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[Intervention Review]

Interventions for improving the adoption of shared decision making by healthcare professionals

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ABSTRACT

Background

Shared decision making (SDM) can reduce overuse of options not associated with benefits for all and respects patient rights, but has not yet been widely adopted in practice.

Objectives

To determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM.

Search methods

For this update we searched for primary studies in *The Cochrane Library*, MEDLINE, EMBASE, CINAHL, the Cochrane Effective Practice and Organisation of Care (EPOC) Specialsied Register and PsycINFO for the period March 2009 to August 2012. We searched the Clinical Trials.gov registry and the proceedings of the International Shared Decision Making Conference. We scanned the bibliographies of relevant papers and studies. We contacted experts in the field to identify papers published after August 2012.

Selection criteria

Randomised and non-randomised controlled trials, controlled before-and-after studies and interrupted time series studies evaluating interventions to improve healthcare professionals' adoption of SDM where the primary outcomes were evaluated using observer-based outcome measures (OBOM) or patient-reported outcome measures (PROM).

Data collection and analysis

The three overall categories of intervention were: interventions targeting patients, interventions targeting healthcare professionals, and interventions targeting both. Studies in each category were compared to studies in the same category, to studies in the other two categories, and to usual care, resulting in nine comparison groups. Statistical analysis considered categorical and continuous primary outcomes separately. We calculated the median of the standardized mean difference (SMD), or risk difference, and range of effect across studies and categories of intervention. We assessed risk of bias.

Main results

Thirty-nine studies were included, 38 randomised and one non-randomised controlled trial. Categorical measures did not show any effect for any of the interventions. In OBOM studies, interventions targeting both patients and healthcare professionals had a positive effect compared to usual care (SMD of 2.83) and compared to interventions targeting patients alone (SMD of 1.42). Studies comparing interventions targeting patients with other interventions targeting patients had a positive effect, as did studies comparing interventions targeting healthcare professionals with usual care (SDM of 1.13 and 1.08 respectively). In PROM studies, only three comparisons showed any effect, patient compared to usual care (SMD of 0.21), patient compared to another patient (SDM of 0.29) and healthcare professional compared to another healthcare professional (SDM of 0.20). For all comparisons, interpretation of the results needs to consider the small number of studies, the heterogeneity, and some methodological issues. Overall quality of the evidence for the outcomes, assessed with the GRADE tool, ranged from low to very low.

Authors' conclusions

It is uncertain whether interventions to improve adoption of SDM are effective given the low quality of the evidence. However, any intervention that actively targets patients, healthcare professionals, or both, is better than none. Also, interventions targeting patients and healthcare professionals together show more promise than those targeting only one or the other.

PLAIN LANGUAGE SUMMARY

A review of the ways in which healthcare professionals can be helped to involve their patients in the healthcare decision making process

When there are several treatments possible, healthcare professionals can involve patients in the process of making decisions about their care so that the patients can choose care that meets their needs and reflects what is important to them. We call this 'shared decision making'. Although the results are better when patients are involved, healthcare professionals often do not involve their patients in these decisions. We wanted to know more about what can be done to encourage healthcare professionals to share decision making with their patients. In our review we identified 39 studies that tested what activities work in helping healthcare professionals involve their patients more in the decision-making process. We learned that any such activity was better than none, and that activities for healthcare professionals and patients together worked somewhat better than activities just for patients or just for healthcare professionals. However, given the small number of studies and the differences across the studies, it was difficult to know which activities worked best. This review suggested ways to better evaluate how much healthcare professionals involve patients in healthcare decisions so that we can understand this process better in the future.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Interventions targeting patients compared with usual care for improving the adoption of shared decision making by healthcare professionals				
Outcomes*	**Type of outcome**	**Median of the standardized mean difference or median of the risk difference (range)**	**No of measures (studies**)**	**Quality of the evidence (GRADE)**
Observer-based SDM measures	Continuous measure	Unavailable data	3 (1)	
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	**0.21 (0.04 to 0.50)**	6 (4)	Very low [1,2,3]
	Categorical measure	-0.02 (-0.28 to -0.01)	5 (4)	Very low [1,2,3]
	Qualitative quote	Unavailable data	0 (0)	
Interventions targeting patients compared with another intervention targeting patients for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	**1.13 (1.04 to 1.21)**	2 (2)	Very low [1,2,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	**0.29 (-0.05 to 0.63)**	6 (2)	Very low [1,2,3]
	Categorical measure	0.04 (-0.21 to 0.12)	11 (8)	Low [1,2]
	Qualitative quote	0 significant study on 3	3 (3)	Very low [1,2,4]
Interventions targeting healthcare professionals compared with usual care for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	**1.08 (0.38 to 2.07)**	4 (3)	Very low [1,2,3,4,5]

	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	0.11	1 (1)	Very low [1,2]
	Categorical measure	0.05 (0.00 to 0.09)	3 (2)	Low [2,3]
	Qualitative quote	0 significant study on 1	1 (1)	Very low [2,4]
Interventions targeting healthcare professionals compared with another intervention targeting patients for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	Unavailable data	0 (0)	
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	-0.12	1 (1)	Very low [1,2]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Interventions targeting healthcare professionals compared with another intervention targeting healthcare professionals for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	-0.3	1 (1)	Very low [2,4,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	**0.20 (-0.09 to 0.48)**	7 (2)	Very low [1,2,3]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	

Interventions targeting both patients and healthcare professionals compared with usual care for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	**2.83**	4 (2)	Very low [1,2,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	1 significant stdy on 1	1 (1)	Very low [2,4]
Patient-reported SDM measures	Continuous measure	0.16	3 (3)	Very low [1,2]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	1 significant study on 2	2 (2)	Very low [1,2,4]
Interventions targeting both patients and healthcare professionals compared with another intervention targeting patients for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	**1.42**	1 (1)	Very low [2,4,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	0.09 (-0.06 to 0.73)	5 (3)	Very low [1,2,3]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	1 significant measure on 2	2 (1)	Very low [2,4]
Interventions targeting both patients and healthcare professionals compared with another intervention targeting healthcare professionals for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	Unavailable data	0 (0)	
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	

Patient-reported SDM measures	Continuous measure	0.06	1 (1)	Very low [1,2]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	1 significant study on 1	1 (1)	Very low [1,2,4]
Interventions targeting both patients and healthcare professionals compared with another intervention targeting both patients and healthcare professionals for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	Unavailable data	0 (0)	
	Categorical measure	-0.04	1 (1)	Very low [1,2]
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	Unavailable data	0 (0)	
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	

* Where studies reported more than one measure for each endpoint, the primary measure (as defined by the authors of the study) or the median measure was abstracted. For **categorical measures**, we calculated the risk difference between the intervention of interest and the control intervention across various outcomes. For**continuous endpoints**, we calculated standardized mean difference by dividing the mean score difference of the intervention and comparison groups in each study by the pooled standard deviation estimate for the two groups across various outcomes
** Three studies reported results in more than one type of measure

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.

[1] Important risk of bias according to EPOC checklist
[2] Indirectness of evidence
[3] Heterogeneity
[4] Imprecision of the observed effect
[5] Publication bias

BACKGROUND

Description of the condition

Shared decision making (SDM) is defined as a process by which a healthcare choice is made by the patient (or significant others, or both) together with one or more healthcare professionals (Charles 1997; Légaré 2011; Towle 1999) and is said to be the crux of patient-centred care (Weston 2001). Briefly, SDM rests upon knowing and understanding the best available evidence on the risks and benefits across all available options while ensuring that the patient's values are taken into account (Charles 1997; Elwyn 1999; Towle 1999). Although SDM represents a complex set of behaviours that must be achieved by both members of the patient-healthcare professional dyad (LeBlanc 2009), it is possible to specify behaviours 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 in one integrative model of SDM in medical encounters (Makoul 2006). This model identifies nine essential elements that can be translated into various SDM-related specific behaviours for healthcare professionals 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,
- arrange follow up.

The notion that the healthcare professional is the only party requiring access to evidence is no longer credible. Instead, SDM assumes that both healthcare professional(s) and patient require access to information about the evidence informing a decision, while understanding and respecting both the patient's values and the healthcare professional's recommendations.

Description of the intervention

A variety of interventions have been designed to change healthcare professionals' behaviour. Based on the Effective Practice and Organisation of Care (EPOC) taxonomy of interventions (EPOC 2008), these 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 (that is any intervention aimed at changing the performance of healthcare professionals through interactions with patients, or information provided by or to patients). Additionally, 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 behaviour change in healthcare professionals (Godin 2008) and complex behaviour change (Michie 2009) allows 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 towards adopting SDM-related behaviours by reinforcing the underlying salient beliefs associated with their intention to adopt SDM (Giguère 2012). The training of professionals in SDM through educational meetings may increase professionals' perceptions of self-efficacy, one of the key determinants of behaviour (Godin 2008). Patient-mediated interventions such as decision aids have been shown to improve patient knowledge (Stacey 2011), and this may provide patients with more resources with which to engage in the decision-making process. In turn, the engagement of patients in the decision making process may change the habits of healthcare professionals by enhancing their knowledge of emerging evidence within their area of expertise and by increasing their use of this evidence (Brouwers 2010).

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) it may reduce the overuse of options not clearly associated with benefits for all; c) it may enhance the use of options clearly associated with benefits for the vast majority of the concerned population; d) it may reduce unwarranted healthcare practice variations (Mulley 2012; Wennberg 2004); and e) it may foster the sustainability of the healthcare system by increasing patient ownership of their own healthcare (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 behaviours (Couët 2013).

OBJECTIVES

The objective of this review was to determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM.

To address this objective, we compared each of the three categories of targeted intervention (targeting patients, targeting healthcare

professionals, and targeting both) to the same category of targeted intervention, to each of the other categories of targeted intervention, and to usual care. Thus there were nine comparison categories.

Group 1. Interventions targeting patients compared to usual care.

Group 2. Interventions targeting patients compared to other interventions targeting patients.

Group 3. Interventions targeting healthcare professionals compared to usual care.

Group 4. Interventions targeting healthcare professionals compared to interventions targeting patients.

Group 5. Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals.

Group 6. Interventions targeting both patients and healthcare professionals compared to usual care.

Group 7. Interventions targeting both patients and healthcare professionals compared to interventions targeting patients alone.

Group 8. Interventions targeting both patients and healthcare professionals compared to interventions targeting healthcare professionals alone.

Group 9. Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals.

METHODS

Criteria for considering studies for this review

Types of studies

This review considered randomised controlled trials (RCTs) and non-randomised controlled trials (NRCTs), controlled before and after studies (CBAs) and interrupted time series (ITS) analyses (EPOC 2008). To be included as a CBA, we required the study to have a minimum of two intervention sites and two control sites. For ITS studies, there needed to be a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention. We considered publications in English and French only for eligible studies that needed data extraction.

Types of participants

In this review, there were two main types of participants. The first type were healthcare professionals, including professionals in training who were responsible for patient care (residents, fellows, and other pre-licensure healthcare professionals). We defined professionals as having licensure or, in the case of professionals in training, basic pre-licensure education (for example residents who had a medical degree). The second type were patients, including healthcare consumers and standardized patients. Standardized patients were only deemed to be acceptable participants if the outcome was observer-reported.

Types of interventions

We included in this review studies that evaluated an intervention designed to increase healthcare professionals' adoption of SDM. We organized interventions into categories using the EPOC taxonomy of interventions (EPOC 2008). Patient decision aids were considered a patient-mediated intervention since one of their purposes is to foster patients' participation in decisions during the clinical encounter (Stacey 2011).

We considered studies that evaluated patient-mediated interventions (for example patients' use of patient decision aids in preparation for their consultation or during their consultation with a healthcare professional) only if these studies directly assessed the healthcare professional-related outcome of interest, that is the professional's adoption of SDM (see Types of outcome measures).

In keeping with the EPOC taxonomy of interventions, we sorted interventions into three categories: interventions targeting patients (for example patient-mediated interventions), interventions targeting healthcare professionals (for example distribution of printed educational material, an educational meeting, audit and feedback, reminders and educational outreach visits) and interventions targeting both patients and healthcare professionals (for example a patient-mediated intervention combined with an intervention targeting healthcare professionals). Usual care was the fourth category. This gave us nine comparison categories in total (see Objectives).

Types of outcome measures

In this updated review, we considered not only observer-based findings but also findings by the patients themselves, presenting a more complete portrait of the impact of interventions on adoption of SDM. We specifically avoided inclusion of healthcare professionals' self-reported SDM behaviours given that they tend to over-rate their personal behaviours.

Thus the primary outcomes evaluated by this review were observer-based outcome measures (OBOM) or patient-reported outcome measures (PROM) of healthcare professionals' adoption of SDM. For each eligible study that included the primary outcome of interest, whether OBOM or PROM, we also extracted secondary outcomes. These were measures of patient health outcomes (for example results of a blood test, health-related quality of life) and other measures reported by healthcare professionals or patients (for example knowledge, attitudes, or satisfaction).

We also extracted potential harms of interventions: a) measures of patient anxiety (from patient health outcomes); b) longer duration of consultations; and c) costs.

Search methods for identification of studies

Electronic searches

An information specialist (S Ratté) developed the search strategies in consultation with the authors.

The SDM component of the search strategy was based on the search strategy developed for a previous systematic review on barriers and facilitators for implementing SDM in clinical practice as perceived by healthcare professionals (Légaré 2008a). Given that the implementation of SDM in clinical practice is a relatively new area of research, we favoured a broad search strategy with high sensitivity as opposed to a very specific search. Searches were conducted at the beginning of August 2012; exact search dates for each database are included in Appendix 1 to Appendix 11.

All databases were searched from their inception to March 2009 for the first review. This update searched for additional literature from 15 March 2009 to August 2012. In addition to our database searches in August 2012, we contacted experts in the field and conducted brief searches in PubMed. By doing so, we identified a number of studies published later than August 2012. We included articles published in English and French only.

The following electronic databases were searched for primary studies:

- Cochrane Central Register of Controlled Trials (CENTRAL), part of *The Cochrane Library* (www.thecochranelibrary.com) (August 2012);
- Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register;
- MEDLINE via Pubmed (1950 to August Week 1, August 2012) using OvidSP;
- EMBASE (1980 to Week 29 2012) via OvidSP;
- CINAHL (Cumulative Index to Nursing and Allied Health Literature) (1981 to August 2012) via EBSCOhost;
- NHS Economic Evaluation Database, Centre for Reviews and Dissemination (CRD);
- Health Technology Assessment Database, CRD;
- PsycINFO (1806 to Week 1 August2012).

Our database searches, in all the databases above, were limited by publication year and month (March 2009 to August 2012). For PsycINFO, we were unable to place strict date limitations and manually excluded citations retrieved outside this date range.

Searching other resources

Trial registries

ClinicalTrials.gov, US National Institutes of Health (NIH) at http://clinicaltrials.gov/ (Week 2 January 2013).

Others

We also:

- handsearched proceeding so the a) International Conference on Shared Decision Making (years 2003, 2005, 2007, 2009, 2011) and b) the annual meetings of the Society for Medical Decision Making (years 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011). Although we intended to search the European Association for Communication in Healthcare (EACH), we were unable to obtain detailed information either online or as a paper copy;
- reviewed reference lists of all included studies, relevant systematic reviews and primary studies;
- contacted authors of relevant studies or reviews to clarify reported published information and to seek unpublished data. Through this process we identified a number of papers published after August 2012;
- included results from searches conducted for a review focused on patient-reported outcomes (Légaré 2012a).

Data collection and analysis

Selection of studies

At least two review authors (MJC, MS, PZ, ST) independently screened each title and abstract to find studies that met the inclusion criteria. 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 on the selection were resolved by discussion among the review authors (FL, DS).

Data extraction and management

To extract data, we designed a form derived from the EPOC Review Group data collection checklist (EPOC 2008). At least two review authors (MJC, MS, PZ, ST) independently extracted data from eligible studies. We reached consensus about discrepancies, and any disagreement was adjudicated by FL and DS. 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 authors of the original reports 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 (i.e. hospitalised patients in acute-care or long-term care facilities).

- Conceptual or theoretical underpinnings of the intervention (i.e. authors stated in their paper that the intervention was based on a theory or at least referred to a theory).

- Barriers assessment (i.e. authors stated in their paper 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, such as the one above, it was considered a component of the intervention).

For ongoing studies, when available we described the primary outcome, the research question(s), the methods and the outcome (see Ongoing studies).

Assessment of risk of bias in included studies

At least two review authors (MJC, MS, PZ, ST) independently assessed the risk of bias in each included study using the criteria outlined in the EPOC Review Group data collection checklist for studies with a separate control group (EPOC 2008) and the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) for ITS designs. We resolved any disagreement by discussion with FL. We assessed each quality criterion as 'Done', 'Not done', or 'Unclear', as recommended by the EPOC Review Group. Then we transformed these three scores into 'Low risk', 'High risk', and 'Unclear' when we entered the data into RevMan 5. The seven standard criteria as suggested for all RCTs and CBA studies are listed below.
1) Concealment of allocation (protection against selection bias).
2) Follow-up of professionals (protection against exclusion bias).
3) Follow-up of patients or episodes of care.
4) Blinded assessment of primary outcome(s) (protection against detection bias).
5) Baseline measurement.
6) Reliable primary outcome measure(s).
7) Protection against contamination.
For PROM measures, the criterion 'reliable primary outcome' was not applicable because of the nature of the outcome.

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. For categorical measures, we calculated the difference in risk between the intervention of interest and the control intervention. We calculated standardized mean difference 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 statistically significant positive effect compared to the control intervention or to usual care. When the baseline was different in the two groups, we used the size of the difference and its associated standard error to compare them. If information was not available for the standard error, we extracted a qualitative 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, the studies were divided into nine categories of intervention, which were applied to both PROM and OBOM outcomes (that is nine categories for each). Where studies reported more than one primary outcome in the same category, the median measure was abstracted. For each category of intervention and outcome for which a significant effect on our main outcome of interest (healthcare professionals' adoption of SDM) was observed, we reported the median of the standardized mean difference (or risk difference) and a range. We considered a standardized mean difference of 0.2 as small, 0.5 as medium, and 0.8 as large (Cohen 1988). For studies in which the quantitative data were absent or insufficient to make the calculation, and if no replies were obtained from the authors, we reproduced the qualitative data as presented in the article. A meta-analysis would have been performed if the nature of the primary outcome of the various comparisons had been similar.

Summary of findings table

The quality of evidence was evaluated according to GRADE for the 18 categories of intervention and outcome. For each category, conclusions were categorized into four ratings: 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), and very low quality (we are very uncertain about the estimate). This rating was downgraded if it met one of the five following criteria.
1) Important risk of bias according to the EPOC checklist: quality of evidence downgraded if the EPOC 'unclear risk' or 'high risk' risk of bias criteria were applicable.
2) Indirectness of evidence: quality of evidence was downgraded if it met one of four further criteria, i) a difference between the population of interest and participants in the studies (applicability); ii) a difference between the intervention of interest and interventions

in the studies (applicability); iii) the use of surrogate endpoints to measure SDM (PROM and OBOM are each prone to particular biases and have their own strengths and weaknesses, we can thus rate PROM and OBOM as being of even quality in the context of a process experienced by the patient); and iv) no head-to-head comparisons were made or comparisons between two or more interventions of interest (e.g. multifaceted intervention compared to another multifaceted intervention).

3) Inconsistency: quality of evidence was downgraded according to the heterogeneity index ($I^2 > 30\%$). This criterion was evaluated separately for categorical and continuous measures. It was not appropriate for qualitative statements.

4) Imprecision of the observed effect: quality of evidence was downgraded if the sample size in a study was insufficient or if there was a qualitative statement.

5) Publication bias: publication bias was tested using a funnel plot. Quality of evidence was upgraded in three cases: 1) demonstration of a strong association in a well-executed observational study; 2) all plausible biases from observational or randomised studies may have been working to underestimate an apparent intervention effect; and 3) there was evidence of a gradient.

Unit of analysis issues

We included cluster-randomised trials in the analyses along with individually randomised trials. Comparisons that randomise 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 primary authors for missing information and attempted to re-analyse studies with potential unit of analysis errors. When missing information was unavailable from the study authors, we only reported the point estimate.

Assessment of heterogeneity

To explore heterogeneity, we designed tables that compared the studies' standardized mean differences and their risk differences. We considered the following variables as potential sources of heterogeneity to explain variations in the results of the included studies: type of intervention; characteristics of the intervention (for example duration); clinical setting (primary care versus specialized care); type of healthcare professional (physicians versus other healthcare professionals); level of training of healthcare professionals (for example healthcare professionals in training versus those in practice); and type of outcome (continuous or categorical).

RESULTS

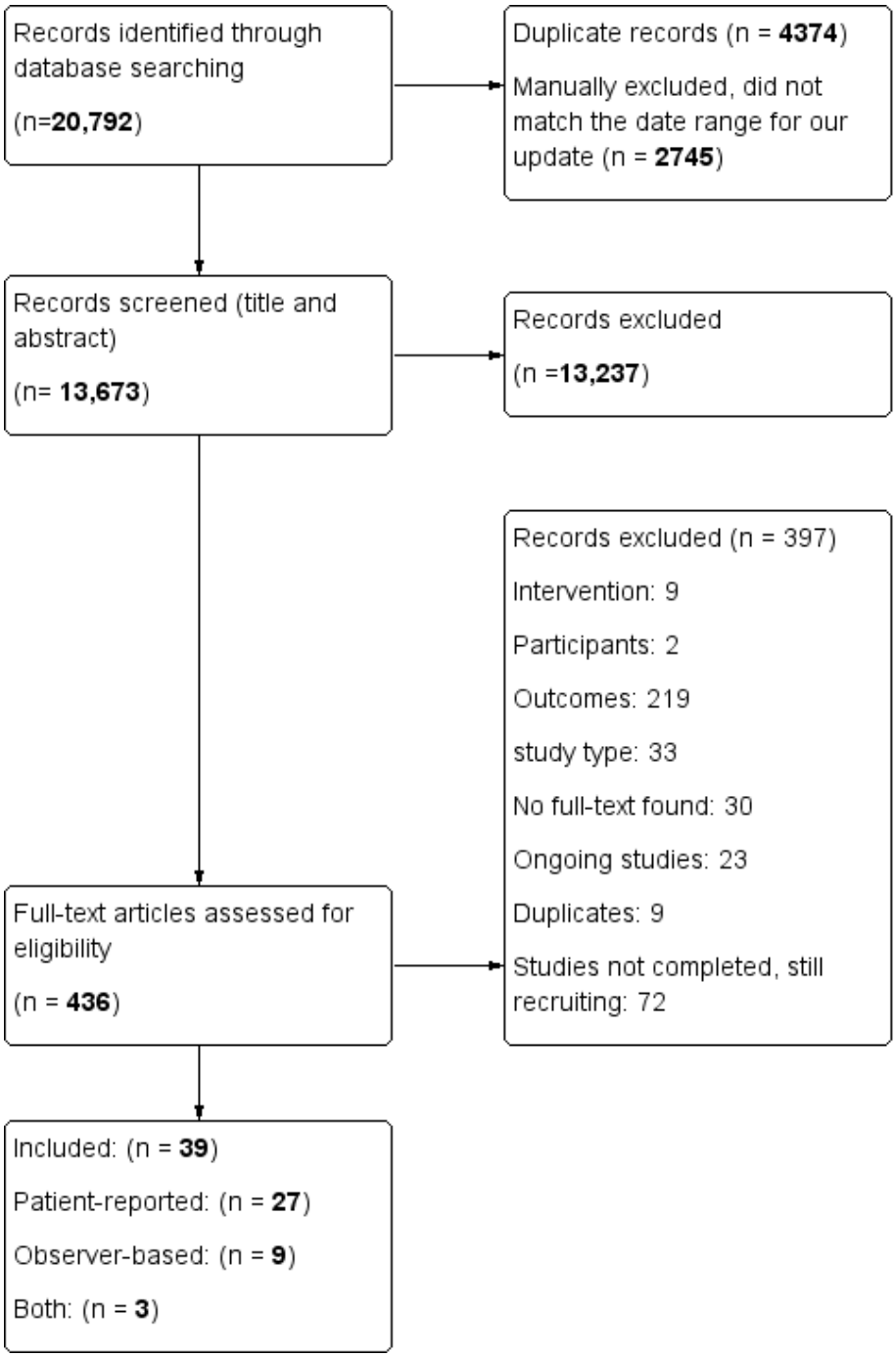
Description of studies

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

Results of the search

For this update, we found 11,757 potentially relevant citations; for previous versions of this review, we screened 9035 citations (Légaré 2012a). This provided a total of 20,792 potentially relevant citations that we considered, of which 7119 were excluded prior to review of the full publications (4374 were duplicates and 2745 did not match the date range for our update). Of the remaining citations, we retrieved 436 full publications for a more detailed screening. From these, we excluded another 397 citations based on the identified inclusion criteria. This resulted in 39 studies. For more details, see Figure 1.

Figure 1. Flow diagram of Cochrane update on interventions for improving the adoption of shared decision making by healthcare professionals (up to 31 December 2012).



Included studies

We included 39 studies in this review. This current version updates our 2010 version (Légaré 2010), which included five OBOM studies and another systematic review of 21 PROM studies (Légaré 2012). Two studies (Butow 2004; Elwyn 2004) were in both reviews. Three studies were excluded: one was excluded because it reported "preferred role during the consultation" (that is the role the patient would like to play) and not 'assumed role' (the role actually played, the outcome relevant to our review) (Brown 2004). Two more were excluded because they reported the more vaguely-worded "active patient" but not 'assumed role' (Kopke 2009; Whelan 2003).

This updated search added 18 new studies to the 21 original studies that were included, for a total of 39 studies (Bernhard 2011; Cooper 2011; Deen 2012; Deinzer 2009; Fossli 2011; Hess 2012; Landrey 2012; Légaré 2012; Leighl 2011; Montori 2011; Mullan 2009; Murray 2010; Myers 2011; Raynes-Greenow 2010; Roter 2012; Schroy 2011; Shepherd 2011; van Peperstraten 2010).

We identified a further 20 RCTs as ongoing studies (see Characteristics of ongoing studies).

All studies in this review were RCTs except for one, which was a non-randomised controlled trial (NRCT) (Deinzer 2009). Among the RCTs, seven were cluster-randomised trials (Elwyn 2004; Hamann 2007; Haskard 2008; Légaré 2012; Loh 2007; O'Cathain 2002; Wetzels 2005).

Characteristics of settings and participants

Interventions targeting patients (18 studies)

Of the 18 studies of interventions targeting patients, eight were conducted in the United States (Deen 2012; Dolan 2002; Krist 2007; Landrey 2012; Montori 2011; Nannenga 2009; Schroy 2011; Street 1995), three in Canada (Davison 1997; Deschamps 2004; Lalonde 2006), two in Germany (Kasper 2008; Vodermaier 2009), two in the Netherlands (Stiggelbout 2008; van Peperstraten 2010), two in Australia (Butow 2004; Raynes-Greenow 2010) and one in the United Kingdom (Murray 2001). With regard to care settings, eight out of 18 trials were conducted in primary care (Deschamps 2004; Dolan 2002; Krist 2007; Lalonde 2006; Landrey 2012; Montori 2011; Murray 2001; Schroy 2011) and nine in specialized care (Butow 2004; Davison 1997; Kasper 2008; Nannenga 2009; Raynes-Greenow 2010; Stiggelbout 2008; Street 1995; van Peperstraten 2010; Vodermaier 2009). One study was carried out both in primary and specialized care (Deen 2012). All studies were conducted and recruited patients in an ambulatory setting except one, which was in non-ambulatory care (Vodermaier 2009).

Although there was a total of 236 reported participating healthcare professionals, this number under-represented the total number of professionals as eight studies did not report the total number of healthcare professionals involved in the study (Deen 2012; Deschamps 2004; Kasper 2008; Lalonde 2006; Murray 2001; Raynes-Greenow 2010; van Peperstraten 2010; Vodermaier 2009). The minimum number of healthcare professionals reported was two (Davison 1997) and the maximum number was 60 (Montori 2011).

All studies reported the number of patients involved in the study. A total of 4055 patients were enrolled in the interventions, with a minimum of 26 (Lalonde 2006) and a maximum of 666 (Schroy 2011). The most common clinical condition was cancer (seven studies) (Butow 2004; Davison 1997; Dolan 2002; Krist 2007; Schroy 2011; Street 1995; Vodermaier 2009).

Interventions targeting healthcare professionals (eight studies)

Of the eight studies of interventions targeting healthcare professionals, two were conducted in Canada (Légaré 2012; Stacey 2006), two in the United Kingdom (Elwyn 2004; O'Cathain 2002), one in Australia (Shepherd 2011), one in Germany (Krones 2008 (ARRIBA-Herz)) and one in Norway (Fossli 2011). One study was conducted with international collaboration, specifically Australia, New Zealand, Switzerland, Germany and Austria (Bernhard 2011). Seven studies were conducted in primary care (Elwyn 2004; Fossli 2011; Krones 2008 (ARRIBA-Herz); Légaré 2012; O'Cathain 2002; Shepherd 2011; Stacey 2006) and one in specialized care (Bernhard 2011). All eight trials recruited patients in ambulatory care settings.

Although a total of 593 participating healthcare professionals were reported, this number under-represented the total number of professionals as one study did not report the total number of healthcare professionals involved in the study (O'Cathain 2002). The minimum number of healthcare professionals reported was 21 (Elwyn 2004) and the maximum number was 270 (Légaré 2012). Two studies (Shepherd 2011; Stacey 2006) used simulated patients facing different clinical situations: depression (Shepherd 2011), gall bladder disorders, attention deficit hyperactivity disorder, amniocentesis, and allergy (Stacey 2006). Among the six studies without standardized patients, one did not report the number of patients in the study (Fossli 2011) and five studies (Bernhard 2011; Elwyn 2004; Krones 2008 (ARRIBA-Herz); Légaré 2012; O'Cathain 2002) had a total of 13,707 patients enrolled (minimum 694 (Bernhard 2011) and maximum 10,070 (O'Cathain 2002) patients per study). The five studies that reported numbers of patients involved diverse clinical conditions: breast cancer (Bernhard 2011), cardiovascular disease (Krones

2008 (ARRIBA-Herz)), acute respiratory infection (Légaré 2012), maternity care (O'Cathain 2002), and multi-clinical conditions of non-valvular atrial fibrillation or prostatism or menorrhagia or menopausal symptoms (Elwyn 2004). Most interventions enrolled both male and female patients, except for two studies (Bernhard 2011; O'Cathain 2002) which involved females only.

Interventions targeting both patients and healthcare professionals (13 studies)

Of the 13 studies of interventions targeting both patients and healthcare professionals, six were conducted in the United States (Cooper 2011; Haskard 2008; Hess 2012; Mullan 2009; Myers 2011; Roter 2012), four in Germany (Bieber 2006; Deinzer 2009; Hamann 2007; Loh 2007), one in the Netherlands (Wetzels 2005) and one in Canada (Murray 2010). One study was conducted with international collaboration, specifically Australia and Canada (Leighl 2011). Care settings were divided between primary care (seven studies) (Cooper 2011; Haskard 2008; Loh 2007; Mullan 2009; Myers 2011; Roter 2012; Wetzels 2005) and specialized care (six studies) (Bieber 2006; Deinzer 2009; Hamann 2007; Hess 2012; Leighl 2011; Murray 2010). Ten trials were conducted in ambulatory care settings (Bieber 2006; Cooper 2011; Haskard 2008; Hess 2012; Leighl 2011; Loh 2007; Mullan 2009; Myers 2011; Roter 2012; Wetzels 2005), two in non-ambulatory care settings (Deinzer 2009; Hamann 2007) and one was set in both ambulatory and non-ambulatory care settings (Murray 2010). A total of 571 healthcare professionals took part in these studies, ranging from 10 (Bieber 2006) to 156 (Haskard 2008) per study. One study (Murray 2010) used five simulated patients facing care related to end of life treatment. Among the 12 studies without standardized patients, a total of 5474 patients were enrolled, with a minimum of 85 (Mullan 2009) and a maximum of 2196 (Haskard 2008). The most common clinical condition was hypertension (two studies) (Cooper 2011; Deinzer 2009), and multi-clinical conditions (two studies) (Haskard 2008; Wetzels 2005). Most interventions enrolled both male and female patients, except for one study (Myers 2011) which involved males only.

In summary, of the 39 studies included in the review, the three most represented countries were the United States (14 studies), Germany (seven studies) and Canada (six studies). Only two of the 39 studies were conducted with international collaborations: Canada and Australia; and Australia; New Zealand, Switzerland, Germany and Austria. The setting was primary care in 22 studies, with only one in both primary and specialized care. More than half (53.8%) of the healthcare professionals involved in the studies were licensed and the three most frequent clinical conditions studied were cancer (nine studies), cardiovascular disease (eight studies) and multiple conditions (four studies).

Characteristics of interventions and comparisons

Characteristics of interventions

For details, see Characteristics of included studies.

Several studies had more than two arms (Cooper 2011; Deen 2012; Haskard 2008; Krist 2007; Raynes-Greenow 2010; Schroy 2011). One study presented a RCT with two-by-two factorial design (Cooper 2011) and four arms: 1) a patient-mediated intervention and an educational meeting; 2) an educational meeting; 3) a patient-mediated intervention; and 4) control (patients and providers receiving minimal intervention). One study presented an RCT with four arms (Deen 2012): 1) a decision aid and patient activation; 2) a decision aid; 3) patient activation; and 4) control (doctor's visit). One study presented a cluster-RCT (Haskard 2008) with four arms. The first arm (training of healthcare professional and patient) consisted of a multifacted intervention (an educational meeting, distribution of educational materials, and a patient-mediated intervention). The second arm (training of healthcare professional only) consisted of a multifaceted intervention (an educational meeting and the distribution of educational materials). The third arm (patient training only) consisted of a single intervention (patient-mediated intervention). The fourth arm (control group) consisted of usual care. One study presented an RCT (Krist 2007) with three arms: 1) mailed paper version of a decision aid; 2) Internet-based decision aid; and 3) control. One study presented an RCT (Raynes-Greenow 2010) with three arms: 1) a decision aid (booklet and audio); 2) a decision aid (booklet); and 3) a pamphlet. One study presented an RCT (Schroy 2011) with three arms: 1) a decision aid and decision guidance; 2) a decision aid only; and 3) control decision aid. Thus there was an overlap of studies between comparison types (objective).

Interventions targeting patients

Eight studies compared interventions targeting patients with usual care (Cooper 2011; Deen 2012; Haskard 2008; Krist 2007; Landrey 2012; Murray 2001; van Peperstraten 2010; Vodermaier 2009). Of these, three studies compared single interventions to usual care (Landrey 2012; Murray 2001; Vodermaier 2009), one compared multifaceted interventions to usual care (van Peperstraten 2010), and four studies (Cooper 2011; Deen 2012; Haskard 2008; Krist 2007) compared patient-mediated interventions to usual care (RCTs with several arms).

Fourteen studies presented comparisons of interventions targeting the patient with other interventions targeting the patient (Butow 2004; Davison 1997; Deen 2012; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Lalonde 2006; Montori 2011; Nannenga 2009; Raynes-Greenow 2010; Schroy 2011; Stiggelbout 2008; Street 1995). Of these, eight studies compared a single intervention to another single intervention (Butow 2004; Davison 1997; Dolan 2002; Kasper 2008; Montori 2011; Nannenga 2009; Stiggelbout 2008; Street 1995), one study compared a multifaceted intervention to a single intervention (Deschamps 2004), one study compared a multifaceted interven-

tion to another multifaceted intervention (Lalonde 2006), and four studies had arms comparing a patient-mediated intervention to another patient-mediated intervention (Deen 2012; Krist 2007; Raynes-Greenow 2010; Schroy 2011).

Interventions targeting healthcare professionals

Seven studies compared interventions targeting the healthcare professional with usual care (Bernhard 2011; Cooper 2011; Fossli 2011; Légaré 2012; O'Cathain 2002; Shepherd 2011; Stacey 2006). Of these, two studies presented interventions containing educational meetings, audit and feedback, and distribution of educational materials (Bernhard 2011; Fossli 2011); two studies presented interventions using educational meetings and distribution of educational materials (Légaré 2012; O'Cathain 2002); and one presented the distribution of educational materials with educational meetings, audit and feedback, and barriers assessment, as part of a multifaceted intervention (Stacey 2006). We also found one study that compared a single intervention (educational outreach visit) to usual care (Shepherd 2011), and one study had an arm that compared an educational meeting to usual care (Cooper 2011).

One study compared an intervention targeting the healthcare professional with one targeting the patient (Cooper 2011). This study presented an arm comparing a educational meeting with a patient-mediated intervention.

Two studies compared interventions targeting the healthcare professional with other interventions targeting the healthcare professional (Elwyn 2004; 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) (Elwyn 2004), 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) (Krones 2008 (ARRIBA-Herz)).

Interventions targeting both patients and healthcare professionals

Eight studies compared an intervention targeting patients and healthcare professionals with usual care (Cooper 2011; Hamann 2007; Haskard 2008; Hess 2012; Leighl 2011; Loh 2007; Murray 2010; Wetzels 2005). Of these, four studies presented interventions that used educational meetings and patient-mediated interventions (Hamann 2007; Hess 2012; Leighl 2011; Loh 2007); one study presented an intervention that used educational meetings, distribution of educational materials, audit and feedback, barriers assessment, and educational outreach visits (Murray 2010); and one study presented a patient-mediated intervention using educational outreach visits (Wetzels 2005). 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); and one study presented a patient-mediated intervention and an educational meeting (Cooper 2011).

Four studies compared interventions targeting both patients and healthcare professionals with interventions targeting patients alone (Bieber 2006; Cooper 2011; Deinzer 2009; Mullan 2009). Of these, three studies compared educational meetings and patient-mediated interventions with patient-mediated interventions alone (Bieber 2006; Deinzer 2009; Mullan 2009), and one study presented an arm comparing an educational meeting and patient-mediated intervention with a patient-mediated intervention alone (Cooper 2011).

Two studies compared interventions targeting both patients and healthcare professionals with interventions targeting healthcare professionals alone (Cooper 2011; Roter 2012). Of these, one study compared patient-mediated interventions and the distribution of educational materials with the distribution of educational materials alone (Roter 2012), and one study presented an arm comparing educational meetings and patient-mediated interventions with educational meetings alone (Cooper 2011).

One study compared an intervention targeting both patients and healthcare professionals with another intervention targeting both patients and healthcare professionals (Myers 2011). This study compared a multifaceted intervention including a patient-mediated intervention and reminders with another multifaceted intervention also including a patient-mediated intervention and reminders.

Conceptual framework and barriers assessment

Interventions targeting patients (18 studies)

Among the studies of interventions targeting patients, six studies explicitly referred to a conceptual framework or a theory to justify their intervention (Butow 2004; Davison 1997; Raynes-Greenow 2010; Schroy 2011; Stiggelbout 2008; van Peperstraten 2010). Three studies (Raynes-Greenow 2010; Schroy 2011; van Peperstraten 2010) referred to the Ottawa Decision Support Framework, one (Davison 1997) referred to the Empowerment Model by Conger and Kanungo, one (Stiggelbout 2008) to the Markov Model, and one (Butow 2004) did not provide detailed information.

One of the studies of interventions targeting patients reported performance of a barriers assessment (van Peperstraten 2010).

Interventions targeting healthcare professionals (eight studies)

Among the studies of interventions targeting healthcare professionals, four studies explicitly referred to a conceptual framework

or a theory to justify their intervention (Elwyn 2004; Fossli 2011; Légaré 2012; Stacey 2006). One study (Stacey 2006) referred to the Ottawa Decision Support Framework, one (Elwyn 2004) referred to a model of interpersonal interaction, one (Fossli 2011) referred to the Four Habit Model, and one study (Légaré 2012) referred to the Theory of Planned Behaviour.

Of the eight studies of interventions targeting healthcare professionals, one (Stacey 2006) reported the performance of a barriers assessment and based its interventions on identified barriers.

Interventions targeting both patient and healthcare professionals (13 studies)

Five of the studies of interventions targeting both patients and healthcare professionals (Haskard 2008; Loh 2007; Murray 2010; Roter 2012; Wetzels 2005) referred to a conceptual framework or a theory to justify their interventions. One study (Murray 2010) referred to the Ottawa Decision Support Framework, one (Haskard 2008) referred to the 4E Model (Engage, Empathize, Educate and Enlist), one study (Roter 2012) referred to the LEAPS (Listen, Educate, Assess, Partner and Support) framework, one (Wetzels 2005) to the SWOT analysis (Strengths, Weaknesses, Opportunities and Threats), and one (Loh 2007) did not provide detailed information.

Of these studies, one (Murray 2010) reported the performance of a barriers assessment and based its interventions on identified barriers.

In summary, 15 studies out of the 39 included in this review used a conceptual framework. The Ottawa Decision Support Framework was the most cited framework. Lastly, only three based their interventions on barriers assessments.

Characteristics of outcomes

Characteristics of primary outcomes

Patient-reported outcome measures (PROM)

Among the 16 PROM studies, 14 unique scales or subscales were used to measure the adoption of SDM by healthcare professionals from a patient perspective. Patient-reported outcomes were predominantly represented by the 'perceived level of control in decision making' or 'assumed role during the consultation' (adaptation of the Control Preference Scale) in 15 studies (Butow 2004; Davison 1997; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Landrey 2012; Légaré 2012; Leighl 2011; Murray 2001; O'Cathain 2002; Raynes-Greenow 2010; Stiggelbout 2008; Street 1995; Vodermaier 2009). Other tools used were: COMRADE (Deinzer 2009; Elwyn 2004; Hamann 2007; Wetzels 2005), and the Man-Son-Hing Instrument or the Patient Participation Satisfaction scale (PPS) (Krones 2008 (ARRIBA-Herz); Loh 2007; Vodermaier 2009). There were also 11 unique scales or subscales used in the studies analysed. For more details, see Characteristics of included studies.

Observer-based outcome measures (OBOM)

Among the three OBOM studies, nine unique scales or subscales were used to measure the adoption of SDM by healthcare professionals from an observer-based perspective. The observer-based outcomes were predominantly represented by the OPTION scale in six studies (Elwyn 2004; Hess 2012; Montori 2011; Mullan 2009; Nannenga 2009; Shepherd 2011), and the Decision Support Analysis Tool (DSAT) in two studies (Murray 2010; Stacey 2006). There were also seven unique scales or subscales used in the studies analysed. For more details, see Characteristics of included studies.

It was noteworthy that the primary outcome of only five out of the 39 studies included in this review was the same as the primary outcome of this review, that is a measure of healthcare professionals' adoption of SDM (Dolan 2002; Elwyn 2004; Krist 2007; O'Cathain 2002; Wetzels 2005).

Characteristics of secondary outcomes

Patient health measures

Eighteen studies (Bernhard 2011; Bieber 2006; Butow 2004; Cooper 2011; Davison 1997; Deinzer 2009; Elwyn 2004; Hamann 2007; Hess 2012; Krones 2008 (ARRIBA-Herz); Légaré 2012; Leighl 2011; Loh 2007; Murray 2001; Mullan 2009; Raynes-Greenow 2010; Stiggelbout 2008; van Peperstraten 2010) reported 51 patient health measures.

Duration of consultation

Thirteen studies (Butow 2004; Elwyn 2004; Fossli 2011; Krist 2007; Loh 2007; Montori 2011; Murray 2001; Murray 2010; Nannenga 2009; Shepherd 2011; Stacey 2006; Vodermaier 2009; Wetzels 2005) reported duration of consultation.

Other measurements reported by healthcare professionals

In 21 studies (Bernhard 2011; Bieber 2006; Butow 2004; Elwyn 2004; Hamann 2007; Haskard 2008; Hess 2012; Krist 2007; Krones 2008 (ARRIBA-Herz); Légaré 2012; Leighl 2011; Loh 2007; Mullan 2009; Murray 2001; Murray 2010; Roter 2012; Stacey 2006; Stiggelbout 2008; Street 1995; van Peperstraten 2010; Vodermaier 2009) 45 other measurements were reported by healthcare professionals.

Other measurements reported by patients

In 32 studies (Bieber 2006; Butow 2004; Deen 2012; Deinzer 2009; Deschamps 2004; Dolan 2002; Elwyn 2004; Fossli 2011; Hamann 2007; Haskard 2008; Hess 2012; Kasper 2008; Krist 2007; Krones 2008 (ARRIBA-Herz); Lalonde 2006; Landrey 2012; Légaré 2012; Leighl 2011; Loh 2007; Montori 2011; Mullan 2009; Murray 2001; Myers 2011; O'Cathain 2002; Raynes-Greenow 2010; Roter 2012; Schroy 2011; Stiggelbout 2008; Street 1995; van Peperstraten 2010; Vodermaier 2009; Wetzels 2005) 140 other measurements were reported by patients.

Risk of bias in included studies

Interventions targeting patients compared with usual care

Among the seven PROM studies (Cooper 2011; Deen 2012; Krist 2007; Landrey 2012; Murray 2001; van Peperstraten 2010; Vodermaier 2009), all had at least one unclear risk out of the seven risk of bias criteria. Four (Deen 2012; Krist 2007; Murray 2001; van Peperstraten 2010) studies had one high-risk bias and three (Cooper 2011; Landrey 2012; Vodermaier 2009) had two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of the evidence, in three studies information reported about participants was inadequate (Deen 2012; Murray 2001; Vodermaier 2009) and in one study the participants were couples (van Peperstraten 2010) and therefore not comparable to the other study populations. The interventions varied from one study to another. In one study (Cooper 2011) comparisons were indirect. In the four studies using continuous measures of SDM (Cooper 2011; Deen 2012; van Peperstraten 2010; Vodermaier 2009) the results reported were inconsistent. In the four studies using categorical measures of SDM (Krist 2007; Landrey 2012; Murray 2001; Vodermaier 2009) results reported were inconsistent.

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

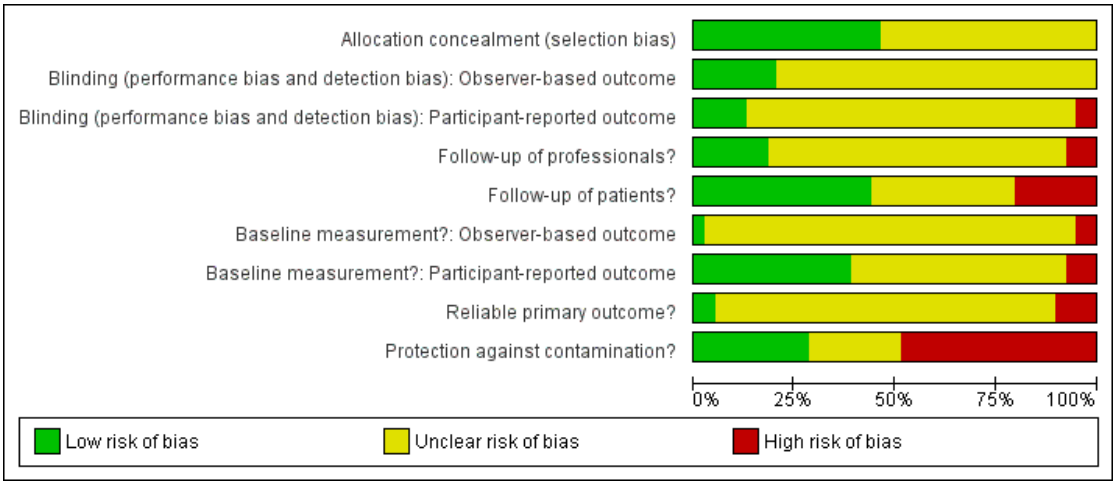
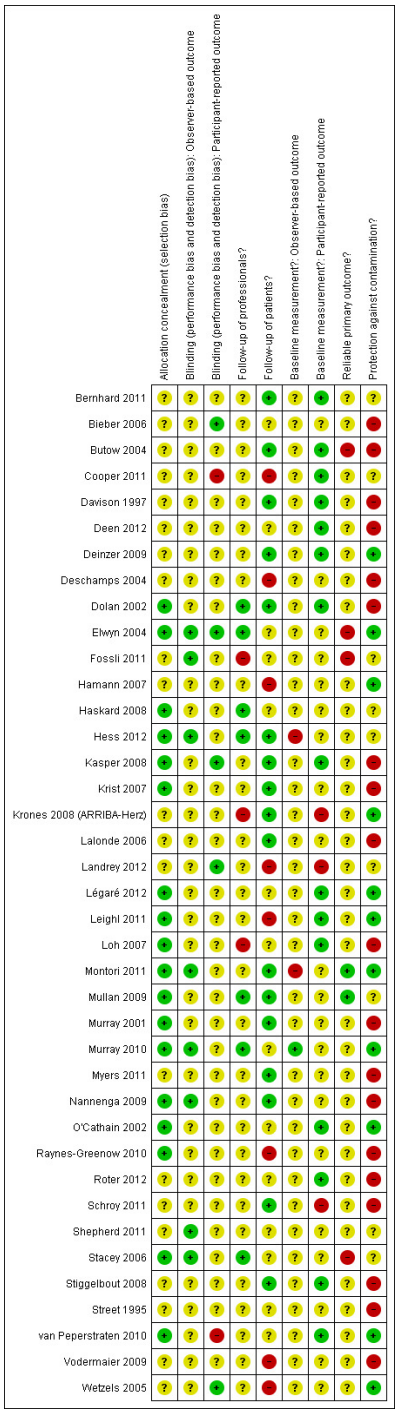


Figure 3. Risk of bias summary for each included study.



There was one OBOM study (Haskard 2008) which had at least one unclear risk out of the seven risk of bias criteria, and no high-risk bias (see Figure 2 and Figure 3). Regarding indirectness of the evidence, the only problematic criterion was intervention variability. There was publication bias in the OBOM studies with continuous outcomes.

Interpretation of results for this comparison needed to consider the heterogeneity across studies and the fact that all studies had potential bias from inadequate protection against contamination.

Interventions targeting patients compared with other interventions targeting patients

Among the 12 PROM studies (Butow 2004; Davison 1997; Deen 2012; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Lalonde 2006; Raynes-Greenow 2010; Schroy 2011; Stiggelbout 2008; Street 1995), 10 (Butow 2004; Davison 1997; Deen 2012; Deschamps 2004; Krist 2007; Lalonde 2006; Schroy 2011; Stiggelbout 2008; Street 1995) had at least one unclear risk out of the seven risk of bias criteria. Eight studies (Davison 1997; Deen 2012; Dolan 2002; Kasper 2008; Krist 2007; Lalonde 2006; Stiggelbout 2008; Street 1995) had one high-risk bias and four (Butow 2004; Deschamps 2004; Raynes-Greenow 2010; Schroy 2011) had two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of the evidence, in four studies there was inadequate information about participants (Deen 2012; Kasper 2008; Lalonde 2006; Raynes-Greenow 2010). The interventions varied from one study to another. In two studies (Deschamps 2004; Lalonde 2006) comparisons reported were indirect. Two studies (Deen 2012; Schroy 2011) used continuous measures of SDM and their results were inconsistent. Eight studies (Butow 2004; Davison 1997; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Raynes-Greenow 2010; Stiggelbout 2008) used categorical measures of SDM and their results were consistent. Three studies reported qualitative statements (Butow 2004; Lalonde 2006; Street 1995) and were imprecise as to the observed effect.

Of the two OBOM studies (Montori 2011; Nannenga 2009), one (Nannenga 2009) had at least one unclear risk out of the seven risk of bias criteria. Both studies had one high-risk bias (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, the only problematic criterion was that the intervention varied from other studies. The two studies used continuous measures of SDM and the results reported were consistent. There was publication bias in the OBOM studies with continuous outcomes.

Interpretation of results for this comparison needed to consider the heterogeneity across the types of patient-mediated interventions and the fact that all studies had potential bias from inadequate protection against contamination.

Interventions targeting healthcare professionals compared with usual care

Among the four PROM studies (Bernhard 2011; Cooper 2011; Légaré 2012; O'Cathain 2002) all reported at least one unclear risk out of the seven risk of bias criteria. One study (Cooper 2011) reported two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, all studies reported on similar populations, but the intervention varied from one study to another. In one study (Cooper 2011) the comparisons were indirect. One study (Cooper 2011) used a continuous measure of SDM. Two studies (Légaré 2012; O'Cathain 2002) used categorical measures of SDM and the results were inconsistent. One study reported qualitative statements (Bernhard 2011) and was imprecise as to the observed effect.

Among the three OBOM studies (Fossli 2011; Shepherd 2011; Stacey 2006) all had at least one unclear risk out of the seven risk of bias criteria. One study had one high-risk bias (Stacey 2006) and one study had two high-risk biases (Fossli 2011) (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, two studies (Shepherd 2011; Stacey 2006) used standardized patients and in one study (Fossli 2011) there was inadequate information about the participants. The interventions varied from one study to another. There were no indirect comparisons in these studies. The three studies used continuous measures, their results were inconsistent, and they were imprecise as to the observed effect because of small sample size. There was publication bias in these studies.

Interpretation of results for this comparison needed to consider that half of the studies were small and there was heterogeneity across the types of population included.

Interventions targeting healthcare professionals compared with another interventions targeting patients

One study used PROM (Cooper 2011). This study had at least one unclear risk out of the seven risk of bias criteria and two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, the quality of evidence was downgraded because: 1) the intervention varied from one study to another, and 2) the comparisons were indirect.

Interpretation of results for this comparison needed to recognize that findings were based on only one highly biased study.

Interventions targeting healthcare professionals compared with other interventions targeting healthcare professionals

In both PROM studies (Elwyn 2004; Krones 2008 (ARRIBA-Herz)) there was at least one unclear risk out of the seven risk of bias criteria. One study (Krones 2008 (ARRIBA-Herz)) had two

high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, both studies reported on similar populations. The intervention varied between studies. There were indirect comparisons in one study (Elwyn 2004). Both studies used continuous measures and results were inconsistent.

In the one OBOM study (Elwyn 2004) there was least one unclear risk out of the seven risk of bias criteria and no high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, the quality of evidence was downgraded because: 1) the intervention varied from one study to another, and 2) the comparisons were indirect. This study used continuous measures of SDM and results were imprecise as to the observed effect because of the small sample size. There was publication bias in the OBOM studies with continuous outcomes.

Interpretation of results for this comparison needed to consider the significant findings from one highly biased study due to problems with follow-up of professionals and baseline measurement.

Interventions targeting both patients and healthcare professionals compared with usual care

All five PROM studies (Cooper 2011; Hamann 2007; Leighl 2011; Loh 2007; Wetzels 2005) had at least one unclear risk out of the seven risk of bias criteria. Three studies (Hamann 2007; Leighl 2011; Wetzels 2005) had one high-risk bias, and two studies (Cooper 2011; Loh 2007) had two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, in two studies there was inadequate information about participants (Hamann 2007; Wetzels 2005). The intervention varied from one study to another. Comparisons in one study (Cooper 2011) were indirect. Three studies (Cooper 2011; Hamann 2007; Wetzels 2005) used continuous measures of SDM and their results were consistent. Two studies reported qualitative statements (Leighl 2011; Loh 2007) and were imprecise as to the observed effect.

All three OBOM studies (Haskard 2008; Hess 2012; Murray 2010) had at least one unclear risk out of the seven risk of bias criteria. One study (Hess 2012) had one high-risk bias (see Figure 2 and Figure 3). Regarding criteria for evaluating the indirectness of evidence, the intervention varied from one study to another. There was publication bias in the two OBOM studies with continuous outcomes (Haskard 2008; Hess 2012). One study (Murray 2010) reported qualitative statements and was imprecise as to the observed effect.

This comparison group had the most homogenous studies. However, interpretation of results needed to consider the small number of studies and the presence of some methodological bias.

Interventions targeting both patients and healthcare professionals compared with interventions targeting patients

All four PROM studies (Bieber 2006; Cooper 2011; Deinzer 2009; Mullan 2009) had at least one unclear risk out of the seven risk of bias criteria. One study (Bieber 2006) had one high-risk bias and one had two (Cooper 2011) (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, all studies reported on similar populations. The intervention varied from one study to another. Comparisons in all studies were indirect. Three studies (Bieber 2006; Cooper 2011; Mullan 2009) used continuous measures of SDM and their results were inconsistent. One study (Deinzer 2009) reported qualitative statements and was imprecise as to the observed effect.

The one OBOM study (Mullan 2009) had at least one unclear risk out of the seven risk of bias criteria and no high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, two criteria were problematic: 1) the interventions varied, and 2) comparisons were indirect. This study used continuous measures of SDM and had a small sample size. There was publication bias in the OBOM studies with continuous outcomes. Interpretation of results for this comparison needed to consider the heterogeneity across studies and the fact that most studies had multiple arms.

Interventions targeting both patients and healthcare professionals compared with interventions targeting only healthcare professionals

Both studies using patient-reported outcome measures (Cooper 2011; Roter 2012) reported at least one unclear risk out of the seven risk of bias criteria. There was one high-risk bias in one study (Roter 2012) and two in the other (Cooper 2011) (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, only two criteria were problematic: the interventions varied, and comparisons were indirect. One study (Cooper 2011) reported continuous measures of SDM. One study (Roter 2012) reported qualitative statements and was imprecise as to the observed effect. Interpretation of results for this comparison needed to consider that findings were based on only two highly biased studies.

Interventions targeting both patients and healthcare professionals compared with other interventions targeting both patients and healthcare professionals

One OBOM study (Myers 2011) had at least one unclear risk out of the seven risk of bias criteria and one high-risk bias (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, two criteria were problematic: 1) the interventions varied, and 2) comparisons were indirect.

None of the included studies were exempt from bias and there was a publication bias for OBOM and PROM studies with continuous data; there appeared to be a lack of published studies with negative results on a continuous score. No publication bias was found in PROM studies with categorical measures (only one OBOM study used categorical measures). For more details, see Figure 4; Figure 5 and Figure 6. As the funnel plot showed there were few negative

OBOM studies, therefore positive OBOM studies could have been over-represented in our review.

Figure 4. Patient-reported outcome (categorical measure).

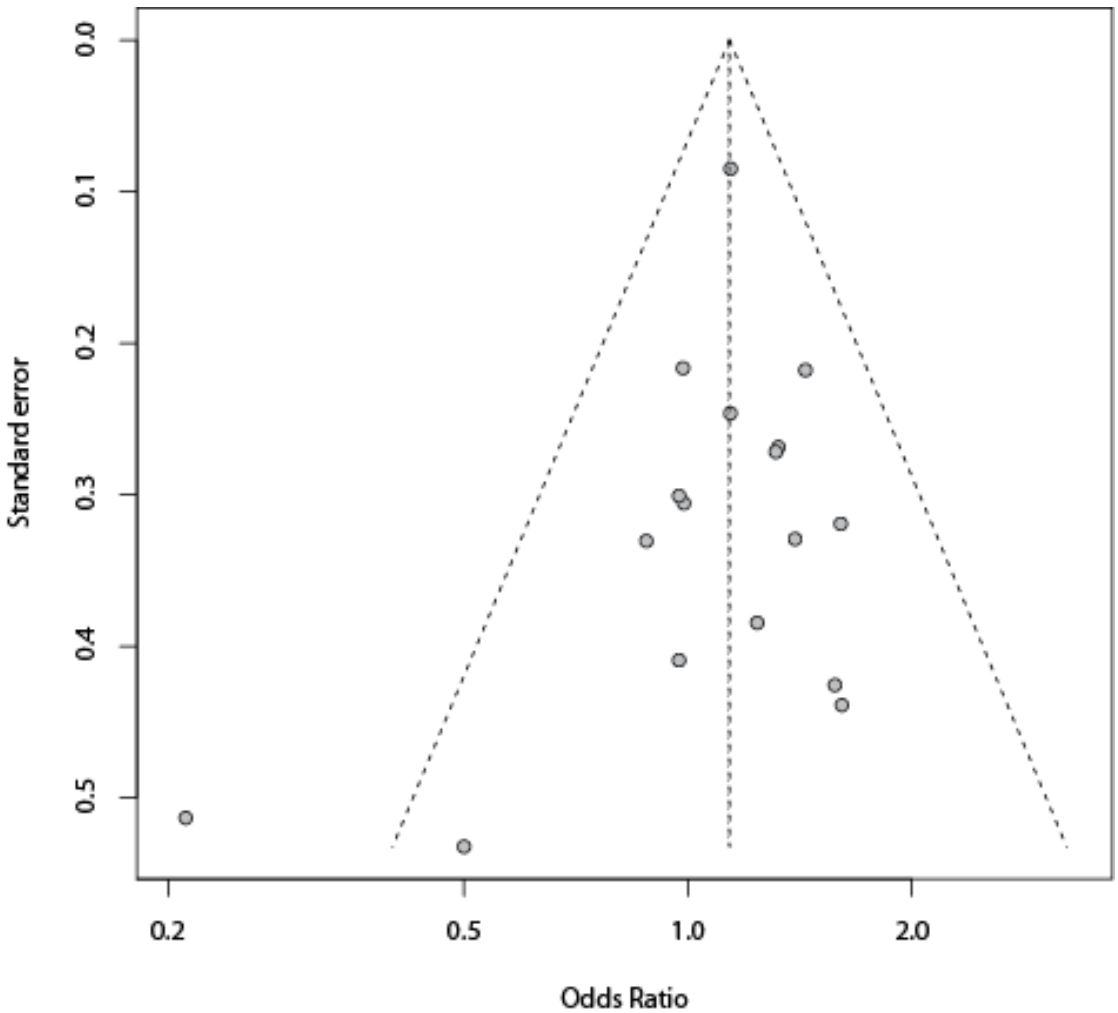


Figure 5. Observer-based outcome (continuous measure).

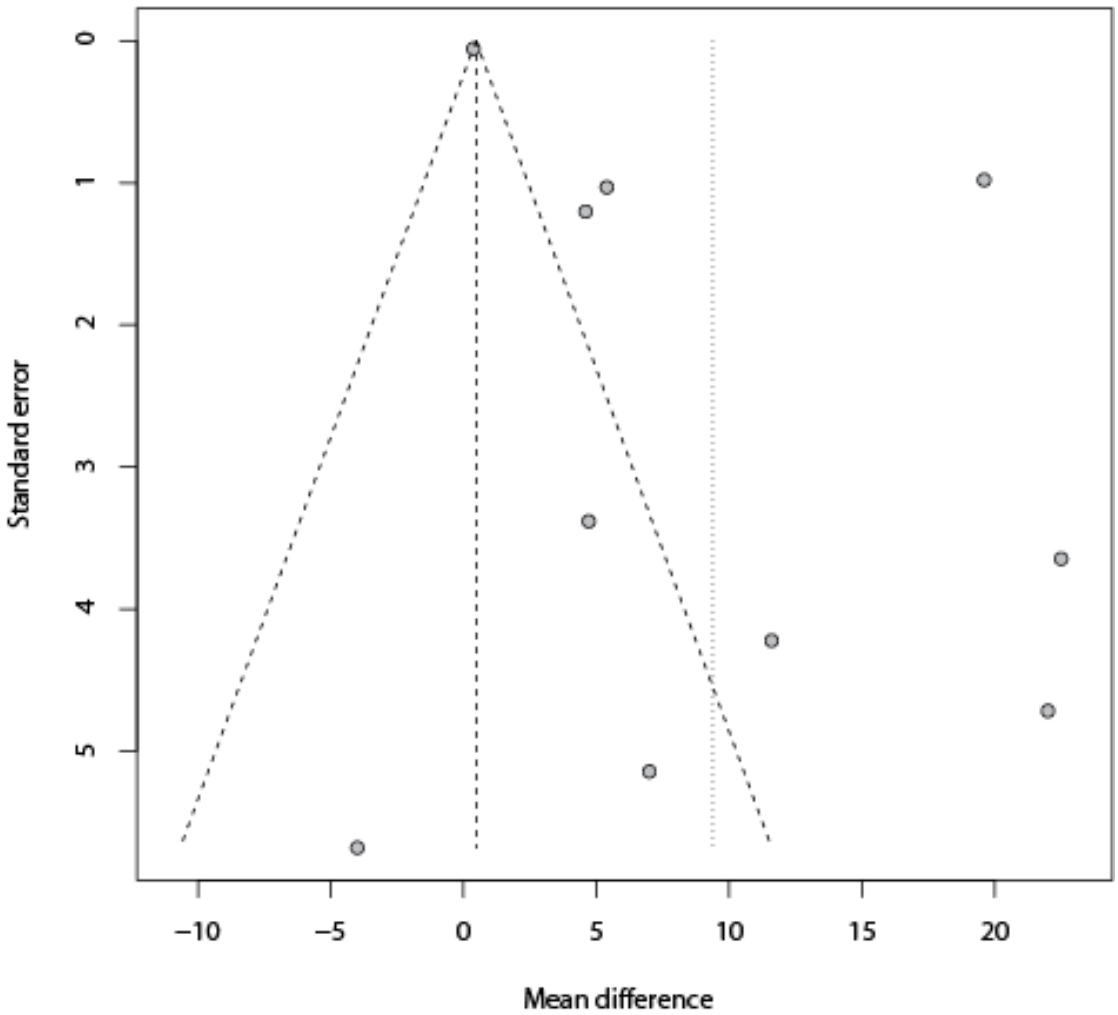
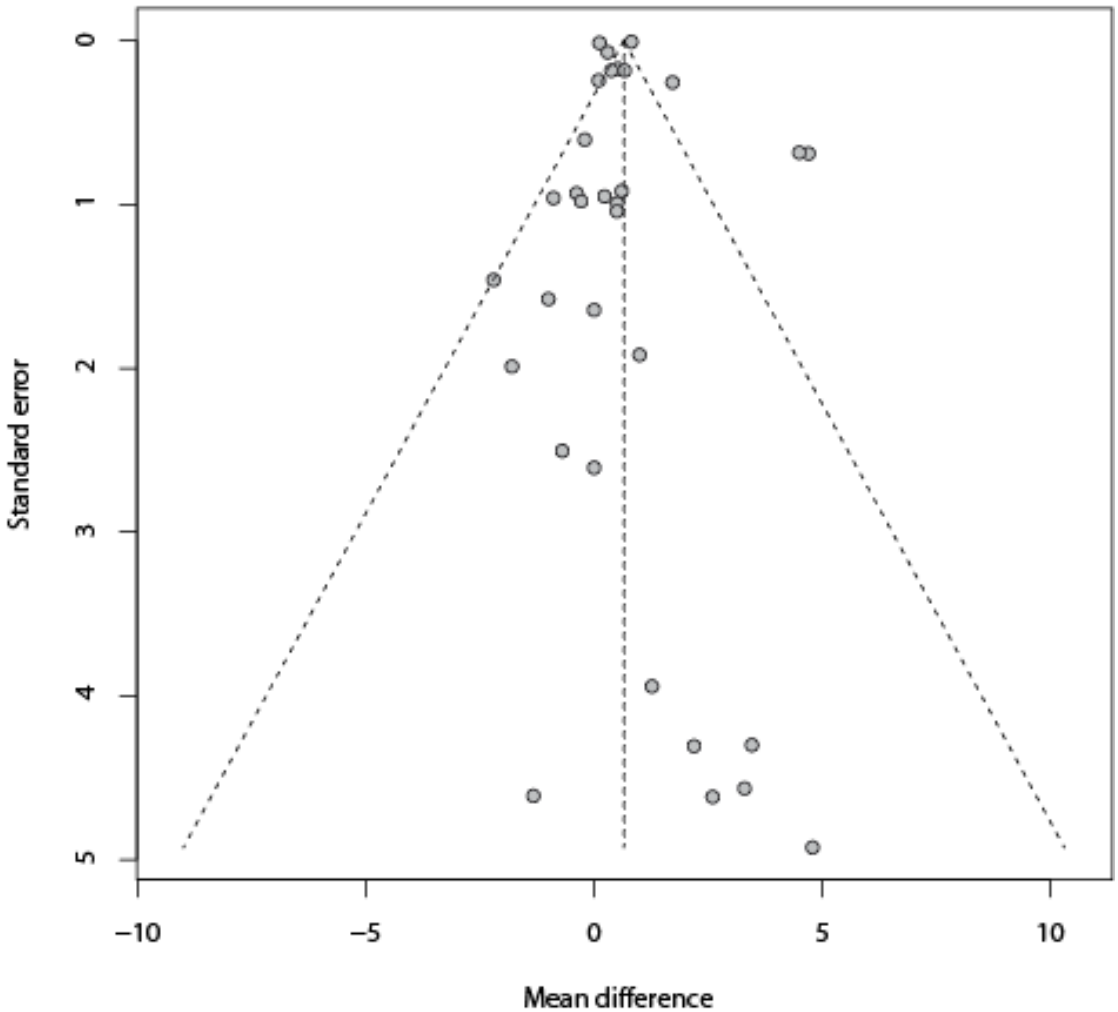


Figure 6. Patient-reported outcome measure (continuous measure).



Interpretation of results for this comparison needed to consider that findings were based on only one highly biased study.

Effects of interventions

See: **Summary of findings for the main comparison**

Primary outcome

Interventions targeting patients compared with usual care

For more details, see Table 1.

Data from six continuous PROMs in four RCTs were evaluated (Cooper 2011; Deen 2012; van Peperstraten 2010; Vodermaier 2009). Data from three studies (Cooper 2011; Deen 2012; van Peperstraten 2010) were available for re-analysis. The median of the standardized mean difference was 0.21 (range 0.04 to 0.50) indicating a small improvement for the group that received the intervention targeting patients.

Data from five categorical PROMs in four RCTs were evaluated (Krist 2007; Landrey 2012; Murray 2001; Vodermaier 2009). We calculated a 0.02 reduction in the median of the risk difference for

these outcomes (range -0.28 to -0.01) indicating no evidence of a difference for the group that received the intervention targeting patients.

Data from three continuous OBOMs in one RCT were evaluated (Haskard 2008). A unit of analysis error was observed in this study, and so we could not estimate the statistical significance of the effects reported.

Interventions targeting patients compared with other interventions targeting patients

For more details, see Table 2.

Data from six continuous PROM in two RCTs were evaluated (Deen 2012; Schroy 2011). The median standardized mean difference was 0.29 (-0.05 to 0.63), indicating a small improvement for the group that received a multifaceted patient-mediated intervention (Schroy 2011) compared to the group that received only educational material (Schroy 2011).

Data from 11 categorical PROMs in eight RCTs were evaluated (Butow 2004; Davison 1997; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Raynes-Greenow 2010; Stiggelbout 2008). We calculated a 0.04 improvement in the median of the risk difference for these outcomes (range -0.21 to 0.12) indicating no evidence of a difference between the two interventions targeting patients.

Three outcomes from three studies (Butow 2004; Lalonde 2006; Street 1995) could not be included in this analysis because of incomplete data sets. None of the authors of the three studies reported any improvement after exposure of study participants to the intervention targeting patients.

Data from two continuous OBOMs in two RCTs were evaluated (Montori 2011; Nannenga 2009). The median of the standardized mean difference was 1.13 (range 1.04 to 1.21) indicating a large improvement for the group that received a patient decision aid (Montori 2011) compared to the group that received a booklet (Montori 2011).

Interventions targeting healthcare professionals compared with usual care

For more details, see Table 3.

Data from one continuous PROM in one RCT were evaluated (Cooper 2011). The standardized mean difference was 0.11.

Data from three categorical PROMs in two RCTs were evaluated (Légaré 2012; O'Cathain 2002). The median of the risk difference was 0.05 (range 0.00 to 0.09) indicating a small improvement for the group that received the healthcare professional targeted intervention.

One outcome from one study (Bernhard 2011) could not be included in this analysis because of incomplete data sets. Study authors reported no improvement after exposure of study participants to the intervention targeting healthcare professionals.

Data from four continuous OBOMs in three RCTs were evaluated (Fossli 2011; Shepherd 2011; Stacey 2006). The median of the standardized mean difference was 1.08 (range 0.38 to 2.07) indicating a significant improvement for the group that received the intervention targeting healthcare professionals.

Interventions targeting healthcare professionals compared with interventions targeting patients

For more details, see Table 4.

Data from one continuous PROM in one RCT were evaluated comparing an intervention targeting healthcare professionals with an intervention targeting patients (Cooper 2011). The standardized mean difference was -0.12.

Interventions targeting healthcare professionals compared with other interventions targeting healthcare professionals

For more details, see Table 5.

Seven continuous PROMs in two RCTs were evaluated (Elwyn 2004; Krones 2008 (ARRIBA-Herz)). The median of the standardized mean difference was 0.20 (range -0.09 to 0.48) indicating some improvement in the group that received a multifaceted intervention (that is an educational meeting, audit and feedback, distribution of educational materials, and educational outreach visit) (Krones 2008 (ARRIBA-Herz)) compared to the group that received a single intervention (for example an educational meeting on an alternative topic) (Krones 2008 (ARRIBA-Herz)).

Data from one continuous OBOM in one RCT were evaluated (Elwyn 2004). The standardized mean difference for this study was -0.30.

Interventions targeting both patients and healthcare professionals compared with usual care

For more details, see Table 6.

Data from three continuous PROMs in three RCTs were evaluated (Cooper 2011; Hamann 2007; Wetzels 2005). Data from two studies (Cooper 2011; Hamann 2007) were available for reanalysis. The median of the standardized mean difference was 0.16 (range 0.16 to 0.16) indicating no evidence of a difference for the group that received the intervention targeting patients and healthcare professionals.

Two outcomes from two studies (Leighl 2011; Loh 2007) could not be included in this analysis because of incomplete data sets. Authors of one of these studies reported that outcomes improved after exposure of study participants to interventions targeting both patients and healthcare professionals (Loh 2007).

Data from four continuous OBOMs in two RCTs were evaluated (Haskard 2008; Hess 2012). A unit of analysis error was observed in one study (Haskard 2008) and so we could not estimate the statistical significance of the effects reported. The standardized mean difference for the other study was 2.83, indicating significant

improvement for the group that received the intervention targeting both patients and healthcare professionals.

One outcome from one study (Murray 2010) could not be included in this analysis because of incomplete data sets. Study authors reported significant improvement after exposure of study participants to an intervention targeting both patients and healthcare professionals.

Interventions targeting both patients and healthcare professionals compared with interventions targeting patients

For more details, see Table 7.

Data from five continuous PROMs were evaluated in three RCTs (Bieber 2006; Cooper 2011; Mullan 2009). The median of the standardized mean difference was 0.09 (range -0.06 to 0.73) indicating no evidence of a difference for the group that received the intervention targeting patients and healthcare professionals.

Data from two outcomes from one study (Deinzer 2009) could not be included in this analysis because of incomplete data sets. Study authors reported significant improvement for one outcome after exposure of study participants to an intervention targeting both patients and healthcare professionals.

Data from one continuous OBOM in one RCT were evaluated (Mullan 2009). The standardized mean difference was 1.42, indicating significant improvement for the group that received the intervention targeting both patients and healthcare professionals.

Interventions targeting both patients and healthcare professionals compared with interventions targeting healthcare professionals only

For more details, see Table 8.

Data from one continuous PROM in one RCT were evaluated (Cooper 2011). The standardized mean difference for this study was 0.06 indicating no evidence of a difference between groups.

One outcome from one study (Roter 2012) could not be included in this analysis because of incomplete data sets. The authors reported that outcomes improved after exposure of study participants to interventions targeting both patients and healthcare professionals.

Interventions targeting both patients and healthcare professionals compared with other interventions targeting both patients and healthcare professionals

For more details, see Table 9.

Data from one categorical OBOM in one RCT were evaluated (Myers 2011). The risk difference for this study was -0.04, indicating no evidence of a difference between the two interventions targeting both patients and healthcare professionals.

Heterogeneity

While the goal of this review was not to conduct a meta-analysis, we did briefly explore causes of heterogeneity. Given that we observed heterogeneity in comparison groups with enough studies, the positive effect found in some studies could not be explained by study characteristics only.

Secondary outcomes

Additional data were available in 'Additional tables': Table 10, Table 11, Table 12 and Table 13.

There was no significant effect detected for most secondary outcomes. No evidence of harms to patients was found following these interventions. We have present outcomes that were statistically significant; however, given that the majority of the outcomes had no effect, caution was needed in determining if the measure was relevant.

Patient health measures

Two studies reported an effect related to patient health (Elwyn 2004; van Peperstraten 2010). The Elwyn 2004 study reported two continuous measures of patient health with a small effect size. The authors nevertheless felt it was not clinically significant. A statistically significant standardized effect size of 0.25 (95% CI 0.02 to 0.49) was reported for one measure of anxiety (lower anxiety) when healthcare professionals received an SDM intervention compared to when they received a risk communication intervention. A statistically significant standardized effect size of 0.24 (95% CI 0.00 to 0.47) was also reported for one measure of mental health status when healthcare professionals received a risk communication intervention compared to when they received an SDM intervention. The van Peperstraten 2010 study reported one categorical measure of patient health with a risk difference of 0.09 (95% CI 0.02 to 0.16) for subclinical depression.

Duration of consultation

An effect related to the duration of the consultation was observed in two studies (Montori 2011; Murray 2010).

Other measurements reported by the healthcare professionals

An effect related to measures reported by the healthcare professionals was observed in five studies (Elwyn 2004; Murray 2010; Roter 2012; Stacey 2006; van Peperstraten 2010) with eight measures. Two studies (Murray 2010; Stacey 2006) showed that the knowledge of the healthcare professional was significantly higher in the intervention group than in the control group. One study (Elwyn 2004) using three measures reported that, according to the healthcare professionals, patients in the intervention group had

greater agreement with their provider, satisfaction with the decision making and overall consultation, and satisfaction with the information reported. One study (Roter 2012) using two measures reported better treatment adherence and interpersonal rapport in the intervention group. Economic evaluation was only performed in one of the studies included in this review (van Peperstraten 2010); the patient-mediated intervention effectively reduced the cost of clinical in vitro fertilization by increasing single (versus multiple) embryo transfers.

Other measurements reported by the patients

Details of these results are presented in Table 13.

DISCUSSION

Summary of main results

This updated search added 34 new studies to the five studies included in the original Cochrane review for a total of 39 studies. It should be noted that 1400 professionals were enrolled in the 39 studies, with a minimum enrolment of two (Davison 1997) and a maximum of 270 (Légaré 2012), and there were 23,236 patients overall.

The countries most represented in this review were the United States, Germany and Canada. Only two of the 39 included studies were conducted with international collaborations (Bernhard 2011; Leighl 2011). Primary care was the setting of the majority of included studies and only one study was conducted in both primary and specialized care (Deen 2012). It is noteworthy that the primary outcome of only five out of the 39 studies was the same as the primary outcome of this review, that is a measure of healthcare professionals' adoption of SDM (Dolan 2002; Elwyn 2004; Krist 2007; O'Cathain 2002; Wetzels 2005).

For categorical measures of SDM, we observed no effect.

For continuous measures of SDM, we observed three main types of results: 1) slight significant effect, 2) dose-response pattern with no conclusive effect, and 3) non-significant effect. More specifically, for studies using continuous PROMs we observed a slight significant effect in three categories of comparison: 1) interventions targeting patients compared to usual care, 2) interventions targeting patients compared to other interventions targeting patients, and 3) interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals. For studies using continuous OBOMs we observed a slight significant effect in two categories of comparisons: 1) interventions targeting patients compared to other interventions targeting patients, and 2) interventions targeting healthcare professionals compared to usual care.

We observed a non-significant effect for studies using continuous PROMs in three categories of comparison: 1) interventions targeting both patients and healthcare professionals compared to usual care, 2) interventions targeting both patients and healthcare professionals compared to interventions targeting patients alone, and 3) interventions targeting both patients and healthcare professionals compared to interventions targeting healthcare professionals alone. There was no study reporting a continuous measure of SDM for the last category of comparison, interventions targeting both patients and healthcare professionals compared to interventions targeting both patients and healthcare professionals.

There was no significant effect detected for most of the secondary outcomes either, even for outcomes that could be impacted by adoption of SDM: duration of consultation, patient's health, and cost of the intervention.

Overall, our main results lead us to make the following observations.

First, while one precise intervention cannot be recommended over another, this review suggests that SDM interventions that actively target patients, health professionals, or both, are better than no intervention at all. Also, these results suggest that interventions targeting health professionals may achieve more than interventions targeting patients when each of these single-target interventions are compared to usual care. In addition, they indicate that among interventions targeting patients some types perform better than others (for example a patient decision aid compared to a booklet (Montori 2011)). Although limited by the number of studies included in each category of comparison, our update does tell us something about whom the intervention should target. Targeting both members of the decision-making dyad (patient and healthcare professional) may be more likely to be effective than those targeting solely the healthcare professional or solely the patient. SDM represents a complex set of behaviours in which both members of the patient-healthcare professional dyad, and preferably the whole patient healthcare team, must engage (LeBlanc 2009). Future studies may consider both participants simultaneously to account for the impact of interaction, reciprocity and interdependence on the process (Guerrier 2013).

Second, among the 39 included studies only three targeted more than one type of healthcare professional, but all were positive. Although this appears promising, the lack of studies addressing the interprofessional approach is clearly a major limitation to understanding the implementation of SDM in clinical practice. Many healthcare systems are moving towards an interprofessional healthcare team-based approach to patient care that will require this approach to decision making (Légaré 2008b). An interprofessional approach to SDM is an emerging field of research (Légaré 2011) and the reporting of an interprofessional approach to SDM is not yet standardized. In this review, authors only needed to report that the intervention involved more than one type of professional to be identified as taking an interprofessional approach to SDM. Therefore, more studies are needed to inform policy makers about

the content, definition and effectiveness of an interprofessional approach to SDM.

Third, although the study of the implementation of SDM in healthcare professionals' practice is growing exponentially, we still need more international collaboration. Studies by international collaborations are starting to be published but these international collaborations do not involve low-income countries, which are still under-represented in the list of countries in which SDM is on the policy makers' agenda (Härter 2011). One international collaboration involves Australia and Canada, for example; another involves Austria, Australia, Canada, Germany, New Zealand and Switzerland. Multi-country approaches permit the sharing of expertise and experiences regarding interventions in a range of settings. It would be important to expand this valuable knowledge base by including middle- and low-income countries (International Shared Decision Making 2013). Specialized care clinical settings were also to some extent under-represented in the studies included in this updated review, with only one study targeting both primary and specialized care. However, only four studies reflected the clinical heterogeneity that is the norm in primary care by focusing on a set of diverse clinical conditions (Elwyn 2004; Haskard 2008; Stacey 2006; Wetzels 2005), indicating that research is still slow in taking this basic characteristic of primary care into account. Most studies included in this updated review focused on licensed healthcare professionals, demonstrating the need for further implementation studies involving healthcare professionals in training as well (Stacey 2009). In terms of the clinical conditions targeted in the included studies, cancer and cardiovascular diseases were the most common. Implementation studies in SDM are thus addressing the diseases that healthcare professionals are most likely to encounter in their practice; these diseases have also been identified as the two most important causes of the global burden of disease (Institute for Helath Metrics and Evaluation 2013). However, more implementation studies in the area of multi-morbidity are needed (Smith 2012).

Fourth, three of the secondary outcomes were worthy of note, but the results of the secondary outcomes must be interpreted with caution because most of the included studies did not show that the intervention had a statistically significant effect on healthcare professionals' adoption of SDM. First, the impact of SDM on length of consultations is still unclear. Second, in this review, 58 patient health measures were used to describe the impact of interventions on patient health outcomes, and all but two of these measurements (measures of anxiety and measure of mental health status) were non-significant. Lastly, an economic evaluation was undertaken in only one of the 39 studies included in this review, although this was effective and resulted in a reduction of the cost of the intervention (van Peperstraten 2010). It should be noted that no evidence of harms to patients was found following these interventions.

Quality of the evidence

Overall, when reviewing studies assessing the impact of any interventions to improve the adoption of SDM by healthcare professionals, we observed that the evidence was of low quality. First, there is still no consensus on which type of measure (OBOM or PROM) is most accurate. However, there were differences between studies based on the type of measure they used. Each kind of study used different scales to capture SDM. In OBOM studies, the most commonly used instrument was OPTION, and in PROM studies the 'perceived level of control in decision making' scale (adapted from the Control Preference Scale) was most common. As for studies not using either of these two scales there were as many instruments as studies. These findings confirm that there is still no standardized instrument for assessing the adoption of SDM by healthcare professionals. However, we observed that studies that had coded SDM behaviours into categories that matched the eight essential elements of Makoul's definition of SDM (Makoul 2006) had the most significant results, and most of these were OBOM studies. This line of inquiry needs to be pursued with a systematic analysis. Finally, it is important to highlight that in only five out of the 39 studies included in this review was the primary outcome of the study the same as the primary outcome of this review (Dolan 2002; Elwyn 2004; Krist 2007; O'Cathain 2002; Wetzels 2005), that is the adoption of SDM by healthcare professionals. This could explain the lack of positive effect in the majority of the studies. As the implementation of SDM in clinical practice was not their primary outcome of interest, they may not have been sufficiently powered to accurately assess its adoption by healthcare professionals.

Second, it is important to note that in line with the EPOC taxonomy of interventions we refer to patient-mediated interventions as single entities and we have not disentangled the effectiveness of various elements of multifaceted patient-mediated interventions. However, this information is contained in the tables. Moreover, we included a number of EPOC intervention types in the same intervention category. It would be important to consider the distinctions between EPOC intervention types in a further update that includes more studies.

In conclusion, due to the heterogeneity of interventions that were used, primary outcomes assessed, and the risks of bias that were observed, we cannot draw a robust conclusion regarding the objectives of our review, that is about the most effective types of intervention for increasing the adoption of SDM by healthcare professionals. The message of the study is nevertheless that SDM interventions that actively target patients, health professionals, or both, are better than no intervention at all. Also, it appears more promising to use interventions that target both the patient and the health professional together than those that target either the patient or the health professional alone. The overall quality of the evidence for the outcomes, assessed with the GRADE tool, ranged from low to very low.

Potential biases in the review process

We observed a potential publication bias in studies reporting a continuous OBOM measure of SDM. There appeared to be a lack of negative, continuous OBOM studies, implying that positive continuous OBOM studies might be over-represented.

The adoption of SDM by healthcare professionals translates into the performance of a number of SDM-related behaviours by both the patient and the healthcare professional (Frosch 2009; Légaré 2007a). We acknowledge that the assessment of this complex behaviour in healthcare professionals, and even more so in dyads of patients and healthcare professionals, is challenging and may suffer from many measurement biases (Butow 2009).

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

The Dwamema update (Dwamena 2012) of a Cochrane systematic review (Lewin 2001) on the effects of interventions targeting healthcare professionals that aim to promote patient-centered care approaches in clinical consultations concluded that some interventions, such as training activities, are effective across studies in transferring patient-centered skills to providers. The new finding of the Dwamema review was that short-term training (less than 10 hours) is as successful as longer training for promoting patient-centered care within clinical consultations. All the studies included in Dwamema's review that identified shared decision making as an aim of patient-centered care (Bieber 2008; Krones 2008 (ARRIBA-Herz); Loh 2007; Longo 2006) were also included in the present review, some as primary studies (Krones 2008 (ARRIBA-Herz); Loh 2007) and others as complementary studies (Bieber 2008; Longo 2006).

Our review sought studies on all the types of intervention suggested by the EPOC taxonomy, including patient-mediated interventions, while the Dwamema review focused solely on interventions targeting healthcare professionals in training. We believe that together the reviews add to the knowledge base and can inform policy makers on important implementation strategies regarding SDM in healthcare professionals' practices.

We also identified a recently published Cochrane review on the effects of interventions to promote SDM with children aged four to 18 years who are suffering from cancer (Coyne 2011). This review did not find any eligible studies.

Finally, the idea that effective interventions for changing clinical practice must target patients as well as healthcare professionals is gaining interest outside the SDM community. A recent systematic review on factors that differentiate between effective and ineffective computerized clinical decision support systems in improving the process of care or improving patient outcomes indicated that the likelihood of success was greater with systems that provided advice to patients and practitioners concurrently (Roshanov 2013).

AUTHORS' CONCLUSIONS

Implications for practice

The results of this Cochrane review do not allow us to draw firm conclusions regarding the types of intervention that are the most effective for increasing healthcare professionals' adoption of SDM across multiple studies. It is uncertain whether interventions aiming to improve adoption of SDM lead to better uptake given the low quality of the evidence. However, SDM interventions that actively target patients, health professionals, or both, are better than no intervention at all. Also, interventions targeting patients and healthcare professional together may be more promising than those targeting only one or the other. However, there were not enough studies (only two) to confirm this.

Implications for research

Several gaps in knowledge exist regarding the effectiveness of interventions focused on improving healthcare professionals' adoption of SDM.

- Future studies should be designed to minimize bias and should have enough power to estimate the effects of active interventions on healthcare professionals' adoption of SDM (primary outcome).
- Further research is needed to develop better patient-derived measures of SDM.
- Further research is required to assess the same intervention across multiple studies and also across diverse jurisdictions (i.e. international collaborations).
- Future research should assess the effect of interventions that target both the patient and the healthcare professional to confirm this result (only two studies at present).
- Further research is required to determine more clearly the effectiveness and the cost of interventions to improve healthcare professionals' adoption of SDM.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Bernhard 2011

Methods	**Study design**: Clinician RCT **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 gynaecological oncologists) ; Fully trained **Patients**: 694; Breast cancer; Female **Recruitment information** "Medical, surgical, radiation and gynaecological oncologists, working in major cancer centres or clinics (including private oncologists) , ... were eligible. The following patient criteria were additionally required: ... capable of participating." Page 2
Interventions	**1. Multifaceted intervention:** Educational meeting, audit and feedback, distribution of educational materials (interactive face-to face workshop and two follow-up telephone calls) "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 2 **2. Usual care (control):** No training workshop "Following baseline assessment and before the scheduled training workshop, they were randomly assigned to ... or control (no training workshop) group" Page 2
Outcomes	Patient involvement preference and actual involvement; Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information:** 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
Allocation concealment (selection bias)	Unclear risk	Method of randomisation not specified in paper

Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	Low risk	See flow-chart, Page 4
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"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 2
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Unclear risk	Not specified in paper

Bieber 2006

Methods	**Study design**: Patient RCT **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 **Recruitment data**: "All patients applying for a first consultation in the outpatient clinic with the main complaint of musculoskeletal pain were asked to participate in the study. When they gave informed consent they were randomised either to the SDM group or the information group. After confirmation of the diagnosis they were included in the study" Page 358

Interventions	**1. 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 **2. 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**
Allocation concealment (selection bias)	Unclear risk	Unit of allocation is not described explicitly in the paper. Patients were randomised but the method was unspecified
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	"Patients were informed on the intervention but they were blinded to the fact in which group they were being treated" Page 359
Follow-up of professionals?	Unclear risk	NA Patient unit of allocation
Follow-up of patients?	Unclear risk	For the scored measured, there were no reported number on those who participated in the trial
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Baseline measurements for the FAPI are not reported, nor were they measured
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome

Protection against contamination?	High risk	It was the patients and not the professionals who were randomised

Butow 2004

Methods	**Study design**: Patient-RCT **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 **Recruitment data**: "Consecutive patients with heterogeneous cancers attending an initial consultation with either of two medical or two radiation oncologists at a University of Sydney teaching hospital outpatient clinic were invited to participate." Page 4402 "A research nurse telephoned eligible patients to inform them of the study and invite their participation. Patients were informed that they would be offered a copy of the audiotape after their consultation. The research nurse assigned an identification to consenting patients, determined random assignment, and sent the appropriate package with a consent form at least 48 hours before the first consultation. Physicians were blinded to which package the patient received." Page 4403
Interventions	**1. 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 **2. 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	"Physician encouragement of patient participation in the consultation and decision making process" 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**
Allocation concealment (selection bias)	Unclear risk	Allocation concealment is not described explicitly in the paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Not specified in the paper
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA - Patient-reported outcome, professionals were not followed up
Follow-up of patients?	Low risk	There were 164 participating patients "A total of 160 audible consultation audiotapes were available for verbatim transcription and coding" Page 4404
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Low risk	No differences in preference before the consultation, page 4406
Reliable primary outcome? All outcomes	High risk	"Each coder coded 10% of the others' consultations and recorded 10% of their own. Inter- and intra-rater reliability as measured by the statistic were good (0.69 and 0.67, respectively)." Page 4404
Protection against contamination?	High risk	One of the outcomes is patient reported and the intervention is patient allocated. Consequently patients could discuss the intervention amongst themselves

Cooper 2011

Methods	**Study design**: RCT (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 **Recruitment information** **"**Physicians recruited for the Patient-Physician Partnership Study were general internists and family physicians who saw patients 02at least 20 hours per week at one of the participating study sites." Page 1298
Interventions	**Four arms:** **1. Patient-mediated intervention**, educational meeting (Physician communication skills training and patient coaching by community health workers) **2. Educational meeting:** Physician communication skills training **3**. **Patient-mediated intervention**: patient coaching by community health workers **4**. **Patient and physician minimal intervention:** (control) "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 "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**
Allocation concealment (selection bias)	Unclear risk	"The Patient-Physician Partnership Study was a randomised controlled trial, with a two-by-two factorial design. Physicians and patients were randomised with equal probability to minimal or intensive interventions"
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome

Cooper 2011 (*Continued*)

Blinding (performance bias and detection bias) Participant-reported outcome	High risk	"Due to the nature of the interventions, complete masking of participants, investigators, and CHWs was not possible" Page 1299
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	High risk	Table 4: Process measures at baseline and change at 12 month follow-up by intervention group
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	Table 4: Process measures at baseline and change at 12 month follow-up by intervention group
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Unclear risk	Not specified in paper

Davison 1997

Methods	**Study design**: Patient RCT **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 **Recruitment data**: "A consecutive sample of 60 men newly diagnosed with prostate cancer was recruited from one Winnipeg community clinic" Page 189
Interventions	**1. 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 **2. Single intervention** (control); patient-mediated intervention (information package) A list of questions, also found in the empowerment session
Outcomes	Perceived level of control in the decision-making process (categorical); joint process between healthcare professionals and patients to make decisions

Davison 1997 (*Continued*)

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**
Allocation concealment (selection bias)	Unclear risk	Randomisation method was not specified in the text
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Patient-mediated intervention and patient reported the outcome, so the patient was not really blind
Follow-up of professionals?	Unclear risk	NA patients unit of allocation
Follow-up of patients?	Low risk	"All men who were approached by the investigator agreed to participate in the study, but one 80 year old man refused to complete the second set of questionnaires." Page 189
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"At the pre-test, no significant differences were found between the role preference of the two groups (Chi^2 = 4.365, P = 0.113) " Page 194
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	The patients in the study reported outcome

Deen 2012

Methods	**Study design**: Patient RCT **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 **Recruitment information:** **"**Patients aged 18 and older attending the William F. Ryan Health Center in New York City were approached ... Patients included those with scheduled appointments as well as walk-in, and those seeing their continuity provider as well as those seeing a covering primary care clinician" Page 2
Interventions	**Four arms:** 1. **Patient-mediated intervention** (Decision aid (DA) and Patient Activation (PA)) 2. **Patient-mediated intervention** (PA) 3. **Patient-mediated intervention** (DA) 4. **Control** (doctor visit) "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 2
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**
Allocation concealment (selection bias)	Unclear risk	Not reported in the paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA healthcare professionals are not described in paper
Follow-up of patients?	Unclear risk	Not specified in paper

Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"Pre and post-visit data were collected in the CHC waiting room prior to and following a physician visit." Page 2
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	It was the patients and not the professionals who were randomised

Deinzer 2009

Methods	**study design**: Controlled clinical 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 **Recruitment data**: "Forty patients were recruited by the 15 study physicians who were trained in special communication skills for SDM. Forty-six patients were recruited and allocated to the hypertension education program." Page 267
Interventions	**1. Multifaceted intervention**: educational meetings (training for physicians), patient-mediated intervention (patient education program) Training for physicians with 4 special consultations "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 **2. Single intervention**: Patient-mediated intervention (patient education program) "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 "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

Deinzer 2009 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	Method not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Observer-based outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA, unit of allocation is the patient
Follow-up of patients?	Low risk	Done, 97% of the patients were present at follow up (86 recruited, 84 analysed)
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"The degree of SDM was significantly higher in the SDM group at baseline and after 1 year visits." Page 268
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	"Physicians of control patients did not take part in such a special communication program thereby avoiding any contamination with the SDM group" Page 267

Deschamps 2004

Methods	**Study design**: Patient RCT **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 **Recruitment data**: "Women aged 48 to 52 years of age were invited to participate." Page 22

Interventions	**1. 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 **2. 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**
Allocation concealment (selection bias)	Unclear risk	The method of randomisation was not specified in the paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Patient-mediated intervention and patient reported the outcome
Follow-up of professionals?	Unclear risk	NA patient unit of allocation
Follow-up of patients?	High risk	Only 87 of the original 128 participated in the intervention, page 23
Baseline measurement? Observer-based outcome	Unclear risk	NA patient randomised controlled trial
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Dolan 2002

Methods	**Study design**: Patient RCT **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 **Recruitment data**: "Most patients were recruited from a suburban practice ... They were told that all participants would receive a $25 stipend upon completion of the study." Page 126
Interventions	**1. Single intervention**: patient-mediated intervention (preliminary phase + detailed analysis of the decision using the analytic hierarchy process (decision aid) 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 to 127) **2. Single intervention** (control): patient-mediated intervention (preliminary phase and educational phase) "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**
Allocation concealment (selection bias)	Low risk	"All randomisation schedules were created using a computer random number generator before the onset of patient enrolment." Page 126
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA patient-mediated intervention and patient-reported outcome
Follow-up of professionals?	Low risk	NA patient unit of allocation

Dolan 2002 (*Continued*)

Follow-up of patients?	Low risk	"...of the 97 patients who entered the study, 1 patient from the experimental group dropped out ... [and] another from the control group ..." Page 130
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"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
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Elwyn 2004

Methods	**Study design**: Cluster-RCT **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 **Recruitment data**: "Patients were approached by the practices for consent to participate in the study if they were known to have one of the four following conditions: non-valvular atrial fibrillation; prostatism; menorrhagia; or menopausal symptoms." Page 339 "These patients were identified from Read Codes on electronic practice databases by staff from the practices using a standard protocol, assisted by a research officer (CA)." Page 339
Interventions	**1. 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 **2. 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**
Allocation concealment (selection bias)	Low risk	"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
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"All consultation recordings were intended to be rated by two raters and ratings were undertaken blind to study group allocation of clinicians or patients." Page 340
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	"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 interventions. " Page 339

Elwyn 2004 (*Continued*)

Follow-up of professionals?	Low risk	"One doctor dropped out after the baseline phase." Page 341
Follow-up of patients?	Unclear risk	"197 patients consulted with 20 practitioners: 182 recording achieved" "95 patients consulted with 20 practitioners: 84 recordings achieved"
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	High risk	"Consistent inter-rater differences for OPTION scores were identified." Page 343
Protection against contamination?	Low risk	Unit of allocation is the provider. "Only one practitioner per practice would be recruited." Page 338

Fossli 2011

Methods	**Study design**: Clinician RCT, cross-over **Unit of allocation**: Clinician **Unit of analysis**: Clinician **Power calculation**: Done
Participants	**Setting of care**: Primary care, ambulatory care; Norway **Healthcare professionals**: 72; Various type of physician (residents, consultants, medical surgeons, neurologist, podiatrists, gynaecologist), fully trained and residents **Patients**: Not reported **Recruitment data**: "This led us to the design of an RCT with cross-over design. The participating doctors were randomised into two groups which both received the intervention, but at different points in time." Page 2
Interventions	**1. Multifaceted intervention**: educational meeting, distribution of educational materials, Audit and feedback after role-play "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 **2. 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**
Allocation concealment (selection bias)	Unclear risk	Not clear, did not specify method used
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"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
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	High risk	72 doctors were included, 51 were included in the final analysis: follow up was 70%
Follow-up of patients?	Unclear risk	NA clinicians are the unit of allocation
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	High risk	Inter-rater correlation is, for the most part less than 0.80, according to Kupart et al 2008
Protection against contamination?	Unclear risk	Not specified in paper

Hamann 2007

Methods	**Study design**: Cluster-RCT **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 **Recruitment data**: "Briefly stated, inpatients (male/female, aged 18-65 years, no exclusion criteria) with a diagnosis of schizophrenia ... were randomly included in a decision aid program or received usual care (randomizations of the wards)." Page 993
Interventions	**1. 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 **2.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 Number of patients per physician: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	Method of randomisation is not specified. Page 993
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in the paper
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	High risk	Wards are the unit of allocation and 2."... at 6 months, follow-up data on 86 patients (80%) were available; and at 18 months, follow-up on 71 patients (66%) were available" Page 994

Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	Wards were randomised, patients remained in their respective wards

Haskard 2008

Methods	**Study design**: Cluster-RCT **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/gynaecology, family medicine, internal medicine); fully trained (87) and in training (69) **Patients**: 2196; various clinical conditions; male or female **Recruitment data**: "Enrollment and informed consent to participate took place in the waiting or examining rooms as patients waited for their primary care medical appointments. Patients scheduled to see a study physician during a specific session were approached by research staff." Page 514
Interventions	1. **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 2. **Multifaceted intervention (physician only trained arm)**: educational meeting + distribution of educational materials; 20 hours See the above description for the physician intervention 3. **Single intervention (patient only trained arm)**: patient-mediated intervention; 20 minutes See the above description for the patient intervention 4. **No intervention (control)**
Outcomes	Physician-patient global rating (continuous). SDM is assessed as the fostering by health-care 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**
Allocation concealment (selection bias)	Low risk	"... physicians were randomised to one of four conditions using a computer-generated random order" Page 515
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Not specified in the paper
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Low risk	Data from 127/156 randomised professionals were analysed at the three points in time. Page 515
Follow-up of patients?	Unclear risk	NA, the unit of randomisation was the provider
Baseline measurement? Observer-based outcome	Unclear risk	Baseline measurements were not reported
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in paper

Protection against contamination?	Unclear risk	Unit of allocation is the provider and not separated by practice. Page 515

Hess 2012

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **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 **Recruitment information:** **"**Eligible patients included adults aged 17 years who presented to the ED with primary symptoms of nontraumatic chest pain and who were being considered for admission to the ED observation unit for monitoring and cardiac stress testing within 24 hours." Page 252
Interventions	**1. Multifaceted intervention:** patient-mediated intervention (one brief demonstration of the use of the decision aid) and educational meeting (one hour training session) "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 **2. 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**
Allocation concealment (selection bias)	Low risk	"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 ... Two investigators who were blinded to allocation assessed outcomes in all enrolled patients." Page 253

Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"Third investigator (H.H.T.), who was also blinded to allocation, reviewed all potentially positive outcomes. ... The principal investigator, blinded to allocation and to patient outcome, reviewed and approved all post randomisation exclusions as prespecified in the study protocol" Page 254
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Low risk	The study is a patient RCT
Follow-up of patients?	Low risk	See flow chart, page 4
Baseline measurement? Observer-based outcome	High risk	Not clear in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in paper "Two trained raters watched 30 videos independently and in duplicate to assess for interrater reliability 17 of scoring, and the remaining videos were scored by 1 of the trained raters." Page 4
Protection against contamination?	Unclear risk	Not clear in paper

Kasper 2008

Methods	**Study design**: Patient RCT **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 **Recruitment data**: "We recruited participants between October 2004 and February 2006. MS patients were alerted by advertisement in local newspapers all over Germany, on web sites and in the national self-help group journal. Patients at Hamburg university hospital were also approached personally." Page 1346

Interventions	1.**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 2. **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**
Allocation concealment (selection bias)	Low risk	"Randomization was carried out by concealed allocation using computer generated random numbers." Page 1346
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	"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
Follow-up of professionals?	Unclear risk	NA Patients are the unit of allocation
Follow-up of patients?	Low risk	Patient follow-up is 95%, page 1346
Baseline measurement? Observer-based outcome	Unclear risk	NA Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	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 Chi^2- value of 5.96, P > 0.05, page 1349

Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Krist 2007

Methods	**Study design**: Patient RCT **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 **Recruitment data**: "Between June 2002 and June 2004, two weeks before their office visit, male patients aged 50 to 70 years who scheduled a health maintenance examination were contacted by telephone." Page 1346
Interventions	1.**Single intervention**: patient-mediated intervention (mailed paper version of the decision aid) The brochure duplicated the content of the website 2. **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 3. **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**
Allocation concealment (selection bias)	Low risk	"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

Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA patient-mediated intervention and an outcome reported by patients
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	Low risk	"Questionnaires were completed by 87% of patients and 91% of physicians overall. " Page 114
Baseline measurement? Observer-based outcome	Unclear risk	NA patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Krones 2008 (ARRIBA-Herz)

Methods	**Study design**: Clinician (RCT) **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) **Recruitment information:** "Thirty CME groups comprised of 162 family doctors who were eligible and agreed to participate. ... After the completion of educational sessions, we asked participating physicians to recruit a maximum of 15 [patients]..." Page 324
Interventions	1. **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 counselling sheet), educational outreach (CME members were invited to moderate the sessions) "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 2. **Single intervention** (control): Placebo educational meeting “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**
Allocation concealment (selection bias)	Unclear risk	Method of randomisation not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	“ ... patients were unaware of their physician's group allocation” Page 219 (Krones 2008)
Follow-up of professionals?	High risk	160 physician were allocated to the intervention, 81 physicians present at follow up and all CMEs were present at follow up (the unit of allocation) Page 325 (Hirsch 2010)
Follow-up of patients?	Low risk	81% of the recruited patients were present at follow up, page.325 (Hirsch 2010)
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	High risk	“Patients' participation preference in decision making also differed significantly in the 2 study arms, which might represent a selection bias in the intervention group or an intervention effect” Page 222 (Krones 2008)

Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	The intervention was stratified in accordance to CME groups

Lalonde 2006

Methods	**Study design**: Patient RCT **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 **Recruitment data**: " A pilot study was conducted in a convenience sample of community pharmacies in Montréal .... Pharmacist received a total of Canadian $45 per patient recruited in partial compensation for their time. Pharmacist identified eligible patients and invited them to participate in the study. " Page 52
Interventions	1. **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. "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 2. **Multifacted intervention (control)**; distribution of educational materials (decision aid + personal risk assessment) + patient-mediated intervention (personal risk profile) 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**

Lalonde 2006 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	"Randomisation was stratified by community pharmacy" Page 52. Method not detailed
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA, the patient is the unit of allocation
Follow-up of patients?	Low risk	In all, 88% of the patients were included in the follow-up (described on page 54)
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Landrey 2012

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **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 **Recruitment data**: "The study was conducted in 2 general internal medicine practices affiliated with the University of Colorado Hospital. Eligible men were between 50 and 74 years old and were scheduled to have an annual health maintenance exam between October 2009 and August 2010. Men were excluded if they had a PSA test within the past 12 months, a history of prostate cancer, or any other diagnosis of cancer, terminal illness or dementia. " Page 2

Interventions	1. **Single intervention (mailed flyer),** patient-mediated intervention "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 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**
Allocation concealment (selection bias)	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	"Two research assistants blinded to group assignment collected chart outcome information by reviewing clinic notes following patient appointment" Page 2
Follow-up of professionals?	Unclear risk	NA - Patient-reported outcome and the unit of allocation is the patient
Follow-up of patients?	High risk	See flow-chart of the study, page 4
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	High risk	There was no baseline, a follow-up telephone survey consisting of 13 items was conducted within 2 weeks of the clinic visit
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Unclear risk	Not specified in paper

Leighl 2011

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Specialized care, Ambulatory care; Australia, Canada **Health professionals**: 13 oncologists; fully trained **Patients**: 207, advanced colorectal cancer; **male and female**: 120 males, 87 females **Recruitment information** **"**Outpatients who attended cancer clinics at participating centers were eligible to participate if they had a diagnosis of incurable metastatic colorectal cancer and ... Patients were excluded if they had previously received chemotherapy for metastatic colorectal cancer . ... Oncologists also provided consent to participate." Page 2079
Interventions	**1. Multifaceted intervention:** Patient-mediated intervention (decision aid), physician training (educational meeting) Decision aid: booklet with accompanying narration on an audiotape or CD "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 **2. No intervention, (control):** Standard 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**
Allocation concealment (selection bias)	Low risk	"Eligible consenting patients ... were randomly assigned to a standard medical oncology consultation or to a consultation in which the DA was reviewed and a take home patient version was provided. Randomization lists, stratified by the consulting oncologist, were computer-generated, and the code was concealed in a sealed envelope until the time of random assignment. " Page 2078
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome

Leighl 2011 (*Continued*)

Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA, the unit of allocation is the patient
Follow-up of patients?	High risk	Figure 1: consort diagram. Q1-Q, questionnaire 1-4. Page 2079
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	See table 1, page 2078
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	"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

Loh 2007

Methods	**Study design**: Cluster RCT **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 **Recruitment data**: "All accredited general practitioners in Freiburg and all general practitioners that are associated as teaching practices with the Department of Primary Care at the University Hospital of Freiburg were defined as the sampling frame and were sent a letter of invitation to participate in the study." Page 326
Interventions	1. **Multifaceted intervention**: educational meeting with physicians and patient-mediated intervention (decision aid as well as a patient information leaflet); 20 hours(educational meeting)

	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 2. **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**
Allocation concealment (selection bias)	Low risk	"...were randomly assigned by drawing blinded lots under supervisions of the principal investigator ..." Page 326
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	High risk	In all, 76% of the physicians were included in the follow up. Page 327
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	Table 2 shows not statistically significant differences between groups (P = 0.999). Page 329
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome

Protection against contamination?	High risk	Patients reported outcome

Légaré 2012

Methods	**Study design**: Cluster RCT **Unit of allocation**: Family practice teaching units **Unit of analysis**: Family physicians and patients **Power calculation**: Done
Participants	**Care setting**: Primary care (family practise), Ambulatory care Canada **Health professionals**: 270 family physician; teachers and residents; Fully trained and in training **Patients**: 712; acute respiratory infections; male and female **Recruitment information** "We finally included patients (adults and children who were accompanied by a parent or legal guardian) with a diagnosis of acute respiratory infection (e.g., bronchitis, otitis media, pharyngitis or rhinosinusitis) and for which the use of antibiotics was subsequently considered either by the patient or physician during the visit" Page E728
Interventions	**1. Multifaceted intervention:** educational meeting, distribution of educational materials (online tutorial and workshop) "DECISION+2 consisted of a 2-hour online tutorial followed by a 2-hour on-site interactive workshop" **2. Usual care (control):** "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

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Low risk	"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
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome

Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	Not clear in the paper
Follow-up of patients?	Unclear risk	NA, the unit of allocation is the cluster
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"Family physicians' intentions to engage in shared decision-making ... were recorded at baseline and again at the end of the study" Page E729
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	"To avoid contamination bias, access to the online tutorial was denied to participants in the control group during the trial" Page E728

Montori 2011

Methods	**Study design**: Patient RCT **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 **Recruitment information** **"**Eligible patients were postmenopausal women, age 50 years and more with bone mineral density levels consistent with a diagnosis of low bone mass (osteopenia) or osteoporosis, ... and had a follow-up appointment with that clinician, and who were available for a phone follow-up 6 months after randomisation." Page 550
Interventions	**1. Single intervention:** patient-mediated intervention; decision aid Osteoporosis Choice decision aid "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 **2. Other single intervention (control):**

	Usual care and booklet "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**
Allocation concealment (selection bias)	Low risk	"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 Choice decision aid)" Page 551
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"After randomisation, data collectors and data analysts were blind to allocation" Page 551
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Unclear risk	NA, the unit of allocation is the patient
Follow-up of patients?	Low risk	"All patients were followed for 6 months after the visit date, except for 7 who were lost to follow-up (decision aid, n5; control, n2)." Page 552
Baseline measurement? Observer-based outcome	High risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Low risk	"Interobserver agreement for the OPTION scale score was 0.97." Page 553

Protection against contamination?	Low risk	"Because few physicians had more than 1 patient in the study, we explored possible clinician contamination descriptively" Page 551

Mullan 2009

Methods	**Study design**: Clinician RCT **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 interprofessional (physicians, physicians assistant, nurse practitioners managing diabetes); Fully trained and residents **Patients**: 85; diabetes type 2; males and females **Recruitment data**: "Enrollment began in November 2006 and finished a year later.Weenrolled 50 clinicians from the 11 locations participating in the trial: 40 clinicians had at least 1 eligible patient and were randomised, 21 to deliver the decision aid to 48 patients and 19 to provide only usual care to 37 patients." Page 1563
Interventions	1. **Multifaceted intervention**: Patient-mediated intervention (decision aid used during the clinical encounter); and educational training (how to use decision aid) "[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 "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 2. **Single intervention (control)**: Patient-mediated intervention (decision aid) "... 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

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Low risk	"We randomised clinicians … using a computer-generated allocation sequence, unavailable to personnel enrolling patients or clinicians, randomised 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	Not specified in paper
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Low risk	No clinicians were lost to follow-up, page 1563
Follow-up of patients?	Low risk	No patiens were lost due to follow-up, page 1563
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Low risk	"Two raters watched each video in duplicate and independently until they achieved near perfect agreement (intraclass correlation for total OPTION score of 0.99), rating the remaining videos separately." Page 1563
Protection against contamination?	Unclear risk	Not specified in paper

Murray 2001

Methods	**Study design**: Patient RCT **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); United Kingdom **Health professionals**: unknown number; general practitioners; Level of training unclear **Patients**: 112; benign prostatic hypertrophy; male **Recruitment data**: "We asked participating doctors to recruit men with benign prostatic hypertrophy opportunistically ...and to refer patients to the study as soon they were confident about the diagnosis." Page 1
Interventions	1.**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 2.**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**
Allocation concealment (selection bias)	Low risk	"The randomisation schedule, stratified according to recruitment centre, was generated by computer" Page 3
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA patient unit of allocation
Follow-up of patients?	Low risk	In all, 91% patients were included in the follow up. Page 4

Baseline measurement? Observer-based outcome	Unclear risk	NA, the study has a patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported the outcome

Murray 2010

Methods	**Study design**: Clinician RCT **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 **Recruitment data**: "Participants were recruited from seven community-based organizations and three hospital-based institutions in three Ontario health networks. Flyers and announcements about the study were posted in staff locations at participating organizations." Page 114
Interventions	1. **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 "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 2. **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**
Allocation concealment (selection bias)	Low risk	"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	"DSAT10 scoring was done by one of two raters who were blinded to group assignment" Page 115
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Obsever-based outcome
Follow-up of professionals?	Low risk	In total 88 consented, 78 were included in the analysis, yielding a 88% follow-up
Follow-up of patients?	Unclear risk	NA, the clinicians are the unit of allocation
Baseline measurement? Observer-based outcome	Low risk	"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
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in paper
Protection against contamination?	Low risk	Yes, separated geographically

Myers 2011

Methods	**Study design**: Patient RCT **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 **Recruitment data**:

	”An electronic appointment scheduling system and medical records were used to identify potentially eligible men with a scheduled visit for non-acute care. These men were mailed a study invitation letter, along with instructions for opting out of the study. A study research assistant then attempted to call patients who did not opt out in order to verify eligibility, obtain verbal consent, and administer a baseline survey” Page 241
Interventions	Interventions 1.**Multifaceted intervention**: Including patient-mediated interventions (pamphlet and counselling) and reminders (prompting) “... 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 “... 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 2. **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**
Allocation concealment (selection bias)	Unclear risk	“Using a system of sealed envelopes, the nurse educator then determined the participant’s study group assignment to either [groups]” Page 241
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Unclear risk	NA Patients were the unit of allocation

Follow-up of patients?	Low risk	For the entire study, there was an over 90% follow-up, however, only 50% audio-recorded encounters; 84% of the audio recording encounters were analysed. Page 242
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in paper
Protection against contamination?	High risk	Certain patients in either the groups received their unassigned intervention. Page 242

Nannenga 2009

Methods	**Study design**: Provider-RCT (factorial 2x2 RCT) **Unit of allocation**: Provider and patient **Unit of analysis**: Patient **Power calculation**: Not done
Participants	**Setting of care**: Specialised care; Ambulatory care (clinic for diabetes at Mayo Clinic in Rochester, MN); USA **Healthcare professionals**: 16; endocrinologists; Fully trained **Patients**: 98; yype 2 diabetes; male or female **Recruitment data**: "Providers and patients were naive to this study objective and randomised by concealed central allocation to a two by two clustered factorial design to intervention from their clinician during the visit or from the researcher prior to the visit, thus creating four groups." Page 39
Interventions	1. **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 2. **Single intervention**: patient-mediated intervention (decision aid administered by researcher prior to visit) See the above description of the decision aid 3. **Single intervention (control)**: pamphlet administered by provider during visit The standard Mayo patient education pamphlet outlined guidelines for reducing hyperlipidaemia, 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 4. **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**
Allocation concealment (selection bias)	Low risk	"...randomisation by concealed central allocation..." Page 39-40
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"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
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Unclear risk	NA, the unit of allocation was the patient
Follow-up of patients?	Low risk	See, figure 1. "All patients received the allocated intervention, with one patient in the decision aid group (researcher arm) failing to complete any of the survey items" Page 40
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in the paper
Protection against contamination?	High risk	Unit of allocation is the patient

O'Cathain 2002

Methods	**Study design**: Cluster-RCT **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 **Recruitment data**: "Women were identified through hospital computer systems and the records of midwives and clerks in hospital and community antenatal clinic" in the first sample; in the second sample "Women were identified through child health computer records and hospital and home delivery registers". Questionaires were sent to all identified individuals. Page 2
Interventions	1. **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 2. **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): 10,070 Number of patients per physician: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Low risk	"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)"
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	Not specified in paper

Follow-up of patients?	Unclear risk	NA providers are the unit of allocation and the patients before the intervention are not the same as the patients after intervention
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	The difference was non significant between groups at P = 0.05 Sample 1:1.13 (0.47 to 2.74); Sample 2: 0. 99 (0.68 to 1.44)
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	Unit of randomisation was the maternity units

Raynes-Greenow 2010

Methods	**Study design**: Patient RCT **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 **Recruitment:** "Primiparous women, in their final trimester, who were planning a vaginal birth of a single infant, were eligible for the study. Primiparous women were selected because previous pregnancy has a strong impact on decision making and analgesia use in labour" Page 2
Interventions	1.**Single intervention**: Patient-mediated intervention (decision aid: booklet and audio guide) 2. **Single intervention** : Patient-mediated intervention (decision aid: booklet) The booklet was 55 pages and the audioguide 40 minutes. "Information was presented in a style that was sparse" Page 2 The content included both pharmacological and non-pharmacological analgesics 3. **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**
Allocation concealment (selection bias)	Low risk	"Treatment allocation was randomly generated by computer using random variable black sizes." Page 3
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	The intervention is patient-mediated intervention and the outcome is reported by the patient
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	High risk	In all, 76% patients were present at follow-up. Page 6
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Roter 2012

Methods	**Study design**: Patient RCT **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 **Recruitment information:** "enrolment averaged 4 patients per day. Patient enrolment was estimated to range be-

	tween 80% and 90% of patients approached but only one site formally collected statistics on refusals ... " Page 407
Interventions	**1. Multifaceted intervention:** patient-mediated intervention (decision aid); distribution of educational materials Separate interactive video glossaries demonstrating communication skills organized by the LEAPS heuristic "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 **2. Single intervention (control):** distribution of educational materials "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**
Allocation concealment (selection bias)	Unclear risk	"Some practices assigned patients to study groups on alternating days and others used a random numbering system." Page 407
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA, the unit of allocation is the patient
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"Communication behaviours were assessed at baseline and after a follow-up visit through an 18-item self-report questionnaire"

Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	The patient reported the outcome

Schroy 2011

Methods	**Study design**: Patient RCT **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 interprofessional (board-certified general internist, nurse practitioners); Fully trained **Patients**: 666; colorectal cancer screening; female and male **Recruitment**: "The vast majority of patients were recruited using an investigator-initiated "opt-out" approach in which patients due for screening were identified from monthly audits ... Two other strategies , including an investigator-initiated "opt-in" letter approach and a provider-mediated, "out-in" letter approach ..." Page 5
Interventions	1. **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) 2. **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) 3. **Single intervention (control)**: educational materials (a modified "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**
Allocation concealment (selection bias)	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome

Schroy 2011 (*Continued*)

Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not clear in the paper
Follow-up of professionals?	Unclear risk	NA, the patients are the unit of allocation
Follow-up of patients?	Low risk	In all, 100% of the patiens were included at follow-up. Page 5
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	High risk	"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
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported the outcome

Shepherd 2011

Methods	**Study design**: RCT (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 **Recruitment information** Two standardized simulated patients were used "Practicing family physicians in Sydney, Australia were identified through the Medical Directory of Australia and Divisions of General Practice (local organizations representing family physicians). Recruitment was by invitations sent directly to recipients from researchers, or through an indirect Division of General Practice mail-out (number and identities of recipients unknown to researchers)." Page 380
Interventions	**1. Single intervention:** Educational outreach visit Healthcare professional visited by an unannounced and standardized patient who asked three questions **2. 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**
Allocation concealment (selection bias)	Unclear risk	"The order of the standardized patient visits (intervention vs. control) was allocated randomly" Page 380
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"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 - specifically that this was an intervention study, nor any information about the intervention." Page 381
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	Unclear risk	NA, the patients are simulated
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not clear in the paper
Protection against contamination?	Unclear risk	Not clear in paper

Stacey 2006

Methods	**Study design**: Provider-RCT **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 hypercholesterolaemia **Recruitment data**: "Allocation was concealed until after the nurses completed their baseline simulated call. Once informed written consent was obtained, each nurse received one call from a simulated patient." Page 411
Interventions	1. **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-h online tutorial and a 3-h 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 2. **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**
Allocation concealment (selection bias)	Low risk	"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	"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
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome

Stacey 2006 (*Continued*)

Follow-up of professionals?	Low risk	Of 41 randomised nurses, 2 dropped out and 1 baseline call was not recorded due to technical errors. There was a 93% follow up rate. Page 411
Follow-up of patients?	Unclear risk	NA OBOM outcome, the patients are simulated
Baseline measurement? Observer-based outcome	Unclear risk	Baseline measures were not reported
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	High risk	"The inter-rater reliability for the quality of decision support scores was moderate (ICC = 0.66; 95% CI = 0.51-0.77)." Page 413
Protection against contamination?	Unclear risk	Unit of allocation is the provider within a province wide call centre. Page 411

Stiggelbout 2008

Methods	**Study design**: Patient RCT **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); Netherlands **Health professionals**: 15; vascular surgeon; fully trained and in training **Patients**: 113; abdominal aortic aneurysm; male and female **Recruitment data**: "Patients with an asymptomatic abdominal aneurysm of the aorta ... who either visited the outpatient clinic for the 1st time or where shown to have an expanding aneurysm at follow-up were recruited from the outpatient clinic of two teaching hospitals ..." Page 752
Interventions	1. **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 2. **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**: Number of approached patients (eligible): 136 Number of patients per physician: not reported	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	Low risk	In all, 88% of the patients are present in the follow-up
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"... 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
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Street 1995

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not done
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 oncologist, 2 radiation oncologist, 4 surgeons); Fully trained

	Patients; 60; breast cancer; female **Recruitment data**: "After orientating the patient to upcoming appointments, the nurse overviewed this project, solicited the patients' participation, and obtained informed consent." Page 2277
Interventions	1. **Single-intervention**: patient-mediated intervention (Interactive multimedia program (decision aid));15-20 minutes 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 2. **Single-intervention** (control): patient-mediated intervention (brochure (decision aid)) 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**
Allocation concealment (selection bias)	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in the paper
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper

Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

van Peperstraten 2010

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient (Client couple) **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Specialized care (fertilization clinics); Ambulatory care; Netherlands **Health professionals**: NA; nurses and staff at the fertilization clinics; Fully trained **Patients**: 308, need in vitro fertilization; Females and males (Client couple) **Recruitment information** "The criteria for inclusion were couples on the waiting list for a first in vitro fertilisation cycle ever or a first cycle after previous successful in vitro fertilisation, with the women younger than 40." Page 2
Interventions	**1. Single intervention,** patient-mediated intervention (decision aid, support call), reimbursement of fees; barriers assessment Decision Aid and reimbursement; discussion; telephone call discussion "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 **2. No intervention, usual care** (control) No intervention (usual discussion) "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**
Allocation concealment (selection bias)	Low risk	"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) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	"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
Follow-up of professionals?	Unclear risk	NA, the unit of allocation is the client couple
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	See Table 3: Decision-making outcomes at baseline and after exposure to multifaceted intervention but before start of in vitro fertilization (IVF), Page 5
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	"The elements of the strategy were sent by post, because use of the Internet or email could have made elements of the intervention available to the control group." Page 2

Vodermaier 2009

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not done
Participants	**Care setting**: Specialized care and non-ambulatory care (gynaecological department of the University of Munich-Grosshadern; Germany **Health professionals**: Unknown number; physicians; Unclear level of training **Patients**: 152; breast cancer; Female **Recruitment data**: "We recruited patients with a strong suspicion of having breast cancer from the gynaecological department of the University of Munich-Grosshadern." Page 591

Interventions	1. **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 2.**Usual care** (control)
Outcomes	1. Perceived level of control in the decision-making process (categorical); joint process between healthcare professionals and patients to make decisions 2. 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**
Allocation concealment (selection bias)	Unclear risk	"Random assignment was performed by means of numbered cards in envelopes for the intervention and the control group ..." Page 591
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper if the patients were blinded
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	High risk	This study only had 73% patient follow-up rate. Page 593
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome

Protection against contamination?	High risk	Patients reported outcome

Wetzels 2005

Methods	**Study design**: Cluster RCT **Unit of allocation**: A group of providers (a practice) **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Primary care and Ambulatory care (20 practices in south-eastern Netherlands); Netherlands **Health professionals**: 25; General practitioners, unclear level of training **Patients**: 1246; Various clinical conditions; male and female **Recruitment data**: "Recruitment of GPs occurred in May and June 2002 by mail." Page 287
Interventions	1. **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 2. **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**
Allocation concealment (selection bias)	Unclear risk	"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. An independent person, who was blinded for the practices as these were numbered, performed the allocation" Page 287
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome

Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	All GPs in one practice were assigned to an intervention by a person blinded to the study. Page 287
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	High risk	See figure 1, page 288
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	The intervention was allocated according to practices

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

Study	Reason for exclusion
Alexander 2006	The design of the study was not appropriate
Allen 2009	The study type was not appropriate. This is a one group pre/posttest quasi-experimental design
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 site, 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
Hermansen Kobulnicky 2002	Relevant data was not presented and is clearly unobtainable
Hirsch 2010	The study in this paper is already included (ARRIBA-Herz 2008)
Kopke 2009	The outcomes were not appropriate, only the active patient was reported and not the shared decision

(*Continued*)

Langewitz 1998	The outcome related to SDM is limited to a single item from observer-based multiple instrument
Leader 2012	The outcomes of the study were not appropriate
Man-Son-Hing 1999	The outcomes of the study were not appropriate
Maslin 1998	Relevant data was not presented and is clearly unobtainable
McCormack 2011	The design of the study was not appropriate. Inappropriate number of control site, less than 4
Ockhuysen-Vermey 2008	The outcomes of the study were 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 shared decision making
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 assumed or preferred
Spertus 2012	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
Whelan 2003	The outcomes of the study were not appropriate, only the active patient was reported and not the shared decision

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

Berg ongoing

Trial name or title	Can health coaching help patients with spinal stenosis make an informed treatment choice? (DEC)
Methods	Patient RCT
Participants	Patients with lumbar spinal stenosis (SS)
Interventions	Decision aid
Outcomes	Patient demographics (e.g., age, gender, and education); Understanding of SS treatment options based on a 3-time multiple choice test; decisional conflict scale (DCS); and coaching status
Starting date	

Berg ongoing (*Continued*)

Contact information	Susan Z Berg Susan.Z.Berg@hitchcock.org Center for Shared Decision Making Dartmouth-Hitchcock Medical Center Lebanon, NH 03756 Phone: (603) 650-5578/Fax: (603) 653-0668
Notes	

Brinkman ongoing

Trial name or title	Pilot Testing of Decision Aids to Improve Decision Making in ADHD Care
Methods	Pre/post open trial
Participants	Pediatricians
Interventions	Intervention to facilitate shared decision making
Outcomes	Primary outcomes included the amount of shared decision-making, parent knowledge of treatment options, parent decisional conflict, and visit duration Secondary outcomes included chart audit of attention-deficit hyperactivity disorder care in 3 months following treatment initiation and physician satisfaction with the intervention
Starting date	
Contact information	Brinkman, William (Bill) Bill.Brinkman@cchmc.org Division of General & Community Pediatrics James M. Anderson Center for Health Systems Excellence Cincinnati Children's Hospital Medical Center
Notes	

Davis ongoing

Trial name or title	Integrating Decision Aids and Enhancing Shared Decision Making in Rural Non-Academic Primary Care: The Essential Role of Practice Facilitation
Methods	Mixed method: qualitative and quantitative
Participants	Clinical staff; patients
Interventions	DA implementation project in four member clinics of the Oregon Rural Practice-based Research Network (ORPRN)
Outcomes	To identify "Best Practices"for integrating DAs in small, rural non-academic primary care clinics

Davis ongoing (*Continued*)

Starting date	
Contact information	Melinda Davis, PhD, CCRP email: davismel@ohsu.edu Research Scientist, Oregon Rural Practice-based Research Network (ORPRN) Research Assistant Professor, Department of Family Medicine Oregon Health & Science University (OHSU), Mail Code L222 3181 SW Sam Jackson Pk Rd Portland, OR 97239 phone: (503) 494-4365
Notes	

Fullwood 2013

Trial name or title	Evaluation of the WISE approach in primary care: improving outcomes in chronic conditions through effective self-management - a two-arm practice-level cluster randomised controlled trial (WISE RCT)
Methods	Two-arm practice-level cluster randomised controlled trial
Participants	Patients with Chronic obstructive pulmonary disease (COPD), diabetes or irritable bowel syndrome (IBS)
Interventions	The intervention is designed to encourage practices to adopt a structured and patient-centred approach in their routine management of long-term conditions, providing the practice with skills, resources and motivation to make changes to service delivery in line with the principles of the WISE approach. The planned approach to training combines evidence-based approaches to changing professional behaviour with approaches to 'normalise' those behaviours in current practice The training will seek to impart three core skills to primary care staff: 1. Assessment of the individual patient's needs in terms of their self-management capabilities and current illness trajectory 2. Shared decision making about the appropriate type of support based on that assessment (types include support from primary care, written information sources, generic support groups or condition specific education) 3. Facilitating patient access to support. This may involve signposting patients to various resources which relate to the assessment and shared decision making processes. The training will encompass ways health professionals can negotiate with and guide patients into more appropriate utilization of health service resources. In the case of IBS, this may also involve referral to psychological treatment services (CBT and hypnotherapy) for eligible patients (so called 'stepped up care') Training of practice staff takes place over two 3 hour sessions - the effects of the training will be determined through recording patient-level outcomes The control group will receive no training Follow-up for both arms will be at 6 months and 12 months post-intervention
Outcomes	1. Shared decision making 2. Self-efficacy 3. Empowerment 4. Health behaviour 5. Positive attitudes 6. Management options

	7. Condition-specific quality of life 8. Health-related quality of life 9. Service utilization Measured at baseline, 6 months and 12 months
Starting date	20/05/2009
Contact information	Prof David Thompson Department of Gastroenterology Clinical Sciences Building Hope Hospital Stott Lane david.thompson@manchester.ac.uk
Notes	

Goss ongoing

Trial name or title	The involvement of breast cancer patients in the informative and decisional processes during oncological consultations. The study protocol of a clinical multi-centre randomised controlled trial
Methods	Not reported in abstract
Participants	Patients with breast cancer at an early stage
Interventions	The intervention consists in the presentation of a list of relevant illness-related questions
Outcomes	The main outcome measures are: a) the number of questions asked by patients during the consultation, b) the involvement of the patient, c) patient's perceived achievement of her informative needs
Starting date	
Contact information	Claudia Goss claudia.goss@univr.it
Notes	

Köpke ongoing

Trial name or title	Patient education program on diagnosis, prognosis and early therapy for persons with early multiple sclerosis - outline and first results of a multi-centre randomised controlled trial (ISRCTN12440282)
Methods	RCT
Participants	Patients

Köpke ongoing (*Continued*)

Interventions	A patient education program to facilitate informed choice in persons with early MS (multiple sclerosis): a comprehensive 60 page information brochure and a 4-hour interactive educational program based on the current evidence about significance of prognostic factors, accuracy of diagnostic procedures and efficacy of drug therapies
Outcomes	"informed choice"after 6 months; decision autonomy, anxiety and depression and risk knowledge
Starting date	
Contact information	Sascha Köpke Nursing Research Group Institute for Social Medicine University of Lübeck Ratzeburger Allee 160 D-23538 Lübeck Germany Tel.: +49 451 500-5467 Mob.: +49 176 20270493 Fax: +49 451 500-5964 Email: sascha.koepke@uksh.de
Notes	

NCT00949611

Trial name or title	Wiser Choices in Osteoporosis Choice II: A Decision Aid for Patients and Clinicians
Methods	RCT
Participants	Patients with osteoporosis or osteopenia or fragility fractures
Interventions	FRAX (Fracture Risk Assessment Tool) and a Decision Aid FRAX estimated fracture risk
Outcomes	Primary outcomes: Medication start/stop, knowledge, and patient involvement
Starting date	Mai 2009
Contact information	Victor Montori Montori.Victor@mayo.edu Annie LeBlanc Mayo Clinic | 200 First Street SW | Rochester MN | 55905 Tel.507.293.0175 Fax.507.538.0850 LeBlanc.Annie@mayo.edu
Notes	

NCT00955188

Trial name or title	Computer-Based Tailored or Standard Information for Colorectal Cancer Screening
Methods	Observational model: case-only
Participants	Patients with colorectal cancer
Interventions	Computer-assisted intervention; educational intervention; medical chart review
Outcomes	Secondary outcomes: Elements of informed decision making; Knowledge about screening options ; Decisional conflict and satisfaction; Intention to get screened
Starting date	August 2004
Contact information	Sarah T Hawley Associate Professor Division of General Medicine, University of Michigan Ann Arbor VA Medical Center sarahawl@med.umich.edu
Notes	

NCT01484665

Trial name or title	Evaluating the Effect of a Decision Aid on Shared Decision Making for Prostate Cancer Screening
Methods	Intervention model: single group assignment
Participants	Patients with prostate cancer
Interventions	PROCASE Decision-Aid
Outcomes	Primary outcome: Provider satisfaction with implementation of the shared decision making process; Secondary outcomes: Patient satisfaction with shared decision making and reach of the intervention
Starting date	December 2011
Contact information	Christopher A Warlick Department of Urologic Surgery University of Minnesota MMC 394 420 Delaware St. S.E. Minneapolis, MN 55455 Ph: 612-625-7486 Fax: 612-626-0428 email: cwarlick@umn.edu
Notes	

NCT01492257

Trial name or title	Shared Decision Making in Patients With Osteoarthritis of the Hip and Knee (SDM)
Methods	RCT
Participants	Patients with hip osteoarthritis and/or knee osteoarthritis
Interventions	Shared decision making intervention: Digital video discs and booklets produced by the Foundation for Informed Medical Decision Making and Health Dialog; a question-prompting phone call with a trained health coach; audio-recordings of the patient-surgeon consultation; and a copy of the surgeon's dictated note
Outcomes	Primary outcome: Stage of decision making
Starting date	July 2011
Contact information	Kevin J Bozic William R. Murray Professor and Vice Chair UCSF Department of Orthopaedic Surgery kevin.bozic@ucsf.edu
Notes	

NCT01606930

Trial name or title	A Pilot Study to Improve Patient-Doctor Communication
Methods	RCT
Participants	Patients with common chronic illnesses: hyperlipidemia, chronic obstructive pulmonary disease, asthma, congestive heart failure, chronic pain, ischemic heart disease, osteoarthritis, depression, back pain, chronic headaches, or diabetes
Interventions	Patient Activation Tool: The instrument is completed before the scheduled appointment and is designed to prompt patients to reflect on their specific goals for the medical encounter, prioritise those goals, and to "Prime" them to engage in a discussion centered on their concerns and expectations. In addition, participants will be encouraged to bring this form into their physician visit and use it to engage their clinician in a discussion about their health needs
Outcomes	Primary outcome: Degree of shared medical decision-making assessed from transcribed audio-tapes of the doctor-patient encounter using Roter Interaction Analysis System (RIAS)
Starting date	November 2010
Contact information	Patrick G O'Malley MD, MPH Division Director, General Internal Medicine Professor of Medicine and Biomedical Informatics Uniformed Services University, Bethesda, MD patrick.omalley@usuhs.edu

NCT01606930 (*Continued*)

Notes	

Omer ongoing

Trial name or title	Personalized decision support for breast cancer prevention
Methods	Patient RCT
Participants	Women aged 40-65 years with no history of breast cancer
Interventions	Decision aid: a web-based tool that provides automated risk assessment and personalized decision support designed for collaborative use between patients and clinicians
Outcomes	Visit duration; patient acceptability and clinician satisfaction
Starting date	
Contact information	Elissa Ozanne elissa.ozanne@ucsfmedctr.org
Notes	

Quinn ongoing

Trial name or title	Factors in informed decision making in hepatitis C testing (DEC)
Methods	Study design not reported in the abstract
Participants	Patients
Interventions	Baseline survey, session with a health educator to review a study-specific booklet and underwent decision counselling
Outcomes	Patient's preferences for or against testing
Starting date	
Contact information	Amy Leader Amy.Leader@jefferson.edu
Notes	

Ruud ongoing

Trial name or title	Conducting a multi-site cluster-randomised practical trial of decision aids: lessons learned
Methods	RCT
Participants	Patients
Interventions	Diabetes medication decision aids
Outcomes	Estimate of the impact of patient decision aids versus usual care on measures of patient involvement in decision making and diabetes control
Starting date	
Contact information	Kari Ruud Knowledge & Evaluation Research Unit Phone: 507-266-9822 ruud.kari@mayo.edu Mayo Clinic, 200 First Street S.W. , Rochester, MN 55905
Notes	

Sanders ongoing

Trial name or title	Training general practitioners in enforcing patients' own expectations in order to maximize health benefits: observed effects on communication in consultations
Methods	RCT in general practice
Participants	GPs and patients
Interventions	A training course to use SDM and positive reinforcement (PR) in a situation of clinical equipoise (non-chronic low back pain) consisting of two training session of 2½ hours and feedback on videotaped consultations
Outcomes	Trained behaviours were systematically observed using an adopted OPTION-scale added with global measurement for patient participation
Starting date	
Contact information	Ariette Sanders ev van Lennep A.R.J.Sanders-vanLennep@umcutrecht.nl
Notes	

Schrijvers ongoing

Trial name or title	Implementation and evaluation of a web-based decision aid in the decision making process of newly diagnosed patients with localized prostate cancer
Methods	Not reported in the abstract
Participants	Newly diagnosed patients with localized prostate cancer, their partners and health care professionals
Interventions	Web-based decision aid: information on the prostate, prostate cancer, the various treatment options and the probability of side effects
Outcomes	Quantity and quality of the information; the impact of the decision aid on the consultation, on the shared decision making process and on the treatment choice
Starting date	
Contact information	Jessie Schrijvers Jessie.Schrijvers@med.kuleuven.be
Notes	

Shah ongoing

Trial name or title	Use of a Decision Aid for Patients Hospitalized with Acute Myocardial Infarction (AMI). A randomised controlled trial
Methods	RCT
Participants	Patients
Interventions	The AMI Choice Decision Aid
Outcomes	Knowledge transfer, decisional conflict, patient involvement in the decision-making process (OPTION scale) , adherence to medications at 6 months, readmissions, and death
Starting date	
Contact information	Nilay Shah shah.nilay@mayo.edu
Notes	

Thompson ongoing

Trial name or title	Cluster-randomised trial of a suite of decision aids for women in pregnancy
Methods	
Participants	
Interventions	Decision aids for pregnancy and birth
Outcomes	Identify effective methods of promoting shared decision making between maternity care consumers and their care providers
Starting date	
Contact information	Rachel L Thompson Rachel.L.Thompson@dartmouth.edu
Notes	

Tinsel ongoing

Trial name or title	Association between patient rated amount of participation in Decision-Making and clinical outcome in patients with hypertension in General Practice
Methods	Cluster-RCT (the present study by analyse baseline data of a RCT, WHO Clinical Trials Registry DRKS00000125)
Participants	Patients and GPs
Interventions	Not reported in abstract
Outcomes	Primary outcomes were optimisation of blood pressure level and enhancement of patients' participation
Starting date	
Contact information	Iris Tinsel UNIVERSITAETSKLINIKUM FREIBURGLehrbereich AllgemeinmedizinSchwerpunkt Forschung Elsässerstr 2m 79110 Freiburg Tel +49 761 270-77920 / Fax -77900 iris.tinsel@uniklinik-freiburg.de
Notes	

Wills ongoing

Trial name or title	Validation of the Shared Decision Making Questionnaire-9 (SDM-Q-9) in a Stratified Age-Proportionate U. S. Sample
Methods	A stratified (race, ethnicity, gender) randomly-selected age-proportionate national sample of adults aged 21-70 years was recruited from the National Institutes of Health ResearchMatch research volunteer registry
Participants	Adults aged 21-70 years
Interventions	No intervention
Outcomes	The SDM-Q-9, other decision-making measures (Satisfaction With Decision scale,the Decisional Conflict Scale), sociodemographic and health conditions questionnaires
Starting date	
Contact information	Celia E Wills, PhD, RN The Ohio State University College of Nursing 384 Newton Hall 1585 Neil Avenue Columbus, OH 43210 (614) 292-4524 or (800) 678-6348 wills.120@osu.edu
Notes	

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Effect of interventions: Intervention targeting patients compared to usual care

Observer-based outcome measure - Continous Data									
Study	**Intervention**	**Control**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Haskard 2008	Patient mediated intervention (n=67)	Usual Care (n=80)	Physician informative and participatory	NA	-0,04 (0, 36)	NA	0,09 (0, 38)	Unit of error analysis	
Haskard 2008	Patient mediated intervention (n=67)	Usual Care (n=80)	Patient active	NA	0,00 (0, 30)	NA	0,05 (0, 35)	Unit of error analysis	
Haskard 2008	Patient mediated intervention (n=67)	Usual Care (n=80)	Physician-patient interaction	NA	-0,01 (0, 43)	NA	0,03 (0, 46)	Unit of error analysis	
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Control**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Control**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									

Table 1. Effect of interventions: Intervention targeting patients compared to usual care (*Continued*)

Study	Intervention	Control	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Deen 2012	Patient mediated intervention (Decision aid) (n=69)	Usual Care (n=69)	Patient Activation Measure (PAM)	41,78 (5, 42)	43,68 (5, 28)	42,21 (5, 22)	44,06 (5, 66)	-0,07 (-0, 40 to 0,26)	0,04 (-0, 07 to 0,09)
Deen 2012	Patient mediated intervention (Patient Activation) (n=73)	Usual Care (n=69)	Patient Activation Measure (PAM)	42,31 (6, 35)	44,57 (6, 16)	42,21 (5, 22)	44,06 (5, 66)	0,09 (-0, 24 to 0,41)	
Deen 2012	Patient mediated intervention (Decision aid + Patient Activation) (n=68)	Usual Care (n=69)	Patient Activation Measure (PAM)	41,67 (5, 68)	44,29 (5, 47)	42,21 (5, 22)	44,06 (5, 66)	0,04 (-0, 29 to 0,38)	
van Peperstraten 2010	Patient mediated intervention (n=124)	Usual Care (n=128)	Decision Evaluation scale	NA	4,1 (0,56)	NA	3,8 (0,57)	0,50 (0,25 to 0,75)	
Vodermaier 2009	Patient mediated intervention	Usual Care	Man-Son-Hing Instrument	No data					
Cooper 2011	Patient mediated intervention (n=40)	Usual Care (n=43)	Participatory Decision making (PDM)	70,94 (24, 67)	74,17 (23, 25)	74,61 (21, 59)	69,38 (21, 50)	0,21 (-0, 22 to 0,64)	
Patient reported outcome measure - Categorical Data									

Table 1. Effect of interventions: Intervention targeting patients compared to usual care *(Continued)*

Study	Intervention	Control	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
Krist 2007	Patient mediated intervention (Decision aid brochure) (n=174)	Usual Care (n=63)	Modified Control Preference Scale	NA	63/174	NA	23/63	0,00 (-0,14 to 0,14)	-0,01 (-0,01 to 0,00)
Krist 2007	Patient mediated intervention (Decision aid web) (n=198)	Usual Care (n=63)	Modified Control Preference Scale	NA	71/198	NA	23/63	-0,01 (-0,14 to 0,13)	
Landrey 2012	Patient mediated intervention (n=74)	Usual Care (n=78)	Modified Control Preference Scale	NA	29/74	NA	33/78	-0,03 (-0,19 to 0,12)	-0,03
Murray 2001	Patient mediated intervention (n=57)	Usual Care (n=48)	Modified Control Preference Scale	NA	34/57	NA	42/48	-0,28 (-0,44 to -0,12)	-0,28
Vodermaier 2009	Patient mediated intervention (n=53)	Usual Care (n=54)	Modified Control Preference Scale	NA	35/53	NA	36/54	-0,01 (-0,19 to 0,17)	-0,01

Patient reported outcome measure - Qualitative statement

Study	Intervention	Control	Outcome	Qualitative quote
No study				

Table 2. Effect of interventions: Intervention targeting patients compared to another intervention targeting patients

Observer-based outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Montori 2011	Patient mediated intervention (n=52)	Patient mediated intervention (n=48)	OPTION	NA	49,80 (21, 40)	NA	27,30 (14, 70)	1,21 (0,78 to 1,64)	1,21
Nannenga 2009	Patient mediated intervention (n=48)	Patient mediated intervention (n=43)	OPTION	NA	7,13 (6, 63)	NA	1,74 (2. 53)	1,04 (0,60 to 1,48)	1,04
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Deen 2012	Patient mediated intervention (Decision aid) (n=69)	Patient mediated intervention (Patient Activation) (n=73)	Patient Activation Measure (PAM)	41,78 (5, 42)	43,68 (5, 28)	42,31 (6, 35)	44,57 (6, 16)	-0,15 (-0, 48 to 0,18)	-0,05 (-0, 15 to 0,11)
Deen 2012	Patient mediated intervention (Decision aid + Patient Activation)	Patient mediated intervention (Patient Activation) (n=73)	Patient Activation Measure (PAM)	41,67 (5, 68)	44,29 (5, 47)	42,31 (6, 35)	44,57 (6, 16)	-0,05 (-0, 38 to 0,28)	

Table 2. Effect of interventions: Intervention targeting patients compared to another intervention targeting patients (*Continued*)

	(n=68)								
Deen 2012	Patient mediated intervention (Decision aid + Patient Activation) (n=68)	Patient mediated intervention (Decision aid) (n=69)	Patient Activation Measure (PAM)	41,67 (5, 68)	44,29 (5, 47)	41,78 (5, 42)	43,68 (5, 28)	0,11 (-0, 22 to 0,45)	
Schroy 2011	Patient mediated intervention (Decision aid) (n=205)	Patient mediated intervention (Educational material) (n=217)	Satisfaction with the decision making process	NA	50,70 (6, 20)	NA	46,00 (7, 90)	0,66 (0,46 to 0,85)	0,63 (-0, 03 to 0,66)
Schroy 2011	Patient mediated intervention (Decision aid + YDR) (n=214)	Patient mediated intervention (Educational material) (n=217)	Satisfaction with the decision making process	NA	50,50 (6, 20)	NA	46,00 (7, 90)	0,63 (0,44 to 0,83)	
Schroy 2011	Patient mediated intervention (Decision aid + YDR) (n=214)	Patient mediated intervention (Decision aid) (n=205)	Satisfaction with the decision making process	NA	50,50 (6, 20)	NA	50,70 (6, 20)	-0,03 (-0, 22 to 0,16)	
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
Butow 2004	Patient mediated intervention	Patient mediated intervention	Modified Control Preference Scale	NA	22/69	NA	17/62	0,04 (-0, 11 to 0,20)	0,04

Table 2. Effect of interventions: Intervention targeting patients compared to another intervention targeting patients (*Continued*)

	(n=69)	(n=62)							
Davison 1997	Patient mediated intervention (n=30)	Patient mediated intervention (n=30)	Modified Control Preference Scale	NA	10/30	NA	15/30	-0,17 (-0,41 to 0,08)	-0,17
Deschamps 2004	Patient mediated intervention (n=42)	Patient mediated intervention (n=48)	Modified Control Preference Scale	NA	24/42	NA	22/48	0,11 (-0,09 to 0,32)	0,11
Dolan 2002	Patient mediated intervention (n=43)	Patient mediated intervention (n=43)	Modified Control Preference Scale	NA	27/43	NA	22/43	0,12 (-0,09 to 0,32)	0,12
Kasper 2008	Patient mediated intervention (n=136)	Patient mediated intervention (n=142)	Modified Control Preference Scale	NA	55/136	NA	53/142	0,03 (-0,20 to 0,27)	0,03
Krist 2007	Patient mediated intervention (Decision aid web) (n=198)	Patient mediated intervention (Decision aid brochure) (n=174)	Modified Control Preference Scale	NA	71/198	NA	63/174	0,00 (-0,10 to 0,09)	0
Raynes-Greenow 2010	Patient mediated intervention (Decision Aid (Audio)) (n=176)	Pamphlet (n=175)	Modified CPS - First Follow-up	NA	39/176	NA	31/175	0,04 (-0,04 to 0,13)	0,04 (0,04 to 0,07)
Raynes-Greenow 2010	Patient mediated intervention (De-	Pamphlet (n=175)	Modified CPS - First Follow-up	NA	37/168	NA	31/175	0,04 (-0,04 to 0,13)	

Table 2. Effect of interventions: Intervention targeting patients compared to another intervention targeting patients (*Continued*)

	cision aid) (n=168)								
Raynes-Greenow 2010	Patient mediated intervention (Decision Aid (Audio)) (n=141)	Pamphlet (n=136)	Modified CPS - Second Follow-up	NA	26/141	NA	19/136	0,04 (-0,04 to 0,13)	
Raynes-Greenow 2010	Patient mediated intervention (Decision aid) (n=150)	Pamphlet (n=136)	Modified CPS - Second Follow-up	NA	31/150	NA	19/136	0,07 (-0,02 to 0,13)	
Stiggelbout 2008	Patient mediated intervention (n=31)	Patient mediated intervention (n=33)	Modified Control Preference Scale	NA	16/31	NA	24/33	-0,21 (-0,44 to 0.02)	-0,21

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
Lalonde 2006	Patient mediated intervention	Patient mediated intervention	Decision satisfaction inventory	No statistically significant differences in patient satisfaction with the decision-making process were detected between the study groups. Page 55
Street 1995	Patient mediated intervention	Patient mediated intervention	Perceived Decision Control Instrument	The experimental manipulation (computer program versus brochure) had very little effect on the dependent variables. Page 2280
Butow 2004	Patient mediated intervention	Patient mediated intervention	Physician behaviours facilitating patient involvement	On average, oncologists demonstrated about 7.5 of the 12 behaviours, with no significant differences between the groups (cancer consiltation preparation package (CCPP) versus control booklet). Page 4406

Table 3. Effect of interventions: Intervention targeting healthcare professionals compared to usual care

Observer-based outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Fossli 2011	Educational meeting, audit and feedback, distribution of educational material (n=26)	Usual Care (n=25)	Fours Habits Coding Scheme (4HCS)	59,66 (8, 78)	63,57 (11, 96)	60,87 (11, 08)	58,85 (12, 19)	0,38 (-0, 17 to 0,94)	0,38
Shepherd 2011	Educational outreach visit (n=18)	Usual Care (n=18)	Assessing Communication about Evidence and Patient Preferences (ACEPP)	NA	21,30 (3, 58)	NA	16,70 (3, 63)	0,90 (0,21 to 1,58)	1,08 (0,90 to 1,25)
Shepherd 2011	Educational outreach visit (n=18)	Usual Care (n=18)	OPTION	NA	36,60 (12, 62)	NA	25,00 (12, 72)	1,25 (0,53 to 1,97)	
Stacey 2006	Distribution of educational materials, educational meeting, audit and feedback and barriers assessment (n= 18)	Usual Care (n=20)	Decision Support Analysis Tool (DSAT)	0,53 (0, 18)	0,81 (0, 17)	0,43 (0, 17)	0,44 (0, 18)	2,07 (1,26 to 2,87)	2,07
Observer-based outcome measure - Categorical Data									

Table 3. Effect of interventions: Intervention targeting healthcare professionals compared to usual care (*Continued*)

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Cooper 2011	Educational meeting (n=51)	Usual Care (n=43)	Participatory Decision making (PDM)	68,46 (22, 81)	71,57 (19, 94)	74,61 (21, 59)	69,38 (21, 50)	0,11 (-0, 30 to 0,51)	0,11
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
Légaré 2012	Educational meeting and distribution of educational material (n= 176)	Usual Care	Modified Control Preference Scale (n=177)	71/182	79/176	59/171	64/177	0,09 (-0, 01 to 0,19)	0,09
O'Cathain 2002	Educational meeting and distribution of educational material (Pre:	Usual Care	Modified Control Preference Scale (antenatal sample) (Pre: n= 1219; Post:	345/1526	263/1531	287/1219	235/1206	-0,02 (-0, 05 to 0,01)	0,00 (-0, 02 to 0,02)

Table 3. Effect of interventions: Intervention targeting healthcare professionals compared to usual care (*Continued*)

	n= 1526; Post: n=1531)		n=1206)						
O'Cathain 2002	Educational meeting and distribution of educational material (Pre: n= 1490; Post: n=1515)	Usual Care	Modified Control Preference Scale (postnatal sample) (Pre: n= 1666; Post: n=1698)	369/1490	354/1515	426/1666	358/1698	0,02 (-0, 01 to 0,05)	

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative 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

Table 4. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting patients

Observer-based outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
No study									

Observer-based outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study

Table 4. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting patients (*Continued*)

No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Cooper 2011	Educational meeting	Patient mediated intervention (n=51)	Participatory Decision making (PDM) (n=40)	68,46 (22, 81)	71,57 (19, 94)	70,94 (24, 67)	74,17 (23, 25)	-0,12 (-0, 53 to 0,29)	-0,12
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									

Table 5. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting healthcare professionals

Observer-based outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**

Table 5. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting healthcare professionals (*Continued*)

Elwyn 2004	Educational Meeting and Audit and feedback (n=9)	Educational Meeting and Audit and feedback (n=11)	OPTION	27,00 (14,00)	39,00 (11,80)	32,00 (13,80)	43,00 (13,60)	-0,30 (-1,19 to 0,59)	-0,3
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Elwyn 2004	Educational Meeting and Audit and feedback (Pre: n=79; Post: n=139)	Educational Meeting and Audit and feedback (Pre: n=108; Post: n=188)	COMRADE (communication) - Time 1	63,50 (18,60)	67,30 (14,10)	66,30 (13,50)	68,30 (14,10)	-0,07 (-0,29 to 0,15)	-0,09 (-0,18 to 0,05)
Elwyn 2004	Educational Meeting and Audit and feedback (Pre: n=69; Post: n=121)	Educational Meeting and Audit and feedback (Pre: n=94; Post: n=169)	COMRADE (communication) - Time 2	62,10 (18,10)	62,40 (17,00)	63,30 (16,20)	64,20 (16,30)	-0,11 (-0,34 to 0,13)	

Table 5. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting healthcare professionals (*Continued*)

Elwyn 2004	Educational Meeting and Audit and feedback (Pre: n=79; Post: n= 139)	Educational Meeting and Audit and feedback (Pre: n= 108; Post: n=188)	COMRADE (confidence) - Time 1	72,00 (9, 90)	74,20 (9, 40)	72,00 (9, 80)	73,70 (9, 20)	0,05 (-0, 17 to 0,27)	
Elwyn 2004	Educational Meeting and Audit and feedback (Pre: n=69; Post: n= 121)	Educational Meeting and Audit and feedback (Pre: n=94; Post: n= 169)	COMRADE (confidence) - Time 2	70,00 (10, 80)	70,00 (13, 10)	71,80 (9, 30)	72,20 (11, 00)	-0,18 (-0, 42 to 0,05)	
Krones 2008	Educational meeting, audit and feedback, educational material and educational outreach visit (n=582)	Educational Meeting (n=550)	PPS (Man Son-Hing) : I made the decision jointly (Score inversé pour respecter le sens de l'échelle)	NA	1,36 (0, 25)	NA	1,24 (0, 25)	0,48 (0,36 to 0,60)	0,48 (0,40 to 6,11)
Krones 2008	Educational meeting, audit and feedback, educational material and educational outreach visit (n=550)	Educational Meeting (n=582)	Shared Decision Making Q (SDM-Q)	NA	9,18 (4, 08)	NA	7,46 (4,5)	0,40 (0,28 to 0,52)	
Krones 2008	Educational meet-	Educational	PPS (Man-Son-Hing)	NA	7,69 (0, 16)	NA	6,87 (0,1)	6,11 (5.82 to 6.40)	

Table 5. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting healthcare professionals (*Continued*)

	ing, audit and feedback, educational material and educational outreach visit (n=539)	Meeting (n=513)							
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									

Table 6. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to usual care

Observer-based outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Haskard 2008	Patient mediated intervention + Distribution of educational material + education meeting (n=61)	Usual Care	Physician informative and participatory (n=66)	NA	0,02 (0, 39)	NA	-0,10 (0, 41)	Unit of error analysis	

Table 6. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to usual care (*Continued*)

Haskard 2008	Patient mediated intervention + Distribution of educational material + education meeting (n=61)	Usual Care	Patient active (n=66)	NA	-0,02 (0, 32)	NA	-0,08 (0, 37)	Unit of error analysis	
Haskard 2008	Patient mediated intervention + Distribution of educational material + education meeting (n=61)	Usual Care	Physician-patient interaction (n=66)	NA	-0,03 (0, 46)	NA	-0,06 (0, 50)	Unit of error analysis	
Hess 2012	Patient mediated intervention + educational meeting (n=100)	Usual Care	OPTION (n=100)	NA	26,60 (8, 10)	NA	7,00 (5, 50)	2,83 (2,44 to 3,22)	2,83
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					

Table 6. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to usual care (*Continued*)

Murray 2010	Educational meeting, audit and feedback, distribution of educational materials, educational outreach, barriers assement	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

Patient reported outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Cooper 2011	Patient mediated intervention + Educational meeting (n=58)	Usual Care	Participatory Decision making (PDM) (n=43)	66,67 (23, 98)	72,84 (21, 19)	74,61 (21, 59)	69,38 (21, 50)	0,16 (-0, 23 to 0,56)	0,16
Hamman 2007	Patient mediated intervention + Educational meeting (n=33)	Usual Care	Combined Outcome Measure for Risk Communication and Treatment (COMRADE) (n=49)	NA	76,8 (20, 9)	NA	73,5 (19, 3)	0,16 (-0, 28 to 0,61)	0,16
Wetzels 2005	Patient mediated Intervention + educational out-	Usual Care	Combined Outcome Measure for Risk Com-	1,82 (NA)	1,83 (NA)	1,89 (NA)	1,80 (NA)	Unable to calculate. No differences between	NA

Table 6. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to usual care (*Continued*)

	reach visit (n=121)		munication and Treatment (COMRADE) - 4 items (n=142)					groups were detected	
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
Leighl 2011	Patient mediated intervention and educational meeting	Usual Care	Modified CPS	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					
Loh 2007	Patient mediated intervention and 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					

Table 7. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting patients

Observer-based outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**

Table 7. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting patients (*Continued*)

Mullan 2009	Patient mediated intervention + Education meeting (n=21)	Patient mediated intervention (n=19)	OPTION	NA	49,70 (17, 74)	NA	27,70 (11, 75)	1,42 (0,72 to 2,12)	1,42
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Bieber 2006	Patient mediated intervention and educational meeting (n=34)	Patient mediated intervention	Questionnaire on the Quality of Physician-Patient Interaction (QQPPI) (first consultation) (n=33)	NA	4,11 (0,7)	NA	3,59 (0,7)	0,73 (0,24 to 1,23)	0,73 (0,50 to 0,88)
Bieber 2006	Patient mediated intervention and educational meeting	Patient mediated intervention	Questionnaire on the Quality of Physician-Patient Interaction	NA	4,05 (0,7)	NA	3,67 (0,8)	0,50 (0,01 to 0,99)	

Table 7. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting patients (*Continued*)

	(n=34)		(QQPPI) (3 months) (n=33)						
Bieber 2006	Patient mediated intervention and educational meeting (n=34)	Patient mediated intervention	Questionnaire on the Quality of Physician-Patient Interaction (QQPPI) (6 months) (n=33)	NA	3,8 (0,8)	NA	3,13 (0,7)	0,88 (0,38 to 1,38)	
Cooper 2011	Patient mediated intervention + Educational meeting (n=58)	Patient mediated intervention	Participatory Decision making (PDM) (n=40)	66,67 (23, 98)	72,84 (21, 19)	70,94 (24, 67)	74,17 (23, 25)	-0,06 (-0, 46 to 0,34)	-0,06
Mullan 2009	Patient mediated intervention + Educational meeting (n=47)	Patient mediated intervention	Validated pictorial instrument (n= 36)	NA	4,8 (1,1)	NA	4,7 (1,1)	0,09 (-0, 34 to 0,52)	0,09

Patient reported outcome measure - Categorical Data

Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									

Patient reported outcome measure - Qualitative statement

Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**
Deinzer 2009	Patient mediated inter-	Patient mediated inter-	Combined Outcome Mea-	The degree of SDM was significantly higher in the SDM group at basline and after 1-year visits. Both groups showed an increase in SDM (both P = 0.001). Page 268

Table 7. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting patients (*Continued*)

	vention + Educational meeting	vention	sure for Risk Communication and Treatment (COMRADE)	
Deinzer 2009	Patient mediated intervention + Educational meeting	Patient mediated intervention	Autonomy Preference Index (API)	The preference for SDM as assessed by the API (Figure 2) showed no differences between the SDM and control group at baseline (P = 0.60) and did not change after 1 year (P = 0.83). Page 268

Table 8. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting healthcare professionals

Observer-based outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**

Table 8. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting healthcare professionals (*Continued*)

Cooper 2011	Patient mediated intervention + Educational meeting (n=58)	Educational meeting (n=51)	Participatory Decision making (PDM)	66,67 (23, 98)	72,84 (21, 19)	68,46 (22, 81)	71,57 (19, 94)	0,06 (-0, 32 to 0,44)	0,06
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
Roter 2012	Patient mediated intervention and distribution of educational materials	Distribution of educational materials	LEAPS	The study interventions led to significant and parallel increases in both patient and physician reported use of patient-centered communication skills, and an increase in patient satisfaction with communication-related visit goals. For patients, the intervention was associated with a positive change in reported skills in five of the six communication areas. Page 412					

Table 9. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to intervention targeting both patients and healthcare professionals

Observer-based outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Categorical Data									

Table 9. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to intervention targeting both patients and healthcare professionals *(Continued)*

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
Myers 2011	Patient mediated intervention + reminders (n=74)	Patient mediated intervention + reminders (n=60)	Informed decision making scale (IDM)	NA	3/74	NA	5/60	-0,04 (-0, 13 to 0,04)	-0,04
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									

Table 10. Secondary outcome: patient health measures (Positive studies are in italics)

Study	Instrument	Intervention			Control			Std. effect size (CI 95%)
		N	Pre	Post	N	Pre	Post	
Continuous data: mean (SD)								
Elwyn 2004	Anxiety (short form of Spielberger) Time 1	Pre: 79 Post: 138	11.33 (3.74)	10.00 (3.55)	Pre: 107 Post: 187	11.62 (3.67)	9.86 (3.78)	Pre: -0.08 (-0.37 to 0.21) Post: 0.04 (-0.18 to 0.26)
Elwyn 2004	*Anxiety (short form of Spielberger) Time 2*	*Pre: 73* *Post: 117*	*9.94 (3.42)*	*11.25 (4.28)*	*Pre: 92* *Post: 164*	*10.36 (3.59)*	*10.23 (3.79)*	*Pre: -0.12 (-0.43 to 0.19)* *Post: 0.25 (0.02 to 0.49)*
Elwyn 2004	Anxiety (short form of Spielberger) Time 3	Pre: 61 Post: 101	10.15 (3.24)	10.51 (3.93)	Pre: 75 Post: 136	10.87 (3.55)	9.99 (3.23)	Pre: -0.21 (-0.55 to 0.13) Post: 0.15 (-0.11 to 0.40)
Elwyn 2004	*Health status (SF-1220) mental subscale Time 1*	*Pre: 101* *Post: 171*	*48.65 (10.26)*	*50.41 (10.90)*	*Pre: 68* *Post: 124*	*50.31 (9.66)*	*47.77 (11.21)*	*Pre: -0.16 (-0.47 to 0.14)* *Post: 0.24 (0.00 to 0.47)*
Elwyn 2004	Health status (SF-1220) mental subscale Time 2	Pre: 79 Post: 149	49.11 (11.14)	51.16 (10.41)	Pre: 68 Post: 108	50.16 (10.73)	49.23 (11.98)	Pre: -0.09 (-0.42 to 0.23) Post: 0.17 (-0.07 to 0.42)
Elwyn 2004	Health status (SF-1220) physical subscale Time 1	Pre: 101 Post: 171	41.16 (13.05)	42.47 (11.76)	Pre: 68 Post:124	43.01 (12.48)	41.90 (13.08)	Pre: -0.14 (-0.45 to 0.16) Post: 0.05 (-0.18 to 0.27)
Elwyn 2004	Health status (SF-1220) phys-	Pre: 79 Post: 149	39.71 (12.35)	40.81 (12.14)	Pre: 68 Post: 108	43.34 (11.46)	40.91 (11.81)	Pre: -0.30 (-0.63 to 0.

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) (*Continued*)

	ical subscale Time 2							02) Post: -0.01 (-0.26 to 0. 24)
Hamann 2007	Clinical global impression scale	35	NA	4.0 (1.5)	40	NA	4.1 (1.4)	-0.07 (-0.52 to 0.38)
Hamann 2007	Global assessment of function scale	30	NA	54.7 (16.5)	37	NA	51.0 (18.5)	0.21 (-0.27 to 0.69)
Légaré 2012	Quality of life physical scale	181	49.30 (8.80)	49.40 (7.50)	178	47.70 (8.90)	48.20 (7.80)	0.16 (-0.05 to 0.36)
Van Peperstraten 2010	Level of anxiety	Pre:150 Post: 127	35.60 (10. 60)	36.40 (10. 20)	Pre: 154 Post: 135	34.60 (9.50)	34.70 (8.20)	0.18 (-0.06 to 0.43)
Categorical data (n/N)								
Hamann 2007	Patient hospitalised within 6 mo after discharge	36	NA	8/36	37	NA	8/37	0.01 (-0.18 to 0.20)
Hamann 2007	Patient hospitalised within 18 mo after discharge	38	NA	20/38	41	NA	19/41	0.06 (-0.16 to 0.28)
Hamann 2007	Patient with drug switches (main antipsychotic) within 6 mo after discharge	36	NA	12/36	40	NA	16/40	-0.07 (-0.28 to 0.15)
Hess 2012	Admitted to hospital	101	NA	6	103	NA	6	0 (-0.06 to 0.07)

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) (*Continued*)

Hess 2012	Repeat emergency department visit	101	NA	3	103	NA	0	0.03 (-0.01 to 0.07)
Hess 2012	Rehospitalization	101	NA	2	103	NA	0	0.02 (-0.01 to 0.05)
Hess 2012	Acute myocardial infarction	101	NA	1	103	NA	0	0.01 (-0.02 to 0.04)
Légaré 2012	Proportion of use of antibiotics	Pre: 182 Post: 180	75	49	Pre :171 Post:178	67	93	-0.25 (-0.35 to -0.15)
Van Peperstraten 2010	*Subclinical depression*	*Pre:147 Post: 126*	*16*	*16*	*Pre: 151 Post: 136*	*13*	*5*	*0.09 (0.02 to 0.16)*
Qualitative data								
Butow 2004	Spielberger State Trait Anxiety Scale	"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 one month later." Page 4407						
Butow 2004	Beck Depression Inventory (short form)	"No significant differences between groups were observed in raw or change scores on depression immediately after the consultation or one month later." Page 4407						
Mullan 2009	Adherence	" ... adherence to diabetes medications were near perfect in both groups and significantly better in the control group." Page 1565						
Mullan 2009	HbA	"The decision aid did not affect glycemic control or patient-reported health status at six months" Page 1565						
Krones 2008 (ARRIBA-Herz)	Framingham Scoring system	Non significant (P = 0.31)						
Bernhard 2011	Anxiety (State Trait Anxiety Inventory)	"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. The quality of life indicators showed similar findings (data not shown)." Page 6						
Bernhard 2011	Quality of life	"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. The quality of life indicators showed similar findings (data not shown)." Page 6						

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) (*Continued*)

Bieber 2006	Center for epidemiological studies depression scale - CES-D	Non significant: P = 0.26 (table 4). Page 363
Bieber 2006	Visual analogue scale for pain intensity	Non significant: P = 0.45 (table 4). Page 363
Bieber 2006	Health status and physical function SF-36	Non significant: P = 0.89 (table 4). Page 363
Bieber 2006	Hannover Functional Questionnaire FFbH	Non significant: P = 0.81 (table 4). Page 363
Cooper 2011	Blood Pressure control	"Improvements in patient adherence and BP control did not differ across groups for the overall patient sample" p1; "In the overall sample, changes in systolic and diastolic BP at 12 months did not differ for any of the intervention groups when compared to the patient+physician minimal intervention group" p1300; "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
Davison 1997	Spielberger State Trait Anxiety Scale	"There was no evidence trait scores were different among groups, among measurement times, or between groups and measurement times" Page 195
Davison 1997	Center for epidemiological studies depression scale - CES-D	"No significant differences in mean depression scores were found among the groups, among measurement times, or between groups and measurement times" Page 196
Deinzer 2009	Self measurement of systolic and diastolic blood pressure	"Thus in both groups BP decreased but there were no significant differences between the 2 groups (systolic P = 0.24 and diastolic P = 0.16 respectively)." Page 268

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) (*Continued*)

Hamann 2007	Severity of illness (PANSS)	NA "... there were no differences between ... PANSS score at discharge" Page 994
Hamann 2007	Plasma level of antipsychotic	Not reported
Hamann 2007	Medication at discharge	Not reported
Hess 2012	Major adverse cardiac event	"Excluding the index presentation, there were no deaths or major adverse cardiac events within 30 days" Page 256
Leighl 2011	Functional Assessment of Cancer Therapy-General (FACT-G)	Patients completed the physical, emotional, and functional subscales of the Functional Assessment of Cancer Therapy - General (FACT-G) and had similar scores in both arms comparable with those of other patients with advanced cancer. Page 2080
Loh 2007	Brief PHQ-D - Depression severity	Non significant (P = 0.236)
Murray 2001	Health status and physical function SF-36	" ... no difference in score was observed between the two groups" Page 5
Murray 2001	Health states and valuation of health states EQ-SD	" ... no difference in score was observed between the two groups" Page 5
Murray 2001	Spielberger state of trait anxiety inventory short form	"The Spielberger scores were similar in the final assessment in the two groups" Page 5
Murray 2001	Prostatic symptoms (American Urolog-	"The amount of change was not significantly different in the two groups" Page 5

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) *(Continued)*

	ical Association symptom scale)	
Raynes-Greenow 2010	Mode of delivery	There were no differences between labour and birth outcomes between the groups P = 0.97 (table 4). See page 10
Raynes-Greenow 2010	Labour Type	There were no differences between labour and birth outcomes between the groups P = 0.97 (table 4). See page 10
Raynes-Greenow 2010	Analgesia used	There were no significant differences between groups in regards to analgesia use (P = 0.18-0.84). See page 7
Raynes-Greenow 2010	Apgar score	P = 0.12 (1 minute) and P = 0.68 (5 minutes) (table 4). See page 10
Stiggelbout 2008	Quality of life (HADS)	"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
Stiggelbout 2008	100 mm visual analogue	"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" (100 mm visual analogue scale) Page 757

Table 11. Secondary outcome: duration of consultation (Positive studies are in italics)

Study	**Instrument**	**Intervention**			**Control**			**Std. effect size (CI 95%)**
		N	**Pre**	**Post**	**N**	**Pre**	**Post**	
Continuous data: mean (SD)								
Stacey 2006	Call length	Pre: 18 Post: 18	17.80 (4.50)	18.50 (6.30)	Pre: 20 Post: 20	16.70 (7.70)	16.70 (6.50)	Pre: 0.17 (-0.47 to 0.81) Post: 0.27 (-0.36 to 0.91)
Qualitative data								
Butow 2004	Consultation length	"Consultation length was similar between groups - on average, 36 minutes per consultation." Page 4407						

Table 11. Secondary outcome: duration of consultation (Positive studies are in italics) (*Continued*)

Elwyn 2004	Consultation length	"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
Fossli 2011	Consultation length	"There was a non significant difference between both groups (RD: -1:03 CI -6:13;4:07) P = 0.69" Page 4
Krist 2007	Consultation length	"These [discussion times] patient-physician differences did not differ significantly across the control, brochure, and Web groups." Page 116
Loh 2007	Consultation length	Non significant differences between the groups (Table 2) Page 329
Montori 2011	*Consultation length*	*"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)" Page 552-553*
Murray 2001	Consultation length	Not reported
Murray 2010	Consultation length	*"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*
Nannenga 2009	Consultation time	"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
Shepherd 2011	Consultation length	"These effects occurred without any significant difference in consultation length, mean consultation lengths were 26 minutes for control and intervention visits." Page 381
Vodermaier 2009	Consultation time	"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
Wetzel 2005	Consultation time	No differences between intervention and control groups were detected, consultations was between 12. 2 and 13 minutes for all groups (Table 4) Page 292

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics)

Study	**Instrument**	**Intervention**			**Control**			**Std. effect size (CI 95%)**
		N	**Pre**	**Post**	**N**	**Pre**	**Post**	
Continuous data: mean (SD)								

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) (*Continued*)

Haskard 2008	Physician satisfaction questionnaire	61	NA	74.82 (5.47)	66	NA	74.60 (6.47)	Unit of error analysis
Haskard 2008	Satisfaction with the management and functioning of their office practice	61	NA	3.20 (0.65)	66	NA	3.08 (0.58)	Unit of error analysis
Haskard 2008	Overall quality of life	63	NA	3.00 (0.83)	63	NA	2.82 (0.73)	Unit of error analysis
Haskard 2008	Stress	61	NA	2.68 (0.69)	66	NA	2.78 (0.60)	Unit of error analysis
Mullan 2009	Acceptability amount of information	21	NA	6.59 (0.91)	19	NA	6.37 (1.14)	0.20 (-0.41 to 0.83)
Mullan 2009	Acceptability clarity of information	21	NA	6.20 (0.96)	19	NA	6.20 (0.80)	0.00 (-0.62 to 0.62)
Mullan 2009	Helpfulness of the information	21	NA	6.15 (0.94)	19	NA	5.74 (1.04)	0.41 (-0.22 to 1.03)
Mullan 2009	Would recommend to others	21	NA	6.16 (1.51)	19	NA	5.89 (1.82)	0.16 (-0.46 to 0.78)
Mullan 2009	Would want to use for other decisions	21	NA	6.04 (1.55)	19	NA	5.69 (1.75)	0.21 (-0.44 to 0.84)
Murray 2010	*Knowledge*	*35*	*NA*	*69.30 (2.98)*	*35*	*NA*	*60.50 (2.27)*	*3.28 (2.55 to 4.02)*
Krones 2008 (ARRIBA-Herz)	Patient participation scale, physician rating	19	NA	1.66 (0.45)	26	NA	1.65 (0.48)	0.02 (-0.57 to 0.61)

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) (*Continued*)

Bieber 2006 (first consultation)	Difficult doctor patient questionnaire	34	NA	29.40 (5.80)	33	NA	33.50 (10.00)	-0.50 (-0.98 to -0.02)
Bieber 2006 (month follow up)	Difficult doctor patient questionnaire	34	NA	28.90 (6.70)	33	NA	32.20 (6.50)	-0.49 (-0.98 to -0.01)
Légaré 2012	Physician quality of decision	Pre: 172 Post: 166	8.20 (1.10)	8.20 (1.30)	Pre: 162 Post: 170	8.20 (1.40)	8.40 (1.00)	-0.17 (-0.39 to 0.04)
Légaré 2012	Physician intention to follow CPG	Pre: 151 Post: 132	1.60 (0.80)	1.70 (0.90)	Pre: 108 Post: 98	1.60 (0.90)	1.80 (0.70)	-0.12 (-0.38 to 0.14)
Loh 2007	Physician's assessment of treatment adherence	96	4.20 (1.10)	4.30 (1.10)	191	4.30 (0.90)	4.80 (0.60)	Intra-cluster correlation error
Categorical data: (n/N)								
Légaré 2012	Physician Decisional Conflict (Proportion who had a value of 2.5 or more)	Pre: 178 Post: 175	8	8	Pre: 166 Post: 176	5	2	0.03 (-0.00 to 0.07)
Murray 2001	Perceived role in decision making: shared role	48	NA	25/48	49	NA	32/49	-0.13 (-0.33 to 0.06)
Vodermaier 2009	Chose Breast-conserving therapy	39	NA	37/39	41	NA	36/41	0.07 (-0.05 to 0.19)
Vodermaier 2009	Chose Chemotherapy	35	NA	11/35	39	NA	11/39	0.03 (-0.18 to 0.24)

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) (*Continued*)

Vodermaier 2009	Chose pre-oper-ative chemo-therapy	16	NA	10/16	15	NA	7/15	0.16 (-0.19 to 0.50)
Qualitative data								
Butow 2004	Physi-cian satisfac-tion with the decision making pro-cess	"Physicians were also equally satisfied with decision making whether or not their patients had received the CCPP or the control booklet" Page 4407						
Elwyn 2004	*Clin-ician percep-tion of the level of clin-ician agree-ment*	*"Clinicians showed significant differences between the RC and SDM arms (see Table S3). Doctors receiving the risk communication tools and training first perceived significantly higher doctor-patient agreement on treatment (P 0.001), patient satisfaction with information (P = 0.01), doctor satisfaction with decision (P = 0.01) and general overall satisfaction (P = 0.001) with the consultation than those who were exposed to SDM training. The latter group of doctors showed lower scores after the interventions. The differences were largely maintained in the second intervention phase, i.e. even when provided with the risk communication training and tools, the group of doctors who had received SDM training first still reported lower levels of satisfaction, agreement, etc. In contrast, doctors who had received risk communication training first maintained their higher levels of satisfactions and agreement, even when later given the SDM training which appeared less beneficial (to doctors) in the first phase." Page 343*						
Elwyn 2004	*Clini-cian satisfac-tion with the decision and overall con-sultation*	*"Clinicians showed significant differences between the RC and SDM arms (see Table S3). Doctors receiving the risk communication tools and training first perceived significantly higher doctor-patient agreement on treatment (P 0.001), patient satisfaction with information (P 0.01), doctor satisfaction with decision (P 0. 01) and general overall satisfaction (P 0.001) with the consultation than those who were exposed to SDM training. The latter group of doctors showed lower scores after the interventions. The differences were largely maintained in the second intervention phase, i.e. even when provided with the risk communication training and tools, the group of doctors who had received SDM training first still reported lower levels of satisfaction, agreement, etc. In contrast, doctors who had received risk communication training first main-tained their higher levels of satisfactions and agreement, even when later given the SDM training which appeared less beneficial (to doctors) in the first phase." Page 343*						
Elwyn 2004	*Patient satis-faction with informa-tion provided (as described by clinicians)*	*"Doctors receiving risk communication tool and training first perceived significantly higher doctor-patient agreement on treatment (P < 0.001), patient satisfaction with information (P < 0.01), doctor satisfaction with decision (P < 0.01) and general overall satisfaction (P < 0.001)" Page 343*						
Mullan 2009	Decision aid acceptability	Not reported						

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) (*Continued*)

Murray 2010	Acceptability of the instrument	"In all, 37 members of the intervention group (97%) commented on the acceptability of the skills building workshop. … The 31 (81%) agreed that the PtDA would be acceptable to patients, while 24 (63%) agreed that it would be acceptable to practitioners." Page 117
Murray 2010	Utility of the intervention PtDA	"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 117
Murray 2010	Intention to engage	"All participants, regardless of group assignment, saw patient decision support as helpful to patients (n = 32 [100 percent] interventions; n = 38 [98 percent] control) While 27 members of the intervention group (87%) and 34 members of the control group (84%) indicated a positive intention to engage in decision support, 16 members of the intervention group (50%) strongly agreed that they could provide decision support compared to 11 members of the control group (28%)" Page 117
Stacey 2006	*Nurses' knowledge*	*"The nurses in the intervention group (n = 19) had a mean knowledge score of 74% and the mean score in the control group (n = 20) was 60%. The difference between the groups was significant (P = 0.007)." Page 413*
Stacey 2006	Nurses' perception of factors influencing use of the coaching protocol	"Most of the 19 nurses in the intervention group agreed that the protocol was compatible with their practice (n = 15), provided a logical approach (n = 17), was easy to try (n = 15) and helped with exploring the benefits and harms of the options available to callers (n = 16). Another advantage of using the protocol, as reported by one nurse, was that it ... increases focus on caller's needs rather than just giving information." Page 413
Bernhard 2011	Maslach Burnout Inventory	"When doctors' stress and burnout factors were accounted for in the mixed effects models for decisional conflict, the ESs became slightly larger in the SGA cohort but remained low. There was no influence by these factors on the ESs in the ANZ cohort (data not shown)." Page 5
Hamann 2007	Doctor patient relationship	"Doctor-patient relationship (WAI) and PANSS scores did not prove to be independent significant prognostic factors" Page 996
Hamann 2007	Physicians satisfaction with treatment results	Not reported
Hess 2012	Clinician satisfaction with and acceptability of the DA	"Of the 51 clinicians who used the decision aid, 50 (98%) considered it helpful, and 32 (63%) indicated their desire to use the decision aid again if given the opportunity. Most clinicians indicated a desire to use a decision aid for other clinical management decisions" Page 255
Krist 2007	Physician perception of	"Physicians tended to reports that they had greater control over the decision than did the patients, as measured by the CPS" Page 116

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) (*Continued*)

	the decision making process	
Krist 2007	Number of test ordered	Not reported
Leighl 2011	Physician satisfaction with decision-making score	"Australian medical oncologists were surveyed regarding their satisfaction with the decision-making process after each consultation;scores were generally high and similar in both arms" Page 2080
Murray 2001	Evaluation of the intervention	"General practitioners were positive about the decision aid; of 50 follow up consultation with patients in the intervention group they said that the decision aid had helped in 46, made no difference in three, and hindered one." Page 5
Roter 2012	Time management	The area in which there was no significant difference in reported skill use was in relation to time management. p.412 Treatment adherence (P = 0.03); Interpersonal rapport (P = 0.004) Table 7, page 412
Roter 2012	*Treatment adherence*	*The area in which there was no significant difference in reported skill use was in relation to time management. page 412* *Treatment adherence (P = 0.03); Interpersonal rapport (P = 0.004) Table 7, page 412*
Roter 2012	*Interpersonal rapport*	*The area in which there was no significant difference in reported skill use was in relation to time management. page 412* *Treatment adherence (P = 0.03); Interpersonal rapport (P = 0.004) Table 7, page 412*
Stiggelbout 2008	Surgeon's perceptions	"No differences were seen between the arms of the trial in the surgeons' reply to the question whether and how they presented probabilities; nor to the question on the risk that were discussed, the total number of risks that were discussed, or the understanding of the information by the patients; nor to the question whether much discussion had taken place during the consultation." Page 757
Street 1995	Physician facilitation	Not reported
Van Peperstraten 2010	*Cost evaluation of the empowerment strategy*	*"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*

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics)

Study	Instrument	Intervention			Control			Std. effect size (CI 95%)
		N	Pre	Post	N	Pre	Post	
Continuous data: mean (SD)								
Bieber 2006	Satisfaction with decision scale	34	NA	4.11 (0.40)	33	NA	4.02 (0.60)	0.17 (-0.30 to 0.65)
Bieber 2006	Satisfaction with decision scale	34	NA	4.10 (0.60)	33	NA	4.07 (0.60)	0.05 (-0.43 to 0.53)
Bieber 2006	Desicional conflict scale	34	NA	12.90 (4.20)	33	NA	12.40 (3.70)	0.12 (-0.35 to 0.60)
Bieber 2006	Desicional conflict scale	34	NA	12.80 (3.00)	33	NA	12.50 (3.40)	0.09 (-0.39 to 0.57)
Deen 2012	Decision self-efficacy (DSE)	17	73.52 (19.13)	79.55 (12.79)	15	76.97 (17.95)	77.42 (19.29)	0.13 (-0.57 to 0.82)
Deen 2012	Decision self-efficacy (DSE)	21	71.54 (25.57)	79.55 (12.79)	15	76.97(17.96)	77.42 (19.30)	0.13 (-0.53 to 0.80)
Deen 2012	Decision self-efficacy (DSE)	17	77.27 (16.13)	83.82 (15.56)	15	76.97(17.97)	77.42 (19.31)	0.36 (-0.34 to 1.06)
Dolan 2002	Decisional conflict scale	45	NA	1.83 (0.52)	43	NA	2.03 (0.81)	-0.30 (-0.71 to 0.27)
Haskard 2009	Patient perceived decision-making	61	NA	2.94 (0.43)	66	NA	2.85 (0.46)	Unit of error Analysis
Haskard 2009	Patient choice	61	NA	4.15 (0.55)	66	NA	3.96 (0.68)	Unit of error Analysis
Krones 2008 (ARRIBA-Herz)	Decisional regret	372	NA	14.69 (NA)	372	NA	18.08 (NA)	Unable to calculate

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Krones 2008 (ARRIBA-Herz)	Knowledge	535	NA	2.03 (NA)	576	NA	1.92 (NA)	Unable to calculate
Lalonde 2006	Decisional conflict scale	26	2.49 (0.53)	2.36 (0.30)	24	2.50 (0.39)	2.33 (0.30)	Pre: -0.02 (-0.58 to 0.53) Post: 0.0.10 (-0.46 to 0.65)
Landrey 2012	Knowledge of prostate cancer screening	71	NA	3.50 (1.50)	77	NA	3.30 (1.40)	0.14 (-0.19 to 0.46)
Légaré 2012	Patients' quality of decision	Pre: 158 Post: 162	8.70 (1.50)	8.50 (1.60)	Pre: 151 Post: 159	8.70 (1.50)	8.50 (1.50)	0 (-0.22 to 0.22)
Légaré 2012	Intention to engage in shared decision-making	Pre: 165 Post: 163	1.90 (1.20)	2.10 (1.10)	Pre: 164 Post: 165	2.00 (1.20)	1.90 (1.20)	0.17 (-0.04 to 0.39)
Légaré 2012	*Regret over decision*	*Pre: 165 Post: 162*	*10.50 (15.40)*	*12.40 (19.10)*	*Pre: 164 Post: 164*	*10.80 (20.80)*	*7.60 (13.70)*	*0.29 (0.07 to 0.51)*
Loh 2007	*Doctor facilitation (PICS-DF)*	*191*	*15.40 (3.50)*	*17.40 (3.10)*	*96*	*14.70 (3.70)*	*14.50 (3.30)*	*Pre: 0.20 (-0.05 to 0.44) Post: 0.91 (0.66 to 1.17)*
Loh 2007	Information seeking (PICS-IS)	191	12.30 (2.70)	12.30 (3.40)	96	11.30 (2.90)	10.30 (2.90)	Pre: 0.36 (0.11 to 0.61) Post: 0.61 (0.36 to 0.87)
Loh 2007	Treament adherence	191	4.30 (0.80)	4.30 (0.90)	96	3.90 (0.80)	3.90 (1.00)	Pre: 0.50 (0.25 to 0.75) Post: 0.43 (0.18 to 0.67)
Loh 2007	*Patients satisfaction (ZUF8)*	*191*	*NA*	*29.80 (2.70)*	*96*	*NA*	*27.00 (3.60)*	*0.92 (0.66 to 1.18)*

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Mullan 2009	Acceptability clarity of information	NA	NA	6.20 (0.96)	NA	NA	6.20 (0.80)	-0.01 (-0.38 to 0.36)
Mullan 2009	*Acceptability helpfulness of the information*	*NA*	*NA*	*6.15 (0.94)*	*NA*	*NA*	*5.74 (1.04)*	*0.38 (0.04 to 0.72)*
Mullan 2009	Acceptability; would recommend to others	NA	NA	6.16 (1.51)	NA	NA	5.89 (1.82)	0.38 (-0.28 to 1.05)
Mullan 2009	Acceptability; would want to use for other decisions	NA	NA	6.04 (1.55)	NA	NA	5.69 (1.75)	0.34 (-0.39 to 1.08)
Mullan 2009	Decisional conflict scale	NA	NA	14.10 (17.89)	NA	NA	14.95 (12.68)	-0.89 (-5.37 to 3.59)
Mullan 2009	Informed subscale of DCS (knowledge)	NA	NA	13.65 (19.84)	NA	NA	15.28 (15.49)	-2.49 (-7.21 to 2.23)
Mullan 2009	Trust in Physician scale	NA	NA	94.69 (7.14)	NA	NA	93.06 (9.58)	2.06 (-1.78 to 5.89)
Mullan 2009	Acceptable amount of information	NA	NA	6.59 (0.91)	NA	NA	6.37 (1.14)	0.2 (-0.41 to 0.83)
Murray 2001	Decisional conflict score	57	NA	2.30 (0.40)	48	NA	2.60 (0.50)	-0.66 (-1.06 to -0.27)
Murray 2001	Prosectomy rates and referrals	57	NA	0.11 (0.31)	48	NA	0.02 (0.14)	0.36 (-0.03 to 0.75)
Myers 2010	Knowledge change	142	NA	0.80 (1.90)	144	NA	1.50 (2.10)	-0.35 (-0.58 to -0.11)

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Myers 2010	Decisional conflict	142	NA	0.32 (0.49)	144	NA	0.29 (0.34)	0.07 (-0.16 to 0.30)
Raynes-Greenow 2010	Decisional conflict at primary follow up	395	31.40 (12.80)	23.90 (10.60)	201	31.20 (13.40)	24.90 (12.90)	Pre: 0.02 (-0.15 to 0.19) Post: -0.09 (-0.25 to 0.08)
Raynes-Greenow 2010	Decisional conflict at second follow up	395	31.40 (12.80)	19.90 (12.30)	201	31.20 (13.40)	20.20 (14.10)	Pre: 0.01 (-0.15 to 0.18) Post: -0.02 (-0.19 to 0.15)
Raynes-Greenow 2010	Anxiety first follow up	395	33.90 (10.10)	33.30 (9.30)	201	34.30 (11.80)	34.30 (11.00)	Pre:-0.04 (-0.21 to 0.13) Post: -0.10 (-0.27 to 0.07)
Raynes-Greenow 2010	Anxiety second follow up	395	33.90 (10.10)	29.40 (8.50)	201	34.30 (11.00)	29.00 (9.50)	Pre: -0.04 (-0.21 to 0.13) Post: 0.04 (-0.12 to 0.21)
Raynes-Greenow 2010	Satisfaction with decision making first follow up	395	NA	81.50 (10.30)	201	NA	80.70 (11.70)	0.07 (-0.10 to 0.24)
Raynes-Greenow 2010	Satisfaction with decision making second follow up	395	NA	84.40 (12.90)	201	NA	82.80 (16.10)	0.11 (-0.06 to 0.28)
Raynes-Greenow 2010	*Knowledge of analgesia first follow up*	*395*	*53.40 (21.90)*	*65.10 (29.50)*	*201*	*54.40 (20.90)*	*56.50 (27.40)*	*Pre: 0.05 (-0.22 to 0.12) Post: 0.30 (0.13 to 0.47)*
Stiggelbout 2008	*Active participation of*	*31*	*NA*	*1.40 (0.90)*	*33*	*NA*	*1.00 (0.20)*	*0.61 (0.11 to 1.18)*

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) (*Continued*)

	the patient							
Van Peperstraten 2010	*Knowledge experienced*	*Pre: 150 Post: 127*	*5.70 (2.50)*	*7.70 (0.60)*	*Pre: 154 Post: 135*	*5.80 (2.50)*	*7.20 (1.20)*	*0.52 (0.27 to 0.77)*
Van Peperstraten 2010	*Knowledge actual*	*127*	*NA*	*6.20 (2.85)*	*135*	*NA*	*4.30 (1.76)*	*0.74 (0.49 to 0.99)*
Vodermaier 2009	Decisional conflict scale	53	NA	1.82 (0.59)	54	NA	1.99 (0.62)	-0.28 (-0.66 to 0.10)
Vodermaier 2009	Perceived involvement in care doctor facilitation (1-4)	53	NA	2.65 (0.66)	54	NA	2.72 (0.67)	-0.10 (-0.48 to 0.27)
Vodermaier 2009	Perceived involvement in care patient information	53	NA	3.04 (0.74)	54	NA	3.09 (0.73)	-0.10 (-0.40 to 0.36)
Vodermaier 2009	ZUF-8	53	NA	29.08 (2.99)	54	NA	28.67 (2.86)	0.14 (-0.24 to 0.52)
Categorical data (n/N)								
Dolan 2002	Annual fecal occult blood test	45	NA	11/23	43	NA	6/17	0.12 (-0.18 to 0.43)
Dolan 2002	No test (wait and see)	45	NA	8/8	43	NA	15/16	0.06 (-0.14 to 0.26)
Dolan 2002	Annual fecal occult blood test and flexible sigmoidoscopy every five years	45	NA	2/6	43	NA	7/8	
Dolan 2002	Flexible sigmoidoscopy every five years	45	NA	4/6	43	NA	1/2	0.17 (-0.15 to 0.48)

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Dolan 2002	Double contrast barium enema every five years	45	NA	0/1	43	NA	0/0	NA
Dolan 2002	Colonoscopy every ten years	45	NA	1/1	43	NA	0/0	NA
Hess 2012	The proportion of patients who decided to undergo observation, unit admission, and cardiac stress testing	100	NA	58	100	NA	77	-0.19 (-0.32 to -0.41)
Krist 2007	PSA test ordered	196	NA	163/196	75	NA	64/75	-0.02 (-0.1 to -0.07)
Krist 2007	PSA test ordered	226	NA	194/226	75	NA	64/75	0.01 (-0.09 to 0.10)
O'Cathain 2002	More anxious (antenatal)	Pre: 600 Post: 803	69/600	96/803	Pre: 595 Post: 724	77/595	87/724	Pre: -0.01 (-0.05 to 0.02) Post: 0 (-0.03 to 0.03)
O'Cathain 2002	More anxious (postnatal)	Pre: 879 Post: 846	99/879	86/846	Pre: 772 Post: 630	89/772	64/630	Pre: -0 (-0.03 to 0.03) Post: 0 (-0.03 to 0.03)
O'Cathain 2002	Drank less (antenatal)	Pre: 599 Post: 796	474/599	623/796	Pre: 595 Post: 696	443/592	551/696	Pre: 0.04 (0.00 to 0.10) Post:-0.10 (-0.03 to 0.03)
O'Cathain 2002	Planned hospitals birth (antenatal)	Pre: 619 Post: 826	608/619	799/826	Pre: 620 Post: 743	604/620	725/743	Pre: 0.01 (0.01 to 0.02) Post:-0.01 (-

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

								0.02 to 0.01)
O'Cathain 2002	Had screening test (antenatal)	Pre: 619 Post: 824	518/619	653/824	Pre: 619 Post:827	619/619	826/827	Pre: -0.16 (-0.19 to 0.13) Post: -0.21 (-0.23 to -0.18)
O'Cathain 2002	Partner/ family present during labour (postnatal)	Pre: 922 Post: 886	867/922	836/886	Pre: 819 Post: 661	777/819	619/661	Pre: -0.01 (-0.03 to 0.01) Post: 0.01 (-0.02 to 0.03)
O'Cathain 2002	Stayed in bed during labour (postnatal)	Pre: 888 Post: 847	420/888	428/847	Pre: 796 Post: 635	409/796	319/635	Pre: -0.04 (-0.09 to 0.01) Post: 0 (-0.05 to 0.05)
O'Cathain 2002	Continuous monitory (postnatal)	Pre: 922 Post: 886	451/922	397/886	Pre: 819 Post: 661	387/819	319/661	Pre: 0.02 (-0.03 to 0.06) Post: -0.03 (-0.08 to 0.02)
O'Cathain 2002	Had epidural (postnatal)	Pre: 922 Post: 886	216/922	223/886	Pre: 819 Post: 661	177/819	160/661	Pre: 0.02 (-0.02 to 0.06) Post: 0.01 (-0.03 to 0.05)
O'Cathain 2002	Breast fed (postnatal)	Pre: 921 Post: 883	518/921	511/883	Pre: 818 Post: 660	482/818	389/660	Pre: -0.03 (-0.07 to 0.02) Post: -0.01 (-0.06 to 0.04)
O'Cathain 2002	Satisfied with amount of information	Pre: 891 Post: 855	619/891	635/855	Pre: 780 Post: 637	536/780	458/637	Pre: 0.01 (-0.04 to 0.05) Post: 0.02 (-0.02 to 0.069)

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

O'Cathain 2002	Satisfied with way choices were made	Pre: 886 Post: 855	683/886	656/855	Pre: 780 Post: 633	600/780	502/633	Pre: 0 (-0.04 to 0.04) Post: -0.03 (-0.07 to 0.02)
O'Cathain 2002	Enough discussion	Pre: 883 Post: 847	570/883	548/847	Pre: 774 Post: 636	481/774	414/636	Pre: 0.02 (-0.02 to 0.07) Post: -0 (-0.05 to 0.04)
Raynes-Greenow 2010	*Enough information to make decision*	*395*	*NA*	*352/395*	*201*	*NA*	*160*	*0.10 (0.03 to 0.16)*
Raynes-Greenow 2010	Analgesia used:support	395	NA	258	201	NA	120	0.06 (-0.03 to 0.14)
Raynes-Greenow 2010	Analgesia used: bath use	395	NA	143	201	NA	65	0.04 (-0.04 to 0.12)
Raynes-Greenow 2010	Analgesia used: epidural used	395	NA	133	201	NA	66	0.01 (-0.07 to 0.09)
Van Peperstraten 2010	*Fully empowered couples, decision empowerment*	*Pre: 150 Post: 127*	*116*	*116*	*Pre: 154 Post: 99*	*112*	*99*	*0.18 (0.09 to 0.27)*
Qualitative data								
Butow 2004	Satisfaction with the consultation and decision	"No significant differences were found between the groups in satisfaction with either the consultation or treatment decision" Page 4407						
Butow 2004	Satisfaction with the booklet	"No significant differences were found between groups in terms of reported anxiety provoked, perceived utility, or ease of understanding of materials. … There was significant reported usefulness of the CCPP and control booklet for the family (P = 0.004)." Page 4405						
Butow 2004	Information subscale of the	"No significant results were obtained" Page 4407						

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) (*Continued*)

	Krantz Health Opinion Survey	
Deinzer 2009	*Hypertension Questionnaire*	*"Only in the SDM group was there an increase in knowledge after 1 year (P = 0.006). After 1 year both groups showed similar levels of knowledge" Page 269*
Deinzer 2009	Short Form 36 Item Health Survey (SF-36)	"There were no differences between the 2 groups concerning health-related quality of life measured with the 8 scales of SF-36" Page 269
Deinzer 2009	*Difficult Doctor Patient Relationship Questionnaire (DDPRQ)*	*"Doctor-patient relationship … was better in the SDM group than the control at the beginning … and after 1 year (p.0016). In the control group … an improvement occurred … (P = 0.045) that did not occur in the SDM group (P = 0.16)" Page 269*
Deinzer 2009	Autonomy Preference Index	"Preference for SDM as assessed by the API showed no differences between the SDM and control group at baseline (P = 0.60) and did not change after 1 year (P = 0.83)" Page 268
Deschamps 2004	Decision conflict score and the informed subscale items	The differences between groups were non-significant (Table 2), page 25
Deschamps 2004	Satisfaction with preparation for decision making	The differences between groups were non-significant (Table 3), page 25
Deschamps 2004	Satisfaction with decision	"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
Deschamps 2004	Adherence to HRT	"There was no statistically significant difference in adherence between the study groups" Page 26
Elwyn 2004	Intention to adhere to chosen treatment	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes ... However, significant effects of the research clinic (i.e. mainly the provision of more time)did lead to improvement (0.7 increase, 95% CI 0.04 to 1.36, P < 0.05)" Page 351

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Elwyn 2004	Patient's 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
Elwyn 2004	Enablement	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes" Page 351
Elwyn 2004	Satisfaction with decision made	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes" Page 351
Elwyn 2004	Patient's perceived support in decision	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes" Page 351
Fossli 2009	Patient global satisfaction	Non significant P = 0.38
Hamann 2007	Autonomy preference index (API)	Differences between groups not reported
Hamann 2007	Patient's satisfaction with overall care	Differences between groups not reported
Hamann 2007	The medication adherence rating scale	Differences between groups not reported
Hamann 2007	Patient knowledge of disease and treatment (7-item multiple choice)	Differences between groups not reported
Hamann 2007	Compliance with drug regime	Overall compliance was "good" for 42 (49%) of the patients at 6 months and 40 (59%) at 18 months

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) (*Continued*)

Hess 2012	*Knowledge*	*Knowledge (P < 0.0001) Table 2. Page 6*
Hess 2012	DCS	DCS (MD=-13.6 (-19.1 to -8.1)) Table 2. Page 6
Hess 2012	Trust in physician	Trust in physician (MD=4.1 (-1.4 to 9.6)), Table 2. Page 6
Hess 2012	*Patient 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% to 33%). Page 5*
Kasper 2008	Treatment decision	”Pearson’s chi square P-value for this table is not significant for patients already on immunotherapy at baseline and patients not yet on immunotherapy at baseline, compared to patients in the CG.“ Page 1350
Kasper 2008	Patients evaluation of the decision	”Six months after randomization, the two groups did not show any significant differences in their evaluation of their decisions“ Page 1350
Kasper 2008	Measure of the decision making process	”Both groups progressed significantly in making their decision. However they did not show differences in the course of progress over the three measurement points“ Page 1349
Krist 2007	*Prostate cancer screening knowledge*	*”… the percentage of correct answers on the knowledge scale was 54% in the control group (P < 0.001) vs 69% in the brochure group (P < 0.001)“ Page 115*
Krist 2007	Decisional conflict score	”DCS scores among all 3 groups were equally low and did not differ significantly … “ Page 115
Krist 2007	Patients and physicians topics covered in the discussion	”The decision aids did not appear to alter … the number of prostate cancer screening topics that patients or physicians recalled addressing“ Page 115
Lalonde 2006	Risk perception	”No statistically significant improvements were observed after the intervention“ p55 No mention of between-group differences
Lalonde 2006	Knowledge of hypertension	”However, knowledge of the estimated benefits of treatment tended to improve after the intervention (29% versus 58%; P = 0.06)“ No mention of differences between group” Page 55

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Landrey 2012	Flyer acceptability	"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 5
Leighl 2011	Decisional conflict score	Decision satisfaction and decisional conflict scores were similar in both arms. Page 2080
Leighl 2011	Patient satisfaction with decision	Decision satisfaction and decisional conflict scores were similar in both arms. Page 2080
Leighl 2011	Patient satisfaction with consultation	"Patients in both arms were highly satisfied with the consultation" Page 2080
Montori 2011	Knowledge: DA specific	Knowledge DA specific (P = 0.001) Table 2, page 553
Montori 2011	Knowledge: Not in the DA	Knowledge not in the DA (P = 0.35) Table 2, page 553
Montori 2011	Decisional conflict scale	Decisional conflict scale (P = 0.72) Table 2, page 553
Montori 2011	Trust	Trust (P = 0.46) Table 2, page 553
Murray 2001	Acceptability of decision aid	"Patients reacted positively to the decision aid" Page 5
Murray 2001	Satisfaction	Not reported
Murray 2001	Choice of treatment	The choice in treatment did not vary significantly from one group to another. For more details, see page 5
Myers 2010	Screening use	"Screening use was lower in EI Group than in SI Group (63% versus 71%), but this difference was not statistically significant (odds ratio= 0.67; 95% confidence interval, CI: 0.41-1.08; P = 0.102)" Page 4
Raynes-Greenow 2010	Stages of decision making	"Even distribution among stages.... A small proportion of women in both groups were not considering their choices …, or had made up their mind and were 'unlikely to change mind' … A large proportion of women … were amenable to change or were in active deliberation stages ... the largest proportion ... were women who 'had made some choices but were willing to reconsider" Page 6

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) (*Continued*)

Raynes-Greenow 2010	Choice predisposition towards analgesia	"Overall, higher proportions of women in both groups intended to use non-pharmacological methods for labour pain relief rather than pharmacological methods." Page 6
Raynes-Greenow 2010	Adherence and acceptability	"Most women had read all of the intervention (decision aid 98% compared to pamphlet group 95%, chi-square = 2.782, df=1, P = 0.061), and 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
Raynes-Greenow 2010	Source of information	"Both groups equally relied on family and friends, books and antenatal classes" Page 7
Raynes-Greenow 2010	Labour, Mode of delivery, Birth Weight, Apgar score	All information can be found in Table 4, page 10. There were no significant differences between groups
Roter 2012	Patient satisfaction: identification of problems and concerns	Patient satisfaction: identification of problems and concerns (P = 0.25) Table 6, page 411
Roter 2012	*Patient satisfaction: information exchange*	*Patient satisfaction: information exchange (P = 0.01) Table 6, page 411*
Roter 2012	*Patient satisfaction: shared decision-making*	*Patient satisfaction: shared decision-making (P = 0.03) Table 6, page 411*
Schroy 2011	*Screening intentions*	*"Differences in intention to schedule or complete a screening test for the 2 intervention groups versus control corresponded to moderate effect sizes ranging between 0.36 and 0.44. Scores were comparable for the 2 intervention groups." Page 9*
Stiggelbout 2008	*Understanding*	*"The only difference that was seen for the items related to understanding was a difference in favour 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 = 0.004)" Page 756*
Stiggelbout 2008	*Consultation with the*	*"A main difference between the 2 groups was seen in satisfaction with the duration of the consultation … (chi-square test P = 0.04). … For patients' impression whether the surgeon perceived them more as a medical*

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) (*Continued*)

	surgeon	*problem that as a person with a problem, an interaction effect was observed F (1.68)=4.31, P = 0.04." Page 757*
Street 1995	Patient knowledge	"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%; SD 13.64%) than did patients in the brochure group (mean, 71.4%; SD, 15.7%)" Page 2279
Street 1995	Patient optimism	"Optimism scores were not affected by … the educational intervention (F = 0.95, P = 0.93)" Page 2279
Street 1995	Patients' behavioural measures	Differences between groups not reported
Street 1995	Perceived involvement in decision making	Differences between groups not reported
Wetzels 2005	Point in time of decision making	The points in time of decision making were not statistically significant (p-value = 0.93) Table 4, page 595
Wetzels 2005	*Patient enablement index*	*Significant effect size difference: -0.232 (-0.444; -0.021) P = 0.03, table 3, page 292*
Wetzels 2005	Satisfaction with their care-EUROPEP	Non significant; effect size difference -0.056 (-0.302; 0.192) P = 0.66, table 3, page 292
Wetzels 2005	Use of leaflet	"Sub-analyses showed that the scores for these 47 patients did not differ significantly on the outcomes measures from those of the control group or the intervention group non-users" Page 290
Wetzels 2005	Discussion of one of the eight known underreported health problems	None of the discussion topics were shown to be statistically significant. Table 4, page 292

APPENDICES

Appendix 1. PubMed strategy

[#]	[Search strategies in Pubmed (2 august 2012)]	[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]))	2118
#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]))	28,283
#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]))	3734
#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]))	16,592
#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]	463,581
#6	(#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)) AND #5	**1235**

Appendix 2. EMBASE strategy

[#]	[Search strategies in Embase (2 august 2012)]	[Results]
#1	'Shared Decision':TI,AB OR 'Sharing Decision':TI,AB OR 'Informed Decision':TI,AB OR 'Informed Choice':TI,AB OR 'Decision Aid':TI,AB OR ((Share*:TI OR Sharing*:TI OR Informed*:TI) AND (Decision*:TI OR Deciding*:TI OR Choice*:TI))	1496
#2	'Clinical Decision Making'/EXP OR 'Decision Making'/EXP OR 'Decision Support System'/EXP OR 'Ethical Decision Making'/EXP OR 'Family Decision Making'/EXP OR 'Medical Decision Making'/EXP OR 'Patient Decision Making'/EXP OR 'Decision Making':TI,AB OR 'Decision Support':TI,AB OR 'Choice Behaviour':TI,AB OR ((Decision*:TI OR Choice*:TI) AND (Making*:TI OR Support*:TI OR Behaviour*:TI))	41,774
#3	Patient Participation'/EXP OR 'Patient Participation':TI,AB OR 'Consumer Participation':TI,AB OR 'Patient Involvement':TI,AB OR 'Consumer Involvement':TI,AB OR ((Patient*:TI OR Consumer*:TI) AND (Involvement*:TI OR Involving*:TI OR Participation*:TI OR Participating*:TI))	3790
#4	Doctor Patient Relation'/EXP OR 'Nurse Patient Relationship'/EXP OR (('Nurse'/EXP OR 'Physician'/EXP OR Nurse*:TI OR Physician*:TI OR Clinician*:TI OR Doctor*:TI OR 'General Practitioners':TI OR GPs:TI OR 'Health Care Professionals':TI OR 'Healthcare Professionals':TI OR 'Health Care Providers':TI OR 'Healthcare Providers':TI OR Resident*:TI) AND ('Patient'/EXP OR Patient*:TI OR Consumer*:TI OR People*:TI))	65,970
#5	clinical trial'/exp OR 'randomized controlled trial'/exp OR 'controlled clinical trial'/exp OR 'controlled trial'/exp OR 'pretest posttest control group design'/exp OR 'comparative study'/exp OR 'evaluation research'/exp OR 'intervention study'/exp OR 'randomization'/exp OR random*:ti,ab OR 'double blind':ti,ab OR 'controlled trial':ti,ab OR 'clinical trial':ti,ab OR pretest*:ti,ab OR 'pre test':ti,ab OR 'pre tests':ti,ab OR posttest*:ti,ab OR 'post test':ti,ab OR 'post tests':ti,ab OR prepost*:ti,ab OR 'pre post':ti,ab OR 'controlled before':ti,ab OR 'before and after':ti,ab OR 'interruped time':ti,ab OR 'time serie':ti,ab OR 'time series':ti,ab OR intervention*:ti,ab	1,113,563
#6	(#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)) AND #5	**2044**

Appendix 3. CINAHL strategy

[#]	[Search strategies in Embase (2 august 2012)]	[Results]
#1	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*))	2075
#2	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*))	22,891
#3	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*))	5167
# 4	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*))	9932
#5	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*	129,817

(*Continued*)

#6	(#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)) AND #5	**2082**

Appendix 4. PsycINFO strategy

[#]	[Search strategies in psycINFO (17 august 2012)]	[Results]
#1	ab=((“Shared Decision”) OR (“Sharing Decision”) OR (“Informed Decision”) OR (“Informed Choice”) OR (“Decision Aid”)) OR ti=((Share* OR Sharing* OR Informed*) AND (Decision* OR Deciding* OR Choice*))	776
#2	it=“Decision Making” OR it=“Choice Behavior” OR it=“Group Decision Making” OR it=“Choice Shift” OR it=“Management Decision Making” Or it=“Decision Support” OR ab=((“Decision Making”) OR (“Decision Support”) OR (“Choice Behaviour”)) OR it=((Decision* OR Choice*) AND (Making* OR Support* OR Behaviour))	17,413
#3	it=“Client Participation” OR ab=((“Consumer Participation”) OR (“Consumer Involvement”) OR (“Patient Participation”) OR (“Patient Involvement”)) OR it=((Patient* OR Consumer*) AND (Participating* OR Participation* OR Involving* OR Involvement*))	583
#4	it=“Therapeutic Processes” OR (it=“Nurses” OR it=“Psychiatric Nurses” OR it=“Public Health Service Nurses” OR it=“School Nurses” OR it=“Physicians” OR it“Family Physicians” OR it=“General Practitioners” OR it=“Gynecologists” OR it=“Internists” OR it=“Neurologists” OR it=“Obstetricians” OR it=“Pathologists” OR it=“Pediatricians” OR it=“Psychiatrists” OR it=“surgeons” OR ti=(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”)) AND (it=“Patients” OR it=“Geriatric Patients” OR it=“Hospitalized Patients” OR it=“Medical Patients” OR it=“Outpatients” OR it=“Psychiatric Patients” OR it=“Surgical Patients” OR it“Terminally ill Patients”) OR ti=(Patient* OR Consumer* OR People*))	5124
#5	#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)	**3787**

Appendix 5. The Cochrane Library (CDSR, CENTRAL, DARE, Technology Assessment and Economic Evaluation) strategy

[#]	[Search strategies in COCHRANE Library (CDSR, CENTRAL, DARE, Technology Assessment and Economic Evaluation) search strategy (17 august 2012)]	[Results]
#1	"Shared Decision*" OR "Sharing Decision*" OR "Informed Decision*" OR "Informed Choice*" OR "Decision Aid*" OR ((Share* OR Sharing* OR Informed*):ti AND (Decision* OR Deciding* OR Choice*):ti)	288
#2	"Decision Making*" OR "Decision Support*" OR "Choice Behaviour" OR ((Decision* OR Choice*):ti AND (Making* OR Support* OR Behaviour*):ti)	1990
#3	"Patient Participation*" OR "Consumer Participation*" OR "Patient Involvement*" OR "Consumer Involvement*" OR ((Patient* OR Consumer*):ti AND (Involvement* OR Involving* OR Participation* OR Participating*):ti)	555
#4	"Professional-Patient Relation*" OR "Nurse-Patient Relation*" OR "Physician-Patient Relation*" 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*" OR Resident*):ti AND (Patient* OR Consumer* OR People*):ti)	237
#5	#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)	**398**

Appendix 6. EPOC Register strategy

[#]	[Search strategies in EPOC Register (18 June 2012)]	[Results]
1	{decision making} OR {shared decision*} OR {sharing decision*} OR {collaborat* decision*} OR {informed decision*}	159
2	{decision*} AND {shar*}	161
3	{decision*} AND {collaborat*}	161
4	{decision*} AND {informed}	162
5	{decision making} OR {shared decision*} OR {sharing decision*} OR {collaborat* decision*} OR {informed decision*}	169

(*Continued)*

6	patient* decision*	169
7	{collaborat*} AND {decision*}	183
8	{share*\} AND {decision*}	194
9	{collaborat*} AND {care}	400
10	{informed} AND {decision*}	410
11	{informed} AND {care}	457
12	{2.0}OR {2009} OR {2010} OR {2011} OR {2012} OR {inc} OR {misc}	**154**

(share* or collaborative or informed) and (care or decision*)

Appendix 7. ClinicalTrials.gov, US National Institutes of Health (NIH)

[#]	[Search strategies in ClinicalTrials.gov (2013-01-15)]	[Results]
#1	"informed choice"	45
#2	"decision making"	342
#3	"decision support"	372
#4	"informed decision"	90
#5	"decision aid"	377
#6	"sharing decision"	65
#7	"shared decision"	172
	Total	**1463**

Appendix 8. International Shared Decision Making Conference (ISDM)

[Search in ISDM proceeding]	[Results]
References	**255**

Appendix 9. Society for Medical Decision Making (SMDM)

[Search in SMDM proceeding]	[Results]
References	**338**

Appendix 10. Previous review on patient-reported outcome measure of SDM

[Previous review (Légaré 2012a)]	[Results]
References	**9035**

Appendix 11. Reference from expert

[Reference sent by expert]	[Results]
Reference	**1**

WHAT'S NEW

Last assessed as up-to-date: 21 August 2014.

Date	Event	Description
12 September 2014	New citation required but conclusions have not changed	New search, 18 additional studies added to the review
12 September 2014	New search has been performed	New search has been performed

HISTORY

Protocol first published: Issue 3, 2007

Review first published: Issue 5, 2010

Date	Event	Description
30 November 2011	Amended	Last assessed as up-to-date
29 September 2011	New search has been performed	Updated observer-reported outcomes to 2010
29 September 2011	Amended	Included patient-reported outcomes to 2010

CONTRIBUTIONS OF AUTHORS

2010 review (Légaré 2010)

SR developed the search strategy.

FL, SR, DS, JK, IDG, MS, LP and KG identified eligible studies for this review.

FL, SR, MS, LP and ST helped with data abstraction.

FL, SR, DS and ST assisted with data analysis.

FL, SR, MS and ST developed the draft of the review.

FL, SR, DS, JK, IDG, MS and ST reviewed and participated in the writing of the final review.

2010 to 2012 update (current review)

FL, DS, ST and MJC identified eligible studies for the update of this review.

FL, ST and MJC helped with data abstraction.

FL, DS, ST and MJC assisted with data analysis.

FL, ST and MJC developed the draft of the review.

AL, DS, ST, MJC, JK, IDG, AL, MCP, RT, GE and NDB reviewed and participated in the writing of the final review.

DECLARATIONS OF INTEREST

This review includes studies that were published by some of its authors (DS, FL, GE, IDG, NDB).

MCP is on the medication adherence advisory board for Merck.

No other conflicts of interest are known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

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- 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.

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 EPOC taxonomy into three categories: interventions targeting patients (for example patient-mediated interventions), interventions targeting healthcare professionals (distribution of printed educational material, educational meetings, audit and feedback, reminders and educational outreach visits), and interventions targeting both patients and healthcare professionals (that is a patient-mediated intervention combined with one that targets the healthcare professional). These three categories correspond to the specific objectives of the review. Also, we split the outcomes into observer-based outcomes and patient-reported outcomes because measures for observer-based outcomes are more objective than patient-reported outcomes. Finally, we used GRADE tools to summarize our findings (see Summary of findings for the main comparison). Since publishing the protocol, two authors were removed (S Ratté and Karine Gravel) and six new authors were added (MJC, AL, MCP, RT, GE and NDB).

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