quantitative synthesis	**Results**	
Hamann 2014	n = 100, no difference between the study groups, unclear risk of bias	
Patient-reported outcome measure - categorical data		Van Tol-Geerdink 2016 does not support the pooled result but given that the pooled estimate of the effect size is in favor of the control group, it is likely that adding this study would move the pooled estimate of the effect size towards a null effect.
Studies included in the quantitative synthesis (n = 754)	**RD (95% IC)**	
Krist 2007	-0,09 (-0.19 to 0.01)	

(Continued)

Landrey 2012		Wolderslund 2017 does not support the pooled result but given its very large sample size, it is likely that adding this study would move the pooled estimate of the effect size towards a positive effect. Korteland 2017 supports the pooled result (null effect).
Murray 2001		
Sheridan 2014		
Vestala 2013		
Vodermaier 2009		
Patient-reported outcome measure - categorical data		
Studies not included in the quantitative synthesis	**Results**	
van Tol-Geerdink 2016	n = 240, significant difference in favor of the intervention group, high risk of bias	
Wolderslund 2017	n = 4349, significant difference in favor of the intervention group, high risk of bias	
Korteland 2017	n = 155, no difference between the study groups, high risk of bias	

Comparison 2. Effect of intervention: Interventions targeting healthcare professionals compared to usual care		
Observer-based outcome measure - continuous data		Murray 2010 and Bernhard 2011 - ANZ (Australia and New Zealand sub-sample) support the pooled result. Bernhard 2011 - SGA (Switzerland, Germany and Austria sub-sample) does not support the pooled result but it is unlikely that adding these data to the quantitative synthesis would move the pooled estimate of the effect size toward a null effect or in the opposite direction, given its very small sample size. Moreover, the different results observed in the two sub-samples is a possible indication of an effect modification
Studies included in the quantitative synthesis (n = 479)	**SMD (95% IC)**	
Fossli 2011	0.70 (0.21 to 1.19)	
Shepherd 2011		
Stacey 2006		
Sanders 2017		
Cox 2017		
LeBlanc 2015b		
Observer-based outcome measure - continuous data		
Studies not included in the quantitative synthesis	**Results**	
Bernhard 2011- SGA	n = 32, no difference between the study groups, high risk of bias	

(Continued)

Bernhard 2011- ANZ	n = 21, significant difference in favor of the intervention group, high risk of bias	
Murray 2010	n = 88, significant difference in favor of the intervention group, low risk of bias	
Patient-reported outcome measure - continuous data		Légaré 2012 does not support the pooled result. However, it is unlikely that adding these data to the quantitative synthesis would move the pooled estimate of the effect size from the null effect to a significant positive effect.
Studies included in the quantitative synthesis (n = 5772)	**SMD (95% IC)**	
Cooper 2011	0.03 (-0.15 to 0.20)	
Kennedy 2013		
Koerner 2014		
Tinsel 2013		
Wilkes 2013		
Patient reported outcome measure - continuous		
Studies not included in the quantitative synthesis	**Results**	
Légaré 2012	n = 359, significant difference in favor of the intervention group, unclear risk of bias	
Patient -reported outcome measure - categorical data		Bernhard 2011 supports the pooled result.
Studies included in the quantitative synthesis (n = 6303)	**RD (95% IC)**	
Légaré 2012	0,01 (-0.03 to 0.06)	
O'Cathain 2002		
Patient-reported outcome measure - categorical		
Studies not included in the quantitative synthesis	**Results**	
Bernhard 2011	n = 694, no difference between the study groups, high risk of bias	

Comparison 3: Interventions targeting both patients and healthcare professionals compared to usual care	
Patient-reported outcome measure - continous data	Although the confidence interval of the pooled estimate of the effect size con-

(Continued)

Studies included in the quantitative synthesis (n = 1479)	SMD (95% IC)	
Cooper 2011	0.13 (-0.02 to 0.28)	tains the null effect, the estimate is in favor of the intervention group. Adding data from Loh 2007 would move the pooled estimate towards a positive effect. Adding Wetzels 2005 would move the result towards a null effect.
Härter 2015		
Hamann 2007		
Rise 2012		
Wilkes 2013		
Tai-Seale 2016		
Epstein 2017		
Patient reported outcome measure - continuous data		
Studies not included in the quantitative synthesis	**Results**	
Loh 2007	n = 405, significant difference in favor of the intervention group, unclear risk of bias	
Wetzels 2005	n = 263, no difference between the study groups, high risk of bias	
Patient-reported outcome measure - categorical data		Leighl 2011 supports the pooled result
Studies included in the quantitative synthesis (n = 266)	**RD (95% IC)**	
Mathers 2012	-0.01 (-0.20 to 0.19)	
Härter 2015		
Patient-reported outcome measure - categorical data		
Studies not included in the quantitative synthesis	**Results**	
Leighl 2011	n = 207, no difference between the study groups, unclear risk of bias	

Comparison 4: Interventions targeting patients compared to other interventions targeting patients		
Patient-reported outcome measure - continuous data		Lalonde 2006 and Street 1995 support the pooled results
Studies included in the quantitative synthesis (n = 1906)	**SMD (95% IC)**	
Causarano 2014	0.03 (-0.18 to 0.24)	

(Continued)

Deen 2012		
Hamann 2011		
Schroy 2011		
van Roosmalen 2004		
Schroy 2016		
Adarkwah 2016		
Eggly 2017		
Hamann 2017		
Jouni 2017		
Smallwood 2017		
Patient-reported outcome measure - continuous data		
Studies not included in the quantitative synthesis	**Results**	
Lalonde 2006	n = 26, no difference between study groups, high risk of bias	
Street 1995	n = 60, no difference between study groups, high risk of bias	
Patient-reported outcome measure - categorical data		Kopke 2014 and Butow 2004 support the pooled results. Wolderslund 2017 does not support the pooled result but given its very large sample size, it is likely that adding this study would move the pooled estimate of the effect size toward a positive effect.
Studies included in the quantitative synthesis (n = 2272)	**RD (95% IC)**	
Butow 2004	0,03 (-0.02 to 0.08)	
Davison 1997		
Deschamps 2004		
Dolan 2002		
Kasper 2008		
Krist 2007		
Raynes-Greenow 2010		
Stiggelbout 2008		
Thomson 2007		
Davison 2002		

(Continued)

Patient-reported outcome measure - categorical data	
Studies not included in the quantitative synthesis	**Results**
Köpke 2014	n = 192, no difference between the study groups, high risk of bias
Butow 2004	n =164, no difference between the study groups, high risk of bias
Wolderslund 2017	n = 4349, significant difference in favor of the intervention group, high risk of bias

Comparison 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals		
Observer-based outcome measure - continuous data		Contrary to Elwyn 2004, which reported null results, Feng 2013 reported significant positive results. However it is unlikely that combining these two studies would move the estimate of the effect towards a significant positive result. More studies are needed to draw robust conclusions.
Studies included in the quantitative synthesis (n = 20)	**SMD (95% IC)**	
Elwyn 2004	-0,30 (-1.19 to 0.59)	
Observer-based outcome measure - continuous data		
Studies not included in the quantitative synthesis	**Results**	
Feng 2013	n =118, significant difference in favor of the intervention group, high risk of bias	

Appendix 7. Previous review on interventions promoting the adoption of SDM

[Previous review (Légaré 2014]	[Results]
References	**20,792**

Appendix 8. Certainty assessment of evidence for primary outcome

Name of outcome	1. Certainty of evidence	2. Starting score for certainty of evidence according to study design	3. Criteria to downgrade score				
			3a. Study limitation	3b. Indirectness of evidence	3c. Inconsistency	3d. Imprecision	3e. Publication bias
Comparison 1: Interventions targeting patients compared with usual care							
OBOM - Continuous	1	4	-2	-1	-2	-2	N/A
PROM - Continuous	1	4	-2	-1	-2	0	0
PROM - Continuous - (Non-randomized control trial)	1	2	-2	-1	N/A	-1	N/A
PROM - Categorical	1	4	-2	-1	-1	0	0
Comparison 2: Interventions targeting healthcare professionals compared to usual care							
OBOM - Continuous	1	4	-1	-1	-2	-1	0
OBOM - Continuous - (Controlled before-after study)	1	2	-2	-1	N/A	-1	N/A
PROM - Continuous	1	4	-1	-1	-2	-1	0
PROM - Categorical	1	4	-1	-1	-2	0	N/A
Comparison 3: Interventions targeting both patients and healthcare professionals compared to usual care							
OBOM - Continuous	1	4	-1	-1	-2	-1	-1
PROM - Continuous	1	4	-1	-1	-1	0	0
PROM - Categorical	1	4	-1	-1	-1	-1	N/A

(Continued)

Comparison 4: Interventions targeting patients compared to other interventions targeting patients							
OBOM - Continuous	1	4	-1	-1	-2	-1	N/A
PROM - Continuous	1	4	-1	-1	-2	-1	0
PROM - Continuous - (Non-randomized control trial)	1	2	-2	-1	N/A	-1	N/A
PROM - Categorical	1	4	-2	-1	-1	0	0
Comparison 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals							
OBOM - Continuous	1	4	0	-1	N/A	-2	N/A
PROM - Continuous	1	4	-1	-1	-2	-1	N/A
Comparison 6: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals							
OBOM - Continuous	1	4	-1	-1	N/A	-1	N/A
OBOM - Categorial	1	4	-2	-1	N/A	-1	N/A
PROM - Continuous	1	4	-1	-1	N/A	-1	N/A

Appendix 9. Certainty assessment of evidence for secondary outcomes

Name of outcome	1. Certainty of evidence	2. Starting score for certainty of evidence according to study design	3. Criteria to downgrade score				
			3a. Study limitation	3b. Indirectness of evidence	3c. Inconsistency	3d. Imprecision	3e. Publication bias
Comparison 1: Interventions targeting patients compared with usual care							
Continous							
Decision regret	1	4	-2	-1	N/A	-1	N/A
Health-related QoL (physical)	1	4	-1	-1	N/A	-1	N/A
Health-related QoL (mental)	1	4	-1	-1	N/A	-1	N/A
Consultation length	1	4	-1	-1	-1	-1	N/A
Cost	1	4	-2	-1	N/A	-1	N/A
Categorical							
No study							
Comparison 2. Effect of intervention: Interventions targeting healthcare professionals compared to usual care							
Continous							
Decision regret	1	4	-1	-1	N/A	-1	N/A
Health-related QoL (physical)	2	4	-1	-1	N/A	0	N/A
Health-related QoL (mental)	2	4	-1	-1	N/A	0	N/A
Consultation length	1	4	-1	-1	N/A	-1	N/A
Categorical							
No study							

(Continued)

Comparison 3: Interventions targeting both patients and healthcare professionals compared to usual care							
Continous							
Decision regret	2	4	-1	-1	N/A	0	N/A
Health-related QoL (physical)	1	4	-1	-1	N/A	-1	N/A
Health-related QoL (mental)	1	4	-1	-1	N/A	-1	N/A
Consultation length	1	4	-1	-1	N/A	-1	N/A
Categorical							
No study							
Comparison 4: Interventions targeting patients compared to other interventions targeting patients							
Continous							
Consultation length	1	4	-1	-1	N/A	-1	N/A
Categorical							
No study							
Comparison 5: Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals							
Continous							
No study							
Categorical							
No study							
Comparison 6: Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals							
Continous							
No study							

Categorical	No study

(Continued)

WHAT'S NEW

Date	Event	Description
15 June 2017	New search has been performed	This is the second update of this Cochrane review first published in 2010. A new search was conducted and other content updated. Forty-eight new studies were added to the review.
15 June 2017	New citation required but conclusions have not changed	Forty-eight new studies were added to the review. The review includes 87 studies.

HISTORY

Protocol first published: Issue 3, 2007
Review first published: Issue 5, 2010

Date	Event	Description
15 September 2014	New search has been performed	Included observer-reported and patient-reported outcomes to 2012
30 November 2011	Amended	
29 September 2011	New search has been performed	Updated observer-reported outcomes to 2010

CONTRIBUTIONS OF AUTHORS

FL, RA, JH, ST, PAN, AB, EC, LA and HR identified eligible studies for the update of this review.

RA, NTD, ST, SC, ABC, JH, AB, LA and HE helped with data extraction including the 'Risk of bias' assessment.

RA and ST assisted with data analysis.

FL, RA and AB assisted in evaluation of the certainty of the evidence (GRADE).

RA and ST drafted the review.

FL, RA, AL, DS, ST, JK, IDG, MCP, RT, GE and NDB reviewed and participated in the writing of the final review.

DECLARATIONS OF INTEREST

FL: none known. DS: none known. ST: none known. JK: none known. IDG: none known. AL: none known. MCP: is on the Medication Adherence Advisory Board for Merck. RT: none known. GE: none known. NDB: none known. RA: none known.

This review includes studies that were published by some of its authors (DS, FL, GE, IDG, NDB). FL was involved in the evaluation of the certainty of the evidence but was blinded to the identification of the included studies to avoid conflict of interest.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Tier 2 Canada Research Chair in Implementation of Shared Decision Making in Primary Care, Université Laval, Québec, Canada.
- Consortium de recherche sur les services de génétique de laboratoire (CanGènetest), Québec, Canada.

- Centre de recherche du Centre Hospitalier Universitaire de Québec, Québec, Canada.
- Tier 1 Canada Research Chair in Shared Decision Making and Knowledge Translation, Canada.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Since publishing the protocol and the 2010 version of this review (Légaré 2010), we organized the types of intervention defined by the Effective Practice and Organisation of Care (EPOC) taxonomy into three target categories: interventions targeting patients (i.e. patient-mediated interventions), interventions targeting healthcare professionals (e.g. distribution of printed educational material, educational meetings, audit and feedback, reminders and educational outreach visits), and interventions targeting both patients and healthcare professionals (i.e. patient-mediated interventions combined with interventions targeting the healthcare professional). These three categories correspond to the specific objectives of the review. We also split the outcomes into observer-based outcomes and patient-reported outcomes because measures for observer-based outcomes are more objective than patient-reported outcomes. We used GRADE tools to summarize our findings (see 'Summary of findings' tables). Since publishing the protocol, three review authors have been removed (S Ratté, K Gravel and M-J Cossi) and six new review authors added (RA, AL, MCP, RT, GE and NDB).

In this update, instead of considering nine comparisons between intervention categories, we considered six: comparisons between each target category and usual care (three) and comparisons between each target category and other interventions with the same targets, or head-to-head comparisons (three). More specifically, our six categories were as follows:

- comparisons between interventions targeting patients and usual care;
- comparisons between interventions targeting healthcare professionals and usual care;
- comparisons between interventions targeting both healthcare professionals and patients and usual care;
- comparisons between interventions targeting patients and other interventions targeting patients;
- comparisons between interventions targeting healthcare professionals and other interventions targeting healthcare professionals;
- comparisons between interventions targeting both healthcare professionals and patients and other interventions targeting both healthcare professionals and patients.

Comparisons between different target categories were not considered in this review as they would have added no additional information to the former one, and there were few studies in these comparisons.

To address some theoretical confusion related to the previous title, a slight change has been made from "*Interventions for improving the adoption of shared decision making by healthcare professionals*" to "*Interventions for increasing the use of shared decision making by healthcare professionals*".

INDEX TERMS

Medical Subject Headings (MeSH)

*Decision Making; *Decision Support Techniques; *Patient Participation; Health Personnel [*education]; Patient Education as Topic [methods]; Randomized Controlled Trials as Topic

MeSH check words

Humans