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Strategies to improve recruitment to randomised trials (Review)

Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, Jackson C, Taskila TK, Gardner H

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[Methodology Review]

Strategies to improve recruitment to randomised trials

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ABSTRACT

Background

Recruiting participants to trials can be extremely difficult. Identifying strategies that improve trial recruitment would benefit both trialists and health research.

Objectives

To quantify the effects of strategies for improving recruitment of participants to randomised trials. A secondary objective is to assess the evidence for the effect of the research setting (e.g. primary care versus secondary care) on recruitment.

Search methods

We searched the Cochrane Methodology Review Group Specialised Register (CMR) in the Cochrane Library (July 2012, searched 11 February 2015); MEDLINE and MEDLINE In Process (OVID) (1946 to 10 February 2015); Embase (OVID) (1996 to 2015 Week 06); Science Citation Index & Social Science Citation Index (ISI) (2009 to 11 February 2015) and ERIC (EBSCO) (2009 to 11 February 2015).

Selection criteria

Randomised and quasi-randomised trials of methods to increase recruitment to randomised trials. This includes non-healthcare studies and studies recruiting to hypothetical trials. We excluded studies aiming to increase response rates to questionnaires or trial retention and those evaluating incentives and disincentives for clinicians to recruit participants.

Data collection and analysis

We extracted data on: the method evaluated; country in which the study was carried out; nature of the population; nature of the study setting; nature of the study to be recruited into; randomisation or quasi-randomisation method; and numbers and proportions in each intervention group. We used a risk difference to estimate the absolute improvement and the 95% confidence interval (CI) to describe the effect in individual trials. We assessed heterogeneity between trial results. We used GRADE to judge the certainty we had in the evidence coming from each comparison.

Main results

We identified 68 eligible trials (24 new to this update) with more than 74,000 participants. There were 63 studies involving interventions aimed directly at trial participants, while five evaluated interventions aimed at people recruiting participants. All studies were in health care.

We found 72 comparisons, but just three are supported by high-certainty evidence according to GRADE.

1. **Open trials rather than blinded, placebo trials**. The absolute improvement was 10% (95% CI 7% to 13%).

2. **Telephone reminders to people who do not respond to a postal invitation**. The absolute improvement was 6% (95% CI 3% to 9%). This result applies to trials that have low underlying recruitment. We are less certain for trials that start out with moderately good recruitment (i.e. over 10%).

3. **Using a particular, bespoke, user-testing approach to develop participant information leaflets**. This method involved spending a lot of time working with the target population for recruitment to decide on the content, format and appearance of the participant information leaflet. This made little or no difference to recruitment: absolute improvement was 1% (95% CI −1% to 3%).

We had moderate-certainty evidence for eight other comparisons; our confidence was reduced for most of these because the results came from a single study. Three of the methods were changes to trial management, three were changes to how potential participants received information, one was aimed at recruiters, and the last was a test of financial incentives. All of these comparisons would benefit from other researchers replicating the evaluation. There were no evaluations in paediatric trials.

We had much less confidence in the other 61 comparisons because the studies had design flaws, were single studies, had very uncertain results or were hypothetical (mock) trials rather than real ones.

Authors' conclusions

The literature on interventions to improve recruitment to trials has plenty of variety but little depth. Only 3 of 72 comparisons are supported by high-certainty evidence according to GRADE: having an open trial and using telephone reminders to non-responders to postal interventions both increase recruitment; a specialised way of developing participant information leaflets had little or no effect. The methodology research community should improve the evidence base by replicating evaluations of existing strategies, rather than developing and testing new ones.

PLAIN LANGUAGE SUMMARY

What improves trial recruitment?

Key messages

We had high-certainty evidence for three methods to improve recruitment, two of which are effective:

1. Telling people what they are receiving in the trial rather than not telling them improves recruitment.

2. Phoning people who do not respond to a postal invitation is also effective (although we are not certain this works as well in all trials).

3. Using a tailored, user-testing approach to develop participant information leaflets makes little or no difference to recruitment.

Of the 72 strategies tested, only 7 involved more than one study. We need more studies to understand whether they work or not.

Our question

We reviewed the evidence about the effect of things trial teams do to try and improve recruitment to their trials. We found 68 studies involving more than 74,000 people.

Background

Finding participants for trials can be difficult, and trial teams try many things to improve recruitment. It is important to know whether these actually work. Our review looked for studies that examined this question using chance to allocate people to different recruitment strategies because this is the fairest way of seeing if one approach is better than another.

Key results

We found 68 studies including 72 comparisons. We have high certainty in what we found for only three of these.

1. Telling people what they are receiving in the trial rather than not telling them improves recruitment. Our best estimate is that if 100 people were told what they were receiving in a randomised trial, and 100 people were not, 10 more would take part n the group who knew. There is some uncertainty though: it could be as few as 7 more per hundred, or as many as 13 more.

2. Phoning people who do not respond to a postal invitation to take part is also effective. Our best estimate is that if investigators called 100 people who did not respond to a postal invitation, and did not call 100 others, 6 more would take part in the trial among the group who received a call. However, this number could be as few as 3 more per hundred, or as many as 9 more.

3. Using a tailored, user-testing approach to develop participant information leaflets did not make much difference. The researchers who tested this method spent a lot of time working with people like those to be recruited to decide what should be in the participant information leaflet and what it should look like. Our best estimate is that if 100 people got the new leaflet, 1 more would take part in the trial compared to 100 who got the old leaflet. However, there is some uncertainty, and it could be 1 fewer (i.e. worse than the old leaflet) per hundred, or as many as 3 more.

We had moderate certainty in what we found for eight other comparisons; our confidence was reduced for most of these because the method had been tested in only one study. We had much less confidence in the other 61 comparisons because the studies had design flaws, were the only studies to look at a particular method, had a very uncertain result or were mock trials rather than real ones.

Study characteristics

The 68 included studies covered a very wide range of disease areas, including antenatal care, cancer, home safety, hypertension, podiatry, smoking cessation and surgery. Primary, secondary and community care were included. The size of the studies ranged from 15 to 14,467 participants. Studies came from 12 countries; there was also one multinational study involving 19 countries. The USA and UK dominated with 25 and 22 studies, respectively. The next largest contribution came from Australia with eight studies.

The small print

Our search updated our 2010 review and is current to February 2015. We also identified six studies published after 2015 outside the search. The review includes 24 mock trials where the researchers asked people about whether they would take part in an imaginary trial. We have not presented or discussed their results because it is hard to see how the findings relate to real trial decisions.

Summary of findings for the main comparison. Open trial versus blinded trial

Open RCT versus blinded RCT

Patient or population: individuals eligible for a trial
Settings: any
Intervention: open trial
Comparison: blinded, placebo trial

Outcomes	Illustrative effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Effect with blinded trial	Effect with open trial			
Number recruited	**As measured**[a]		**RR 1.25** (1.18 to 1.34)	4833 (2 studies)	⊕⊕⊕⊕ **High**
	41 per 100	**50 per 100** (51 to 55)			
	Low[b]				
	10 per 100	**13 per 100** (12 to 13)			
	Moderate[b]				
	30 per 100	**38 per 100** (35 to 40)			
	High[b]				
	50 per 100	**63 per 100** (59 to 67)			

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **effect for the open trial** (and its 95% confidence interval) is based on the assumed risk in the the comparison group (blinded trial) and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **RR**: risk ratio.

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

[a]This is the baseline recruitment measured in the studies presented in the 'Summary of findings' table.
[b]We selected the low, moderate and high illustrative recruitment levels of 10%, 30% and 50% based on our prior experience with trial recruitment.

Summary of findings 2. Telephone reminder versus no telephone reminder

Telephone reminder versus no telephone reminder

Patient or population: individuals eligible for a trial
Settings: any
Intervention: telephone reminder
Comparison: no telephone reminder

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Effect with no telephone reminder	Effect with telephone reminder				
Number recruited	**As measured**[a]		**RR 1.90** (1.35 to 2.67)	978 (2 studies)	⊕⊕⊕⊕ **High**[c]	Both included studies had very low baseline recruitment of < 10%.
	6 per 100	11 per 100 (8 to 16)				
	Low[b]					
	10 per 100	**19 per 100** (14 to 27)				
	Moderate[b]					
	30 per 100	**57 per 100** (41 to 80)				
	High[b]					
	50 per 100	**95 per 100** (68 to 100)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **effect with the telephone reminder** (and its 95% confidence interval) is based on the assumed risk in the comparison group (no reminder) and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR**: risk ratio.

GRADE Working Group grades of evidence

High quality: further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: we are very uncertain about the estimate.

[a]This is the baseline recruitment measured in the studies presented in the 'Summary of findings' table.
[b]We selected the low, moderate and high illustrative recruitment levels of 10%, 30% and 50% based on our prior experience with trial recruitment..
[c]The evidence for this intervention comes entirely from trials with low (< 10%) underlying recruitment. When applied to trials with higher recruitment we would downgrade the assessment of certainty to moderate due to indirectness.

Summary of findings 3. Bespoke, user-tested participant information leaflet (PIL) vs usual PIL

Bespoke user-tested participant information leaflet (PIL) vs usual PIL

Patient or population: individuals eligible for trial
Settings: any
Intervention: bespoke, user-tested PIL
Comparison: usual PIL

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Effect with usual PIL	Effect with bespoke user-tested PIL			
Willingness to participate/number recruited	**As measured**[a]		**RR 1.15** (0.92 to 1.44)	6634 (3 studies)	⊕⊕⊕⊕ **High**
	5 per 100	**6 per 100** (5 to 7)			
	Low[b]				
	10 per 100	**12 per 100** (9 to 14)			
	Moderate[b]				
	30 per 100	**35 per 100** (28 to 43)			
	High[b]				
	50 per 100	**58 per 100**			

	(46 to 72)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **effect with the bespoke user-tested PIL** (and its 95% confidence interval) is based on the assumed risk in the comparison group (usual PIL) and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR**: risk ratio.

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

[a]This is the baseline recruitment measured in the studies presented in the 'Summary of findings' table.
[b]We selected the low, moderate and high illustrative recruitment levels of 10%, 30% and 50% based on our prior experience with trial recruitment..

Summary of findings 4. Brief participant information leaflet (PIL) vs usual PIL

Brief participant information leaflet (PIL) vs usual PIL

Patient or population: individuals eligible for a trial
Settings: any
Intervention: brief PIL
Comparison: usual PIL

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Effect with usual PIL	Effect with brief PIL			
Number recruited	**As measured**[a]		**RR 1.00** (0.93 to 1.07)	4633 (2 studies)	⊕⊕⊕⊖ **Moderate**[c]
	33 per 100	**33 per 100** (31 to 35)			
	Low[b]				
	10 per 100	**10 per 100** (9 to 11)			
	Moderate[b]				
	30 per 100	**30 per 100**			

	(28 to 32)	
High[b]		
50 per 100	**50 per 100** (47 to 54)	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **effect with the brief PIL** (and its 95% confidence interval) is based on the assumed risk in the comparison group (usual PIL) and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR**: risk ratio.

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

[a]This is the baseline recruitment measured in the studies presented in the 'Summary of findings' table.
[b]We selected the low, moderate and high illustrative recruitment levels of 10%, 30% and 50% based on our prior experience with trial recruitment.
[c]We downgraded the certainty by 1 level because of indirectness: Chen 2011 actually measures entry to pre-randomisation phase, not recruitment.

Summary of findings 5. Participant information leaflet (PIL) developed with feedback from users vs usual PIL

Participant information leaflet (PIL) developed with feedback from users vs usual PIL

Patient or population: individuals eligible for a trial
Settings: any
Intervention: PIL developed with feedback from users
Comparison: usual PIL

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**No of participants (studies)**	**Quality of the evidence (GRADE)**
	Effect with usual PIL	**Effect with PIL developed with feedback from users**			
Number recruited	**As measured**[a]		**RR 1.09** (0.96 to 1.25)	16763 (2 studies)	⊕⊕⊕⊖ **Moderate**[c]
	5 per 100	**5 per 100** (5 to 6)			
	Low[b]				

10 per 100	**11 per 100** (10 to 13)	
Moderate[b]		
30 per 100	**33 per 100** (29 to 38)	
High[b]		
50 per 100	**55 per 100** (48 to 63)	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **effect with a PIL developed with feedback from users** (and its 95% confidence interval) is based on the assumed risk in the comparison group (usual PIL) and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR**: risk ratio.

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

[a]This is the baseline recruitment measured in the studies presented in the 'Summary of findings' table.
[b]We selected the low, moderate and high illustrative recruitment levels of 10%, 30% and 50% based on our prior experience with trial recruitment.
[c]We downgraded evidence by 1 level because of indirectness: Chen 2011 actually measures entry to pre-randomisation phase, not recruitment.

Summary of findings 6. Providing information by video versus by standard means alone

Video information versus standard information alone

Patient or population: individuals eligible for trial
Settings: any
Intervention: video information
Comparison: standard information (mixed but not including video)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Effect with standard information	Effect with video information			
Number recruited	**As measured**[a]		**RR 1.08**	4695	⊕⊖⊖⊖

33 per 100	**36 per 100** (29 to 43)	(0.89 to 1.31)	(3 studies)	**Very low**[c, d, e]
Low[b]				
10 per 100	**11 per 100** (9 to 13)			
Moderate[b]				
30 per 100	**32 per 100** (27 to 39)			
High[b]				
50 per 100	**54 per 100** (45 to 66)			

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **effect with the video information** (and its 95% confidence interval) is based on the assumed risk in the comparison group (standard information) and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR**: risk ratio.

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

[a]This is the baseline recruitment measured in the studies presented in the 'Summary of findings' table.
[b]We selected the low, moderate and high illustrative recruitment levels of 10%, 30% and 50% based on our prior experience with trial recruitment.
[c]We downgraded by 1 level because of study limitations: both Du 2008 and Du 2009 were at unclear risk of bias.
[d]We downgraded 1 level because of inconsistency. All 3 studies suggest little or no difference in recruitment due to the intervention but the Hutchison 2007 point estimate was in favour of control, while that of Du 2008 and Du 2009 studies was in favour of the intervention.
[e]We downgraded 1 level because of imprecision and wide CIs.

Summary of findings 7. Financial incentive vs no incentive

Financial incentive vs no incentive
Patient or population: individuals eligible for a trial **Settings**: any

Intervention: financial incentive
Comparison: no incentive

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Effect with no incentive	Effect with financial incentive			
Number recruited	**As measured**[a]		**RR 1.48** (0.85 to 2.58)	1506 (6 studies)	⊕⊕⊕⊖ **Moderate**[c]
	9 per 100	**13 per 100** (8 to 23)			
	Low[b]				
	10 per 100	**15 per 100** (9 to 26)			
	Moderate[b]				
	30 per 100	**44 per 100** (26 to 77)			
	High[b]				
	50 per 100	**74 per 100** (43 to 100)			

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **effect with a financial incentive** (and its 95% confidence interval) is based on the assumed risk in the comparison group (no incentive) and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR**: risk ratio.

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

[a]This is the baseline recruitment measured in the studies presented in the 'Summary of findings' table.
[b] We selected the low, moderate and high illustrative recruitment levels of 10%, 30% and 50% based on our prior experience with trial recruitment.
[c]We downgraded 1 level for inconsistency. There was substantial heterogeneity, $I^2 = 65\%$.

BACKGROUND

All randomised trials need to recruit participants, but this is often a challenge. Poor recruitment can lead to an underpowered study, which may report clinically relevant effects as statistically non-significant. A non-significant finding increases the risk that an effective intervention will be abandoned before its true value is established, or that there will be a delay in demonstrating this value while more trials or meta-analyses are done. Underpowered trials also raise an ethical problem: trialists have exposed participants to an intervention with uncertain benefit but may still be unable to determine whether the intervention does more good than harm on completion. Poor recruitment can also lead to the extension of the trial, increasing costs.

Although investigations differ in their estimates of how many studies achieve their recruitment targets, the proportion is likely to be less than half (Charlson 1984; Foy 2003; Haidich 2001; McDonald 2006; Sully 2013). For example, McDonald 2006 found that only 38 (31%) of 114 trials achieved their original recruitment target, and 65 (53%) were extended. More recent replications of this work by Sully 2013 and Walters 2017 found that the number of trials meeting recruitment targets had increased to around 50%. In Sully 2013, the overall start to recruitment was delayed in 47 (41%) trials and early recruitment problems occurred in 77 (63%). The costs of poor recruitment can be huge (Kitterman 2011).

Trialists use many interventions to improve recruitment (see for example Caldwell 2010, Watson 2006 and Prescott 1999), but it is generally difficult to predict their effect.

This review updates our previous reviews (Treweek 2010; Treweek 2013). In addition to updating the search, we have made some important changes that affect how studies are selected for presentation in the Results and Discussion sections; essentially we neither present nor discuss studies that we consider are at high risk of bias unless it was possible to include them in a meta-analysis.

OBJECTIVES

To quantify the effects of strategies for improving recruitment of participants to randomised trials. A secondary objective is to assess the evidence for the effect of the research setting (e.g. primary care versus secondary care) on recruitment.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised and quasi-randomised trials of interventions to improve recruitment of participants to randomised trials.

Types of data

Randomised and quasi-randomised trials of recruitment strategies set in the context of trials but not limited to health care; interventions that work in other fields (e.g. education, housing) could be applicable to healthcare settings. Strategies both within real settings and in hypothetical trials (studies that ask potential participants whether they would take part in a trial if it was run but the trial does not actually exist) are eligible for this version of the review.

However, in future versions of this review we will exclude hypothetical trials since we consider their design to confer a high risk of bias because the recruitment decision is not a real one; many also have other methodological problems. The three main reasons for excluding these trials in future versions of the review are as follows.

1. The relevance of the results of hypothetical trials will always be in doubt because of uncertainty as to how people would have reacted had the decision to take part in a trial been real rather than hypothetical.
2. It is possible to study recruitment interventions in real trials, avoiding the above problem.
3. Now that the number of evaluations in real trials has increased, we do not think the trade-off between value added and work involved to include hypothetical trials is worthwhile for future versions of this review.

We excluded research into ways to improve questionnaire response and research looking at incentives and disincentives for clinicians to recruit participants to trials, as complementary Cochrane Methodology Reviews address these issues (Edwards 2009; Rendell 2007; Preston 2016). We also excluded studies of retention strategies, as a Cochrane Methodology Review on strategies to reduce attrition from trials already exists (Brueton 2013).

Types of methods

Any intervention that aimed to improve recruitment of participants to a randomised trial. The interventions being studied could be directed at potential participants (e.g. patients being randomised to a trial), collaborators (e.g. clinicians recruiting patients for a trial), or others (e.g. research ethics committees). Examples of such interventions are signed letters introducing the trial from influential people, alternative methods of providing information about the trial to potential participants, presenting ethics committees with (and getting approval for) a ranked list of recruitment strategies that might be used depending how recruitment goes so as to avoid delays before trials teams can implement additional recruitment strategies, additional training for collaborators, financial incentives for participants, telephone follow-up of expressions of interest and modifications to the design of the trial (e.g. using a preference design).

Types of outcome measures

Primary outcomes

Proportion of eligible individuals or centres recruited.

Secondary outcomes

None.

Note: the lack of any secondary outcomes is a change from the previous version of the review, which gave 'Rate at which participants were recruited' as a secondary outcome. We have removed this because rate is rarely reported. We will continue to report rate of recruitment if the primary outcome is not available but will no longer consider it as a secondary outcome. We will reconsider this decision in future versions of this review.

Search methods for identification of studies

We searched the following electronic databases without language restriction for eligible studies.

- The Cochrane Methodology Review Group Specialised Register (CMR) in the Cochrane Library (July 2012; searched 11 February 2015).
- MEDLINE and MEDLINE In Process (OVID) (1946 to 10 February 2015).
- Embase (OVID) (1996 to 2015 Week 06).
- Science Citation Index & Social Science Citation Index (ISI) (2009 to 11 February 2015)
- ERIC (EBSCO) (2009 to 11 February 2015).

Appendix 1 details the full search strategies for all databases. We downloaded the search results to Endnote reference management software and de-duplicated them.

Data collection and analysis

We prepared a revised protocol for this updated review, including it as Appendix 2 to make it available alongside this review in the Cochrane Library.

Selection of studies

Two review authors independently screened the titles and abstracts of all references identified by the search strategy. We obtained the full versions of papers not definitely excluded at that stage for detailed review. Two review authors independently assessed all potentially eligible studies to determine if they met the inclusion criteria. We discussed differences of opinion and when necessary, a third review author read the full papers.

Data extraction and management

Two review authors independently carried out data extraction for each included record (using a proforma specifically designed for the purpose). We resolved differences in data extraction by discussion. We extracted data on the method evaluated; country where the study took place; nature of the population; nature of the study setting; nature of the study to be recruited into; randomisation or quasi-randomisation method; and numbers and proportions of participants in the intervention and comparator groups of the study comparing recruitment strategies.

Assessment of risk of bias in included studies

We assessed the risk of bias using the Cochrane 'Risk of bias' tool (Cochrane Risk of Bias tool), including reassessing all 44 of the included studies from the previous version of this review carried forward into the update. We used GRADE on all studies where relevant data were available (Guyatt 2008). Where we have done a meta-analysis, we provide the details of the GRADE assessment in the relevant 'Summary of findings' table. Where we used GRADE on a single study, we used the following rules for assigning a GRADE rating of high, moderate, low or very low certainty.

1. Baseline rating: all studies start at high.
2. Study limitations: downgrade all studies at high risk of bias by two levels; downgrade all studies at uncertain risk of bias by one level.
3. Inconsistency: assume no serious inconsistency.
4. Indirectness: downgrade all hypothetical studies by two levels.
5. Imprecision: downgrade all single studies by one level because of the sparsity of data; downgrade by a further level if the confidence interval is wide and includes a risk difference of 0.
6. Reporting bias: assume no serious reporting bias.

At least two reviewers performed all GRADE assessments. We generated 'Summary of findings' tables using only studies with real recruitment (i.e. not data for hypothetical studies). We present information on risk of bias for all included studies in Characteristics of included studies.

Although we did not exclude studies because of a high of risk of bias, we do not mention them in the text of the Results or Discussion because of the low confidence we have in the data they present, except in cases where we could include them in a meta-analysis and interpret the datatogether with data from other studies.

Studies at high risk of bias do appear in Data and analyses, but we suggest that readers use these data only to make decisions as to whether they would like to evaluate the intervention themselves in a more rigorous way. We do not believe the data support judgements about effect.

Data for hypothetical studies are included in Data and analyses for this version of the review. We will exclude these studies from future versions of this review.

Assessment of heterogeneity

We sought statistical evidence of heterogeneity of results of trials using the Chi^2 test for heterogeneity, and we quantified the degree of heterogeneity observed in the results using the I^2 statistic (Higgins 2003). Where we detected substantial heterogeneity, we informally investigated possible explanations and summarised the data using a random-effects analysis if appropriate. We planned to explore the following factors in subgroup analyses, assuming enough studies were identified, as we believed that these were plausible explanations for heterogeneity.

- Type of design used to evaluate recruitment strategies (randomised versus quasi-randomised) and allocation concealment (adequate versus inadequate or unclear).
- Setting of the study recruiting participants (e.g. primary versus secondary care; healthcare versus non-healthcare settings).
- Disease area in which the evaluation was done (e.g. cancer versus lifestyle change).
- Design of the study recruiting participants (e.g. open versus blinded studies, trials with placebo arms versus those without).
- Target group (e.g. ethics committees, clinicians, patients).
- Recruitment to hypothetical versus real trials (future versions of this review, which will exclude hypothetical trials, will not include this subgroup).

Assessment of reporting biases

We investigated reporting (publication) bias for the primary outcomes using a funnel plot where 10 or more studies were available.

Data synthesis

We grouped trials according to the type of intervention based on the categorisation used in the Online Resource for Recruitment research in Clinical triAls (ORRCA) project. We split one ORRCA category (Recruitment Information Needs) into two so as to separate out interventions aimed at the consent process from those aimed at more general participant information. This classification results in seven categories.

1. **Design (category A)**. This includes changes to the general design of the trial specifically done to increase recruitment.
2. **Pre-trial planning (category B)**. This includes work done before the trial starts (possibly in a separate study) to explicitly make it more likely that recruitment will be successful.
3. **Trial conduct changes (category C)**. This includes initiatives implemented once the trial has started such as better ways of identifying participants, changes to how data are collected, changes to the type of data collected and tailoring recruitment to different types of participant.
4. **Modifications to the consent process (category D)**. This includes changes to the staff member helping with consent, when consent is taken, what sort of consent information is presented and how it is presented.
5. **Modification to the information given to potential participants about the trial (category E).** This includes who provides it, when, where what sort of information is presented, how the information is presented.
6. **Interventions aimed at the recruiter or recruitment site (category F)**. This includes anything that is aimed at the recruiter or recruitment site staff rather than the person being recruited, such as changes to training.
7. **Incentives (category G)**. Financial and other incentives for participants (but not staff, which is covered by a separate review).

We present results as risk differences (RD) with the associated 95% confidence intervals (CIs) where sufficient data were available. We only included cluster-randomised trials in the meta-analysis if sufficient data were reported to allow inclusion of analyses that adjusted for clustering; an odds ratio (OR) was used as the summary effect in the meta-analysis result if risk difference or risk ratio clustering adjusted analyses were not possible with available data. Where two or more studies could be included in a meta-analyses, we used a fixed-effect approach to produce a pooled estimate in the absence of substantial heterogeneity.

RESULTS

Description of studies

See Characteristics of included studies and Characteristics of excluded studies.

We screened 25,432 titles and abstracts (9098 in this update) and sought the full text of 377 records (76 in this update) to confirm inclusion or clarify uncertainties regarding eligibility, generally due to the lack of an abstract. We were able to obtain the full text of 374 of these articles; the remaining three records were not retrievable because the title or abstract reference was incomplete or incorrect.

Additionally, we retrieved the full text of six articles identified outside the search. A colleague identified Fleissig 2001 as missed in the previous version of the review; our search strategy had picked up the article, but we had rejected it in error during abstract checking. Man 2015a and Man 2015b (a single study describing two embedded recruitment trials), Jennings 2015a, Jennings 2015b, Jennings 2015c, Jennings 2015d, Jennings 2015e (a single study describing five embedded recruitment trials), Foss 2016, Lee 2017 and Cockayne 2017 are more recent studies that we identified while updating the review. We excluded one study that we had included in the previous version of the review, Harris 2008, because it was not recruiting to a trial and was therefore ineligible.

A total of 68 studies were eligible for inclusion. Studies came from 12 countries; there was also one multinational study involving 19 countries. The USA and UK dominated, with 25 and 22 studies, respectively. The next largest was Australia with eight studies. The full breakdown is given in Table 1.

There were 63 studies involving interventions aimed directly at trial participants, and five evaluated interventions aimed at those recruiting participants. At least 74,519 individuals were involved in the 68 studies; it was not clear how many participants were recruited in two studies. The figure of 74,519 includes both individuals who were recruited as well as those who were approached about recruitment but declined. A breakdown of participant numbers is given in Appendix 3.

There were too few studies evaluating the same or similar interventions to allow us to do any of our planned subgroup analyses.

Risk of bias in included studies

See Characteristics of included studies; Figure 1; Figure 2.

Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

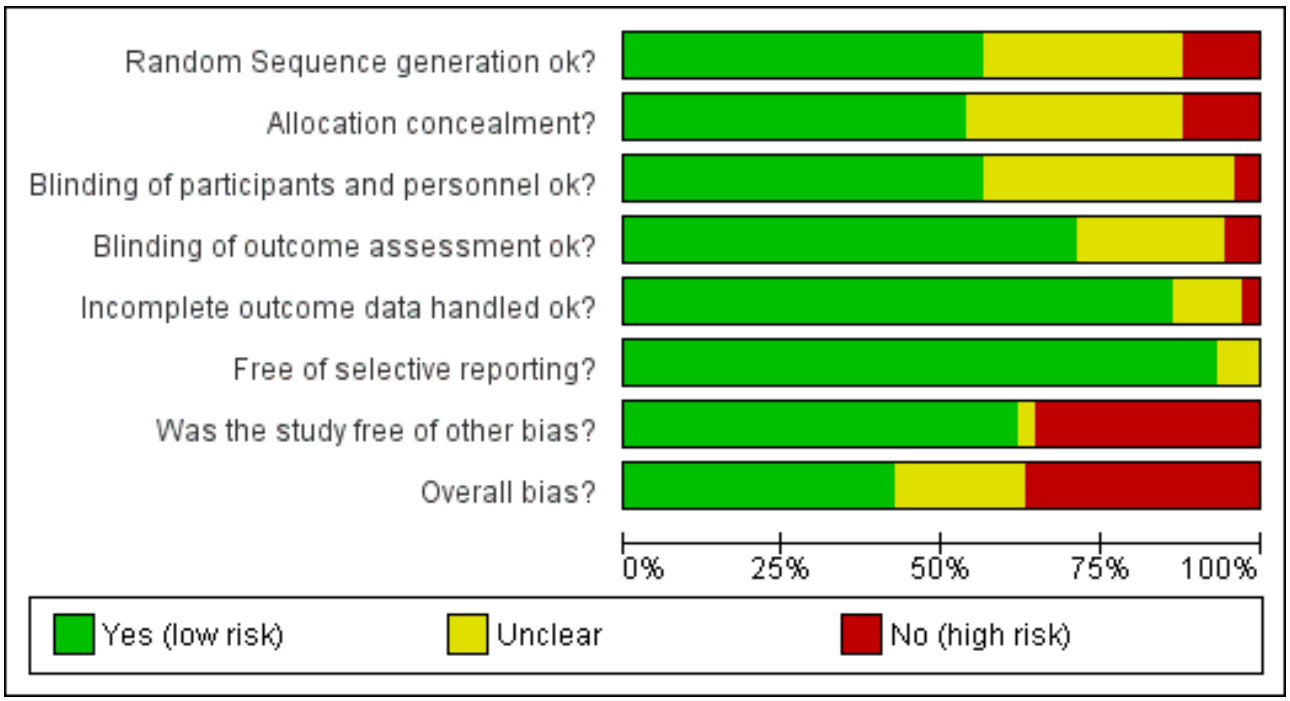


Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

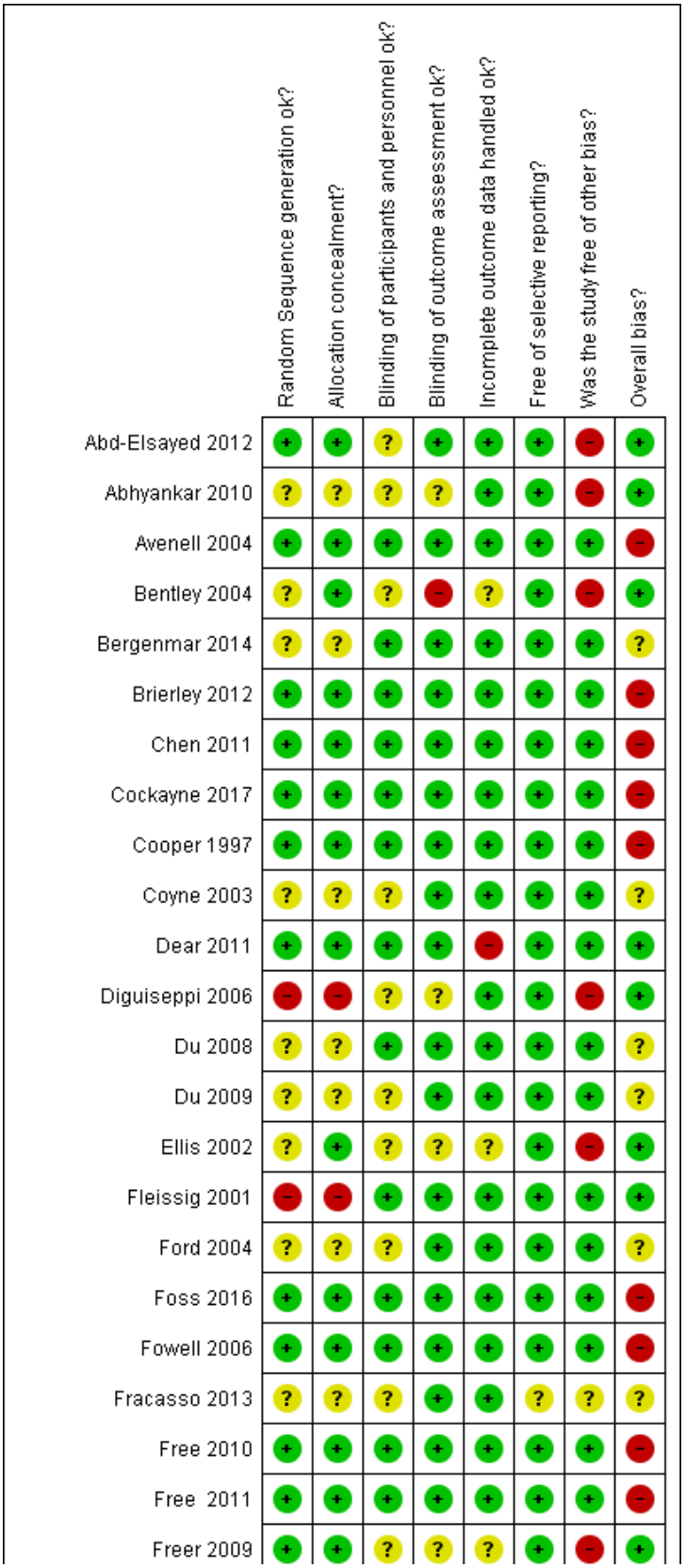


Figure 2. (Continued)

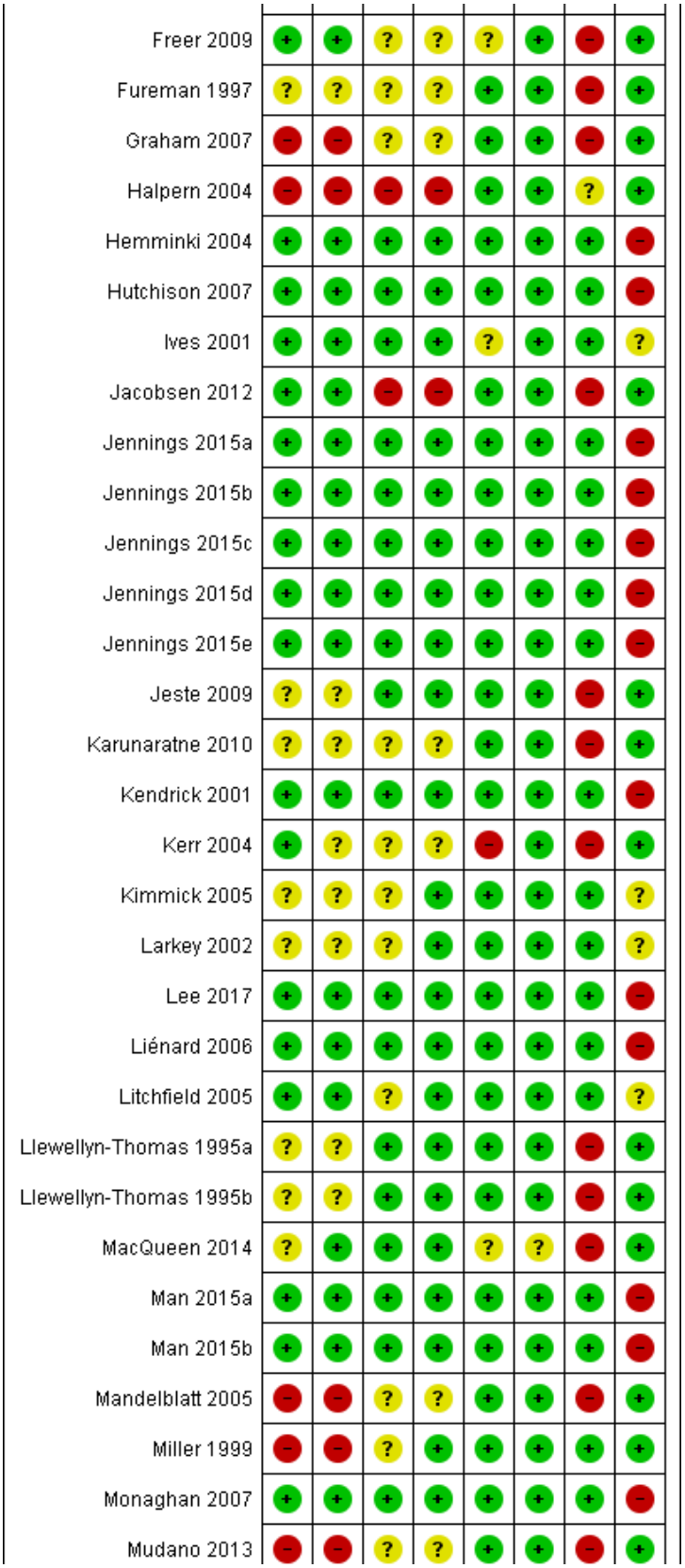
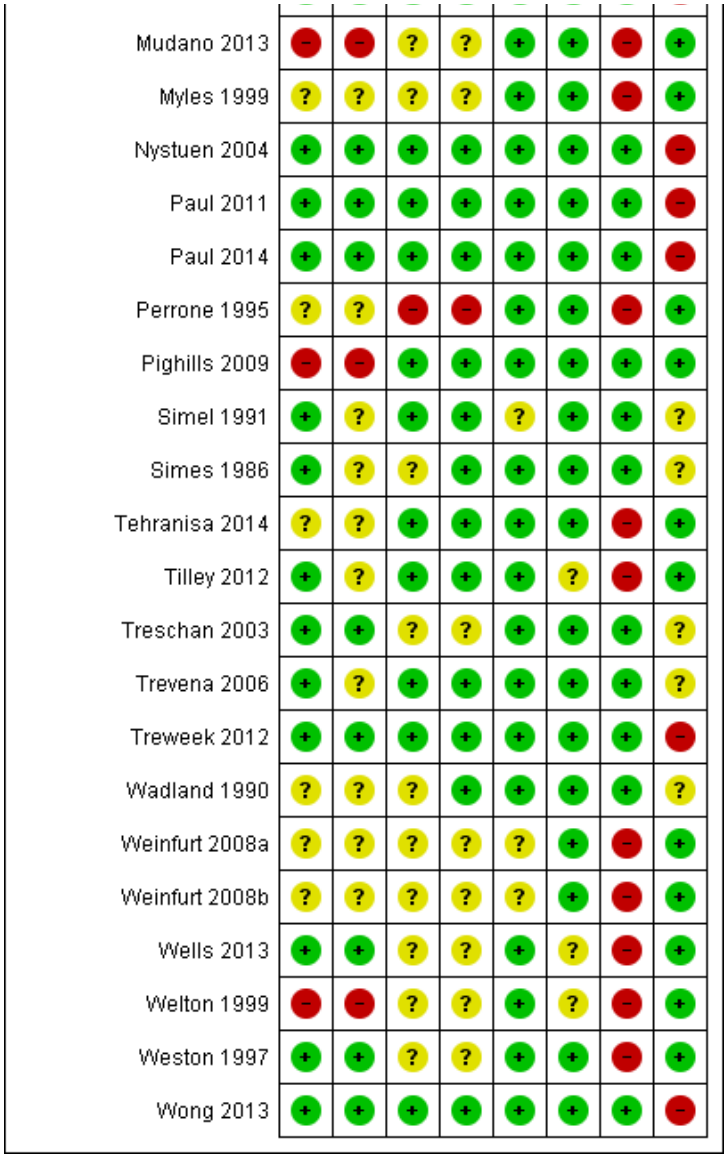


Figure 2. (Continued)



Trialists described all their studies as either randomised (62 studies) or quasi-randomised (6 studies). We considered the overall assessment of the risk of bias as low for 22 studies, unclear for 14 studies and high for 32 studies.

There were 26 studies involving hypothetical trials, and we judged 24 of these to be at high risk of bias because the participation decision was not a real one (there may also have been other weaknesses). We judged Treschan 2003 to be at unclear risk of bias because although participants were not told the trial was hypothetical initially, it was not clear if this remained the case throughout. Simel 1991 also involved a hypothetical trial, but participants were unaware of this; the use of a hypothetical trial did not therefore affect our risk of bias assessment for this study, and we judged it to be at unclear risk of bias.

Effect of methods

See: **Summary of findings for the main comparison** Open trial versus blinded trial; **Summary of findings 2** Telephone reminder versus no telephone reminder; **Summary of findings 3** Bespoke, user-tested participant information leaflet (PIL) vs usual PIL; **Summary of findings 4** Brief participant information leaflet (PIL) vs usual PIL; **Summary of findings 5** Participant information leaflet (PIL) developed with feedback from users vs usual PIL; **Summary of findings 6** Providing information by video versus by standard means alone; **Summary of findings 7** Financial incentive vs no incentive

Table 2 shows the list of included studies in each of our seven categories. The divisions between categories were not always clear, and we placed studies according to the original study authors' stated focus.

We report the results of studies rated as being at low or uncertain risk of bias here. The full list of 72 comparisons tested, irrespective of risk of bias, is given in Appendix 4.

We produced 'Summary of findings' tables for all interventions where more than one study done in a real trial was available, giving seven in total (Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3; Summary of findings 4; Summary of findings 5; Summary of findings 6; Summary of findings 7).

Design - category A

Eight studies focused on trial design as a way to improve recruitment; we judged two (25%) of these to be at high risk of bias and do not present them here. The remaining six studies involved 5637 participants; one study also targeted general practices and recruited 28 centres.

We summarise the results for the six studies as follows.

1. An open design compared to a blinded, placebo-controlled design increases recruitment: RD = 10% (95% CI 7% to 13%); GRADE: high; Analysis 1.1; Summary of findings for the main comparison. This is based on two studies: Avenell 2004 (fracture prevention); RoB: low; Hemminki 2004 (postmenopausal hormone therapy) RoB: low.
2. A patient preference design increased total participation but made little or no difference to recruitment to the randomised trial: RD = -4% (reduced recruitment) (95% CI -15% to 7%); GRADE: low (-2 levels: imprecision– single study; wide CI crossing RD=0); Analysis 2.1. This is based on one study: Cooper 1997 (management strategies for heavy menstrual bleeding) RoB: low.
3. Internet-based, electronic data collection compared to paper-based may reduce recruitment: RD = -13% (reduced recruitment) (95% CI -24% to -3%); GRADE: low (-1 level: study limitations–unclear RoB; -1 level: imprecision–single study); Analysis 3.1. This is based on one study: Litchfield 2005 (delivery systems for insulin) RoB: unclear.
4. Cluster-randomised design compared to Zelen design. The study had only two sites (clusters) with few participants: 6 out of 24 potential participants were recruited in the cluster arm, compared to 0 out of 29 in the Zelen arm; RoB: low. This is based on one study: Fowell 2006 (palliative care) RoB: low.
5. Two-stage randomisation to choose duration of treatment. Data on numbers recruited not available for one arm but up-front randomisation to 3 or 6 months treatment gave a recruitment rate of 5.21 per year per centre compared to 4.09 for delayed randomisation to decide whether second 3 month treatment given. This is based on one study: Paul 2011 (adjuvant treatment for colorectal cancer) RoB: low.

Pre-trial planning - category B

There were no studies in this category.

Trial conduct changes - category C

Nine studies assessed changes in trial conduct to improve recruitment. We judged four (44%) to be at high risk of bias and do not present them here. The remaining five studies involved 4531 participants.

1. Using a telephone reminder to contact non-responders to a postal invitation increases recruitment. RD = 6% (95% CI 3% to 9%); GRADE: high; Analysis 6.1; Summary of findings 2. This is based on two studies: Nystuen 2004 (getting people to return to work); RoB: low; Wong 2013 (colorectal cancer) RoB: low. **NOTE**: the evidence for this intervention comes entirely from trials with low (<10%) underlying recruitment. When applied to trials with higher recruitment we would downgrade the GRADE assessment because of Indirectness to moderate.
2. Mentioning scarcity of trial places in SMS messages probably increased recruitment. RD = 3% (95% CI = 1% to 6%); GRADE: moderate (-1 level: imprecision–single study); Analysis 7.1. This is based on one study: Free 2011 (smoking cessation) RoB: low..
3. Giving quotes from previous participants in SMS messages probably increased recruitment. RD = 4% (95% CI = 2% to 6%); GRADE: moderate (-1 level: imprecision–single study); Analysis 8.1. This is based on one study: Free 2010 (smoking cessation) RoB: low.
4. Using email invitations made little or no difference to recruitment compared to postal invitations. RD = 1% (95% CI = -3% to 4%); GRADE: moderate (-1 level: imprecision–single study); Analysis 9.1. This is based on one study: Treweek 2012 (antibiotic prescribing by GPs) RoB: low.

Modification to the consent process - category D

Eight studies assessed the effect of modifying the consent process on trial recruitment. Of the five (63%) we judged to be at high risk of bias, we could have combined two (Myles 1999; Perrone 1995): however, both were hypothetical, and we do not present them here. The three studies presented here involved 482 participants.

1. Opt-out consent may improve recruitment. RD = 19% (95% CI = 3% to 35%); GRADE: low (-1 level: study limitations–unclear RoB; -1 level: imprecision–single study); Analysis 15.1. This is based on one study: Trevena 2006 (colorectal cancer) RoB: unclear.
2. It is very uncertain whether a researcher reading out the consent details affects recruitment. RD = 6% (95% CI = -13% to 25%); GRADE: very low (-1 level: study limitations–unclear RoB; -2 levels: imprecision–single study; wide CI crossing RD=0); Analysis 18.1. This is based on one study: Wadland 1990 (smoking cessation) RoB: unclear.
3. Easy to read consent form. Although the authors of this cluster trial did not present centre-level recruitment data, or provide an intracluster correlation coefficient, they did consider intracluster correlation in their analysis and found that recruitment did not differ significantly between the two trial groups (RD=3; P = 0.32). This is based on one study: Coyne 2003 (cancer) RoB: unclear.

Modification to the information given to potential participants about the trial - category E

Thirty-five studies assessed the effects of modifying the information given to potential participants about the trial for trial recruitment. We judged 17 (49%) to be at high risk of bias and do not present them here. The remaining 17 studies involved 42,826 participants.

1. Optimising the participant information leaflet (PIL) through a particular, bespoke process involving formal user-testing makes little or no difference to recruitment. RD = 1% (95% CI = -1% to 3%); GRADE: high; Analysis 25.1; Summary of findings 3. This is based on three studies: Man 2015a (depression) RoB: low; Man 2015b (cardiovascular disease) RoB: low; Cockayne 2017 (falls prevention) RoB: low.

2. Using a brief patient information leaflet (PIL) makes little or no difference to recruitment compared to a full PIL. RD = 0% (95% CI = -2% to 2%); GRADE: moderate (-1 level: indirectness, Chen 2011 actually measures entry to pre-randomisation phase); Analysis 26.1; Summary of findings 4. This is based on two studies: Chen 2011 (unclear) RoB: low; Brierley 2012 (depression) RoB: low.
3. Enclosing a questionnaire covering issues relevant to trial with the invitation probably increases recruitment. RD = 18% (95% CI = 16% to 20%); GRADE: moderate (-1 level: imprecision–single study); Analysis 27.1 This is based on one study: Kendrick 2001 (injury prevention, recruiting family units) RoB: low.
4. Optimising the PIL through using user feedback probably makes little or no difference in recruitment. RD = 0% (95% CI = 0% to 1%); GRADE: moderate (-1 level: indirectness, Chen 2011 actually measures entry to pre-randomisation phase); Analysis 28.1; Summary of findings 5 This is based on two studies: Chen 2011 (unclear) RoB: low; Cockayne 2017 (falls prevention) RoB: low.
5. Sending a recruitment primer letter may have little or no effect on recruitment. RD = 0% (95% CI = -6% to 6%); GRADE: low (-2 levels: imprecision–single study; wide CI crossing RD=0); Analysis 29.1 This is based on one study: Paul 2014 (colorectal cancer) RoB: low.
6. Providing information over the telephone may have little or no effect on recruitment. RD = -7% (reduced recruitment) (95% CI = -18% to 5%); GRADE: low (-2 levels: imprecision–single study; wide CI crossing RD=0); Analysis 30.1 This is based on one study: Foss 2016 (vaccination) RoB: low.
7. Recruitment at a church and other enhancements may improve recruitment. RD = 1% (95% CI = 0% to 2%); GRADE: low (-1 level: study limitations–unclear RoB; -1 level: imprecision–single study); Analysis 31.1 This is based on one study: Ford 2004 (cancer) RoB: unclear.
8. An enhanced recruitment package including more contact may make little or no difference in recruitment. RD = 0% (95% CI = -1% to 0%); GRADE: low (-1 level: study limitations–unclear RoB; -1 level: imprecision–single study); Analysis 32.1 This is based on one study: Ford 2004 (cancer) RoB: unclear.
9. An enhanced recruitment package including more contact by telephone may make little or no difference in recruitment. RD = 0% (95% CI = -1% to 1%); GRADE: low (-1 level: study limitations–unclear RoB; -1 level: imprecision–single study); Analysis 33.1 This is based on one study: Ford 2004 (cancer) RoB: unclear.
10. Emphasising risk in information may make little or no difference to recruitment. RD = 0% (95% CI = -1% to 1%); GRADE: low (-1 level: study limitations–unclear RoB; -1 level: imprecision–single study); Analysis 34.1 This is based on one study: Treschan 2003 (unclear) RoB: unclear.
11. Writing treatment effect as 'twice as fast' rather than 'half as fast' may improve recruitment. RD = 26% (95% CI = 7% to 45%); GRADE: low (-1 level: study limitations–unclear RoB; -1 level: imprecision–single study); Analysis 35.1 This is based on one study: Simel 1991 (pain relief) RoB: unclear.
12. Emphasising pain in information may reduce recruitment. RD = -29% (reduced recruitment) (95% CI = -48% to -10%); GRADE: low (-1 level: study limitations–unclear RoB; -1 level: imprecision–single study); Analysis 36.1 Thsi is based on one study: Treschan 2003 (unclear) RoB: unclear.
13. It is very uncertain whether providing trial information by video affects recruitment. RD = 3% (95% CI = -3% to 9%); GRADE: very low (-1 level: study limitations–unclear RoB; -1 level: inconsistency; -1 level: imprecision–wide CI crossing RD=0); Analysis 37.1; Summary of findings 6 This is based on three studies: Hutchison 2007 (cancer) RoB: low; Du 2008 (lung cancer) RoB: unclear; Du 2009 (breast cancer) RoB: unclear.
14. It is very uncertain whether providing an audio record of the discussion about the trial affects recruitment. RD = -3% (reduced recruitment) (95% CI = -19% to 13%); GRADE: very low (-1 level: study limitations–unclear RoB; -2 levels: imprecision–single study; wide CI crossing RD=0); Analysis 38.1 This is based on one study: Bergenmar 2014 (cancer) RoB: unclear.
15. It is very uncertain whether providing a clinical trial booklet together with standard information affects recruitment. RD = 20% (95% CI = -5% to 46%); GRADE: very low (-1 level: study limitations–unclear RoB; -2 levels: imprecision–single study; wide CI crossing RD=0); Analysis 39.1 This is based on one study: Ives 2001 (HIV) RoB: unclear.
16. It is very uncertain whether providing total information disclosure rather than leaving it to recruiters as to what to reveal affects recruitment. RD = 11% (95% CI = -6% to 28%); GRADE: very low (-1 level: study limitations–unclear RoB; -2 levels: imprecision–single study; wide CI crossing RD=0); Analysis 40.1 This is based on one study: Simes 1986 (cancer) RoB: unclear.
17. Educational material to provide additional information about a trial. Although the authors of this cluster trial did not present centre-level recruitment data, or provide an intracluster correlation coefficient, they did consider intracluster correlation in their analysis. An educational package did not significantly increase recruitment compared to standard information alone (31% of participants aged over 65 in both intervention and control groups in year 2, P = 0.83). This is based on one study: Kimmick 2005 (cancer) RoB: unclear.
18. Trained recruiters from a similar ethnic background to study population already taking part in a trial as lay advocates. The authors of this cluster trial did not report an analysis that corrected for the clustering or provide an intracluster correlation coefficient. Data at the recruiter aggregate level were reported on whether a recruiter did or did not recruit anyone to the trial. Eight of the 28 trained Hispanic recruiters recruited one or more women to the trial whereas none of the 26 untrained Hispanic women recruited anyone the trial. Two of the 42 untrained Anglo control group recruited two women. This is based on one study: Larkey 2002 (unclear) RoB: low.

Interventions aimed at the recruiter or recruitment site - category F

Five studies assessed interventions aimed at the recruiter or recruitment site. We judged two (40%) of these to be at high risk of bias and do not present them here. The remaining three studies involved at least 602 participants; it was not clear how many participants were involved in one study, although 167 recruitment sites were involved.

1. Using a postcard teaser campaign made little or no difference to recruitment. RD = 0% (95% CI = -4% to 5%); GRADE: moderate (-1 level: imprecision–single study); Analysis 55.1 This is based on one study: Lee 2017 (recruiting GP practices to low back pain trial) RoB: low.
2. Onsite initiation visits. The authors did not present the proportion of eligible participants recruited, only the number

recruited: visited sites recruited 302 participants while those not receiving visits recruited 271. This is based on one study: Liénard 2006 (breast cancer) RoB: low.

3. Additional communication strategies such as tailored feedback on recruitment. The median total number of participants in the additional communication group was 37.5, compared to 37.0 in the standard communication group. Intervention centres achieved half their recruitment targets in 4.4 months, compared to 5.8 months for control centres. This is based on one study: Monaghan 2007 (diabetes) RoB: low.

Incentives - category G

Four studies assessed incentives for recruitment, but we judged two (50%) to be at high risk of bias and do not present them here. The remaining two studies included one that involved five trials of the same intervention and together both studies involved a total of 1,506 participants.

1. Financial incentives offered to potential participants probably improve recruitment. RD = 4% (95% CI = -1% to 8%); GRADE: moderate (-1 level: inconsistency); Analysis 57.1; Summary of findings 7 This is based on six studies, one including five trials within a single published study: Free 2010 (smoking cessation) RoB: low; Jennings 2015a; Jennings 2015b; Jennings 2015c; Jennings 2015d; Jennings 2015e (primary care, older people, mainly hypertension) RoB: low.

DISCUSSION

Principal findings

Trialists looking to the literature to select components of an evidence-informed trial recruitment strategy will be disappointed to find that the literature has plenty of variety but little depth, and therefore much uncertainty. There are three findings that carry a GRADE high certainty of the evidence.

1. An open design compared to a blinded, placebo-controlled design increases recruitment (RD 10%, 95% CI 7% to 13%; Analysis 1.1; Summary of findings for the main comparison; intervention category A).
2. Using a telephone reminder to contact non-responders to a postal invitation increases recruitment (RD 6%, 95% CI 3% to 9%; Analysis 6.1; Summary of findings 2); intervention category C; see note below).
3. Optimising the participant information leaflet (PIL) through bespoke development plus formal user-testing makes little or no difference to recruitment (RD 1%, 95% CI −1% to 3%; Analysis 25.1; Summary of findings 3; intervention category E).

Findings 2 and 3 could in principle be considered for many trials. Finding 1 is unlikely to be widely attractive because of the internal validity problem that open trial designs present. Moreover, the evidence for finding 2 comes entirely from trials with low (< 10%) underlying recruitment. When seeking to apply this to trials with higher recruitment, we would downgrade the GRADE assessment to moderate certainty due to indirectness.

There are eight findings that carry a moderate GRADE certainty of the evidence, mostly from single, well-conducted studies (three in intervention category C, three in category E, one in category F and one in Category G). We rated the GRADE certainty of the evidence for all other findings as low or very low, or as being at high risk of bias if insufficient data were available to do a GRADE assessment. There are no evaluations of an intervention used pre-trial to support recruitment (category B) and no evaluations of a consent-related intervention (category D) with a GRADE certainty of the evidence better than low.

Of the 68 included studies, none addresses recruitment to paediatric trials (see Table 2), meaning trialists lack any evidence to inform decisions around participation in these trials. Therefore, identifying effective interventions to support recruitment to paediatric trials is also a priority. Researchers may be wary of adding research methods evaluations to paediatric trials because of, among other challenges, additional ethical requirements. However, because the challenges of recruitment to paediatric trials are likely to be different from those of other trials, extrapolating from trials in adults is unlikely to be sufficient. Moreover, one of the key ethical requirements for research with children – that it is not possible to do the work with adults – is met. For some trials it is likely that the target of the recruitment intervention will be parents rather than children despite being a paediatric trial, so the ethical requirements may in fact be similar to those for trials in adults. Finally, recruitment to paediatric trials will remain less efficient than it could be without work evaluating alternative approaches to recruitment.

While new studies were added to the review, the overall picture with regard to interventions to improve recruitment to trials remains similar to our 2010 version (Treweek 2010), which was in turn largely unchanged from the 2007 version before it (Mapstone 2007). In other words, a decade of research into the effect of interventions to improve trial recruitment has not substantively reduced our uncertainty with regards to which interventions make recruitment more likely. The chief reasons for this are a preference for methodology researchers to evaluate new interventions rather than to replicate evaluations of existing interventions. Poor reporting also leads to uncertain risk of bias assessments.

There is some good news, though. While the intervention type of the studies added to this update is the same as in the 2010 update (Category E, modification to the information given to participants dominates both updates), the methodological quality of studies seems to be improving. Of the 18 studies new to the 2010 update, 12 were at high risk of bias (66%), compared to 11 out of 24 (46%) added in 2017. We judged all 5 of the included studies published in the last three years (2015 to 2017) and all 10 of the recruitment evaluations they describe, to be at low risk of bias (Cockayne 2017; Foss 2016; Jennings 2015a; Jennings 2015b; Jennings 2015c; Jennings 2015d; Jennings 2015e; Lee 2017; Man 2015a; Man 2015b). Equally important, initiatives such as START (research.bmh.manchester.ac.uk/mrcstart) are leading to coordinated evaluation of recruitment interventions in many trials, participant information leaflets and video information in the case of START. The three studies in the bespoke, user-tested participant information leaflet analysis (Analysis 25.1; Summary of findings 3) came via START over a three-year period (2015 to 2017). By contrast, the two studies in the telephone reminder analysis (Analysis 6.1; Summary of findings 2) are nine years apart (2004 to 2013). START will provide more studies for the next update of this review. Timely reduction in uncertainty around interventions needs focus, coordination and replication.

Nevertheless, we judged around half of the 68 included studies to be at high risk of bias, meaning that we have so little confidence in their findings that we chose to neither present nor discuss their results. We will continue to make this choice in future versions of this review. Encouragingly, more recent studies are better reported and much more likely to be judged to be at low risk of bias. A recent reporting standard for embedded recruitment studies may improve things further (Madurasinghe 2016).

We will exclude 24 hypothetical studies from future versions of this review because their findings are not based on real decisions and provide only indirect evidence. It is clearly possible to do studies in real trials, and these will be our focus inthe future.

Finally, we would welcome feedback about studies that we have missed or newly published studies that we should include in future versions of the review.

AUTHORS' CONCLUSIONS

Implication for methodological research

The methodological literature with regard to recruitment needs more depth. The current approach of uncoordinated evaluation has led to the usable information content of this review remaining largely unchanged for more than a decade despite the addition of 41 studies. The implications for methodological research are clear.

1. The research community should establish a process for prioritising which recruitment interventions are most in need of evaluation. While an ongoing, formal process is developed, we suggest that trialists focus on the evaluations highlighted below and the comparisons in this review with moderate-certainty evidence, especially where there is still only a single study. The PRioRiTy project, which ran a James Lind Alliance prioritisation process for recruitment methods research, is due to publish in 2018 and will provide an excellent list of prioritised areas in need of recruitment intervention work.
2. The development and evaluation of recruitment interventions for use in paediatric trials is a priority.
3. We need much more replication and perhaps a little less innovation. This review of 72 comparisons has a total of only seven meta-analyses. The remainder of the comparisons are single study evaluations of a new intervention.
4. Trialists evaluating recruitment interventions should do so through Studies Within A Trial (SWATs), using a registered protocol for replication or developing one for new evaluations (Clarke 2015). The SWAT Repository (go.qub.ac.uk/SWAT-SWAR) supports this at no cost.
5. Trialists should consider notifying Trial Forge (www.trialforge.org) about their planned recruitment (and other trial process) evaluations to favour better coordination and wider dissemination of evaluation efforts.
6. Trialists should aim to include evaluations of recruitment strategies in their trials, preferably using a SWAT for a prioritised intervention. Funders should support this to avoid another decade with little progress regarding which interventions are effective in improving trial recruitment.

Based on the results of this review we suggest prioritising evaluations in three SWATs.

1. Although telephone reminders seem effective and have a high certainty of the evidence rating (Analysis 6.1, Summary of findings 2), both included studies had underlying recruitment of less than 10%. Beyond trials with low underlying recruitment, the GRADE certainty in the evidence is moderate due to indirectness. Evaluations in trials expected to have higher underlying recruitment are needed, especially given the potentially substantial workload and cost of involving a telephone reminder component to a recruitment strategy. The SWAT-61 protocol is available through the Northern Ireland Network for Trials Methodology Research.
2. Use of a financial incentive probably improves recruitment (Analysis 57.1, Summary of findings 7), but the GRADE certainty of the evidence is currently moderate because of inconsistency between included study results. Moreover, financial incentives are widely used but at more modest levels than the GBP 100 used in Jennings 2015a, Jennings 2015b, Jennings 2015c, Jennings 2015d and Jennings 2015e. Use of incentives, including financial ones, also matches Priority no. 17 from the PRioRiTy top 20. More evaluations of financial incentives would therefore be welcome. The SWAT-59 protocol is available through the Northern Ireland Network for Trials Methodology Research.
3. There are two text message-based interventions in the review (Analysis 7.1; Analysis 8.1), both of which suggest small but potentially useful improvements in recruitment. We rated both as having moderate-certainty evidence because the comparisons are based only on single evaluations. Text messaging is cheap, can be easily scaled up and could be widely applicable given the high usage of mobile telephones. The content of messages needs further work, though, including replications with regard to scarcity and quotes from participants, which are the two interventions evaluated in this review. Use of text messaging also matches priorities no. 2, 4 and 10 in the PRioRiTy top 10. We have developed the SWAT-60 protocol for the intervention used in Analysis 7.1 on scarcity as a template for such evaluations, and it is available through the Northern Ireland Network for Trials Methodology Research.

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their determination and have now excluded Harris 2008 from the review.

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Sully 2013

Sully BGO, Julious SA, Nicholl J. A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies. *Trials* 2013;**14**:166. [DOI: 10.1186/1745-6215-14-166]

Walters 2017

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CHARACTERISTICS OF STUDIES

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

Abd-Elsayed 2012

Methods	Randomised controlled trial
Data	Setting: secondary care in USA. 499 participants were eligible for 1 of 3 trials; all had substantial illness requiring major surgery (cardiac) at least 24 hours after being asked about consent
Comparisons	Investigated the use of different consent form presentations Intervention A: consent documents on heavy weight cream-coloured paper (20-pound) and a blue folder Comparator: consent documents as photocopies stapled together.
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Adequate
Allocation concealment?	Yes	Adequate

Abd-Elsayed 2012 *(Continued)*

Blinding of participants and personnel ok?	Unclear	Participants did not know there was a study. Personnel knew, and there was possibility that this could influence consent conversation, but there was substantial training so the effect is less clear.
Blinding of outcome assessment ok?	Yes	Participants were blind and data entered by someone who was blinded
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Review only interested in recruitment, which is reported
Was the study free of other bias?	No	Trial stopped early because of host trials stopping early and consent responsibility for the third trial site moving to a different department
Overall bias?	Yes	High risk of bias

Abhyankar 2010

Methods	Randomised controlled trial
Data	Setting: university, UK. 30 participants were women students and staff aged over 18 years on the university email list
Comparisons	Investigated the use of trial information with clarification of values Intervention A: study information plus implicit values clarification task (look at info) Intervention B: study information plus implicit and explicit values clarification task (look at info and engage with it by making ratings of what is important to you) Comparator: routine information
Outcomes	Willingness to take part in a hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Insufficient detail in paper to be sure what was done
Allocation concealment?	Unclear	Uncertain if the random numbers list was open and so investigators could in principle influence allocation
Blinding of participants and personnel ok?	Unclear	Linked to qualitative work; possible that investigators could influence quantitative work through qualitative work and they know allocation by this stage (if not before).
Blinding of outcome assessment ok?	Unclear	Willingness to take part is self-report; not clear what participants were told beforehand, which could influence what they report

Abhyankar 2010 *(Continued)*

Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported, and this is the only outcome needed for review.
Was the study free of other bias?	No	Trial is hypothetical so outcome is just a proxy for real decision
Overall bias?	Yes	High risk of bias

Avenell 2004

Methods	Randomised controlled trial
Data	Setting: secondary care, UK. 538 participants aged 70 years or over, attending a fracture clinic or orthopaedic ward
Comparisons	Investigated the effect of different trial designs Open trial design comparing vitamin D versus calcium versus vitamin D plus calcium versus no tablets. Compared to conventional trial comparing vitamin D versus calcium versus vitamin D plus calcium versus placebo.
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Pre-programmed laptop computer-generated sequence
Allocation concealment?	Yes	Adequate
Blinding of participants and personnel ok?	Yes	Not all participants were blinded, but this was the point of the evaluation so the trial has not been penalised on this risk of bias item. Those in comparison group were blinded. Tablets were sent out centrally by trial staff, not handed out by clinical staff.
Blinding of outcome assessment ok?	Yes	Objective outcome recorded by trial team
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Bentley 2004

Methods	Randomised controlled trial
Data	Setting: university, USA. 270 pharmacy student participants
Comparisons	Investigated the effect of financial incentives and trial risk 9-arm trial looking at the effect of financial incentives and bonus based on the level of risk (high, medium or low) associated with the intervention drug Interventions A-C: information on high-risk trial for a drug not yet tested on humans, paying USD 1800, USD 800 or USD 350 Interventions D-F: information on medium-risk study for a generic drug already on the market, paying USD 1800, USD 800 or USD 350 Intervention G-I: information on low-risk study measuring salivary levels of stress hormones, paying USD 1800, USD 800 or USD 350
Outcomes	Willingness to take part in hypothetical studies
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Text just says 'randomly distributed' but does not say how the randomisation was done.
Allocation concealment?	Yes	Not entirely clear, but trial team handed packs to course instructors to distribute, and it is unlikely that instructors of students receiving packs could foresee allocation.
Blinding of participants and personnel ok?	Unclear	Participants potentially able to discuss, though people handing out envelopes (course instructors) were blinded
Blinding of outcome assessment ok?	No	Participants gave self-reported 'willingness to participate' response, which could potentially have been influenced by ability to discuss allocation with other participants
Incomplete outcome data handled ok?	Unclear	Some responses were discarded because of missing data, unclear why
Free of selective reporting?	Yes	Willingness to participate outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Bergenmar 2014

Methods	Randomised controlled trial

Bergenmar 2014 *(Continued)*

Data	Setting: secondary care, Sweden. Participants were 130 patients eligible for a phase II or III cancer drug trial involving 1 of 13 oncologists consenting to be recorded during study period
Comparisons	Investigated use of audio recording to improve communication about the trial Intervention: an audio recording (CD), using a portable voice recorder, of the information given at the medical consultation in which the patients were informed about a clinical drug trial Comparator: no CD
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Nurse did randomisation but does not say how
Allocation concealment?	Unclear	As above
Blinding of participants and personnel ok?	Yes	Adequate
Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Brierley 2012

Methods	Randomised controlled trial
Data	Setting: primary care, UK. 2330 participants were people eligible for a trial about computerised CBT in depression
Comparisons	Investigated effect of length of the participant information leaflet on recruitment. Intervention: short participant information leaflet (not clear how short) as initial info about trial Comparator: full length participant information leaflet (8-pages) as initial info about trial
Outcomes	Proportion recruited to trial
Notes	

Brierley 2012 *(Continued)*

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Adequate
Allocation concealment?	Yes	Adequate
Blinding of participants and personnel ok?	Yes	People sending out packs blind, as well as potential participants
Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review.
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Chen 2011

Methods	Randomised controlled trial
Data	Setting: unclear but probably secondary, UK. Participants were eligible for 3 host trials but unclear what the trials were. 2 comparisons against original PIL: 2302 participants in analysis for first, 12,164 participants in analysis for second
Comparisons	Investigated different version of the participant information leaflet (PIL) Intervention 1: invitation letter with brief summary of PIL Intervention 2: PIL modified after focus group discussions; enclosed with letter Comparator: invitation letter with full original PIL
Outcomes	Proportion recruited to pre-randomisation phase of trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Conference abstract and limited details. Additional information from co-author R Haynes: randomisation by computer (Haynes 2016).
Allocation concealment?	Yes	As above. R Haynes provided datasets from hospitals with typically thousands of potentially eligible participants and (under section 251 support) we mailed these patients from Cancer Trials Support Unit. The invitations were generat-

Chen 2011 *(Continued)*

		ed by a computer programme with an incorporated randomisation element (so the different invitations were produced automatically according to the random allocation); this is how allocation was kept concealed so the investigator had no way of knowing what their patients were going to receive.
Blinding of participants and personnel ok?	Yes	Participants definitely blinded. Staff blinding unclear but effect of knowing on recruitment probably minimal
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported, and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Cockayne 2017

Methods	Randomised controlled trial
Data	Setting: community NHS clinics, UK. 6900 patients eligible for the REFORM study (over 64 years, routine podiatry appointment in past 6 months) and offered an appointment at NHS podiatry clinics across 5 centres. Ineligible if report neuropathy, dementia or other neurological condition, unable to walk unaided, lower limb amputation, unwilling to attend local podiatry clinic. 3-arm trial of a bespoke user-tested PIL and a template-developed PIL against the usual PIL
Comparisons	Investigated different version of the participant information leaflet (PIL) Intervention 1: bespoke, user-tested PIL and letter, with graphic design input Intervention 2: template developed PIL and original study letter with public and patient involvement (PPI) feedback but no user-testing or design input Comparator: PIL developed for REFORM trial using NRES (ethics) template with study invitation letter
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Generated electronically, stratified by centre
Allocation concealment?	Yes	Independent data manager, IDs used, invitation packs sent centrally
Blinding of participants and personnel ok?	Yes	Participants and research staff blinded; not admin staff but unlikely to have affected the allocation

Cockayne 2017 *(Continued)*

Blinding of outcome assessment ok?	Yes	Objective assessment
Incomplete outcome data handled ok?	Yes	No missing data
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent. Sensitivity analysis showed negligible effect of newsletter in pack. May be underpowered
Overall bias?	No	Low risk of bias

Cooper 1997

Methods	Randomised controlled trial
Data	Setting: secondary care, UK. 273 first-time attendees at a gynaecological clinic
Comparisons	Investigated the effect of different trial designs Partially randomised patient preference design allocating to medical management or transcervical resection of the endometrium or preferred option. Comparator was a conventional trial design allocating to medical management or transcervical resection of the endometrium.
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Computer-generated list
Allocation concealment?	Yes	Series of sealed, opaque envelopes
Blinding of participants and personnel ok?	Yes	Participants were blinded but not investigators. All participants (intervention and control) were seen by the same trial investigator. Impossible not to unblind investigator since he/she had to know allocation to deliver information to participant
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent

Cooper 1997 *(Continued)*

Overall bias?	No	Low risk of bias

Coyne 2003

Methods	Cluster-randomised controlled trial
Data	Setting: secondary care, USA. 226 patients eligible for participation in a cancer treatment trial
Comparisons	Investigated the effect of different consent methods Easy to read consent statements (altered text style, layout, font size, vocabulary; reading level 7th to 8th grade) were compared to standard consent statements
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Definitely randomised but unclear how this was done
Allocation concealment?	Unclear	As above
Blinding of participants and personnel ok?	Unclear	Nurse clearly knew that the participant had intervention or control consent statement; not clear how much participant was told about the intervention. Not clear if telephone interviewers knew the allocation
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Dear 2011

Methods	Cluster-randomised controlled trial
Data	Setting: secondary care, Australia. 340 participants with cancer who had Internet access
Comparisons	Investigated whether information provided through a website improved recruitment Intervention: access to a consumer-friendly cancer clinical trials site, which enables people to search for trials

Dear 2011 *(Continued)*

	Comparator: usual care (no access to site)
Outcomes	Self-reported (by participant) recruitment to a trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Adequate
Allocation concealment?	Yes	Adequate
Blinding of participants and personnel ok?	Yes	Participants were blind to purpose of study. Doctors knew purpose but only intervention group got link to website.
Blinding of outcome assessment ok?	Yes	Assessors were blinded
Incomplete outcome data handled ok?	No	More than double amount of missing data in intervention group because consultations not recorded and participants not completing follow-up questionnaires.
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Yes	High risk of bias

Diguiseppi 2006

Methods	Quasi-randomised controlled trial
Data	Setting: health maintenance organisation, USA. Participants were 469 patients aged 18 or over attending the HMO with an acute injury
Comparisons	Investigated the effect of different methods of pre-screening participants Telephone administered questionnaire on hazardous drinking and willingness to participate in lifestyle intervention. This was compared to face-to-face administered questionnaire on hazardous drinking and willingness to participate in behavioural intervention
Outcomes	Proportion recruited to hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description

Diguiseppi 2006 *(Continued)*

Random Sequence generation ok?	No	By week
Allocation concealment?	No	As above
Blinding of participants and personnel ok?	Unclear	Potential participants were probably blind but researchers and practice staff were not blind.
Blinding of outcome assessment ok?	Unclear	Not clear what impact researcher and practice staff being unblinded may have on discussions with participants. Outcome not objective (willingness to participate not actual participation)
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to participate outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Du 2008

Methods	Randomised controlled trial
Data	Setting: secondary care, USA. 126 patients aged 21 to 80 attending multidisciplinary lung clinic at a cancer centre
Comparisons	Investigated the effect of different methods of providing information about the trial 18-minute educational video giving an overview of clinical trials and the importance of cancer clinical research to society. This was compared to standard care (i.e. normal first visit to oncologist).
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomised but no more details
Allocation concealment?	Unclear	As above
Blinding of participants and personnel ok?	Yes	Oncologist was blinded but the participant was not (not clear if they were told that intervention was a video versus standard care). Outcome objective so probably not a problem
Blinding of outcome assessment ok?	Yes	Objective outcome

Du 2008 *(Continued)*

Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Du 2009

Methods	Randomised controlled trial
Data	Setting: secondary care, USA. 196 women scheduled for treatment evaluation by medical oncology specialist at Karmanos Cancer Institute (KCI) breast clinic. Aged 21 to 80, new female patient at clinic, with diagnosis of histologically confirmed invasive breast cancer, and self-determined as white or African American. Plus: the ability to read and understand English at least at the 6th grade level, the capability to make their own treatment decisions, not having previously participated in a cancer clinical trial, and performance status (PS) B 2 (Southwest Oncology Group (SWOG) scale)
Comparisons	Intervention: 18-minute video. The video presents an overview of phase I, II and III clinical trials and the importance of cancer clinical research to society. The video addresses common concerns regarding clinical trials and cancer treatment from the patient's perspective such as side effects, expected risks and benefits, eligibility criteria, the enrolment process, and treatment costs. Comparator: usual practice - return to waiting room but not clear what 'standard care' actually is
Outcomes	Enrolment in therapeutic trials
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomised but no more details
Allocation concealment?	Unclear	As above
Blinding of participants and personnel ok?	Unclear	Not clear if staff were blinded, and for participants it depended on what they had been told about study. Participants completed questionnaires themselves so may not have been influenced by staff if staff were unblinded.
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs

Du 2009 *(Continued)*

Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Ellis 2002

Methods	Randomised controlled trial
Data	Setting: secondary care, Australia. 60 women undergoing definitive surgical operation for early stage breast cancer
Comparisons	Intervention: booklet explaining trials, how treatment is selected in RCT, discussion of treatment options, examples of trials, where to get more info, advantages and disadvantages of participating + usual information from clinician, discussion of treatment which may include discussion of RCT, no standardisation of what is discussed Comparator: usual information from clinician, discussion of treatment which may include discussion of RCT, no standardisation of what is discussed
Outcomes	Willingness to take part in hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomised but no more details
Allocation concealment?	Yes	Text says 'randomised centrally' but doesn't say how
Blinding of participants and personnel ok?	Unclear	Not clear what participants were told. Not clear if clinicians providing general advice knew allocation.
Blinding of outcome assessment ok?	Unclear	Outcome not objective and not clear what influence lack of blinding might have had on this.
Incomplete outcome data handled ok?	Unclear	84 were randomised but only had baseline data for 79 and outcome data for 60. No difference across groups in number of questionnaires not returned.
Free of selective reporting?	Yes	Willingness to take part was outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Fleissig 2001

Methods	Quasi-randomised trial (used order in which people turned up for consultations)

Fleissig 2001 *(Continued)*

Data	Setting: secondary care, UK. 265 participants were cancer patients 16 or older eligible for 1 of 40 local trials. 23 trials were offered to both control and intervention groups
Comparisons	Investigated improving communication between recruiter and potential participant Intervention: doctor presented with patient preferences on trial participation prior to discussion about trial participation Comparator: doctor does normal trial discussion without knowing patient preferences
Outcomes	Proprortion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	No	Consultation sequence is part of allocation, so it is possible to predict who will get control and who gets intervention
Allocation concealment?	No	As above
Blinding of participants and personnel ok?	Yes	Participants blinded but not doctors, but hard to avoid this
Blinding of outcome assessment ok?	Yes	Main outcome for review is recruitment, which is objective. Also some independent assessment though probably not necessary for recruitment
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Yes	High risk of bias

Ford 2004

Methods	Randomised controlled trial
Data	Setting: community, USA. 12,400 African American men aged 55 to 74 eligible for a prostate, lung and colorectal cancer screening trial
Comparisons	Investigated the effect of different trial information and consent methods Intervention A: enhanced recruitment letter, telephone call by African American interviewer, baseline information by mail, reminder calls/mailings for baseline information/consent Intervention B: enhanced recruitment letter, telephone call by African American interviewer, baseline information over telephone, reminder calls/mailings for consent form Intervention C: enhanced recruitment letter, telephone call by African American interviewer, church session, baseline information at church session

Ford 2004 *(Continued)*

	Compared to standard recruitment letter, telephone assessment by African American or white interviewer, baseline information by mail, reminder calls/mailings for baseline information/consent
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomised but no more details
Allocation concealment?	Unclear	As above
Blinding of participants and personnel ok?	Unclear	Potential participants were blinded but the researchers probably were not blinded
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Foss 2016

Methods	Randomised controlled trial
Data	Setting: secondary care, Denmark. 118 women giving birth at 1 of 3 hospitals and eligible for the Danish Calmette Study
Comparisons	Investigated the effect of different trial information and consent methods
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Central, web-based block-randomisation with variable block sizes of 2, 4, and 6 in random order
Allocation concealment?	Yes	See above

Foss 2016 *(Continued)*

Blinding of participants and personnel ok?	Yes	Participants blinded although staff giving information were not , though they followed an SOP regarding what to say. Probably didn't affect outcome
Blinding of outcome assessment ok?	Yes	Outcome objective
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Fowell 2006

Methods	Cluster-randomised cross-over trial
Data	Setting: secondary care, UK. 53 Cancer inpatients receiving palliative care and starting on a syringe driver
Comparisons	Investigated the effect of different trial designs Cluster-randomisation compared to Zelen's design (in which only those randomised to the intervention group were asked for consent)
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Coin-tossing for initial allocation to cluster or Zelen (2 sites only)
Allocation concealment?	Yes	Only 2 sites and allocation to intervention (Zelen or cluster) by coin toss almost certainly done centrally
Blinding of participants and personnel ok?	Yes	Blinding only partial, but looking at the effect of open study design was the purpose of the study
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs

Fowell 2006 *(Continued)*

Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Fracasso 2013

Methods	Randomised controlled trial
Data	Setting: secondary care, USA. Participants were 60 patients with cancer recruited through the Siteman Cancer Center (SCC). Patients were identified by their medical, radiation, or surgical oncologist at the time of evaluation for treatment. Patients were ≥ 18 years of age; English speaking; self-reported as a member of a racial or ethnic minority; diagnosed with advanced breast, colorectal, lung, or prostate carcinoma with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2
Comparisons	Investigated coaching as a way of improving recruitment Intervention: African American coach providing individualised, flexible education and support to create context of trust promoting trial enrollment Comparator: no coach (usual care)
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Says randomly allocated but nothing more
Allocation concealment?	Unclear	As above
Blinding of participants and personnel ok?	Unclear	Not clear what participants knew about the intervention prior to being randomised; all provided consent so they were told something
Blinding of outcome assessment ok?	Yes	Objective outcome (recruitment)
Incomplete outcome data handled ok?	Yes	6 died or were lost to follow-up, but not clear which groups they were in. But unlikely due to intervention.
Free of selective reporting?	Unclear	Recruitment reported, and this is only outcome needed for review
Was the study free of other bias?	Unclear	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Free 2011

Methods	Randomised controlled trial
Data	Setting: primary care, UK. Participants were 1592 smokers eligible for a smoking cessation trial
Comparisons	Investigated effect of mentioning scarcity on recruitment Intervention: SMS reminder message including scarcity message 'only 300 places left' Comparator: SMS reminder without mention of scarcity
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Adequate
Allocation concealment?	Yes	Adequate
Blinding of participants and personnel ok?	Yes	Adequate
Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Free 2010

Methods	Randomised controlled trial
Data	Setting: community, UK. Participants were 1302 daily smokers, 16 or over, wanting to stop smoking in next month
Comparisons	Investigated whether including GBP 5 with invitation or sending SMS messages to potential participants increased recruitment Intervention A: GBP 5 with participant info sheet and consent form Intervention B: series of 4 text messages with quotes from existing participants Comparator: normal trial procedures - letter with participant information sheet and consent form

Free 2010 *(Continued)*

Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	For the 2 trials covered in this review the data manager placed registration ID numbers of participants in ascending numerical order and alternate participants were allocated systematically to the intervention or control group. The ID numbers were not linked to any names or other personally identifying information, so allocation was concealed. Additional information from the study author: all the data manager had was a list of numbers with no other linked information. The order of numbers were generated by the timing of recruitment to the txt2stop randomisation. The allocation could be checked, i.e. there was no way of manipulating it.
Allocation concealment?	Yes	Central (web-based)/data manager
Blinding of participants and personnel ok?	Yes	Participants blind but not research staff, unlikely to affect outcome measurement (assessment was blinded)
Blinding of outcome assessment ok?	Yes	Objective outcome and assessors were blind
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Registration to trial outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Freer 2009

Methods	Randomised controlled trial
Data	Setting: secondary care, UK. Participants were 41 parents of immature infant(s) were admitted to a large tertiary NICU but who did not require intensive care (i.e. not requiring mechanical ventilation or continuous observation)
Comparisons	Intervention A: US trial leaflet with explanation Intervention B: US trial leaflet alone Intervention C: UK trial leaflet with explanation Intervention D: UK trial leaflet alone
Outcomes	Willingness to take part in a hypothetical study

Freer 2009 *(Continued)*

Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Randomisation done by independent person using sequential, sealed opaque envelopes
Allocation concealment?	Yes	See above
Blinding of participants and personnel ok?	Unclear	Depends what researchers providing standard statements knew and what participants were told about the study.
Blinding of outcome assessment ok?	Unclear	Outcome not objective and not clear what influence lack of blinding might have had on this.
Incomplete outcome data handled ok?	Unclear	54 were randomised but 41 provided questionnaires. Reasons for non-completion are not given per group. No real difference in the number of questionnaires returned per group.
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs.
Was the study free of other bias?	No	Hypothetical trial.
Overall bias?	Yes	High risk of bias

Fureman 1997

Methods	Randomised controlled trial
Data	Setting: university, USA. 188 participants in the Risk Assessment Project (injection drug users)
Comparisons	Investigated the effect of different trial information methods Enhanced video on an HIV vaccine trial plus 1-hour pamphlet presentation (5 minutes pre-test, 26 minutes of video, 10 minutes to review pamphlet, research assistant initiated question and answer session, post-test questionnaire, survey at 1 month. This was compared to standard half-hour pamphlet-only presentation (5 minutes pre-test, 10 minutes to review trial information pamphlet; research assistant initiated question and answer session, post-test questionnaire, survey at 1 month
Outcomes	Willingness to take part in hypothetical trial (expressed as a score on a willingness scale)
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomisation mentioned but no details
Allocation concealment?	Unclear	See above

Fureman 1997 *(Continued)*

Blinding of participants and personnel ok?	Unclear	Not clear how much participants were told before the study, not clear what the research assistant running sessions knew about randomisation; probably knew that video was the intervention. Assistant could in principle influence post-test questionnaire responses of participants because these were done during the session
Blinding of outcome assessment ok?	Unclear	Outcome not objective and not clear what influence lack of blinding might have had on this
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Graham 2007

Methods	Quasi-randomised controlled trial
Data	Setting: health maintenance organisation, USA. 370 participants were patients aged 18 or over attending the HMO with an acute injury
Comparisons	Investigated the effect of different methods of pre-screening participants Intervention A: electronic questionnaire on hazardous drinking and willingness to participate in lifestyle intervention Intervention B: oral questionnaire read aloud to patients in the clinic, potential answers printed on cards and patients asked to point Compared to standard self-completed paper questionnaire
Outcomes	Willingness to take part in a hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	No	Allocated by week
Allocation concealment?	No	See above
Blinding of participants and personnel ok?	Unclear	Potential participants probably blind but not researchers or practice staff
Blinding of outcome assessment ok?	Unclear	Outcome not objective and not clear what influence lack of blinding might have had on this

Graham 2007 *(Continued)*

Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Halpern 2004

Methods	Randomised controlled trial
Data	Setting: secondary care, USA. 126 participants who had mild to moderate hypertension and who met standard entry criteria (unclear what these are) for phase II and III trials at the clinic), attending clinic on selected interview days. Exclusion criteria were unable/unwilling to give oral informed consent and any exclusion criteria for the current phase III trials at the clinic (it was unclear what these were)
Comparisons	Intervention A: the variables altered were information regarding the percentage of previous patients who experienced adverse effects from the study drug (10%, 20% and 30%) and the payment participants would receive (USD 100, USD 1000, and USD 2000). Intervention B: the variables altered were the percentage of patients who would be assigned to placebo (10%, 30% and 50%) and the payment level
Outcomes	Willingness to participate in a hypothetical trial (patients were told the trial was real but then told trial was not after decision)
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	No	Allocated by alternate day of week
Allocation concealment?	No	See above
Blinding of participants and personnel ok?	No	Participants blind but not investigator, who could, in principle, influence their responses because data collection was via interview
Blinding of outcome assessment ok?	No	Outcome not objective and not clear what influence unblinded investigator might have had on this.
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	Unclear	Hypothetical study, though participants were initially told it was real; yet each was told about 9 scenarios "after patients had indicated their [willingness to

Halpern 2004 *(Continued)*

		participate] in all 9 trials …" Not clear if participant considered these real or not.
Overall bias?	Yes	High risk of bias

Hemminki 2004

Methods	Randomised controlled trial
Data	Setting: 'local clinics', Estonia. 4295 postmenopausal women aged 50 to 64
Comparisons	Investigated the effect of different design methods Non-blinded allocation comparing active HRT treatment versus no treatment. This was compared to traditional blinded allocation comparing active HRT treatment versus placebo.
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Computer-based random number sequence
Allocation concealment?	Yes	Sealed opaque envelope with ID on it
Blinding of participants and personnel ok?	Yes	Blinding only partial but looking at the effect of open study design was the purpose of the study
Blinding of outcome assessment ok?	Yes	Partial (see above) but objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Hutchison 2007

Methods	Randomised controlled trial
Data	Setting: secondary care, UK. 173 patients with colorectal, breast, lung cancer and clinically eligible to enter 1 of centre's trials; access to a video recorder, CD-ROM or DVD player; can understand English

Hutchison 2007 *(Continued)*

Comparisons	Intervention: video covering general trial info, randomisation, pictures of patients receiving care + voiceover discussing uncertainty + standard practice (clinician discussing treatment options and possibility of taking part in a trial) + standard practice Comparator: standard practice (clinician discussing treatment options and possibility of taking part in a trial)
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Minimisation in Oracle database done by clinical trials unit
Allocation concealment?	Yes	Centrally by CTU
Blinding of participants and personnel ok?	Yes	Not clear if patients know about video versus normal info when consenting. Staff may also be unblinded although materials are sent to them at home and all participants receive standard care so probably small chance of introducing bias.
Blinding of outcome assessment ok?	Yes	Partial (see above) but objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Ives 2001

Methods	Randomised controlled trial
Data	Setting: secondary care, UK. 50 patients attending an HIV hospital clinic
Comparisons	Investigated the effect of different trial information methods Standard trial information plus booklet entitled, 'Clinical Trials in HIV and AIDS: Information for people who are thinking about joining a trial'. This was compared to standard trial information (information sheet specific to proposed trial, plus discussion with trial doctor and research nurse)
Outcomes	Proportion recruited to trial
Notes	

Ives 2001 *(Continued)*

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Randomisation done sequence of numbered envelopes
Allocation concealment?	Yes	See above
Blinding of participants and personnel ok?	Yes	Patients and investigators not blinded. Not clear if interviewers were the investigators and therefore blind or unblinded. Unlikely to have affected outcome
Blinding of outcome assessment ok?	Yes	Partial (see above) but objective outcome
Incomplete outcome data handled ok?	Unclear	50 were randomised but outcome data available for only 31, most of whom had joined a trial. There were some difference between those who provide only baseline data and those who provided follow-up data. Not clear if there were differences between groups
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Jacobsen 2012

Methods	Randomised controlled trial
Data	Setting: secondary and university-based cancer centre, community-based oncology centres, USA. Participants were 462 people 18 or over diagnosed with cancer who were scheduled for a visit with an oncologist and who had not been in a trial before. Could speak and read English
Comparisons	Investigated of multimedia provision of trial information. Intervention: multimedia (DVD) psychoeducation giving general info and addressing misperceptions and concerns about trials Comparator: written information about trials
Outcomes	Willingness to participate in a hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Adequate
Allocation concealment?	Yes	Adequate

Jacobsen 2012 *(Continued)*

Blinding of participants and personnel ok?	No	Unclear what participants knew beforehand but outcome was self-reported. Staff were not blinded.
Blinding of outcome assessment ok?	No	Willingness to take part is self-report, and it's not clear what participants were told beforehand, which could influence what they report. Staff were not blinded but not clear if central person doing outcome assessments was also blinded.
Incomplete outcome data handled ok?	Yes	Only an 'as treated'/'per protocol' analysis was done and there was more deviation from the intended treatment in the intervention group.
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	No	Hypothetical trial so not a real decision about trial recruitment
Overall bias?	Yes	High risk of bias

Jennings 2015a

Methods	Randomised controlled trial
Data	Setting: primary care, UK. Participants were 181 people who were over 60 taking long-term NSAIDS for arthritis.
Comparisons	Investigated effect of financial incentive on recruitment Intervention: offer of GBP 100 Comparison: no offer
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Random Sequence generation ok?	Yes	Done centrally using a computer algorithm. There was a slight imbalance in favour of control because of algorithm used but allocation still random
Allocation concealment?	Yes	Done centrally
Blinding of participants and personnel ok?	Yes	Research nurses and staff not blinded but interventions sent out to patients on GP list so staff could not influence response. Patients blinded
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate

Jennings 2015a *(Continued)*

Free of selective reporting?	Yes	Recruitment data reported, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Jennings 2015b

Methods	Randomised controlled trial
Data	Setting: primary care, UK. Participants were 332 people who were aged over 60 with symptomatic hyperuricaemia
Comparisons	Investigated effect of financial incentive on recruitment Intervention: offer of GBP 100 Comparison: no offer
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Done centrally using the computer algorithm. There was a slight imbalance in favour of control because of algorithm used but allocation still random
Allocation concealment?	Yes	Done centrally
Blinding of participants and personnel ok?	Yes	Research nurses and staff not blinded but invitations sent out to patients on GP list so staff could not influence response. Participants blinded
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment data reported, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Jennings 2015c

Methods	Randomised controlled trial
Data	Setting: primary care, UK. Participants were 93 people who were aged 18 to 79 years comparing monotherapy with dual therapy as initial hypertension treatment.
Comparisons	Investigated effect of financial incentive on recruitment. Intervention: offer of GBP 100 Comparison: no offer
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Done centrally using computer algorithm. There was a slight imbalance in favour of control because of algorithm used but allocation still random
Allocation concealment?	Yes	Done centrally
Blinding of participants and personnel ok?	Yes	Research nurses and staff not blinded but invitations sent out to patients on GP list so staff could not influence response. Participants blinded
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment data reported, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Jennings 2015d

Methods	Randomised controlled trial
Data	Setting: primary care, UK. Participants were 210 people who were aged 18 to 79 years with uncontrolled blood pressure on 3 antihypertensive agents
Comparisons	Investigated effect of financial incentive on recruitment Intervention: offer of GBP 100 Comparison: no offer
Outcomes	Proportion recruited to trial

Jennings 2015d *(Continued)*

Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Done centrally using computer algorithm. There was a slight imbalance in favour of control because of algorithm used but allocation still random
Allocation concealment?	Yes	Done centrally
Blinding of participants and personnel ok?	Yes	Research nurses and staff not blinded but invitations sent out to patients on GP list so staff could not influence response. Participants blinded
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment data reported, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Jennings 2015e

Methods	Randomised controlled trial
Data	Setting: primary care, UK. Participants were 199 people who were 18 to 80 years with at least 1 component of the metabolic syndrome
Comparisons	Investigated effect of financial incentive on recruitment Intervention: offer of GBP 100 Comparison: no offer
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Done centrally using computer algorithm. There was a slight imbalance in favour of control because of algorithm used but allocation still random
Allocation concealment?	Yes	Done centrally

Jennings 2015e *(Continued)*

Blinding of participants and personnel ok?	Yes	Research nurses and staff not blinded but invitations sent out to patients on GP list so staff can not influence response. Participants blinded
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment data reported, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Jeste 2009

Methods	Randomised controlled trial
Data	Setting: secondary care, USA. The 128 participants were > 40 years, with schizophrenia, fluency in English and an absence of a *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (DSM-IV), 34 diagnosis of current substance use disorder, dementia or other known conditions likely to influence decisional capacity independent of the effects of schizophrenia and/or by verbal report from the patients' treating clinicians.
Comparisons	Intervention: DVD presenting key information from consent form plus a narrator explaining consent relevant info, video and slides as well. A research assistant was also there to answer questions. Comparator: printed consent information plus a 10-minute control DVD giving general info about research. A research assistant was also there to answer questions.
Outcomes	Willingness to participate in a hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomisation mentioned but doesn't say more
Allocation concealment?	Unclear	See above
Blinding of participants and personnel ok?	Yes	Researchers were blind but not clear how much participants knew about aim of study. They were probably blind.
Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate

Jeste 2009 *(Continued)*

Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Karunaratne 2010

Methods	Randomised controlled trial
Data	Setting: secondary care, Australia. Participants were English speaking, computer-literate 60 patients with diabetes aged 18 to 70, able to travel to hospital.
Comparisons	Intervention: computer-based presentation of information on leaflet but with interactive explanatory features, e.g. text linked to keywords, video clips Comparator: paper-based information
Outcomes	Willingness to take part in a hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomisation mentioned but doesn't say more
Allocation concealment?	Unclear	See above
Blinding of participants and personnel ok?	Unclear	Unclear if participants knew nature of the intervention when consenting. Not clear if staff doing 1-to-1 interviews were blinded.
Blinding of outcome assessment ok?	Unclear	See above and not objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Kendrick 2001

Methods	Cluster-randomised controlled trial
Data	Setting: primary care, UK. Families with children aged under 5 years, living in deprived areas; 2393 participants
Comparisons	Investigated the effect of different trial information methods Mailed invitation to participate in an injury prevention trial, including a home safety questionnaire. This was compared to mailed invitation to participate excluding the home safety questionnaire.
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Randomised using ACCESS software by neutral researcher
Allocation concealment?	Yes	See above
Blinding of participants and personnel ok?	Yes	Participants blinded, but researchers know (probably). However, because questionnaire was mailed, there was no way researchers could influence result.
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Kerr 2004

Methods	Randomised controlled trial
Data	Setting: further Education colleges, UK. 130 participants were aged 18 or over and enrolled on further education and leisure courses
Comparisons	Investigated the effect of describing trial treatments as new or standard for 2 disease areas, arthritis and back pain Intervention A: arthritis: treatment A described as standard, treatment B described as standard Intervention B: arthritis: treatment A described as new, treatment B described as standard Intervention C: arthritis: treatment A described as new, treatment B described as new

Kerr 2004 *(Continued)*

	Intervention D: back pain: treatment A described as standard, treatment B described as standard Intervention E: back pain: treatment A described as new, treatment B described as standard Intervention F: back pain: treatment A described as new, treatment B described as new
Outcomes	Willingness to participate in a hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Random number tables
Allocation concealment?	Unclear	The starting point was selected randomly, from then on there is no concealment because the scenarios were ordered consecutively from a starting point. Materials handed to students where they chose to sit. Not clear if materials were in an envelope or open to staff.
Blinding of participants and personnel ok?	Unclear	Students were probably blind but not clear about staff
Blinding of outcome assessment ok?	Unclear	Partial blinding (see above) and not objective outcome
Incomplete outcome data handled ok?	No	Willingness to participate responses only given for 113/130
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Kimmick 2005

Methods	Cluster-randomised controlled trial
Data	Setting: secondary care and academic institutions, USA. Practitioners and researchers from 126 Cancer and Leukaemia Group B (CALGB) institutions
Comparisons	Investigated the effect of different trial information methods Educational intervention of standard information plus an educational symposium, geriatric oncology educational materials, monthly mailings and emails for 1 year, lists of available protocols for use on patient charts, case discussion seminar. This was compared to standard information of periodic notification of all existing CALGB trials by the CALGB Central Office, and CALGB website access.
Outcomes	Proportion recruited to trial
Notes	Clustering was accounted for in the analysis.

Kimmick 2005 *(Continued)*

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomisation mentioned but no more details
Allocation concealment?	Unclear	As above
Blinding of participants and personnel ok?	Unclear	Not clear what details were given to the participants about the study before it started
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Larkey 2002

Methods	Cluster-randomised controlled trial
Data	Setting: various existing trial sites, USA. 96 participants in the Women's Health Initiative trial
Comparisons	Investigated the effect of different methods of training lay advocates for trials Intervention A: Hispanic lay advocates; attended 6 hour-long training sessions, 5 quarterly meetings and received brochures with interest cards to distribute to other women Intervention B: Hispanic women controls, received quarterly telephone calls and brochures with interest cards to distribute to other women Compared to Anglo women controls, received quarterly telephone calls and brochures with interest cards to distribute to other women
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomisation mentioned but no more details
Allocation concealment?	Unclear	See above

Larkey 2002 *(Continued)*

Blinding of participants and personnel ok?	Unclear	Not clear if the participants were blinded
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Lee 2017

Methods	Cluster-randomised controlled trial
Data	Setting: primary care, Australia. 744 primary care clinics (372 general practice and 372 physiotherapy clinics) in the Sydney metropolitan area. Recruiting clinics for a trial of an intervention to reduce low back pain
Comparisons	Investigated the use of a teaser campaign to increase recruitment of clinical centres Mailed 3 postcards out as a part of a staged teaser campaign to raise awareness of trial prior to invitation letter. This was compared to no teaser postcards.
Outcomes	Proportion of clinics recruited
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	An investigator not involved in outcome assessment generated a 1:1 randomisation schedule using a random number generator and assigned clinics to the groups.
Allocation concealment?	Yes	See above
Blinding of participants and personnel ok?	Yes	The clinicians and support staff were blind to the different recruitment strategies that were being tested in this study.
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome available, which is all the review needs

Lee 2017 *(Continued)*

Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Litchfield 2005

Methods	Cluster-randomised controlled trial
Data	Setting: primary care, UK. Participants were general practices participating in a trial of 2 delivery systems for insulin, NovoPen and Innovo. 28 practices were involved and 73 participants recruited
Comparisons	Intervention: electronic data capture Comparator: paper data capture
Outcomes	Number of participants recruited to the trial. Improving recruitment was not the main aim (improving efficiency was the main aim) of the study though this information is provided.
Notes	Clustering was not accounted for in analysis.

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Computer-generated randomisation code in compliance with FDA and EU regulations
Allocation concealment?	Yes	Done centrally (inferred rather than explicit but seems reasonable to assume for this cluster trial)
Blinding of participants and personnel ok?	Unclear	Investigators knew that both paper and electronic data collection were to be used so study was not blinded. Unlikely that patient decisions to join study would be affected by this. Not clear how much influence knowledge of data collection method might have had on practices.
Blinding of outcome assessment ok?	Yes	Objective outcome. Improving recruitment was not the main aim (improving efficiency was the main aim) of the study, though this information is provided
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Liénard 2006

Methods	Cluster-randomised controlled trial

Liénard 2006 *(Continued)*

Data	Setting: secondary care, France. Centres recruiting to a randomised controlled trial for breast cancer; 573 participants
Comparisons	Investigated the effect of organising visits by the trial co-ordination team to centres participating in a multicentre trial Site visits including an initiation visit to review trial protocol, inclusion/exclusion criteria, safety, randomisation etc. plus ongoing review visits. This was compared to no site visits (unless requested).
Outcomes	Proportion recruited to trial
Notes	Clustering was not accounted for in the analysis.

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Minimisation
Allocation concealment?	Yes	Done centrally by the coordinating office
Blinding of participants and personnel ok?	Yes	Centres blind. Somewhat unclear if monitors were blind but probably were not
Blinding of outcome assessment ok?	Yes	Partial (see above) but objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Llewellyn-Thomas 1995a

Methods	Randomised controlled trial
Data	Setting: secondary care, Canada. 90 colorectal cancer patients attending cancer hospital as outpatients
Comparisons	Investigated the effect of different trial information methods Intervention A: booklet with negatively-framed intervention about treatment side effects and survival Intervention B: booklet with positively-framed intervention about treatment side effects and survival Compared to booklet with neutrally framed intervention about treatment side effects and survival
Outcomes	Proportion recruited to hypothetical trial

Llewellyn-Thomas 1995a *(Continued)*

Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Mentions randomisation but no further details.
Allocation concealment?	Unclear	Used sealed envelopes although doesn't mention numbering
Blinding of participants and personnel ok?	Yes	Interviewer was blinded, but unclear about participants
Blinding of outcome assessment ok?	Yes	Partial (see above) but subjective outcome but probably not influenced by partial blinding (interviewer was blind, probably tricky for participant to figure out what was being tested).
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Llewellyn-Thomas 1995b

Methods	Randomised controlled trial
Data	Setting: secondary care, Canada. 100 patients attending the outpatient department of a cancer hospital
Comparisons	Investigated the effect of different trial information methods Searchable computerised information on a hypothetical trial, including purpose, description of treatment group and randomisation, possible benefits, side effects and patients' rights. This was compared to tape-recorded information on a hypothetical trial, including purpose, description of treatment arm and randomisation, possible benefits, side effects and patients' rights
Outcomes	Proportion recruited to hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Just says framing was randomly determined
Allocation concealment?	Unclear	Used sealed envelopes although doesn't mention numbering

Llewellyn-Thomas 1995b *(Continued)*

Blinding of participants and personnel ok?	Yes	Unclear if the interviewer or the participants were blinded. It depends on what the participants were told. Interviewer did not seem to do more than help with equipment, so perhaps limited room for bias
Blinding of outcome assessment ok?	Yes	Somewhat unclear (see above), subjective outcome but probably did not affect outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

MacQueen 2014

Methods	Randomised controlled trial
Data	Setting: community care, Tanzania. Participants were women aged 18 to 35 living in particular districts, had had sex in last 14 days, or had more than 1 sexual partner in last 30 days. Women who had been in trial before excluded
Comparisons	Investigated alternative ways of assessing informed consent (comprehension) Intervention: open-ended (verbal description of each of 7 components) comprehension assessment of informed consent information prior to deciding whether to take part Comparator: closed-ended (true or false rating of statements read out by interviewer of each of 7 components) comprehension assessment of informed consent information prior to deciding whether to take part
Outcomes	Willingness to take part in hypothetical trial
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Random Sequence generation ok?	Unclear	No mention of method
Allocation concealment?	Yes	Adequate
Blinding of participants and personnel ok?	Yes	Participants were blinded, staff weren't but probably given outcome of willingness to take part in trial
Blinding of outcome assessment ok?	Yes	Adequate

MacQueen 2014 *(Continued)*

Incomplete outcome data handled ok?	Unclear	Doesn't specify how many women responded to willingness question
Free of selective reporting?	Unclear	Recruitment data are presented but not clear if they are all presented
Was the study free of other bias?	No	Trial was hypothetical
Overall bias?	Yes	High risk of bias

Man 2015a

Methods	Randomised controlled trial
Data	Setting: primary care, UK. 1364 participants who were identified as potentially eligible for the Healthlines CVD study
Comparisons	Investigated the alternative was of presenting patient information materials Intervention: participant information that developed in collaboration with patients together with a graphic designer Comparator: standard participant information materials
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Computer-generated random numbers to split those to be invited
Allocation concealment?	Yes	Use of IDs, sorted by random number
Blinding of participants and personnel ok?	Yes	Patients unaware of recruitment study. Researchers blind to patient allocation
Blinding of outcome assessment ok?	Yes	Objective outcomes
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Man 2015b

Methods	Randomised controlled trial
Data	Setting: primary care, UK. 671 participants who were identified as potentially eligible for the Healthlines CVD study
Comparisons	Investigated the alternative ways of presenting patient information materials Intervention: participant information that developed in collaboration with patients together with a graphic designer Comparator: standard participant information materials
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Computer-generated random numbers to split those to be invited
Allocation concealment?	Yes	Use of IDs, sorted by random number
Blinding of participants and personnel ok?	Yes	Patients unaware of recruitment study. Researchers blind to patient allocation
Blinding of outcome assessment ok?	Yes	Objective outcomes
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Mandelblatt 2005

Methods	Randomised controlled trial
Data	Setting: community cancer clinics, USA. 450 participants who were eligible for cancer prevention trial (high risk of breast cancer but low risk of side effects)
Comparisons	Intervention: 5, 10-minute educational sessions about STAR cancer prevention trial following short interview about prior knowledge, risk perceptions and background. Education emphasised benefits of participation, lack of financial burden and need for minority participation in trials. Also given a brochure.

Mandelblatt 2005 *(Continued)*

	Comparator: brochure plus short background interview
Outcomes	Intention/likelihood of taking part in STAR cancer prevention trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	No	Based on clinic day
Allocation concealment?	No	See above
Blinding of participants and personnel ok?	Unclear	Not clear how much info participants given about intervention during consent process, or whether staff doing interviews were blind
Blinding of outcome assessment ok?	Unclear	See above. Outcome was intention to participate so possible to introduce bias depending on what information participants were given
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Intention to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Intention to participate, not actual participation
Overall bias?	Yes	High risk of bias

Miller 1999

Methods	Quasi-randomised controlled trial
Data	Setting: USA, secondary care, 347 participants. Participants were eligible for 1 of the 2 trials being run through the unit: 18 to 75 years old and DSM-IV dysthymic disorder, double depression (major depression superimposed on antecedent dysthymia), or chronic major depression. Exclusion criteria were history of psychosis, mania or hypomania; comorbid substance abuse; severe medical illness; failed 3 adequate trials of antidepressants from 2 different classes of antidepressants in the past 3 years; and failed study medication or study psychotherapy
Comparisons	Investigated whether screening by research assistants was more cost-effective than by senior investigators Intervention: screening by senior investigator Comparator: screening by research assistant
Outcomes	Proportion recruited to trials
Notes	

Risk of bias

Miller 1999 *(Continued)*

Item	Authors' judgement	Description
Random Sequence generation ok?	No	Alternating screening calls were given to senior investigator
Allocation concealment?	No	See above
Blinding of participants and personnel ok?	Unclear	Investigator and research assistants knew allocation, and they were the people interviewing potential participants (who would be blind)
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Yes	High risk of bias

Monaghan 2007

Methods	Cluster-randomised controlled trial
Data	Setting: existing, multicentre, international trial. 167 clinical sites in 19 countries recruiting to a diabetes and vascular disease treatment trial
Comparisons	Investigated the effect of different levels of communication between the trial co-ordination team and participating sites Additional communication – usual plus frequent emails, regular personalised mail-outs of league tables/graphs of performance against other sites, certificates of achievement for recruitment/other study items (1 per month). This was compared to usual communication (provided via the regional centre) plus occasional direct communications from the co-ordinating centre in the form of generic newsletters, emails and faxes.
Outcomes	Proportion recruited to trial
Notes	Clustering was not accounted for in analysis.

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Computer-generated randomisation
Allocation concealment?	Yes	Central randomisation
Blinding of participants and personnel ok?	Yes	Centres were blinded, but the central office was not blind

Monaghan 2007 *(Continued)*

Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome (per site) presented, which is what review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Mudano 2013

Methods	Quasi-randomised trial (used date of birth)
Data	Setting: primary care, USA. Participants were 155 women ≥ 65 years with Medicare drug coverage and no reported use of osteoporosis medication in last year. Also bone fracture since 50, or osteo diagnosis by healthcare professional (based on self-report)
Comparisons	Investigated effect of systems to support eligibility screening Intervention: tablet computer to support eligibility screening Comparator: integrated voice response system (IVRS) to support eligibility screening
Outcomes	Willingness to participate in hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	No	Used day of birth, even date allocated to tablet
Allocation concealment?	No	See above
Blinding of participants and personnel ok?	Unclear	Unclear how much participants knew; study staff not blinded
Blinding of outcome assessment ok?	Unclear	Outcome was willingness to take part, and participants possibly knew that they were in study and therefore that there was another arm to which they could have been allocated. Could influence this subjective outcome.
Incomplete outcome data handled ok?	Yes	160 participants, all 93 in tablet arm completed, only 46 of 67 in IVRS arm completed screening. Does seem that most provided willingness to participate data though
Free of selective reporting?	Yes	Willingness to take part is reported, and this is only outcome needed for review.

Mudano 2013 *(Continued)*

Was the study free of other bias?	No	Trial was hypothetical. Almost a third more people in intervention arm than in control.
Overall bias?	Yes	High risk of bias

Myles 1999

Methods	Randomised controlled trial
Data	Setting: secondary care, Australia. 769 inpatients aged 18 or over, scheduled for elective surgery
Comparisons	Investigated the effect of different consent methods Intervention A: pre-randomised to experimental drug and asked to provide consent; if no consent, standard treatment given Intervention B: pre-randomised to standard drug and asked to provide consent; if no consent, experimental treatment given Intervention C: told that the physician thinks experimental drug superior, if consent given, has 70% chance of receiving this; if no consent, standard treatment given Intervention D: allowed to increase or decrease their chance of receiving the experimental drug if consent given, and if no preference, 50% chance of receiving it; if no consent, standard treatment given Compared to standard randomisation method (equal chance of experimental or standard drug)
Outcomes	Proportion recruited to hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Mentions randomisation but no details given
Allocation concealment?	Unclear	See above
Blinding of participants and personnel ok?	Unclear	Patient is blinded (they are not told the exact details of the study in the patient information). Researchers (probably) knew the allocation.
Blinding of outcome assessment ok?	Unclear	Outcome was subjective and unclear what potential researchers had to influence this while participants answered questions about intentions
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to take part outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial

Myles 1999 *(Continued)*

Overall bias?	Yes	High risk of bias

Nystuen 2004

Methods	Randomised controlled trial
Data	Setting: community, Norway. 498 sick-listed employees attending a participating social security office
Comparisons	Investigated the effect of different telephone reminders Written invitation to participate in a community-based trial followed by a telephone reminder if no response within 2 weeks; guide used for discussion. This was compared to written invitation to participate in a community-based trial followed by no reminder if no response within 2 weeks.
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Computer-generated list
Allocation concealment?	Yes	Central allocation
Blinding of participants and personnel ok?	Yes	Participants were blinded but not the research team who makes the phone calls. The team do not contact the control group.
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Paul 2011

Methods	Randomised controlled trial
Data	Setting: secondaty care, UK. Participants were patients with colorectal cancer receiving adjuvant treatment. 215 were allocated to the comparator; it was unclear how many received the intervention.
Comparisons	Investigated the effect of the randomisation time point Intervention: randomise prior to treatment to get 3 or 6 months treatment

Paul 2011 *(Continued)*

	Comparator: randomise after 3 months of treatment to see if participant gets another 3 months of treatment
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Received additional information from Jim Paul by email (Paul 2016). Minimisation programmed in PL/SQL in Oracle
Allocation concealment?	Yes	Central allocation
Blinding of participants and personnel ok?	Yes	Participants blinded
Blinding of outcome assessment ok?	Yes	Objective outcome (recruitment)
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome available, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Paul 2014

Methods	Randomised controlled trial
Data	Setting: community (via cancer registry), Australia. 1062 participants were 18 years or older, primary colorectal cancer diagnosis and within 3 months of diagnosis and on registry
Comparisons	Investigated pre-recruitment primer letter Intervention: pre-recruitment primer letter designed to encourage participation Comparison: no primer letter
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Adequate

Paul 2014 *(Continued)*

Allocation concealment?	Yes	Done centrally from register
Blinding of participants and personnel ok?	Yes	Adequate
Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported ,and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Perrone 1995

Methods	Randomised controlled trial
Data	Setting: community, Italy. 3573 members of the general public aged under 80 years, attending a scientific exhibition
Comparisons	Intervention A: 1-sided informed consent (participants refusing were given standard treatment) Intervention B: 2-sided informed consent (participants refusing could choose between experimental and standard treatment) Intervention C: randomised to experimental (participants refusing were given standard treatment) Intervention D: randomised to standard (participants refusing were given experimental treatment)
Outcomes	Willingness to participate in a hypothetical trial
Notes	This is same trial as Gallo 1995 but Perrone 1995 includes participants under 20

Risk of bias

Item	**Authors' judgement**	**Description**
Random Sequence generation ok?	Unclear	Randomisation mentioned but no details given
Allocation concealment?	Unclear	See above
Blinding of participants and personnel ok?	No	Not clear what participants were told. Researchers unblinded and since researcher asked participants for his/her views at end of test, there is the potential for bias
Blinding of outcome assessment ok?	No	See above

Perrone 1995 *(Continued)*

Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Pighills 2009

Methods	Quasi-randomised controlled trial
Data	Setting: community, UK. 4488 participants were over 70 and on a participating GP's listarticipants.
Comparisons	Intervention A: newspaper article about the trial Intervention B: more favourable newspaper article about the trial Intervention C: the original newspaper article Comparator: no article (i.e. usual recruitment materials)
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	No	Control and intervention were stacked alternately in packs given to GP practice
Allocation concealment?	No	See above
Blinding of participants and personnel ok?	Yes	Recipients and practice staff blinded
Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Yes	High risk of bias

Simel 1991

Methods	Randomised controlled trial
Data	Setting: secondary care, USA. 100 patients attending an ambulatory care clinic
Comparisons	Investigated the effect of different consent methods Consent form including a statement that the new treatment may work twice as fast as usual treatment. This was compared to a consent form including a statement that the new treatment may work half as fast as usual treatment
Outcomes	Number consenting (inferred from data rather than being an outcome presented by authors)
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Randomisation using a computer-generated scheme
Allocation concealment?	Unclear	Single centre and unclear whether the randomisation list was open or not
Blinding of participants and personnel ok?	Yes	Participants probably were blind but the investigators were not. Investigators got an independent reviewer to look at a portion of interviews, and he/she thought they were fair. They also used a script so less room for investigator initiative.
Blinding of outcome assessment ok?	Yes	See above
Incomplete outcome data handled ok?	Unclear	Adequate
Free of selective reporting?	Yes	Number consenting not presented as an outcome but inferred from data, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent. Trial was hypothetical but participants were not told this so they thought decision was real
Overall bias?	Unclear	Unclear risk of bias

Simes 1986

Methods	Randomised controlled trial
Data	Setting: secondary care, Australia. 57 patients attending an oncology unit
Comparisons	Investigated the effect of different consent methods Individual approach to consent – patients given information about aims, expected results, potential toxicities of treatment; details of treatment left to discretion of consultant; patients given opportunity to ask questions, verbal consent obtained. This was compared to total disclosure approach – participants were fully informed about all trial aspects by consultant, with opportunity to ask questions and a

Simes 1986 *(Continued)*

	consent form outlining the information; this was kept overnight, and written consent was obtained the following day.
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Sealed envelopes using balanced randomisation
Allocation concealment?	Unclear	Unclear if envelopes were sequentially numbered
Blinding of participants and personnel ok?	Unclear	Participants were probably blinded. Clinicians were probably not blinded. It is not clear if it is the same clinicians provided information in to both groups.
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Tehranisa 2014

Methods	Randomised controlled trial
Data	Setting: secondary care, USA. Participants were 418 non-critically ill emergency department adult (18 or older) patients without without presenting symptoms consistent with stroke, altered mental status, or alcohol intoxication.
Comparisons	Investigated the use of response-adaptive designs Intervention: video describing a hypothetical trial that uses a response-adaptive design Comparator: video describing a hypothetical trial that uses a standard design
Outcomes	Willingness to take part in a hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description

Tehranisa 2014 *(Continued)*

Random Sequence generation ok?	Unclear	Mentions block size and randomisation in protocol
Allocation concealment?	Unclear	As above
Blinding of participants and personnel ok?	Yes	Participants were blind but not investigators. Outcome (willingness to take part in hypothetical trial) unlikely to be influenced by investigators because intervention is watching a video alone
Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to take part in trial reported and this is only outcome needed for review
Was the study free of other bias?	No	Trial was hypothetical
Overall bias?	Yes	High risk of bias

Tilley 2012

Methods	Cluster-randomised controlled trial
Data	Setting: primary care, USA. Participants were neurologists, primary care docs and internists within 30 miles of trial site. Intention was that this would increase proportion of non-white, non-Hispanic participants into the trial. Participants being enrolled had Parkinson's. 606 participants in analysis
Comparisons	Investigated effect of a recruitment coordinator Intervention: recruitment coordinator plus package of training, materials and events, some carrying CME points. Comparator: whatever recruitment procedures sites wanted to use
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Adequate
Allocation concealment?	Unclear	No details given
Blinding of participants and personnel ok?	Yes	Possible that intervention sites mentioned what they were doing to control sites but controls did not have the coordinator and funding for events so unlikely to really influence outcome, which was anyway objective (recruitment)

Tilley 2012 *(Continued)*

Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Unclear	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	No	Stopped early because of a formal stopping rule
Overall bias?	Yes	High risk of bias

Treschan 2003

Methods	Randomised controlled trial
Data	Setting: secondary care, Austria. Participants were 150 patients undergoing minor surgery with general anaesthetic, 19 to 80 years old. Exclusion criteria were pain, cancer, unable to give unformed consent, could not speak German
Comparisons	Investigated the effect of mentioning risk or discomfort on recruitment Intervention A: said no risk but emphasised the painful nature of tests. etc. Intervention B: said no pain but emphasised risk Comparator: said extra oxygen is harmless and the wound evaluations are painless. This study thus poses essentially no risk and will not produce any significant pain
Outcomes	Willingness to participate in a hypothetical trial - participants were not told the trial was hypothetical until after decision to take part
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Random Sequence generation ok?	Yes	Computer-generated randomisation code
Allocation concealment?	Yes	Randomisation assignment held in sealed, opaque envelopes opened just before presentation
Blinding of participants and personnel ok?	Unclear	Participants were blinded (just given general statement that study was about pain and risk) but not clear if interviewers were. They were, however, told not to give personal comments to influence the decision-making process.
Blinding of outcome assessment ok?	Unclear	Subjective outcome and interviewers could potentially influence, depending on whether they were blind or not.
Incomplete outcome data handled ok?	Yes	Adequate

Treschan 2003 *(Continued)*

Free of selective reporting?	Yes	Willingness to participate outcome presented, which is all the review needs
Was the study free of other bias?	Yes	Hypothetical trial but patients were not told the trial was hypothetical until after decision to take part
Overall bias?	Unclear	Unclear risk of bias

Trevena 2006

Methods	Randomised controlled trial
Data	Setting: primary care, Australia. 152 participants aged 50 to 74 eligible for a colorectal cancer screening trial
Comparisons	Investigated the effect of different trial information methods Opt-in recruitment; letter from doctor advising that the practice is taking part in screening trial; would only be contacted if contact details returned. This was compared to opt-out recruitment; letter from doctor advising that the practice is taking part in screening trial; would be contacted unless the practice was advised to withhold contact details The distribution of participants between intervention and comparison groups is uneven: 60 versus 92, respectively. This was due to a change in legislation in Australia, which meant that the trialists could no longer continue with the opt-out procedure and had to change to opt-in to keep their ethical approval.
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Computer-generated randomisation
Allocation concealment?	Unclear	Unclear if randomisation list was open
Blinding of participants and personnel ok?	Yes	Participants not told about different recruitment methods. Not clear if clinicians were blinded but they were not involved in recruitment, which was done by letter and then contact with research team.
Blinding of outcome assessment ok?	Yes	See above
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent

Trevena 2006 *(Continued)*

Overall bias?	Unclear	Unclear risk of bias

Treweek 2012

Methods	Randomised controlled trial
Data	Setting: primary care, UK. Participants were 1760 GPs
Comparisons	Investigated use of different modes of invitation to take part in trial Intervention: email invitation (email plus link to info sheet - text the same as with intervention) Comparator: postal invitation (letter plus 2-page information sheet)
Outcomes	Proportion recruited to trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Centrally generated by statistician using computer
Allocation concealment?	Yes	3rd party used to send out invitations
Blinding of participants and personnel ok?	Yes	Research team blind. Participants did not know study was ongoing so also blind
Blinding of outcome assessment ok?	Yes	Adequate
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

Wadland 1990

Methods	Randomised controlled trial
Data	Setting: primary care, USA. Participants were 104 smokers > 18 years old
Comparisons	Intervention: consent form read out by researcher Comparator: consent form read by patient

Wadland 1990 *(Continued)*

Outcomes	Proportion recruited to trial
Notes	Only site 2 in the study ran a randomised evaluation so only its data are included

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomisation mentioned but no more details
Allocation concealment?	Unclear	See above
Blinding of participants and personnel ok?	Unclear	Both actively involved but not clear if the participants were told about how consent might be varied
Blinding of outcome assessment ok?	Yes	Objective outcome
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment outcome presented, which is all the review needs
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	Unclear	Unclear risk of bias

Weinfurt 2008a

Methods	Randomised controlled trial
Data	Setting: community, USA. 3623 participants aged 18 or over and diagnosed with coronary artery disease
Comparisons	Intervention A: drug company pays investigator running costs plus general statement saying ethics committee did not think this would affect patient safety Intervention B: drug company pays investigator money for things outside the study plus general statement saying ethics committee did not think this would affect patient safety Intervention C: Investigator owns part of drug company plus general statement saying ethics committee did not think this would affect patient safety. Intervention D: Institution owns part of drug company plus general statement saying ethics committee did not think this would affect patient safety Comparator: generic financial disclosure: general statement about investigator possibly gaining financially plus general statement saying ethics committee did not think this would affect patient safety
Outcomes	Willingness to take part in hypothetical trial
Notes	

Weinfurt 2008a *(Continued)*

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomisation mentioned but no more details
Allocation concealment?	Unclear	See above
Blinding of participants and personnel ok?	Unclear	Not clear what participants were told about the purpose of the study although there were 5 disclosure statements so everyone got a statement (i.e. hard to tell which group they were in). Participants completed a questionnaire (probably) so research team unable to influence
Blinding of outcome assessment ok?	Unclear	See above
Incomplete outcome data handled ok?	Unclear	Only P values presented, not absolute numbers
Free of selective reporting?	Yes	Willingness to participate outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Weinfurt 2008b

Methods	Randomised controlled trial
Data	Setting: community but recruited through outpatient dept, USA. The 470 participants were 18 or over and diagnosed with coronary artery disease. articipants.
Comparisons	Intervention A: financial disclosure saying that the drug company pays hospital Intervention B: financial disclosure saying that the drug company pays the investigator Comparator: no financial disclosure
Outcomes	Willingness to take part in hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Unclear	Randomisation mentioned but no more details
Allocation concealment?	Unclear	See above

Weinfurt 2008b *(Continued)*

Blinding of participants and personnel ok?	Unclear	Not clear what participants were told about disclosure study; not clear if interviewers knew allocation
Blinding of outcome assessment ok?	Unclear	See above
Incomplete outcome data handled ok?	Unclear	Only a mean score presented, not absolute numbers so hard to know
Free of selective reporting?	Yes	Willingness to participate outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Wells 2013

Methods	Randomised controlled trial
Data	Setting: secondary care, USA. Participants were Hispanic cancer 31 patients, scheduled for consultation with medical oncologist, never asked about cancer trial, Spanish as preferred language
Comparisons	Investigated multimedia presentation of information Intervention: Spanish-language multimedia information about clinical trials Comparator: Spanish-language written information about clinical trials
Outcomes	Willingness to participate in a hypothetical trial
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Random Sequence generation ok?	Yes	Adequate
Allocation concealment?	Yes	Adequate
Blinding of participants and personnel ok?	Unclear	Given that trial was hypothetical, not clear whether being unblinded might influence stated willingness to take part in a future trial, especially if it was the same research assistant who was there when participants watched video/read booklet, and phoned them to do outcome assessment
Blinding of outcome assessment ok?	Unclear	As above
Incomplete outcome data handled ok?	Yes	Adequate

Wells 2013 *(Continued)*

Free of selective reporting?	Unclear	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	No	Trial was hypothetical
Overall bias?	Yes	High risk of bias

Welton 1999

Methods	Quasi-randomised controlled trial
Data	Setting: primary care, UK. 436 women aged 45 to 64 who had not had a hysterectomy
Comparisons	Investigated the effect of different trial information methods Verbal information about a trial of HRT, comparing oestrogen only versus combined oestrogen and progestogen. This was compared to verbal information about a trial of HRT, comparing oestrogen only, versus oestrogen plus progestogen versus placebo
Outcomes	Willingness to take part in hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	No	By week
Allocation concealment?	No	See above
Blinding of participants and personnel ok?	Unclear	Participants were blinded but the nurses were not
Blinding of outcome assessment ok?	Unclear	Subjective outcome and not clear what influence nurses might have
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Unclear	Willingness to participate outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Weston 1997

Methods	Randomised controlled trial

Weston 1997 *(Continued)*

Data	Setting: secondary care, Canada. 90 women attending for antenatal visits
Comparisons	Investigated the effect of different trial information methods Written study information followed by viewing of Term Prelabour Rupture of the Membranes (Term PROM) video. This was compared to written study information only.
Outcomes	Proportion recruited to hypothetical trial
Notes	

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Randomisation used random numbers table held centrally
Allocation concealment?	Yes	See above
Blinding of participants and personnel ok?	Unclear	Depends if the women were told they might watch a video - they were probably told. Women completed a questionnaire so they were probably not influenced by the study nurse.
Blinding of outcome assessment ok?	Unclear	See above
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Willingness to participate outcome presented, which is all the review needs
Was the study free of other bias?	No	Hypothetical trial
Overall bias?	Yes	High risk of bias

Wong 2013

Methods	Randomised controlled trial
Data	Setting: primary care, Canada. Participants were 952 people aged 50-70 years who had not responded to initial invitation by 4 weeks. People were being recruited to a colorectal cancer screening trial not had recent colorectal cancer screening
Comparisons	Investigated use of telephone reminders to non-responders Intervention: up to 3 telephone reminders to those not responding to initial posted invitation Comparison: no telephone reminders (but did get a 2nd invitation)
Outcomes	Proportion recruited to trial
Notes	

Wong 2013 *(Continued)*

Risk of bias

Item	Authors' judgement	Description
Random Sequence generation ok?	Yes	Adequate
Allocation concealment?	Yes	Adequate
Blinding of participants and personnel ok?	Yes	Participants blinded, study nurse making calls clearly not but outcome objective
Blinding of outcome assessment ok?	Yes	Recruitment objective (this was study's secondary outcome, primary was attendance at eligibility screening)
Incomplete outcome data handled ok?	Yes	Adequate
Free of selective reporting?	Yes	Recruitment reported and this is only outcome needed for review
Was the study free of other bias?	Yes	No other biases apparent
Overall bias?	No	Low risk of bias

CBT: cognitive behavioural therapy; **CME**: continuing medical education; **CVD**: cardiovascular disease; **DSM-IV**: *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition; **GP**: general practitioner; **HRT**: hormone replacement therapy; **NICU**: neonatal intensive care unit; **NSAIDs**: non-steroidal anti-inflammatory drugs; **PIL**: participant information leaflet; **PL/SQL**: procedural language extension to Structured Query Language; **RCT**: randomised controlled trial; **SMS**: short message service; **SOP**: standard operating protocol.

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

Study	Reason for exclusion
Aalborg 2012	Engagement not recruitment
Aaronson 1996	Not studying a recruitment intervention
Agoritsas 2010	Not studying recruitment intervention
Alexander 2008	Not recruiting to a trial
Andrew 1993	Used Zelen design but its use was not part of a randomised evaluation of the design to increase recruitment
Barnard 2010	Systematic review
Berman 2005	Allocation not randomised
Brach 2013	Allocation not randomised
Brealey 2007	Allocation not randomised
Breland-Noble 2012	Engagement not recruitment

Study	Reason for exclusion
Brocklehurst 2007	The study never started (personal communication from member of study team, 6 April 2017) Farrell 2017
Brown 2012	Response not recruitment
Burns 2008	Not studying a recruitment intervention
Caldwell 2002	An earlier version of work later published in a systematic review (Caldwell 2010), the references of which we checked for this Cochrane Review
Calimlim 1977	Not studying a recruitment intervention
Carney 2014	Not recruiting to a trial
Celentano 1995	Recruiting to a survey
Chin Feman 2008	Allocation not randomised
Chlebowski 2010	Allocation not randomised
Clagett 2013	Not recruiting to a trial
Cook 2010	Allocation not randomised
Coronado 2012	Allocation not randomised
Dal-Ré 1991	Not recruiting to a randomised controlled trial (simulated trial was a non-randomised phase I study)
Davis 1998	Allocation not randomised
Donovan 2009	Allocation not randomised
Donovan 2010	Allocation not randomised
Eckardt 2011	Not recruiting to a trial
Embi 2012	Allocation not randomised
Enama 2012	Not a recruitment study. Participants already had decided to take part; this study was just to see if different consent forms would have different levels of comprehension and satisfaction.
Feman 2008	Allocation not randomised
Foradori 2012	Not studying a recruitment intervention
Gallo 1995	This study presents a subset of the data given in Perrone 1995, which is included in this review
Gillan 2009	Not recruiting to a trial
Gilligan 2014	Not recruiting to a trial
Gillon 2009	Not studying a recruitment intervention
Ginexi 2003	Allocation not randomised

Study	Reason for exclusion
Gitanjali 2003	Allocation not randomised
Goldstein 2010	Allocation not randomised
Gomez 1998	Letter
Graham 2011	Allocation not randomised
Grubbs 2009	Not studying a recruitment intervention
Halpern 2002	Allocation not randomised
Harris 2008	Not recruiting to a trial
Harron 2012	Allocation not randomised
Heiney 2010	Allocation not randomised
Henkel 2010	Not studying recruitment intervention
Hillsdon 2011	This conference abstract only presents time to recruit first patient; it isn't studying actual rate of recruitment into the trial.
Hoffner 2011	Not studying a recruitment intervention
Homish 2009	Not recruiting to a trial
Jaffee 2009	Allocation not randomised
Jay 2007	Not studying a recruitment intervention
Jenkins 2013	No recruitment outcome, just number of patients approached
Ji 2008	Allocation not randomised
Junghans 2005	Not recruiting to a trial but to an observational study of patients with angina
Juraskova 2014	Not studying recruitment
Karlawish 2008	Allocation not randomised
Keedy 2009	Allocation not randomised
Kelechi 2010	Allocation not randomised
Kernan 2009	Hospitals not randomised to intervention
Kiernan 2000	Studying response to an advertisement not actual recruitment
Kirkby 2013	Allocation not randomised
Korde 2009	Allocation not randomised
Kruse 2000	Looking at impact on knowledge, not recruitment

Study	Reason for exclusion
Labrique 2011	Not studying recruitment intervention
Lancet 2001	Editorial
Lang 1991	Not studying a recruitment intervention
Larkey 2009	Allocation not randomised
Leader 1978	Allocation not randomised
Lee 2011	Allocation not randomised
Lichter 1991	Editorial
Lloyd-Williams 2002	Not studying a recruitment intervention
Macias 2005	Not studying a recruitment intervention
Marco 2008	Not recruiting to a trial
Masood 2006	Not recruiting to a trial
May 2007	Not studying a recruitment intervention
McGuire 2011	Not recruiting to a trial
Menoyo 2006	Not studying a recruitment intervention
Monane 1991	Not studying a recruitment intervention
Murphy 2011	Allocation not randomised
O'Lonergan 2011	Does not present recruitment data; about understanding
Olver 2009	Not recruiting to a trial
Paskett 2002	Allocation not randomised
Perri 2006	Allocation not randomised
Porucznik 2010	Allocation not randomised
Quinaux 2003	An earlier version of Liénard 2006, which is included in this review
Rogers 1998	Studying recall, understanding and satisfaction rather than effect on recruitment
Rowbotham 2013	Not studying recruitment
Ruffin 2011	Allocation not randomised
Santoyo-Olsson 2011	Allocation not randomised
Saul 2002	News item
Scholes 2007	Not recruiting to a trial

Study	Reason for exclusion
Schrott 1982	Not studying a recruitment intervention
Schroy 2009	Allocation not randomised
Sherman 2009	Allocation not randomised
Swain 2011	Allocation not randomised
Tenorio 2014	Allocation not randomised
Ubel 1997	Allocation not randomised
Unger 2006	Not studying a recruitment intervention
Unger 2010	Allocation not randomised
Vaidya 2010	Not studying recruitment intervention
Wang 2014	Allocation not randomised
Woodford 2011	Allocation not randomised
Wragg 2000	Allocation not randomised
Yates 2009	Allocation not randomised
Zhou 2013	Allocation not randomised

Most studies that we considered in detail but excluded arose from records that we had retrieved because the database reference gave no abstract and it was not possible to exclude them on the basis of the title. We excluded most of the records falling into this category as soon as we checked the full text, with the most common reason being that the study did not evaluate a recruitment intervention.
The two exceptions are Aaronson 1996 and Kiernan 2000, which we excluded at the data extraction stage for the reasons given in the table.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Cramer 1993

Methods	—
Data	—
Comparisons	—
Outcomes	—
Notes	Full text to be obtained

Glen 1980

Methods	—
Data	—

Glen 1980 *(Continued)*

Comparisons	—
Outcomes	—
Notes	Full text to be obtained

Greenlee 2003

Methods	—
Data	—
Comparisons	—
Outcomes	—
Notes	Full text to be obtained

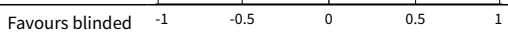
DATA AND ANALYSES

Comparison 1. A–Open trial vs blinded trial (GRADE: high)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	2	4833	Risk Difference (M-H, Fixed, 95% CI)	0.10 [0.07, 0.13]

Analysis 1.1. Comparison 1 A–Open trial vs blinded trial (GRADE: high), Outcome 1 Participants recruited.

Study or subgroup	Open n/N	Blinded n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Hemminki 2004	134/180	233/358		10.04%	0.09[0.01,0.17]
Avenell 2004	1027/2159	796/2136		89.96%	0.1[0.07,0.13]
Total (95% CI)	**2339**	**2494**		**100%**	**0.1[0.07,0.13]**
Total events: 1161 (Open), 1029 (Blinded)					
Heterogeneity: Tau^2=0; Chi^2=0.05, df=1(P=0.83); I^2=0%					
Test for overall effect: Z=7.23(P<0.0001)					



Comparison 2. A–Patient preference design vs conventional RCT (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	273	Risk Difference (M-H, Fixed, 95% CI)	-0.04 [-0.15, 0.07]

Analysis 2.1. Comparison 2 A–Patient preference design vs conventional RCT (GRADE: low), Outcome 1 Participants recruited.

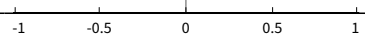
Study or subgroup	Patient preference design n/N	Conventional design n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Cooper 1997	90/135	97/138		100%	-0.04[-0.15,0.07]
Total (95% CI)	**135**	**138**		**100%**	**-0.04[-0.15,0.07]**
Total events: 90 (Patient preference design), 97 (Conventional design)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.64(P=0.52)					

Comparison 3. A–Electronic data capture vs paper-based data capture (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	80	Risk Difference (M-H, Fixed, 95% CI)	-0.13 [-0.24, -0.03]

Analysis 3.1. Comparison 3 A–Electronic data capture vs paper-based data capture (GRADE: low), Outcome 1 Participants recruited.

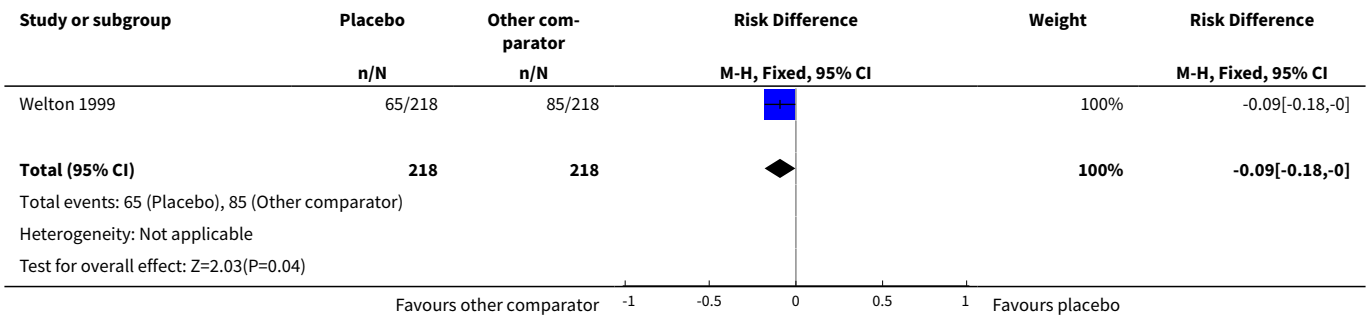
Study or subgroup	Electronic data capture n/N	Paper data capture n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Litchfield 2005	45/52	28/28		100%	-0.13[-0.24,-0.03]
Total (95% CI)	**52**	**28**		**100%**	**-0.13[-0.24,-0.03]**
Total events: 45 (Electronic data capture), 28 (Paper data capture)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.51(P=0.01)					



Comparison 4. A–Placebo vs other comparator (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	436	Risk Difference (M-H, Fixed, 95% CI)	-0.09 [-0.18, -0.00]

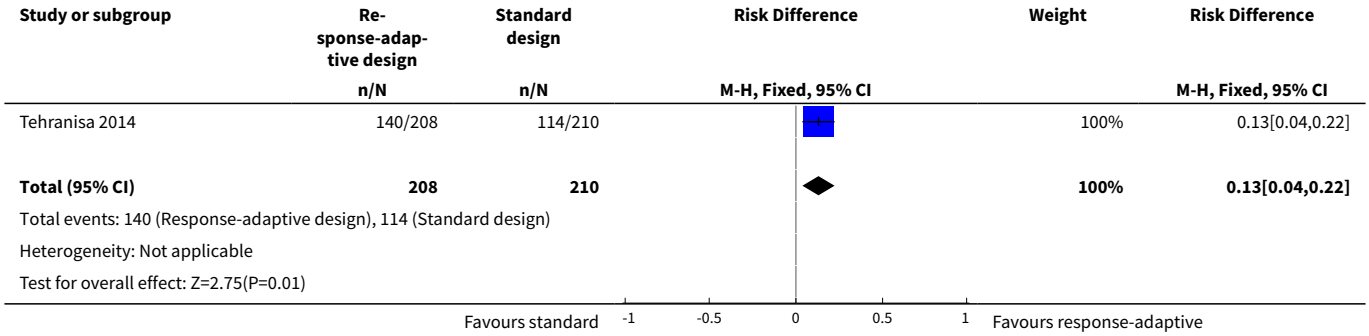
Analysis 4.1. Comparison 4 A–Placebo vs other comparator (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 5. A–Video describing response-adaptive design vs video describing standard design (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	418	Risk Difference (M-H, Fixed, 95% CI)	0.13 [0.04, 0.22]

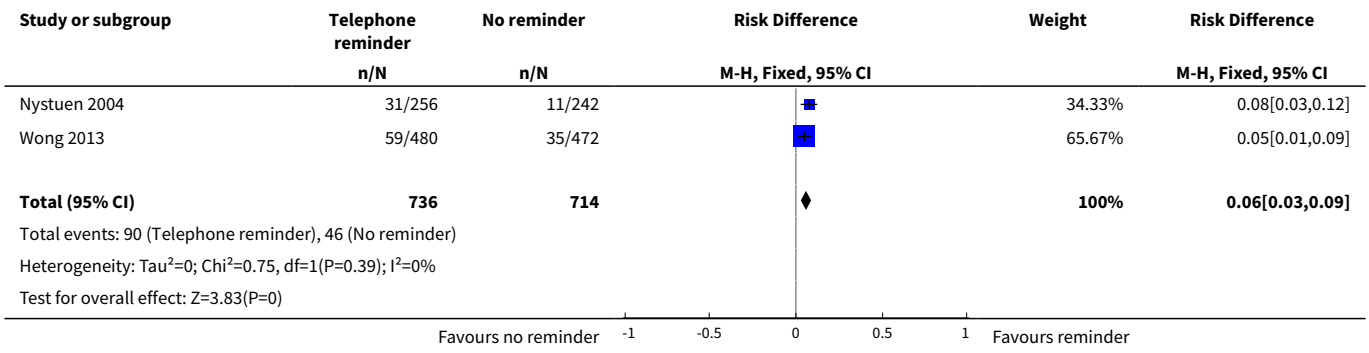
Analysis 5.1. Comparison 5 A–Video describing response-adaptive design vs video describing standard design (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 6. C–Telephone reminder vs no telephone reminder (GRADE: high)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	2	1450	Risk Difference (M-H, Fixed, 95% CI)	0.06 [0.03, 0.09]

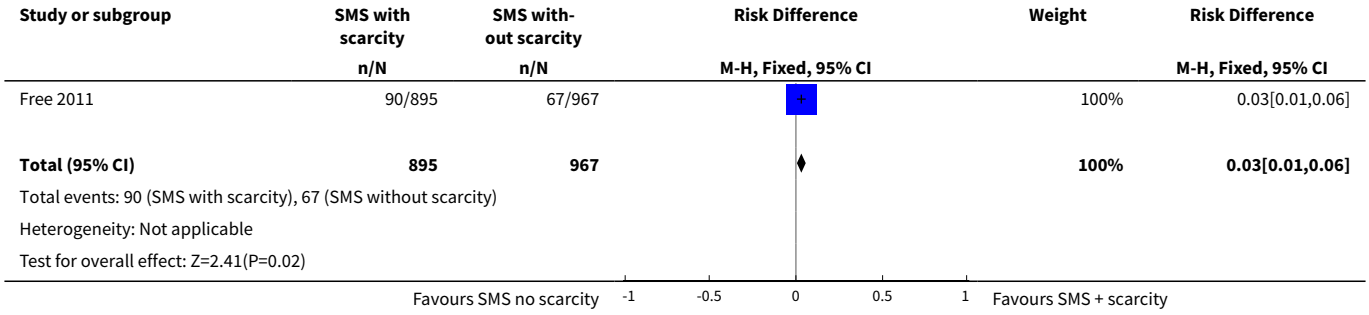
Analysis 6.1. Comparison 6 C–Telephone reminder vs no telephone reminder (GRADE: high), Outcome 1 Participants recruited.



Comparison 7. C–SMS reminder mentioning scarcity vs SMS reminder with no mention (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	1862	Risk Difference (M-H, Fixed, 95% CI)	0.03 [0.01, 0.06]

Analysis 7.1. Comparison 7 C–SMS reminder mentioning scarcity vs SMS reminder with no mention (GRADE: moderate), Outcome 1 Participants recruited.

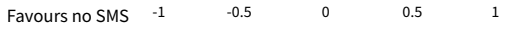


Comparison 8. C–SMS messages containing quotes from existing participants vs no messages (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	811	Risk Difference (M-H, Fixed, 95% CI)	0.04 [0.02, 0.06]

Analysis 8.1. Comparison 8 C–SMS messages containing quotes from existing participants vs no messages (GRADE: moderate), Outcome 1 Participants recruited.

Study or subgroup	SMS n/N	No SMS n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Free 2010	17/405	0/406		100%	0.04[0.02,0.06]
Total (95% CI)	**405**	**406**		**100%**	**0.04[0.02,0.06]**
Total events: 17 (SMS), 0 (No SMS)					
Heterogeneity: Not applicable					
Test for overall effect: Z=4.1(P<0.0001)					

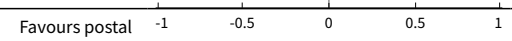


Comparison 9. C–Email invitation vs postal invitation (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	1760	Risk Difference (M-H, Fixed, 95% CI)	0.01 [-0.03, 0.04]

Analysis 9.1. Comparison 9 C–Email invitation vs postal invitation (GRADE: moderate), Outcome 1 Participants recruited.

Study or subgroup	Email n/N	Postal n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Treweek 2012	138/880	132/880		100%	0.01[-0.03,0.04]
Total (95% CI)	**880**	**880**		**100%**	**0.01[-0.03,0.04]**
Total events: 138 (Email), 132 (Postal)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.4(P=0.69)					

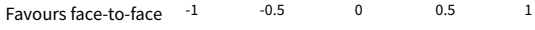


Comparison 10. C–Telephone screening vs face-to-face screening (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	469	Risk Difference (M-H, Fixed, 95% CI)	0.13 [0.03, 0.24]

Analysis 10.1. Comparison 10 C–Telephone screening vs face-to-face screening (high risk of bias), Outcome 1 Participants recruited.

Study or subgroup	Telephone screening n/N	Face-to-face screening n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Diguiseppi 2006	64/99	190/370		100%	0.13[0.03,0.24]
Total (95% CI)	**99**	**370**		**100%**	**0.13[0.03,0.24]**
Total events: 64 (Telephone screening), 190 (Face-to-face screening)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.43(P=0.01)					

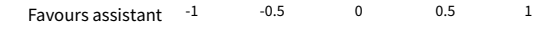


Comparison 11. C–Screening by senior investigator vs screening by research assistant (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	347	Risk Difference (M-H, Fixed, 95% CI)	0.05 [-0.02, 0.13]

Analysis 11.1. Comparison 11 C–Screening by senior investigator vs screening by research assistant (high risk of bias), Outcome 1 Participants recruited.

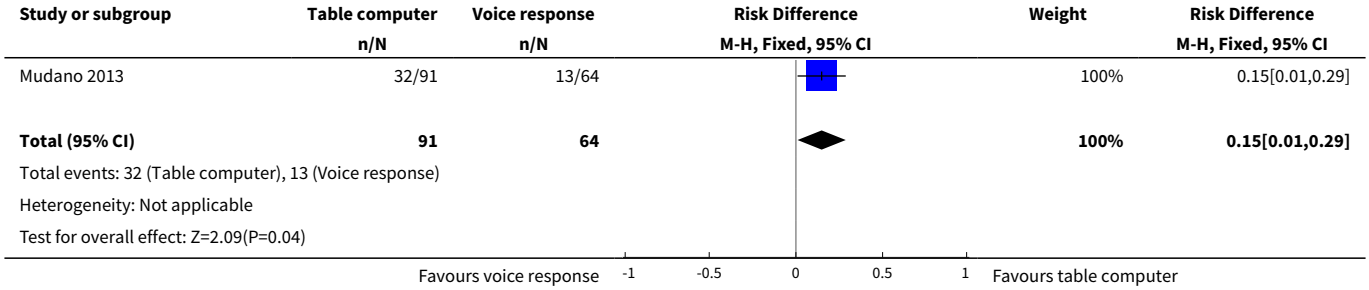
Study or subgroup	Senior investigator n/N	Research assistant n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Miller 1999	28/162	22/185		100%	0.05[-0.02,0.13]
Total (95% CI)	**162**	**185**		**100%**	**0.05[-0.02,0.13]**
Total events: 28 (Senior investigator), 22 (Research assistant)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.42(P=0.16)					



Comparison 12. C–Tablet computer to support screening vs voice response system to support screening (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Willingness to take part if eligible	1	155	Risk Difference (M-H, Fixed, 95% CI)	0.15 [0.01, 0.29]

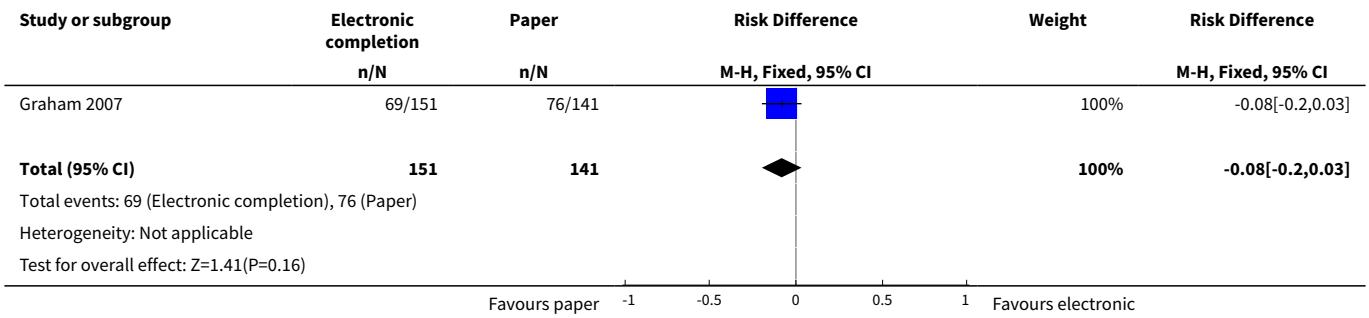
Analysis 12.1. Comparison 12 C–Tablet computer to support screening vs voice response system to support screening (high risk of bias), Outcome 1 Willingness to take part if eligible.



Comparison 13. C–Electronic completion of screening questionnaire vs standard paper completion (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	292	Risk Difference (M-H, Fixed, 95% CI)	-0.08 [-0.20, 0.03]

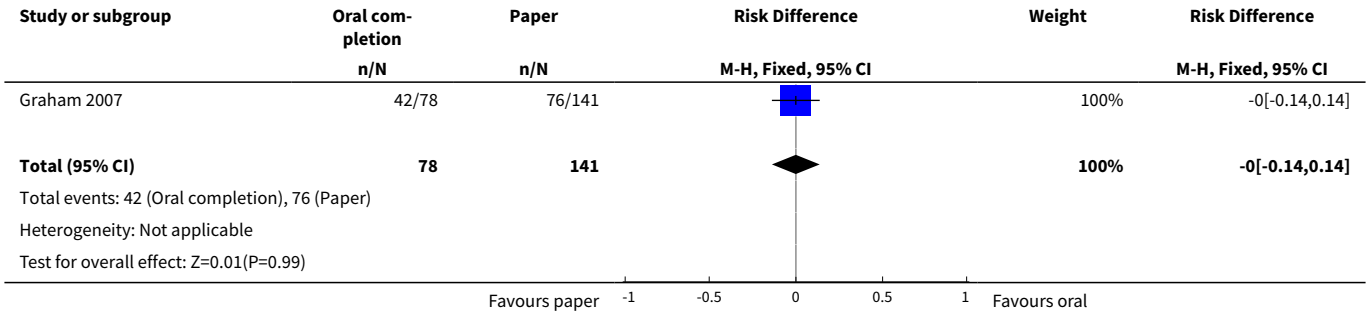
Analysis 13.1. Comparison 13 C–Electronic completion of screening questionnaire vs standard paper completion (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 14. C–Oral completion of screening questionnaire vs standard paper completion (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	219	Risk Difference (M-H, Fixed, 95% CI)	-0.00 [-0.14, 0.14]

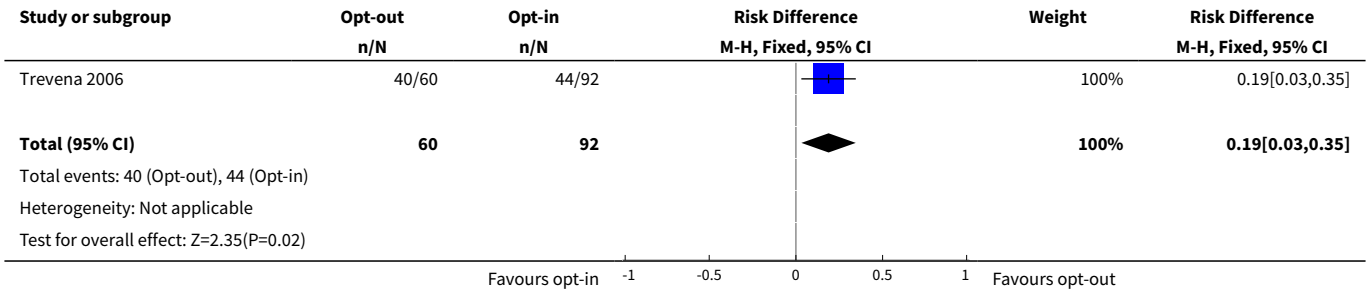
Analysis 14.1. Comparison 14 C–Oral completion of screening questionnaire vs standard paper completion (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 15. D–Opt-out consent vs opt-in consent (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	152	Risk Difference (M-H, Fixed, 95% CI)	0.19 [0.03, 0.35]

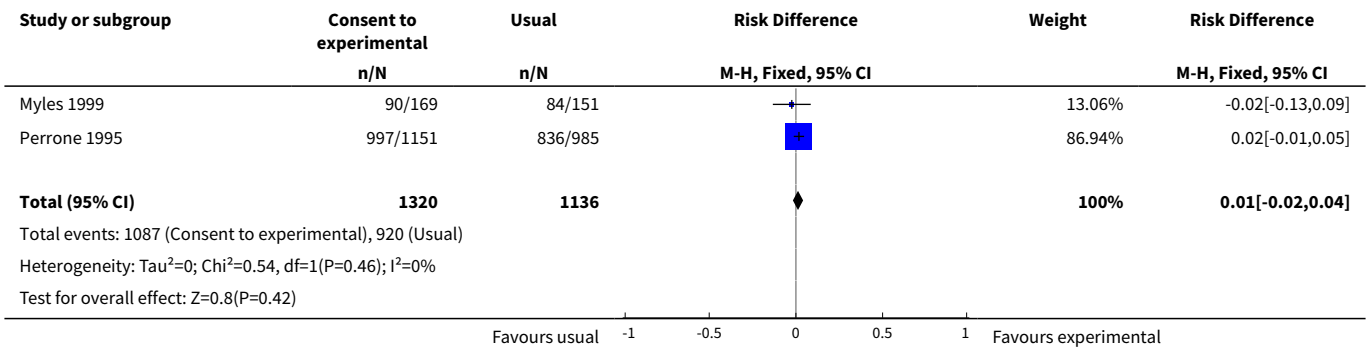
Analysis 15.1. Comparison 15 D–Opt-out consent vs opt-in consent (GRADE: low), Outcome 1 Participants recruited.



Comparison 16. D–Consent to experimental care vs usual consent (GRADE: very low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	2	2456	Risk Difference (M-H, Fixed, 95% CI)	0.01 [-0.02, 0.04]

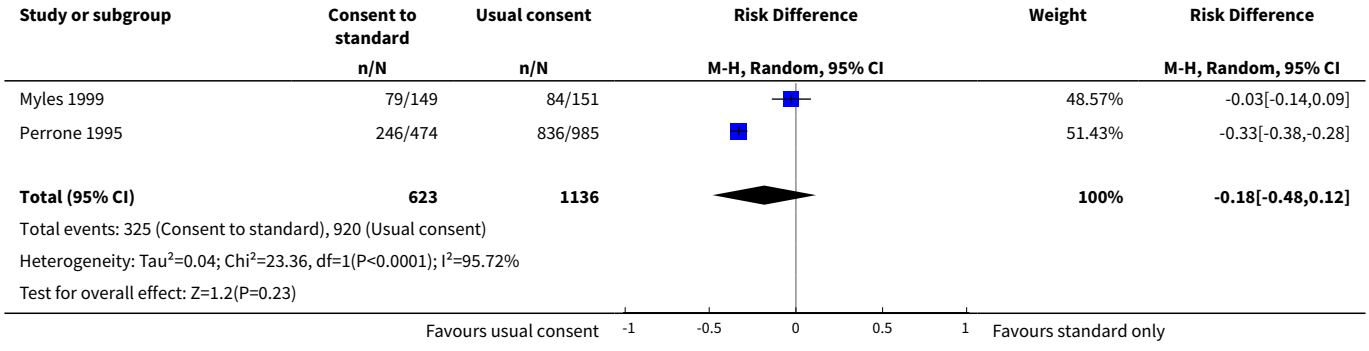
Analysis 16.1. Comparison 16 D–Consent to experimental care vs usual consent (GRADE: very low), Outcome 1 Participants recruited.



Comparison 17. D–Consent to standard care vs usual consent (GRADE: very low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	2	1759	Risk Difference (M-H, Random, 95% CI)	-0.18 [-0.48, 0.12]

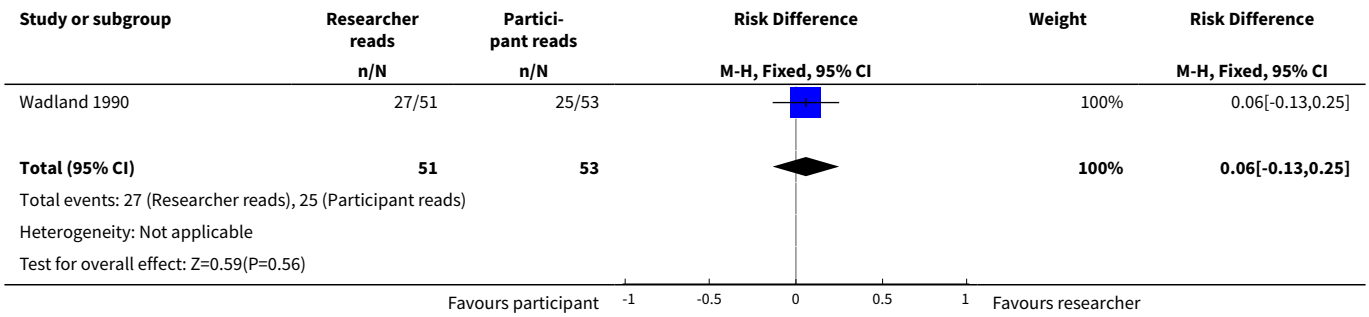
Analysis 17.1. Comparison 17 D–Consent to standard care vs usual consent (GRADE: very low), Outcome 1 Participants recruited.



Comparison 18. D–Researcher reading out consent vs participant reading consent (unclear risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	104	Risk Difference (M-H, Fixed, 95% CI)	0.06 [-0.13, 0.25]

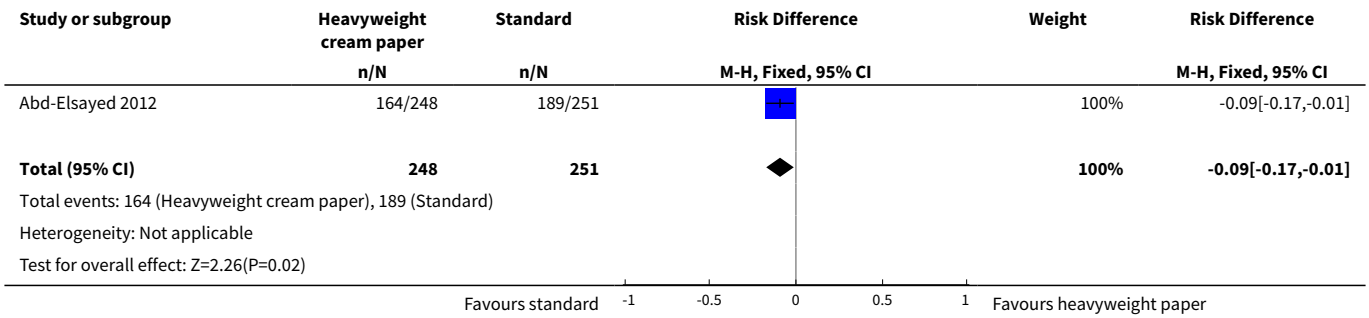
Analysis 18.1. Comparison 18 D–Researcher reading out consent vs participant reading consent (unclear risk of bias), Outcome 1 Participants recruited.



Comparison 19. D–Information printed on heavyweight paper and blue folio vs standard (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	499	Risk Difference (M-H, Fixed, 95% CI)	-0.09 [-0.17, -0.01]

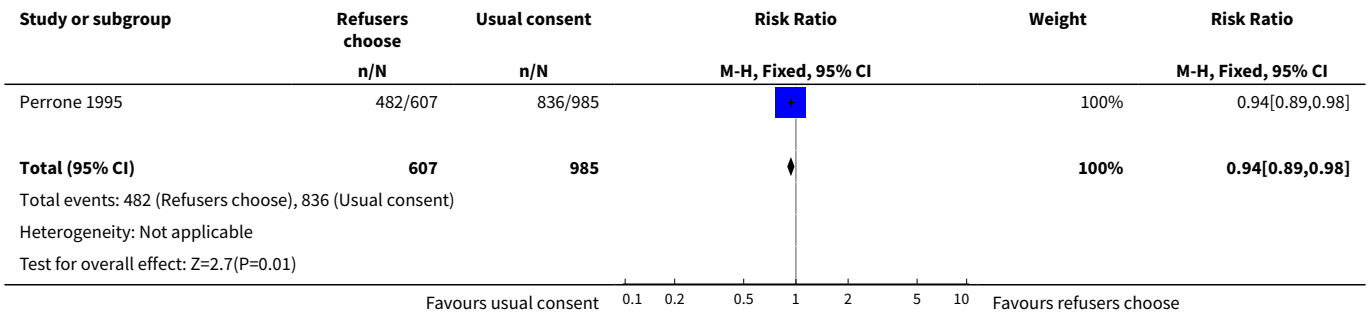
Analysis 19.1. Comparison 19 D–Information printed on heavyweight paper and blue folio vs standard (high risk of bias), Outcome 1 Participants recruited.



Comparison 20. D–Refusers choose treatment vs usual consent (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	1592	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.89, 0.98]

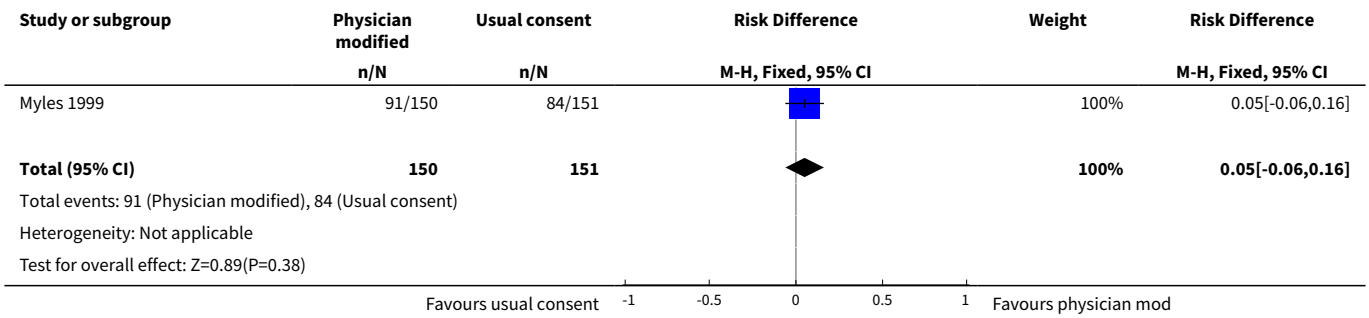
Analysis 20.1. Comparison 20 D–Refusers choose treatment vs usual consent (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 21. D–Physician-modified consent vs usual consent (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	301	Risk Difference (M-H, Fixed, 95% CI)	0.05 [-0.06, 0.16]

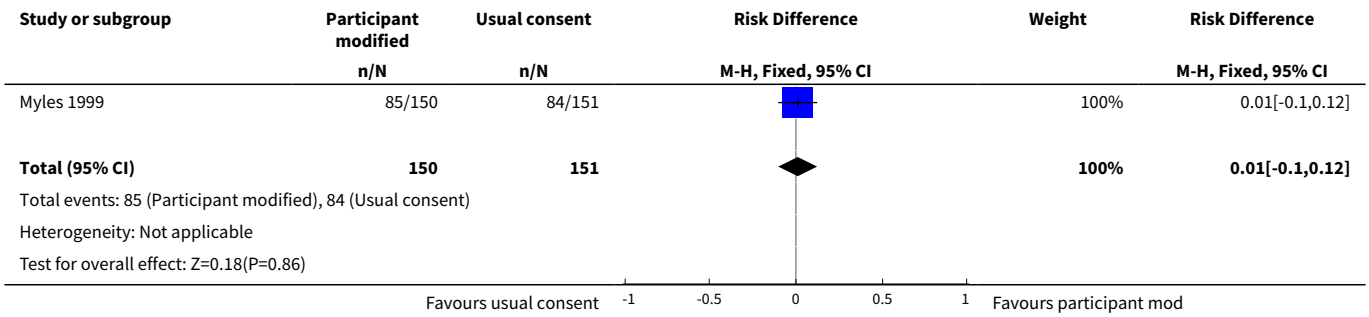
Analysis 21.1. Comparison 21 D–Physician-modified consent vs usual consent (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 22. D–Participant-modified consent vs usual consent (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	301	Risk Difference (M-H, Fixed, 95% CI)	0.01 [-0.10, 0.12]

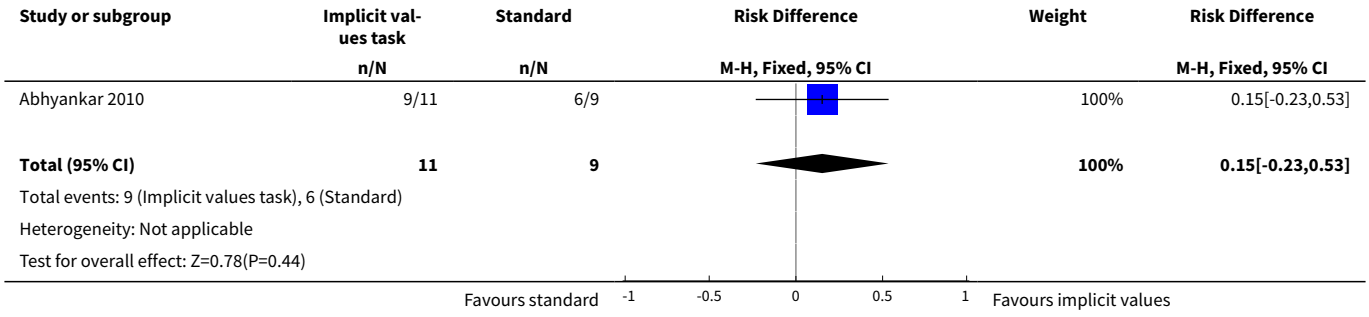
Analysis 22.1. Comparison 22 D–Participant-modified consent vs usual consent (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 23. D–Implicit participant values clarification task vs standard consent procedure (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	20	Risk Difference (M-H, Fixed, 95% CI)	0.15 [-0.23, 0.53]

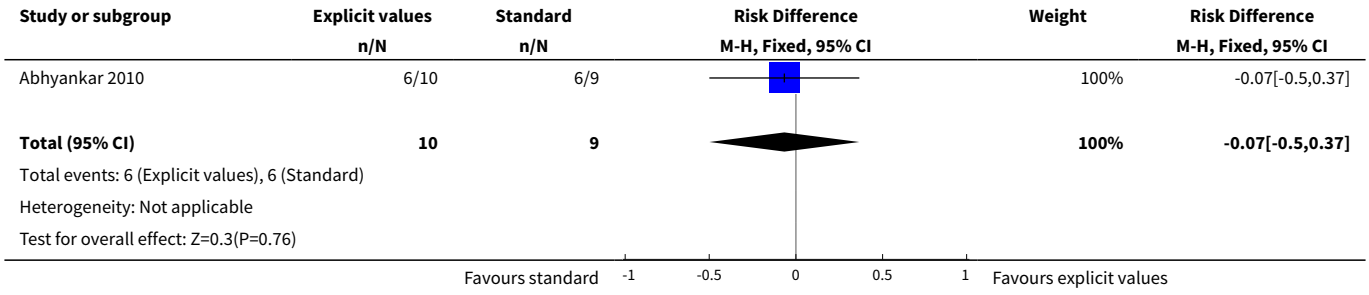
Analysis 23.1. Comparison 23 D–Implicit participant values clarification task vs standard consent procedure (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 24. D–Explicit participant values clarification task vs standard (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	19	Risk Difference (M-H, Fixed, 95% CI)	-0.07 [-0.50, 0.37]

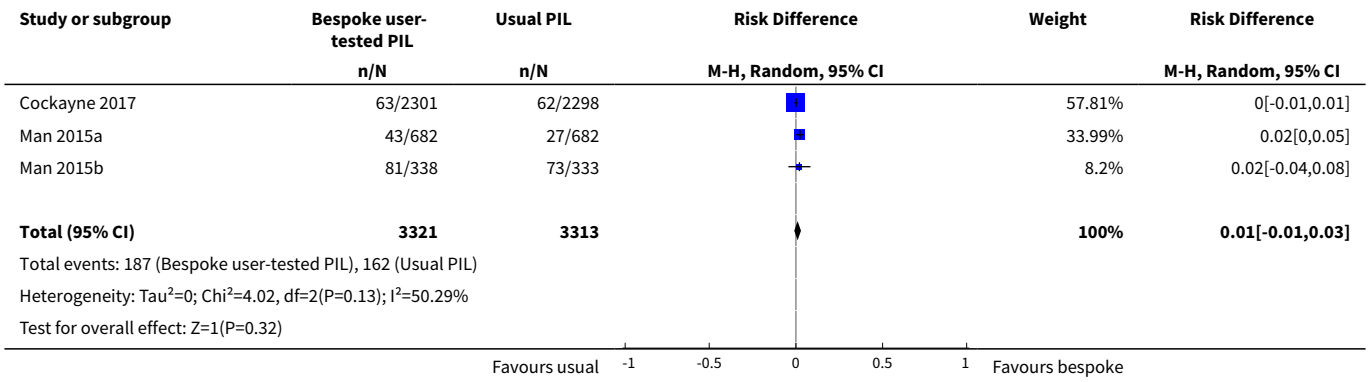
Analysis 24.1. Comparison 24 D–Explicit participant values clarification task vs standard (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 25. E–Bespoke, user-tested PIL vs usual PIL (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	3	6634	Risk Difference (M-H, Random, 95% CI)	0.01 [-0.01, 0.03]

Analysis 25.1. Comparison 25 E–Bespoke, user-tested PIL vs usual PIL (GRADE: moderate), Outcome 1 Participants recruited.

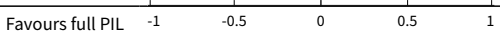


Comparison 26. E–Brief participant information leaflet (PIL) vs full PIL (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	2	4633	Risk Difference (M-H, Fixed, 95% CI)	-0.00 [-0.02, 0.02]

Analysis 26.1. Comparison 26 E–Brief participant information leaflet (PIL) vs full PIL (GRADE: moderate), Outcome 1 Participants recruited.

Study or subgroup	Brief PIL n/N	Full PIL n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Brierley 2012	63/1165	59/1165		50.31%	0[-0.01,0.02]
Chen 2011	720/1181	690/1122		49.69%	-0.01[-0.05,0.03]
Total (95% CI)	**2346**	**2287**		**100%**	**-0[-0.02,0.02]**
Total events: 783 (Brief PIL), 749 (Full PIL)					
Heterogeneity: Tau^2=0; Chi^2=0.27, df=1(P=0.6); I^2=0%					
Test for overall effect: Z=0.08(P=0.93)					

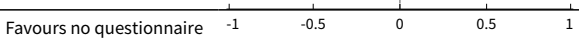


Comparison 27. E–Study-related questionnaire + trial invitation vs trial invitation (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	2393	Risk Difference (M-H, Fixed, 95% CI)	0.05 [0.02, 0.08]

Analysis 27.1. Comparison 27 E–Study-related questionnaire + trial invitation vs trial invitation (GRADE: moderate), Outcome 1 Participants recruited.

Study or subgroup	Study questionnaire n/N	No study questionnaire n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Kendrick 2001	217/1203	157/1190		100%	0.05[0.02,0.08]
Total (95% CI)	**1203**	**1190**		**100%**	**0.05[0.02,0.08]**
Total events: 217 (Study questionnaire), 157 (No study questionnaire)					
Heterogeneity: Not applicable					
Test for overall effect: Z=3.27(P=0)					

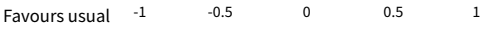


Comparison 28. E–PIL developed with feedback from users vs usual PIL (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	2	16763	Risk Difference (M-H, Fixed, 95% CI)	0.00 [-0.00, 0.01]

Analysis 28.1. Comparison 28 E–PIL developed with feedback from users vs usual PIL (GRADE: moderate), Outcome 1 Participants recruited.

Study or subgroup	PIL plus feedback n/N	Usual PIL n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Chen 2011	373/6104	339/6060		72.56%	0.01[-0,0.01]
Cockayne 2017	68/2301	62/2298		27.44%	0[-0.01,0.01]
Total (95% CI)	**8405**	**8358**		**100%**	**0[-0,0.01]**
Total events: 441 (PIL plus feedback), 401 (Usual PIL)					
Heterogeneity: Tau^2=0; Chi^2=0.18, df=1(P=0.67); I^2=0%					
Test for overall effect: Z=1.32(P=0.19)					

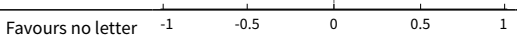


Comparison 29. E–Recruitment primer letter vs no letter (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	1062	Risk Difference (M-H, Fixed, 95% CI)	-0.00 [-0.06, 0.06]

Analysis 29.1. Comparison 29 E–Recruitment primer letter vs no letter (GRADE: low), Outcome 1 Participants recruited.

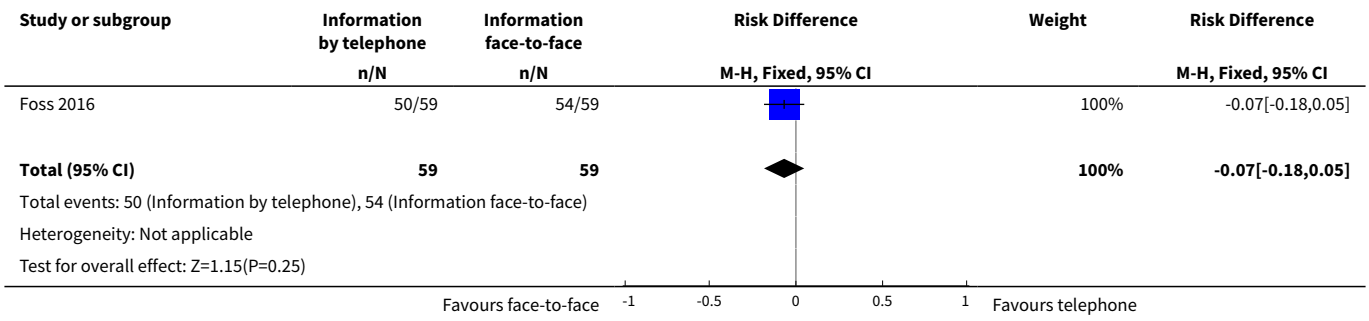
Study or subgroup	Primer letter n/N	No letter n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Paul 2014	207/519	218/543		100%	-0[-0.06,0.06]
Total (95% CI)	**519**	**543**		**100%**	**-0[-0.06,0.06]**
Total events: 207 (Primer letter), 218 (No letter)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.09(P=0.93)					



Comparison 30. E–Information provided over telephone vs information provided face-to-face (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	118	Risk Difference (M-H, Fixed, 95% CI)	-0.07 [-0.18, 0.05]

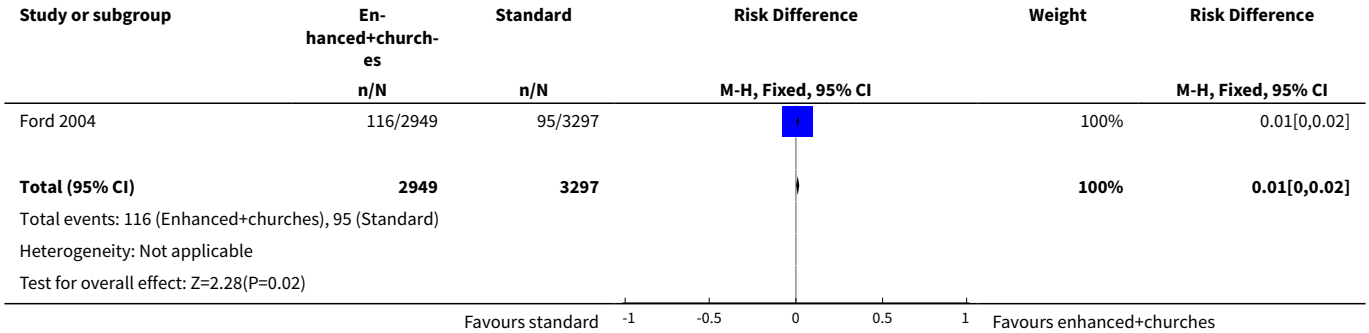
Analysis 30.1. Comparison 30 E–Information provided over telephone vs information provided face-to-face (GRADE: low), Outcome 1 Participants recruited.



Comparison 31. E–Enhanced recruitment package + recruitment at churches vs standard recruitment package (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	6246	Risk Difference (M-H, Fixed, 95% CI)	0.01 [0.00, 0.02]

Analysis 31.1. Comparison 31 E–Enhanced recruitment package + recruitment at churches vs standard recruitment package (GRADE: low), Outcome 1 Participants recruited.

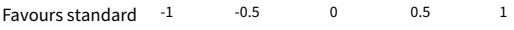


Comparison 32. E–Enhanced recruitment package vs standard recruitment package (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	6376	Risk Difference (M-H, Fixed, 95% CI)	-0.00 [-0.01, 0.00]

Analysis 32.1. Comparison 32 E–Enhanced recruitment package vs standard recruitment package (GRADE: low), Outcome 1 Participants recruited.

Study or subgroup	Enhanced n/N	Standard n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Ford 2004	78/3079	95/3297		100%	-0[-0.01,0]
Total (95% CI)	**3079**	**3297**		**100%**	**-0[-0.01,0]**
Total events: 78 (Enhanced), 95 (Standard)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.86(P=0.39)					

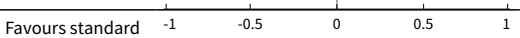


Comparison 33. E–Enhanced recruitment package + baseline data over telephone vs standard recruitment package (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	6372	Risk Difference (M-H, Fixed, 95% CI)	-0.00 [-0.01, 0.01]

Analysis 33.1. Comparison 33 E–Enhanced recruitment package + baseline data over telephone vs standard recruitment package (GRADE: low), Outcome 1 Participants recruited.

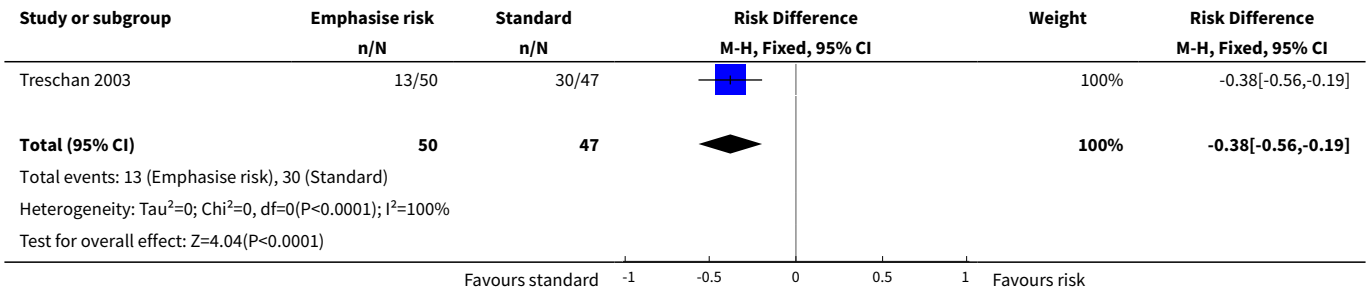
Study or subgroup	Enhanced+phone n/N	Standard n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Ford 2004	87/3075	95/3297		100%	-0[-0.01,0.01]
Total (95% CI)	**3075**	**3297**		**100%**	**-0[-0.01,0.01]**
Total events: 87 (Enhanced+phone), 95 (Standard)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.12(P=0.9)					



Comparison 34. E–Emphasising risk in information vs standard information (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	97	Risk Difference (M-H, Fixed, 95% CI)	-0.38 [-0.56, -0.19]

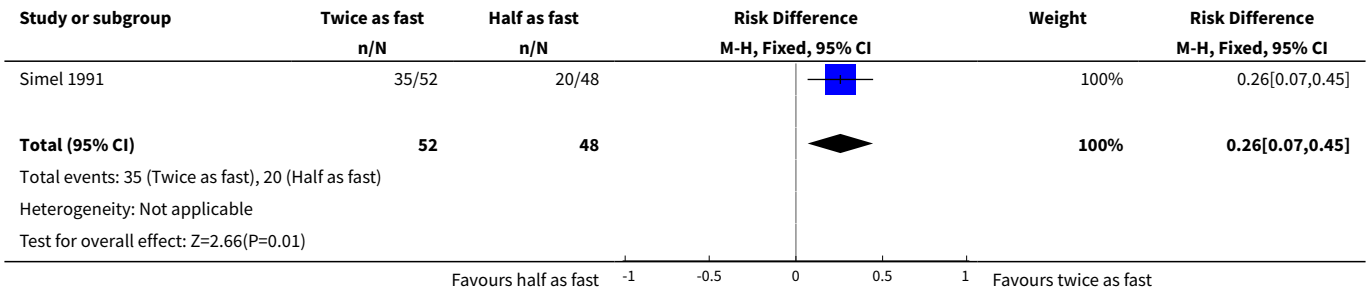
Analysis 34.1. Comparison 34 E–Emphasising risk in information vs standard information (GRADE: low), Outcome 1 Participants recruited.



Comparison 35. E–Wording treatment effect as 'twice as fast' in trial information vs writing 'half as fast' (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	100	Risk Difference (M-H, Fixed, 95% CI)	0.26 [0.07, 0.45]

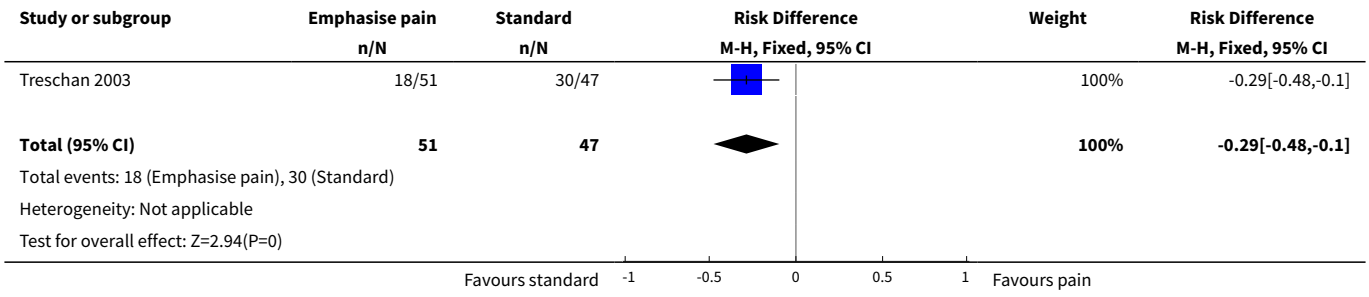
Analysis 35.1. Comparison 35 E–Wording treatment effect as 'twice as fast' in trial information vs writing 'half as fast' (GRADE: low), Outcome 1 Participants recruited.



Comparison 36. E–Emphasising pain in information vs standard information (GRADE: low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	98	Risk Difference (M-H, Fixed, 95% CI)	-0.29 [-0.48, -0.10]

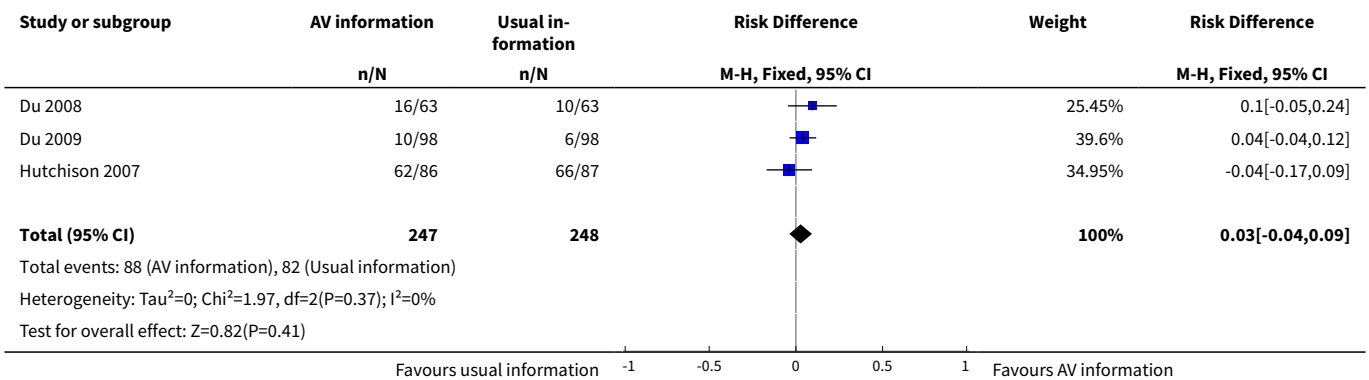
Analysis 36.1. Comparison 36 E–Emphasising pain in information vs standard information (GRADE: low), Outcome 1 Participants recruited.



Comparison 37. E–Providing information by video vs standard information (GRADE: very low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	3	495	Risk Difference (M-H, Fixed, 95% CI)	0.03 [-0.04, 0.09]

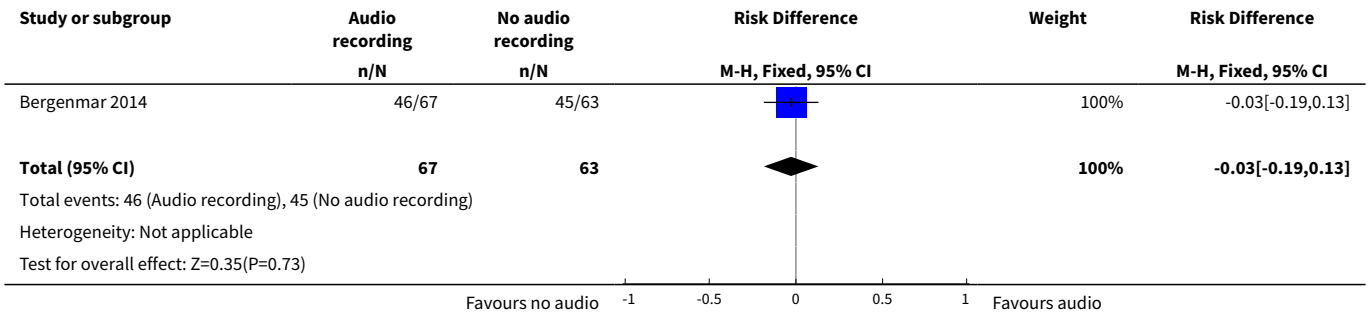
Analysis 37.1. Comparison 37 E–Providing information by video vs standard information (GRADE: very low), Outcome 1 Participants recruited.



Comparison 38. E–Audio record of information given about trial vs no audio record (GRADE: very low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	130	Risk Difference (M-H, Fixed, 95% CI)	-0.03 [-0.19, 0.13]

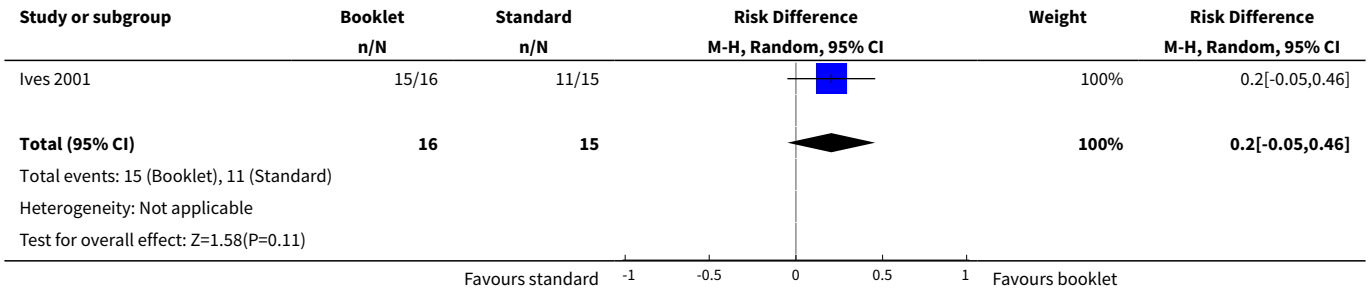
Analysis 38.1. Comparison 38 E–Audio record of information given about trial vs no audio record (GRADE: very low), Outcome 1 Participants recruited.



Comparison 39. E–Clinical trial booklet + standard information vs standard information (GRADE: very low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	31	Risk Difference (M-H, Random, 95% CI)	0.20 [-0.05, 0.46]

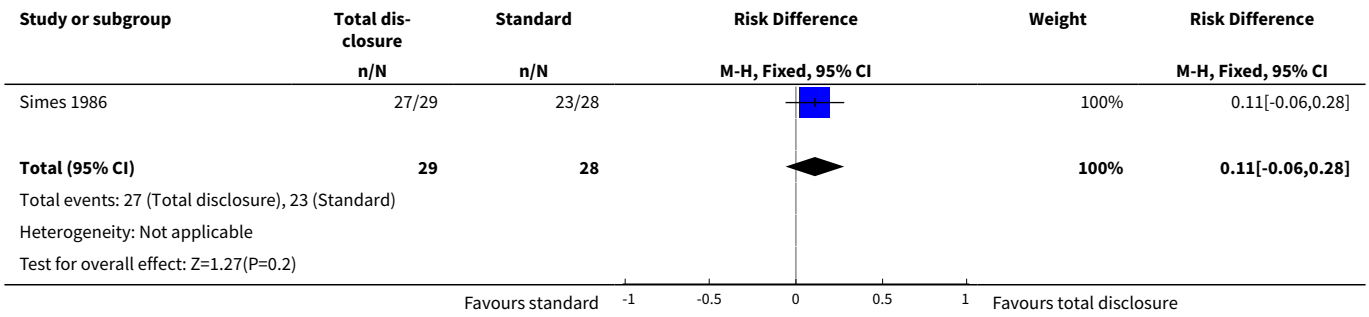
Analysis 39.1. Comparison 39 E–Clinical trial booklet + standard information vs standard information (GRADE: very low), Outcome 1 Participants recruited.



Comparison 40. E–Total information disclosure vs standard disclosure (GRADE: very low)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	57	Risk Difference (M-H, Fixed, 95% CI)	0.11 [-0.06, 0.28]

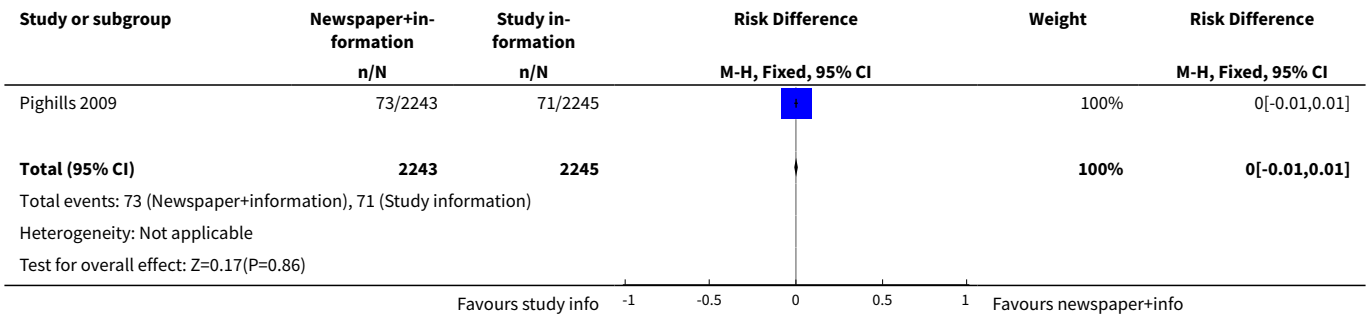
Analysis 40.1. Comparison 40 E–Total information disclosure vs standard disclosure (GRADE: very low), Outcome 1 Participants recruited.



Comparison 41. E–Newspaper article + study information vs study information only (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	4488	Risk Difference (M-H, Fixed, 95% CI)	0.00 [-0.01, 0.01]

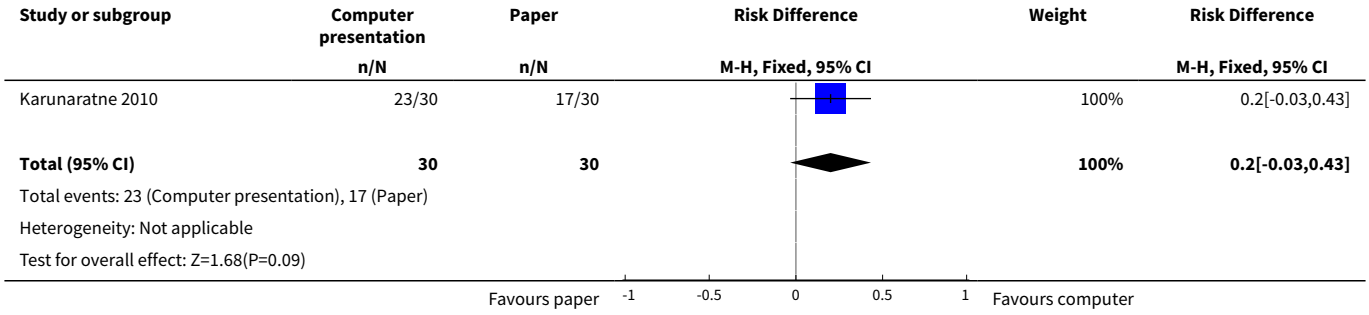
Analysis 41.1. Comparison 41 E–Newspaper article + study information vs study information only (high risk of bias), Outcome 1 Participants recruited.



Comparison 42. E–Interactive computer presentation of trial information vs standard paper presentations (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	60	Risk Difference (M-H, Fixed, 95% CI)	0.20 [-0.03, 0.43]

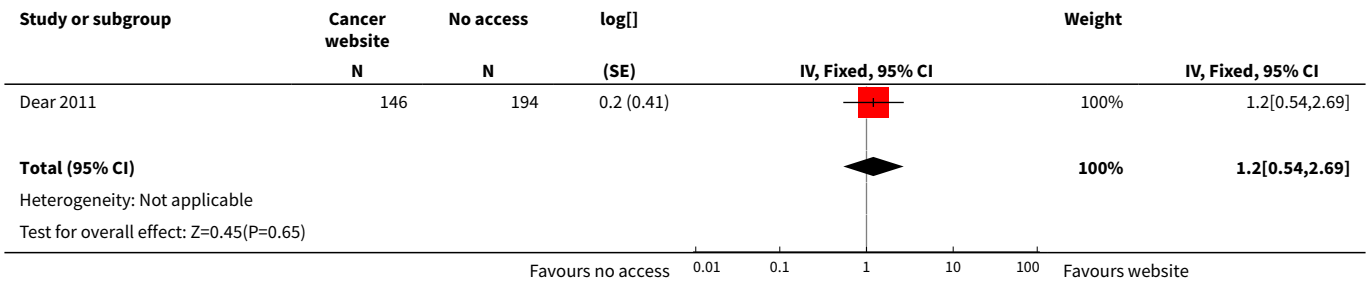
Analysis 42.1. Comparison 42 E–Interactive computer presentation of trial information vs standard paper presentations (high risk of bias), Outcome 1 Participants recruited.



Comparison 43. E–Access to cancer trials website vs no access (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1		(Fixed, 95% CI)	1.20 [0.54, 2.69]

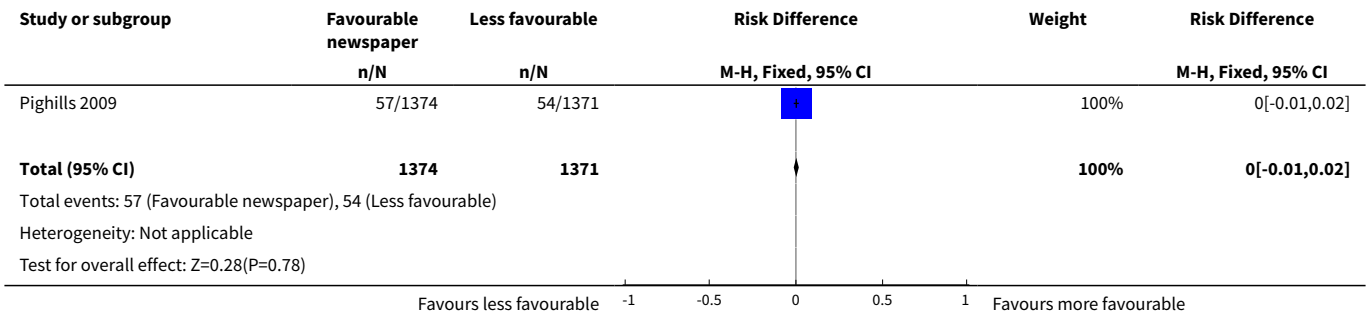
Analysis 43.1. Comparison 43 E–Access to cancer trials website vs no access (high risk of bias), Outcome 1 Participants recruited.



Comparison 44. E–More favourable newspaper article + study information vs less favourable newspaper article + study information (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	2745	Risk Difference (M-H, Fixed, 95% CI)	0.00 [-0.01, 0.02]

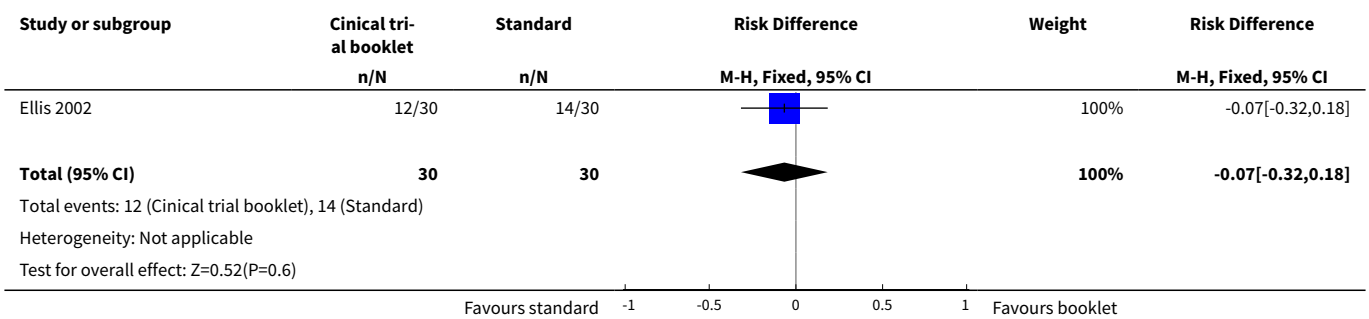
Analysis 44.1. Comparison 44 E–More favourable newspaper article + study information vs less favourable newspaper article + study information (high risk of bias), Outcome 1 Participants recruited.



Comparison 45. E-Clinical trial booklet + standard information vs standard information (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	60	Risk Difference (M-H, Fixed, 95% CI)	-0.07 [-0.32, 0.18]

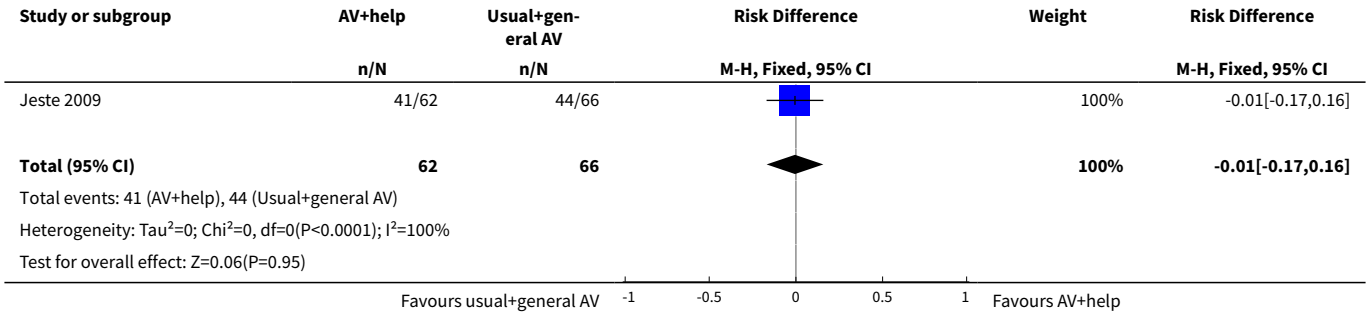
Analysis 45.1. Comparison 45 E-Clinical trial booklet + standard information vs standard information (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 46. E–Educational audiovisual information + help vs standard information + general audiovisual information + help (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	128	Risk Difference (M-H, Fixed, 95% CI)	-0.01 [-0.17, 0.16]

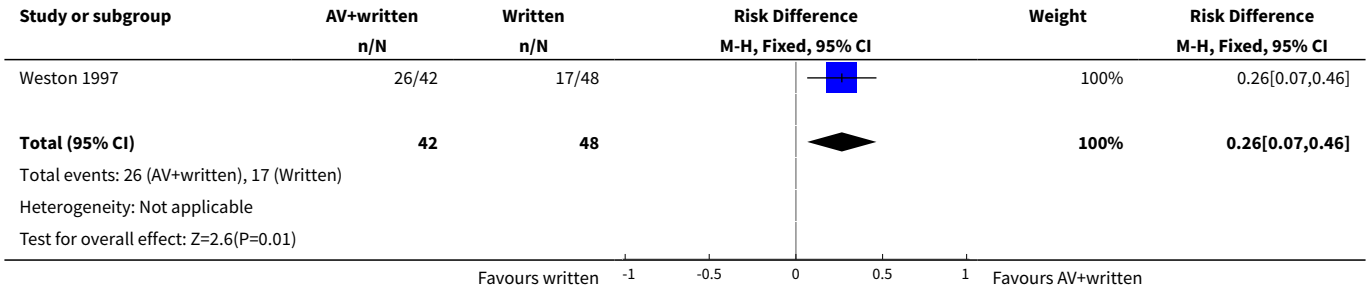
Analysis 46.1. Comparison 46 E–Educational audiovisual information + help vs standard information + general audiovisual information + help (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 47. E–Educational audiovisual information + written information vs written information (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	90	Risk Difference (M-H, Fixed, 95% CI)	0.26 [0.07, 0.46]

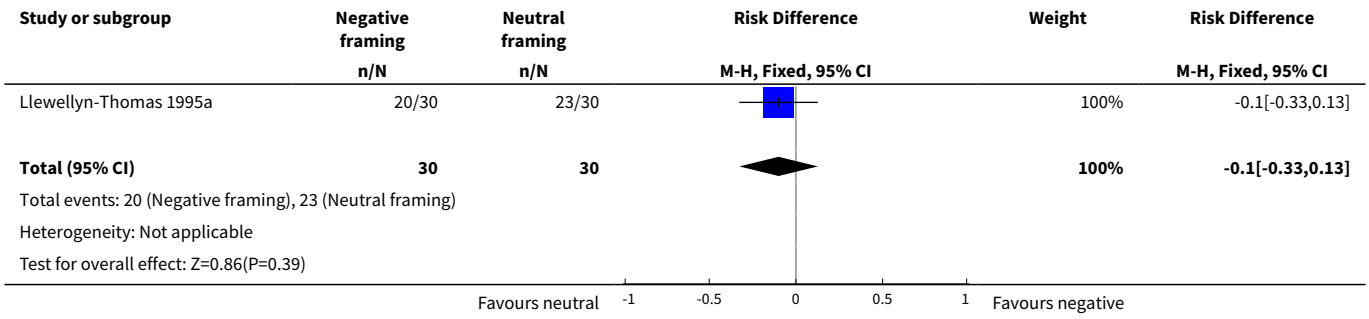
Analysis 47.1. Comparison 47 E–Educational audiovisual information + written information vs written information (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 48. E–Negative framing of side effects vs neutral framing (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	60	Risk Difference (M-H, Fixed, 95% CI)	-0.10 [-0.33, 0.13]

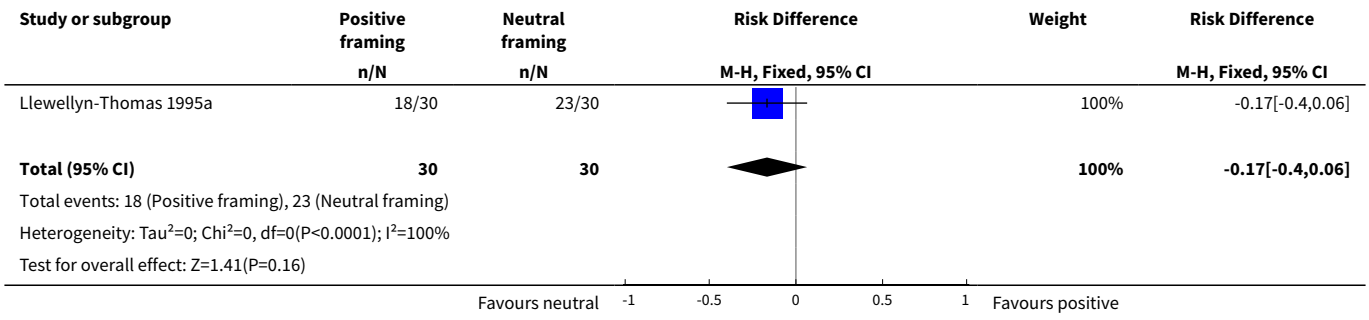
Analysis 48.1. Comparison 48 E–Negative framing of side effects vs neutral framing (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 49. E–Positive framing of side effects vs neutral framing (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	60	Risk Difference (M-H, Fixed, 95% CI)	-0.17 [-0.40, 0.06]

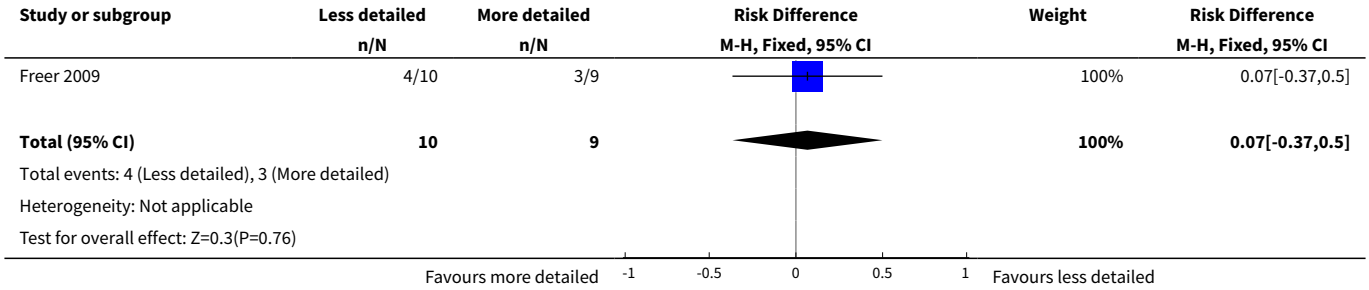
Analysis 49.1. Comparison 49 E–Positive framing of side effects vs neutral framing (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 50. E–Less detailed presentation of risk and other information vs more detailed presentation (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	19	Risk Difference (M-H, Fixed, 95% CI)	0.07 [-0.37, 0.50]

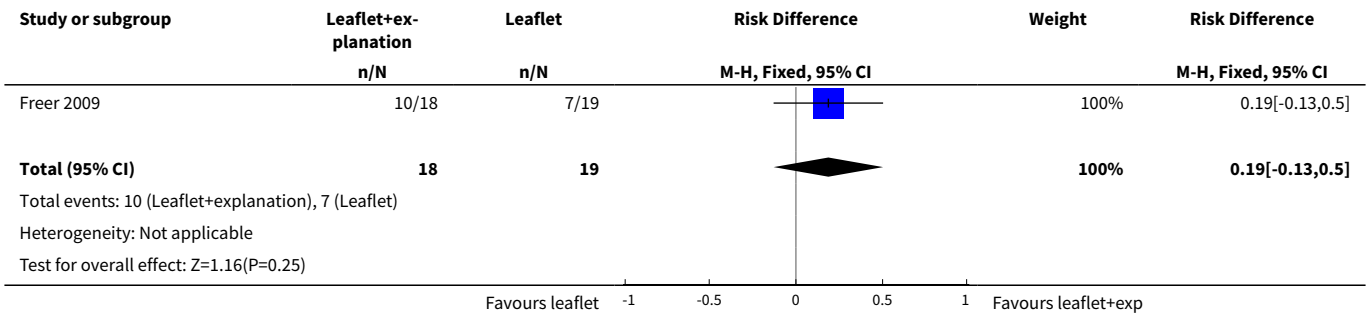
Analysis 50.1. Comparison 50 E–Less detailed presentation of risk and other information vs more detailed presentation (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 51. E–Information leaflet with explanation vs information leaflet without explanation (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	37	Risk Difference (M-H, Fixed, 95% CI)	0.19 [-0.13, 0.50]

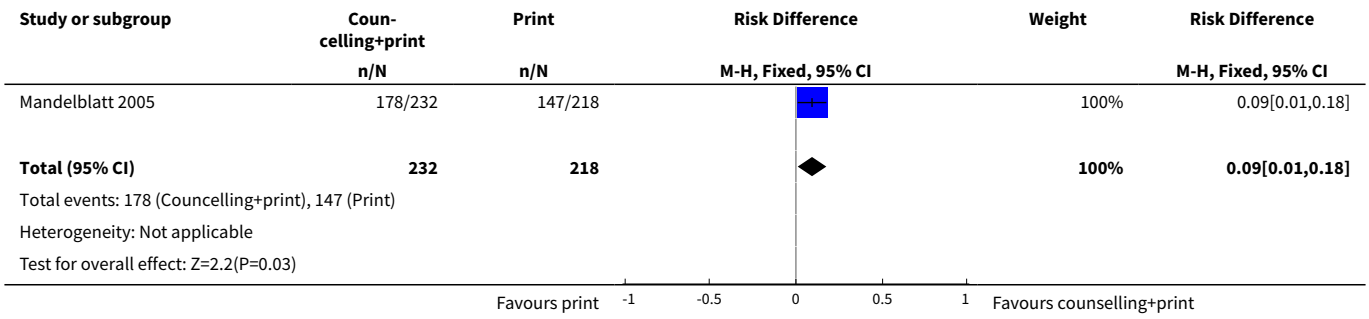
Analysis 51.1. Comparison 51 E–Information leaflet with explanation vs information leaflet without explanation (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 52. E–Brief counselling + print materials vs print alone (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	450	Risk Difference (M-H, Fixed, 95% CI)	0.09 [0.01, 0.18]

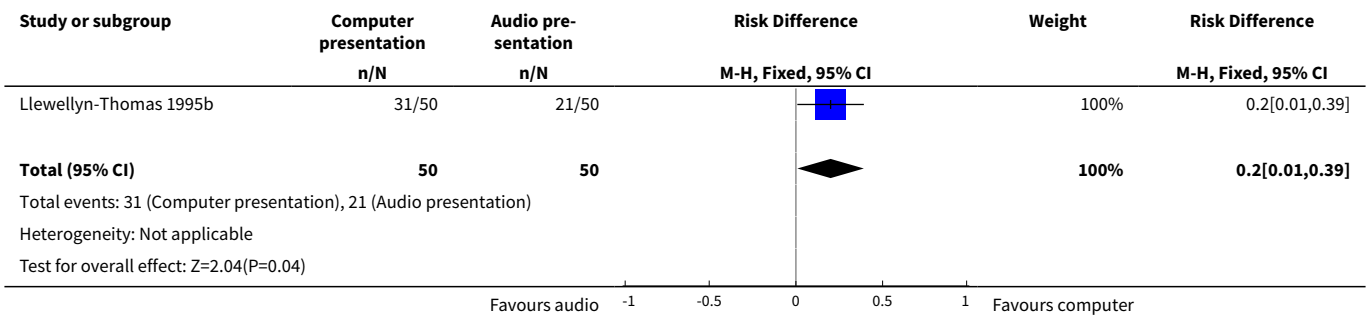
Analysis 52.1. Comparison 52 E–Brief counselling + print materials vs print alone (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 53. E–Interactive computer presentation of trial information vs audio-taped presentation (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	100	Risk Difference (M-H, Fixed, 95% CI)	0.2 [0.01, 0.39]

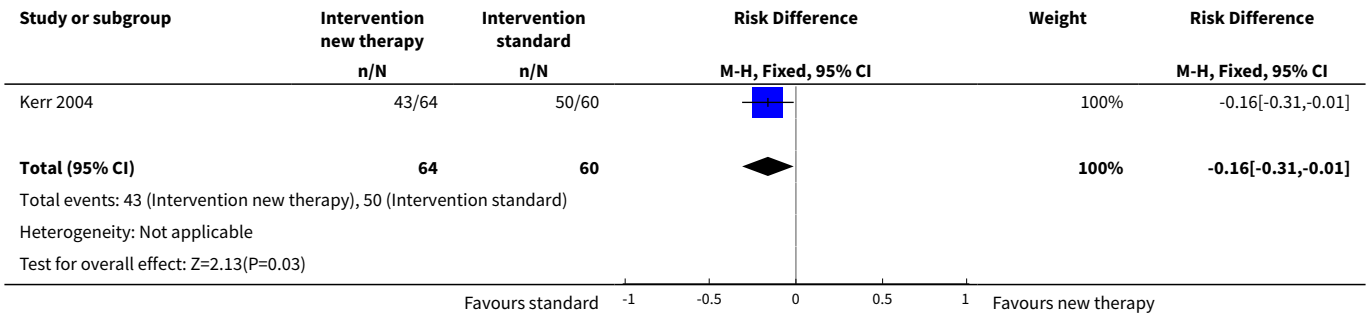
Analysis 53.1. Comparison 53 E–Interactive computer presentation of trial information vs audio-taped presentation (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 54. E–One new vs both standard (intervention description) (high risk of bias; hypothetical)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	124	Risk Difference (M-H, Fixed, 95% CI)	-0.16 [-0.31, -0.01]

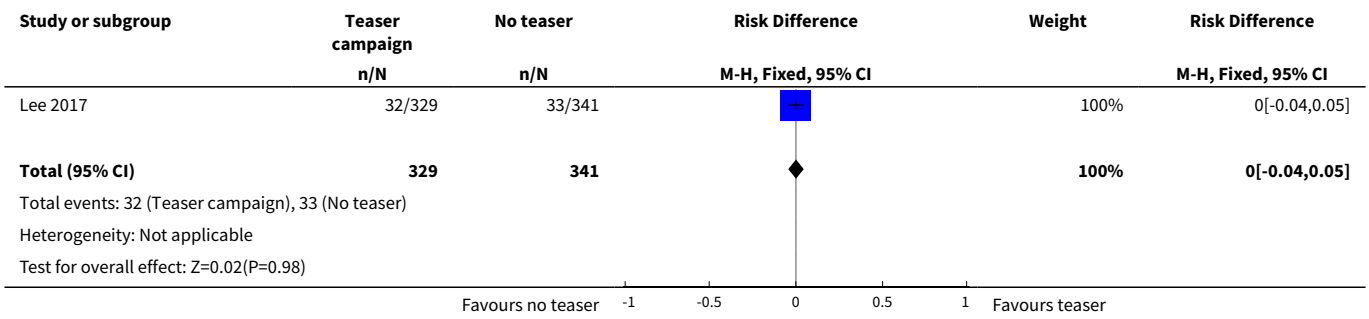
Analysis 54.1. Comparison 54 E–One new vs both standard (intervention description) (high risk of bias; hypothetical), Outcome 1 Participants recruited.



Comparison 55. F–Teaser campaign using postcards vs no teaser (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Primary care centre recruited	1	670	Risk Difference (M-H, Fixed, 95% CI)	0.00 [-0.04, 0.05]

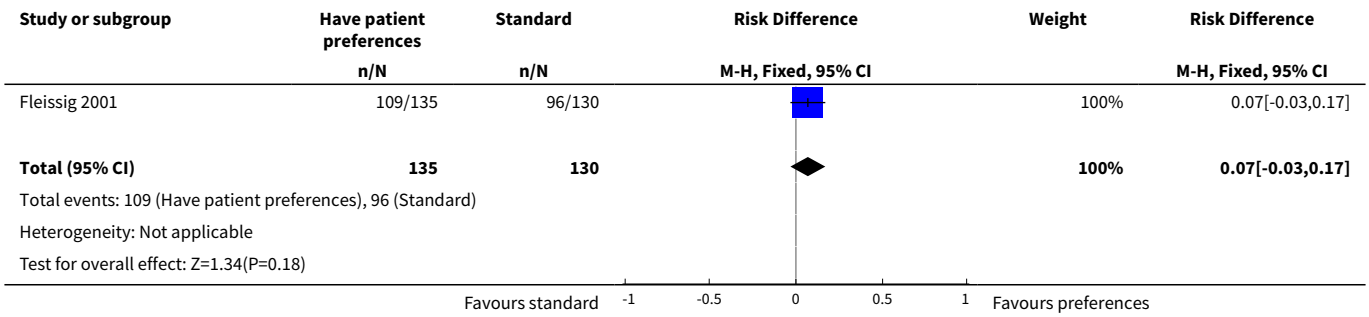
Analysis 55.1. Comparison 55 F–Teaser campaign using postcards vs no teaser (GRADE: moderate), Outcome 1 Primary care centre recruited.



Comparison 56. F–Doctor knows patient preferences about participation vs standard (high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	1	265	Risk Difference (M-H, Fixed, 95% CI)	0.07 [-0.03, 0.17]

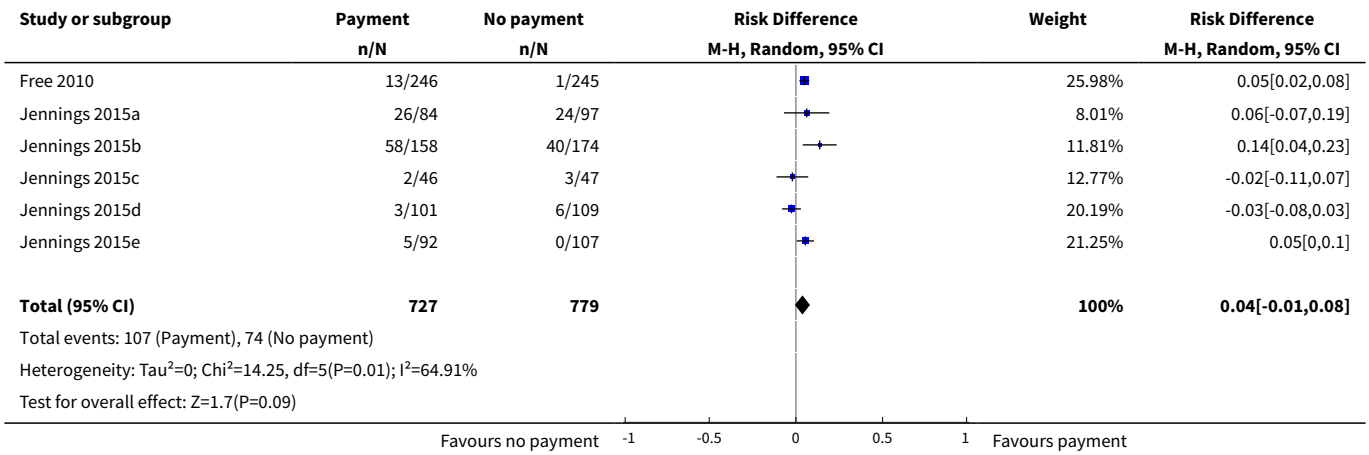
Analysis 56.1. Comparison 56 F–Doctor knows patient preferences about participation vs standard (high risk of bias), Outcome 1 Participants recruited.



Comparison 57. G-Financial incentive vs no incentive (GRADE: moderate)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participants recruited	6	1506	Risk Difference (M-H, Random, 95% CI)	0.04 [-0.01, 0.08]

Analysis 57.1. Comparison 57 G-Financial incentive vs no incentive (GRADE: moderate), Outcome 1 Participants recruited.



ADDITIONAL TABLES

Table 1. Countries where the included studies took place

Country	Number of studies
Australia	8
Austria	1
Canada	4
Denmark	1
Estonia	1
France	1
Italy	1
Multinational	1 (involved 19 countries)
Norway	1
Sweden	1
Tanzania	1
UK	22
USA	25

Table 2. Intervention categories

Study	Host trial intervention	Type of participants
A–Design. This includes changes to the general design of the trial specifically done to increase recruitment.		
Avenell 2004	Drug: vitamin D tablet	Patients (adults): attending a fracture clinic or orthopaedic ward
Cooper 1997	Drug/surgery: medical management or transcervical resection of the endometrium	Patients (adults): first-time attendees at a gynaecological clinic
Fowell 2006	Drug: anti-emetics only if symptomatic	Patients (adults): cancer inpatients receiving palliative care
Hemminki 2004	Drug: HRT	Patients (adults): postmenopausal women considering HRT
Litchfield 2005	Device: alternative delivery systems (NovoPen and Innovo) for insulin	Patients (probably adults): people with type 1 diabetes
Paul 2011	Drug: adjuvant treatment	Patients (probably adults): with colorectal cancer
Tehranisa 2014[a]	Hypothetical drug: acute stroke trial	Patients (adults): people attending emergency department

Table 2. Intervention categories *(Continued)*

Welton 1999[a]	Hypothetical drug: HRT	Healthy volunteers (adults): women who had not had a hysterectomy
B–Pre-trial planning. This includes work done before the trial starts (possibly in a separate study) that explicitly aims to increase recruitment success.		
None		
C–Trial conduct changes. This includes initiatives implemented once the trial has started, such as better ways of identifying participants, changes to how data are collected, changes to the type of data collected and tailored recruitment to different types of participant.		
Diguiseppi 2006[a]	Hypothetical behavioural trial	Patients (adults): attending hospital with acute injury
Free 2010	Behaviour: mobile phone-based smoking cessation	Healthy volunteers (adults): smokers
Free 2011	Behaviour: mobile phone-based smoking cessation	Healthy volunteers (adults): smokers
Graham 2007[a]	Hypothetical lifestyle trial	Patients (adults): attending hospital with acute injury
Miller 1999	Drug or therapy: psychotherapy, antidepressant medication, or both	Patients (adults): eligible for 1 of the 2 trials being run through the unit: 18-75 years old and DSM-IV dysthymic disorder, double depression (major depression superimposed on antecedent dysthymia), or chronic major depression
Mudano 2013	Hypothetical drug: osteoporosis	Healthy volunteers (adults): women 65 years or over with no reported use of osteoporosis medication in last year
Nystuen 2004	Therapy: psychologist intervention for issues linked to psychological problems or musculoskeletal pain	Patients (adults): on sick leave receiving benefits
Treweek 2012	Drug: antibiotic prescribing	Health professionals (adults): family doctors
Wong 2013	Screening: colorectal cancer screening	Healthy volunteers (adults): eligible for colorectal cancer screening
D–Modification to the consent form or process. This includes changes to the staff member helping with consent, when consent is taken, what sort of consent information is presented and how it is presented.		
Abd-Elsayed 2012	Drug or blood storage trials	Patients (adults): eligible for 1 of 3 trials, all of whom had substantial illness requiring major surgery (cardiac)
Abhyankar 2010[a]	Hypothetical drug or surgery	Healthy volunteers (adults): women and students on university mailing list
Coyne 2003	Drug: various	Patients (adults): eligible for cancer trial
MacQueen 2014[a]	Hypothetical drug: HIV treatment	Healthy volunteers (adults): sexually active women
Myles 1999[a]	Hypothetical drug: various	Patients (adults): eligible for surgery
Perrone 1995[a]	Hypothetical drug: various	Healthy volunteers (adults): attending a public event

Table 2. Intervention categories *(Continued)*

Trevena 2006	Screening: colorectal cancer	Healthy volunteers (adults): eligible for colorectal screening
Wadland 1990	Lifestyle: smoking cessation	Healthy volunteers (adults): smokers
E–Modification to the information given to potential participants about the trial. This includes who provides it, when, where what sort of information is presented, how the information is presented.		
Bergenmar 2014	Drug: various	Patients (probably adults): eligible for cancer trials
Brierley 2012	Therapy: cognitive behavioural therapy	Patients (adults): depression
Chen 2011	Unclear	Patients (probably adults): unclear what type
Cockayne 2017	Device: orthosis	Patients (adults): podiatry
Dear 2011	Information: access to cancer trials site	Patients (adults): have cancer
Du 2008	Cancer trials (unspecified)	Patients (adults): lung cancer
Du 2009	Cancer trials (unspecified)	Patients (adults): women with breast cancer
Ellis 2002[a]	Hypothetical cancer trials (unspecified)	Patients (adults): women with breast cancer
Ford 2004	Screening: prostate, lung and colorectal cancer screening	Healthy volunteers (adults): men eligible for prostate, lung and colorectal cancer screening
Foss 2016	Vaccination	Healthy volunteers (adults): pregnant women
Fracasso 2013	Cancer trials (unspecified)	Patients (adults): cancer (various)
Freer 2009[a]	Hypothetical intensive care (unspecified)	Healthy volunteers (adults): parents of infants admitted to hospital
Fureman 1997[a]	Hypothetical vaccine trial: HIV	Healthy volunteers (adults): drug users
Hutchison 2007	Cancer trials (unspecified)	Patients (probably adults): cancer (various)
Ives 2001	Unclear but probably drug	Patients (adults): people with HIV
Jacobsen 2012[a]	Hypothetical cancer trial	Patients (adults): cancer (various)
Jeste 2009[a]	Hypothetical drug trial	Patients (adults): schizophrenia
Karunaratne 2010[a]	Hypothetical device trial	Patients (adults): diabetes
Kendrick 2001	Injury prevention trial	Healthy volunteers (adults and children): families
Kerr 2004[a]	Hypothetical drug trial	Healthy volunteers (adults): attending college
Kimmick 2005	Cancer trials (various)	Patients (adults): cancer (various)
Larkey 2002	Various targeting cardiovascular disease, cancer and osteoporosis	Healthy volunteers: (adults) women

Table 2. Intervention categories *(Continued)*

Llewellyn-Thomas 1995a[a]	Hypothetical drug trial	Patients (adults): colorectal cancer
Llewellyn-Thomas 1995b[a]	Hypothetical drug trial	Patients (adults): cancer
Man 2015a[b]	Therapy: telephone support and self-management	Patients (adults): cardiovascular
Man 2015b[b]	Therapy: telephone support and self-management	Patients (adults): cardiovascular
Mandelblatt 2005[a,c]	Hypothetical drug trial	Healthy volunteers (adults): cancer prevention
Paul 2014	Screening: colorectal cancer	Healthy volunteers (adults): colorectal cancer screening
Pighills 2009	Therapy: falls prevention	Healthy volunteers (adults): older people at risk of falling
Simel 1991[a,c]	Hypothetical drug trial (participants were not told it was hypothetical)	Patients (adults): people attending ambulatory care clinic
Simes 1986	Unclear: cancer	Patients (adults): cancer
Treschan 2003[a,c]	Hypothetical surgery trial (participants were not told it was hypothetical)	Patients (adults): people undergoing minor surgery with general anaesthetic
Weinfurt 2008a[a]	Hypothetical drug trial	Patients (adults): coronary heart disease
Weinfurt 2008b[a]	Hypothetical drug trial	Patients (adults): coronary heart disease
Wells 2013[a]	Hypothetical: unclear what type, probably drug	Patients (adults): cancer
Weston 1997[a]	Hypothetical surgery trial	Healthy volunteers (adults): women attending antenatal clinics.
F–Interventions aimed at the recruiter or recruitment site. This includes anything that is aimed at the recruiter or recruitment site staff rather than the person being recruited such as changes to training		
Fleissig 2001	Diverse: cancer	Patients (adults): cancer
Lee 2017	Therapy: pain education	Staff at primary care clinics (sites are target, not patients)
Liénard 2006	Drug: breast cancer treatment	Staff at breast cancer treatment centres (sites are target, not patients)
Monaghan 2007	Unclear: diabetes management	Staff at clinical sites recruiting to a diabetes and vascular disease treatment trial (sites are target, not patients)
Tilley 2012	Drug: Parkinson's disease	Neurologists, primary care doctors and internists (adults)
G–Incentives. Financial and other incentives for participants		
Bentley 2004[a]	Hypothetical drug trial	Healthy volunteers (adults): students
Free 2010	Lifestyle: mobile phone-based smoking cessation	Healthy volunteers (adults): smokers

Table 2. Intervention categories *(Continued)*

Halpern 2004[a,c]	Hypothetical drug study	Patients (probably adults): mild hypertension
Jennings 2015a[d]	Drug: NSAID	Patients (adults): arthritis
Jennings 2015b[d]	Drug: hyperuricaemia	Patients (adults): symptomatic hyperuricaemia
Jennings 2015c[d]	Drug: hypertension	Patients (adults): hypertension
Jennings 2015d[d]	Drug: hypertension	Patients (adults): hypertension
Jennings 2015e[d]	Drug: diuretic therapy	Patients (adults): metabolic syndrome

DSM-IV: *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition; **HRT**: hormone replacement therapy; **NSAID**: non-steroidal anti-inflammatory drugs.
[a]Studies were recruiting to hypothetical trials or asking questions about intention to participate rather than asking people to make a real decision about participation.
[b]Man 2015a and Man 2015b are actually a single study that describes 2 embedded recruitment trials.
[c]Simel 1991, Treschan 2003 and Halpern 2004 used hypothetical trials but did not tell participants until after they had made their decisions; Mandelblatt 2005 involved a real trial but asked about intention to take part, not actual taking part.
[d]Jennings 2015a, Jennings 2015b, Jennings 2015c, Jennings 2015d and Jennings 2015e are actually a single study that describes 5 embedded recruitment trials.

APPENDICES

Appendix 1. Search strategies

Searches undertaken 11 February 2015

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to February Week1 2015>

Search Strategy:

---

1 Patient Selection/ (50436)

2 ((participat$ or recruit$ or enrol$) adj4 trial?).tw. (16427)

3 1 or 2 (65322)

4 Informed Consent/ (31549)

5 informed consent.tw. (24225)

6 4 or 5 (47497)

7 exp Clinical Trials as Topic/ (283986)

8 Research Subjects/ (5055)

9 (trial? or study or studies or research).tw. (7218575)

10 7 or 8 or 9 (7314164)

11 3 or (6 and 10) (86896)

12 (research support nih extramural or research support nih intramural or research support non us govt or research support us govt non phs or research support us govt phs).pt. (7410137)

13 recruitment.ab. /freq=2 (18332)

14 participation.ab. /freq=2 (16979)

15 12 or 13 or 14 (7422665)

16 11 and 15 (27568)

17 randomized controlled trial.pt. (383951)

18 controlled clinical trial.pt. (88580)

19 random$.ab. (724307)

20 17 or 18 or 19 (914167)

21 16 and 20 (9907)

22 exp animals/ not humans/ (3982927)

23 21 not 22 (9883)

24 23 not (comment or editorial).pt. (9860)

25 24 and ("2009" or "2010" or "2011" or "2012" or "2013" or "2014" or "2015").yr. (4913)

26 25 not 2009$.ed (4453)

****

Database: Ovid Embase <1996 to 2015 Week 06>

Search Strategy:

---

1 ((participat$ or recruit$ or enrol$ or enter$ or entry) and (trial? or study)).ti. (9063)

2 (select$ adj3 (participants or patients or controls)).tw. (102178)

3 recruit$.ab. /freq=2 (46720)

4 participat$.ab. /freq=2 (55568)

5 research.tw. (987167)

6 2 and (3 or 4 or 5) (7329)

7 Informed Consent/ (55296)

8 (informed consent or consent process$ or consent procedure?).tw. (40057)

9 exp "controlled clinical trial (topic)"/ (67171) term

10 (trial? or study or studies or research).tw. (6952871)

11 (7 or 8) and (9 or 10) (40723)

12 1 or 6 or 11 (56375)

13 Randomized Controlled Trial/ (313117)

14 Cross-over Procedure/ (37035)

15 random$.tw. (807376)

16 (factorial or crossover or cross-over or assign$ or allocat$).tw. (345538)

17 13 or 14 or 15 or 16 (1062995)

18 nonhuman/ (3059129)

19 editorial.pt. (373977)

20 conference abstract.pt. (1746506)

21 17 not (18 or 19 or 20) (749148)

22 12 and 21 (8476)

23 limit 22 to yr="2009 -Current" (3953)

24 23 not 2009$.dd (3534)

The Cochrane Library Cochrane Methodology Register : Issue 3 of 4, July 2012

#1 "accrual and sample size" or "attitudes to trials" or "informed consent":kw (Word variations have been searched) 3040

#2 (participat* or recruit* or enrol* or select*) near/8 (trial* or research or study):ti (Word variations have been searched) 3910

#3 (participat* or recruit* or enrol* or select*) near/8 (trial* or research or study):ab (Word variations have been searched) 59388

#4#1 or #2 or #3 515

Publication Year from 2009 to 2012, in Methods Studies

SCI & SSCI (ISI)

5 #4 OR #3 OR #2 OR #1 629

4 (TS=(recruitment NEAR/8 "controlled trial")) AND DOCUMENT TYPES: (Article) 175

3 (TS=(recruitment NEAR/8 "controlled trials")) AND DOCUMENT TYPES: (Article) 54

2 (TS=(recruitment NEAR/8 "clinical trials")) AND DOCUMENT TYPES: (Article) 306

1 ((TS=(recruitment NEAR/8 "clinical trial"))) AND DOCUMENT TYPES: (Article) 187

Indexes=SCI-EXPANDED, SSCI Timespan=2009-2015

ERIC (EBSCO)

S4 (S1 AND S2) Limiters - Date Published: 20090101-20141231 521

S3 (S1 AND S2) 884

S2 clinical trial* OR controlled trial* OR randomi* 4379

S1 (recruit* or participat*) 152,558

Appendix 2. Protocol

Cover sheet

Title

Strategies to improve recruitment to randomised trials

Reviewers

Treweek S, Pitkethly M, Cook J, Mitchell E, Sullivan F,Fraser C, Jackson C, Johansen M, Taskila T, Wilson S, Jones R, Lockhart P, Gardner H.

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Contribution of reviewers

All authors contributed to the writing of the protocol.

Internal sources of support

Scottish Higher Education Funding Council, Scotland

External sources of support

None

Background

Essentially all trials need to recruit participants but this is often a challenge. Poor recruitment can lead to an underpowered study, which may report clinically relevant effects to be statistically non-significant. A non-significant finding increases the risk that an effective intervention will be abandoned before its true value is established, or that there will be a delay in demonstrating this value while more trials or meta-analyses are done. Underpowered trials also raise an ethical problem: trialists have exposed participants to an intervention with uncertain benefit but may still be unable to determine whether the intervention does more good than harm on completion of the trial. Poor recruitment can also lead to the trial being extended, increasing costs.

Although investigations of recruitment differ in their estimates of the proportion of studies that achieve their recruitment targets, it is likely that less than 50% meet their target (Charlson 1984; Foy 2003; Haidich 2001; McDonald 2006; Sully 2013). For example, McDonald and colleagues found that only 38 (31%) of 114 trials achieved their original recruitment target and 65 (53%) were extended (McDonald 2006). More recent replications of this work by Sully and colleagues and by Walters and colleagues found that the the number of trials meeting recruitment targets had increased to around 50% (Sully 2013; Walters 2017). The overall start to recruitment was delayed in 47 (41%) trials and early recruitment problems were identified in 77 (63%) trials (Sully 2013). The costs of poor recruitment can be huge (Kitterman 2011).

Trialists use many interventions to improve recruitment (see for example Caldwell 2010, Watson 2006 and Prescott 1999) but it is generally difficult to predict the effect of these interventions.

This review updates the Treweek 2010 review.

Objectives

The primary objective is to quantify the effects of strategies to improve recruitment of participants to randomised controlled trials. A secondary objective is to assess the evidence for the effect of the research setting (e.g. primary care versus secondary care) on recruitment.

Criteria for considering studies for this review

Types of studies

Randomised and quasi-randomised trials of interventions to improve recruitment to randomised trials.

Types of participants

Randomised and quasi-randomised trials of recruitment strategies set in the context of trials but not limited to health care; interventions that work in other fields (e.g. education, housing) could be applicable to healthcare settings. Strategies both within real settings and in hypothetical trials (studies that ask potential participants whether they would take part in a trial if it was run but the trial does not actually exist) are eligible for this version of the review.

Note: future versions of this review will exclude hypothetical trials since these are all considered to be at high risk of bias because the recruitment decision is not a real one; many also have other methodological problems. There are three reasons for deciding to exclude them in future versions:

1. The relevance of the results of hypothetical trials will always be in doubt because of uncertainty as to how people would have reacted had the decision to take part in a trial been a real one not a hypothetical one.
2. It clearly is possible to study recruitment interventions in real trials, avoiding the above problem.
3. Now that the number of evaluations in real trials has increased, we do not think the trade-off between value-added and work involved to include hypothetical trials comes down in favour of including hypothetical trials in future versions of this review.

We excluded research into ways to improve questionnaire response and research looking at incentives and disincentives for clinicians to recruit patients to trials as these issues are addressed by complementary Cochrane Methodology Reviews (Edwards 2009; Rendell 2007). Studies of retention strategies were also excluded as a Cochrane Methodology Review on strategies to reduce attrition from trials is already exists (Brueton 2013).

Types of interventions

Any intervention that aimed to improve recruitment of participants to a randomised trial. The interventions being studied could be directed at potential participants (e.g. patients being randomised to a trial), collaborators (e.g. clinicians recruiting patients for a trial), or others (e.g. research ethics committees). Examples of such interventions are letters introducing the trial being signed by influential people, alternative methods of providing information about the trial to potential participants, additional training for collaborators, financial incentives for participants, telephone follow-up of expressions of interest and modifications to the design of the trial (e.g. using a preference design).

Types of outcome measures

Primary

Proportion of eligible individuals or centres recruited.

Secondary

None.

Search strategy for identification of studies

We will search the following electronic databases without language restriction for eligible studies:

- The Cochrane Methodology Review Group Specialised Register (CMR)
- MEDLINE and MEDLINE In Process (OVID)
- EMBASE (OVID)
- Science Citation Index & Social Science Citation Index (ISI)
- ERIC (EBSCO)

The search results will be downloaded to Endnote reference management software and de-duplicated.

The following MEDLINE search strategy will be adjusted according to the above listed databases.

Search Strategy:

---

1 Patient Selection/ (50436)

2 ((participat$ or recruit$ or enrol$) adj4 trial?).tw. (16427)

3 1 or 2 (65322)

4 Informed Consent/ (31549)

5 informed consent.tw. (24225)

6 4 or 5 (47497)

7 exp Clinical Trials as Topic/ (283986)

8 Research Subjects/ (5055)

9 (trial? or study or studies or research).tw. (7218575)

10 7 or 8 or 9 (7314164)

11 3 or (6 and 10) (86896)

12 (research support nih extramural or research support nih intramural or research support non us govt or research support us govt non phs or research support us govt phs).pt. (7410137)

13 recruitment.ab. /freq=2 (18332)

14 participation.ab. /freq=2 (16979)

15 12 or 13 or 14 (7422665)

16 11 and 15 (27568)

17 randomized controlled trial.pt. (383951)

18 controlled clinical trial.pt. (88580)

19 random$.ab. (724307)

20 17 or 18 or 19 (914167)

21 16 and 20 (9907)

22 exp animals/ not humans/ (3982927)

23 21 not 22 (9883)

24 23 not (comment or editorial).pt. (9860)

25 24 and ("2009" or "2010" or "2011" or "2012" or "2013" or "2014" or "2015").yr. (4913)

26 25 not 2009$.ed (4453)

****

Methods of the review

Identifying trials

Two authors will independently screen the titles and abstracts of all records retrieved from the searches of the electronic bibliographic databases. Any disagreements will be resolved through discussion and, if necessary, the involvement of a third author. The full text will be obtained for studies that appear to meet the inclusion criteria. All potentially eligible studies will be independently assessed by two authors to determine if they meet the inclusion criteria. Any disagreements will be resolved through discussion or the involvement of a third author.

Assessment of methodological quality

We will use the Cochrane Risk of Bias tool (Cochrane Risk of Bias tool) to assess risk of bias. We will use GRADE (Guyatt 2008) on all studies where relevant data are available. Where we do a meta-analysis, the details of the GRADE assessment will be given in the relevant Summary of Findings table. Where we use GRADE on a single study, we will use the following rules for assigning a GRADE rating of High, Moderate, Low or Very low:

- All studies start at High
- Study limitations: downgrade all high RoB studies by two levels; downgrade all uncertain RoB studies by one level.
- Inconsistency: assume no serious inconsistency.
- Indirectness: downgrade all hypothetical studies by two levels.
- Imprecision: downgrade all single studies by one level because of the sparseness of data; downgrade by a further one level if the confidence interval is wide and crosses the line where risk difference = 0.
- Reporting bias: assume no serious reporting bias.

Data on methodological quality will be presented in an additional table for all included studies.

Although we will not exclude studies because of a high of risk of bias, the low confidence we have in the data they present means that these studies will not be mentioned in the text of the Results or Discussion, except where it has been possible to include them in a meta-analysis and the data can be interpreted together with data from other studies.

High risk of bias studies will appear in Data and analyses but we suggest that readers use these data only to make decisions as to whether they would like to evaluate the intervention themselves in a more rigorous way. We do not believe they should be used to make judgements about effect.

Data for hypothetical studies will be included in Data and analyses for this version of the review. All of these studies will be excluded from future versions of this review.

Data extraction

Two review authors independently carried out data extraction of each included article (using a proforma specifically designed for the purpose). Differences in data extraction were resolved by discussion. We extracted data on the method evaluated; country in which the study was carried out; nature of the population; nature of the study setting; nature of the study to be recruited into; randomisation or quasi-randomisation method; and numbers and proportions of participants in the intervention and comparator groups of the study comparing recruitment strategies.

Data analysis

Trials will be grouped according to the type of intervention based on the categorisation used in the Online Resource for Recruitment research in Clinical triAls (ORRCA) project. We split one ORRCA category (Recruitment Information Needs) into two so as to separate out interventions aimed at the consent process from those aimed at more general participant information. Our seven categories are therefore:

1. **Design (Category A).** This includes changes to the general design of the trial specifically done to increase recruitment.
2. **Pre-trial planning (Category B).** This includes work done before the trial starts (possibly in a separate study) to explicitly make it more likely that recruitment will be successful.
3. **Trial conduct changes (Category C).** This includes initiatives implemented once the trial has started such as better ways of identifying participants, changes to how data are collected, changes to the type of data collected, tailor recruitment to different types of participant.
4. **Modifications to the consent process (Category D).** This includes changes to the staff member helping with consent, when consent is taken, what sort of consent information is presented and how it is presented.
5. **Modification to the information given to potential participants about the trial (Category E).** This includes who provides it, when, where what sort of information is presented, how the information is presented.
6. **Interventions aimed at the recruiter or recruitment site (Category F).** This includes anything that is aimed at the recruiter or recruitment site staff rather than the person being recruited such as changes to training.
7. **Incentives (Category G).** Financial and other incentives for participants (but not staff, which is covered by a separate review).

We will present results as risk difference (RD) with the associated 95% confidence intervals (CIs) where sufficient data are available. We will only include cluster-randomised trials in the meta-analysis if sufficient data were reported to allow inclusion of analyses that adjusted for clustering; an odds ratio (OR) wil be used as the summary effect in the meta-analysis result if risk difference or risk ratio clustering adjusted anlayses were not possible with available data. Where two or more studies could be included in a meta-analyses we will use a fixed effect approach to produce a pooled estimate in the absence of susbtantial heterogeneity.

Publication bias will be investigated for the primary outcomes using a funnel plot where 10 or more studies are available.

Potential conflict of interest

None known.

Additional references

None. All are listed in main review reference list.

Contributions to the protocol

Updated May 2017 by Treweek S, Pitkethly M, Cook J, Mitchell E, Sullivan F, Fraser C, Jackson C, Gardner H.

Contributing authors (October 2007): Treweek S, Sullivan F, Pitkethly M, Jackson C, Wilson S, Kjeldstrøm M, Johansen M, Jones R, Cook J.
Comments on drafts (October 2007): Treweek S, Sullivan F, Pitkethly M, Jackson C, Wilson S, Kjeldstrøm M, Johansen M, Jones R, Cook J.

Glossary of selected terms

See the GET IT Glossary (http://getitglossary.org) for plain language definitions of a wide range of terms relevant to fair tests of treatments.

Appendix 3. Participant numbers per study

Category A - Design					
Low and uncertain risk of bias			**High risk of bias**		
Study	*N participants*	*N clusters*	*Study*	*N participants*	*N clusters*
Avenell 2004	538	28	Tehranisa 2014	418	—

(Continued)

Cooper 1997	273		Welton 1999	436	
Fowell 2006	53				
Hemminki 2004	4295				
Litchfield 2005	80				
Paul 2011	398				
Total	5637	28	**Total**	854	—

Category B - pre-trial planning

Low and uncertain risk of bias			**High risk of bias**		
Study	*N participants*	*N clusters*	*Study*	*N participants*	*N clusters*
None					
Total	0	—	**Total**	0	—

Category C - Trial conduct changes

Low and uncertain risk of bias			**High risk of bias**		
Study	*N participants*	*N clusters*	*Study*	*N participants*	*N clusters*
Free 2010[a]	811	—	Diguiseppi 2006	469	—
Free 2011	1862		Graham 2007	370	
Nystuen 2004	498		Miller 1999	347	
Treweek 2012	880		Mudano 2013	155	
Wong 2013	480				
Total	4531		**Total**	1341	

Category D - Modification to the consent process

Low and uncertain risk of bias			**High risk of bias**		
Study	*N participants*	*N clusters*	*Study*	*N participants*	*N clusters*
Coyne 2003	226	—	Abhyankar 2010	30	—
Trevena 2006	152		Abd-Elsayed 2012	499	
Wadland 1990	104		MacQueen 2014	80	
			Myles 1999	769	
			Perrone 1995	3217	
Total	482	—	**Total**	4595	—

Category E - Modification to the information given to potential participants about the trial

Low and uncertain risk of bias			**High risk of bias**		
Study	*N participants*	*N clusters*	*Study*	*N participants*	*N clusters*
Bergenmar 2014	130	—	Dear 2011	340	—
Brierley 2012	2330		Ellis 2002	60	
Chen 2011	14,467		Freer 2009	41	
Cockayne 2017	6,900		Fracasso 2013	69	
Du 2008	126		Fureman 1997	186	
Du 2009	196		Jacobsen 2012	462	

(Continued)

Ford 2004	12,400		Jeste 2009	188	
Foss 2016	118		Karunaratne 2010	60	
Hutchison 2007	173		Kerr 2004	130	
Ives 2001	50		Llewellyn-Thomas 1995a	90	
Kendrick 2001	2393		Llewellyn-Thomas 1995b	100	
Kimmick 2005	126		Mandelblatt 2005	450	
Larkey 2002	15		Pighills 2009	4488	
Man 2015a[b]	1364		Weinfurt 2008a	3623	
Man 2015b[b]	671		Weinfurt 2008b	470	
Paul 2014	1062		Wells 2013	31	
Simel 1991	100		Weston 1997	90	
Simes 1986	57				
Treschan 2003	148				
Total	42,826	—	**Total**	10,878	—

Category F - Interventions aimed at the recruiter or recruitment site

Low and uncertain risk of bias			**High risk of bias**		
Study	*N participants*	*N clusters*	*Study*	*N participants*	*N clusters*
Monaghan 2007	573	167	Fleissig 2001	265	32
Liénard 2006	29	744	Tilley 2012	606	
Lee 2017					
Total	602	1046	**Total**	871	32

Category G - Incentives

Low and uncertain risk of bias			**High risk of bias**		
Study	*N participants*	*N clusters*	*Study*	*N participants*	*N clusters*
Free 2010[c]	491	—	Bentley 2004	270	—
Jennings 2015a[d]	181		Halpern 2004	126	
Jennings 2015b[d]	332				
Jennings 2015c[d]	93				
Jennings 2015d[d]	210				
Jennings 2015e[d]	199				
Total	1506	—	**Total**	396	—

Overall totals

Low and uncertain risk of bias			**High risk of bias**		
N studies	*N participants*	*N clusters*	*N studies*	*N participants*	*N clusters*
36	55,584	1343	32	18,935	32

(Continued)

All risk of bias

N studies	*N participants*	*N clusters*
66	74,519	1405

[a]Contained two interventions (see Category G).
[b]Both included in same article.
[c]Included two interventions (see Category C).
[d]All included in same article.

Appendix 4. Full list of interventions

- **Design (Category A)**
  - Open RCT versus blinded RCT (GRADE: high; Analysis 1.1)
  - Patient preference design versus conventional RCT design (GRADE: low; Analysis 2.1)
  - Electronic data capture versus paper-based data capture (GRADE: low; Analysis 3.1)
  - Cluster randomisation versus Zelen design (risk of bias: low Analysis 4.1)
  - Two-stage randomisation to choose duration of treatment versus single randomisation (low risk of bias; Paul 2011)
  - Placebo versus other comparator (high risk of bias; Analysis 4.1)
  - Video describing response-adaptive design vs video describing standard design (high risk of bias; Analysis 5.1)
- **Pre-trial planning (Category B)**
  - None
- **Trial conduct changes (Category C)**
  - Telephone reminder versus no telephone reminder (GRADE: high; Analysis 6.1)
  - SMS reminder mentioning scarcity vs SMS reminder with no mention (GRADE: moderate; Analysis 7.1)
  - SMS messages containing quotes from existing participants vs no messages (GRADE: moderate; Analysis 8.1)
  - Email invitation versus postal invitation (GRADE: moderate; Analysis 9.1)
  - Telephone screening versus face-to-face screening (high risk of bias; Analysis 10.1)
  - Screening by senior investigator versus screening by research assistant (high risk of bias; Analysis 11.1)
  - Tablet computer to support screening vs voice response system to support screening (high risk of bias; Analysis 12.1)
  - Electronic completion of screening questionnaire versus standard paper completion (high risk of bias; Analysis 13.1)
  - Oral completion of screening questionnaire versus standard paper completion (high risk of bias; Analysis 14.1)
- **Modifications to the consent process (Category D)**
  - Opt-out consent versus opt-in consent (GRADE: low; Analysis 15.1)
  - Consent to experimental care versus usual consent (GRADE: very low; Analysis 16.1)
  - Consent to standard care versus usual consent (GRADE: very low; Analysis 17.1)
  - Researcher reading our consent versus participant reading consent (GRADE: very low; Analysis 18.1)
  - Easy to read consent versus standard consent (unclear risk of bias; Coyne 2003)
  - Information printed on heavyweight paper and blue folio vs standard (high risk of bias; Analysis 19.1)
  - Refusers choose treatment versus usual consent (high risk of bias; Analysis 20.1)
  - Physician-modified consent versus usual consent (high risk of bias; Analysis 21.1)
  - Participant-modified consent versus usual consent (high risk of bias; Analysis 22.1)
  - Implicit participant values clarification task vs standard (high risk of bias; Analysis 23.1)
  - Explict participant values clarification task vs standard (high risk of bias; Analysis 24.1)
  - Open ended assessment of comprehension versus closed-ended assessment (high risk of bias; MacQueen 2014)
- **Modification to the information given to potential participants about the trial (Category E)**
  - Bespoke user-tested PIL vs usual PIL (GRADE: high; Analysis 25.1)
  - Brief participant information leaflet (PIL) vs full PIL (GRADE: moderate; Analysis 26.1)
  - Study-related questionnaire + trial invitation versus trial invitation (GRADE: moderate; Analysis 27.1)
  - PIL developed with feedback from users vs usual PIL (GRADE: moderate; Analysis 28.1)
  - Recruitment primer letter vs no letter (GRADE: low; Analysis 29.1)

- Information provided over telephone vs information provided face-to-face (GRADE: low; Analysis 30.1)
- Enhanced recruitment package + recruitment at churches versus standard recruitment package (GRADE: low; Analysis 31.1)
- Enhanced recruitment package versus standard recruitment package (GRADE: low; Analysis 32.1)
- Enhanced recruitment package + baseline data over telephone versus standard recruitment package (GRADE: low; Analysis 33.1)
- Emphasising risk in information versus standard information (GRADE: low; Analysis 34.1)
- Wording treatment effect is 'twice as fast' in trial information versus writing 'half as fast' (GRADE: low; Analysis 35.1)
- Emphasising pain in information versus standard information (GRADE: low; Analysis 36.1)
- Providing information by video versus standard information (GRADE: very low; Analysis 37.1)
- Audio record of information given about trial vs no audio record (GRADE: very low; Analysis 38.1)
- Clinical trial booklet + standard information versus standard information (GRADE: very low; Analysis 39.1)
- Total information disclosure versus standard disclosure (GRADE: very low; Analysis 40.1)
- Standard information about trial plus symposium + other educational material versus standard information (unclear risk of bias; Kimmick 2005)
- Newspaper article + study information versus study information only (high risk of bias; Analysis 41.1)
- Interactive computer presentation of trial information versus standard paper presentation (high risk of bias; Analysis 42.1)
- Access to cancer trials website vs no access (high risk of bias; Analysis 43.1)
- More favourable newspaper article + study information versus less favourable article + study information (high risk of bias; Analysis 44.1)
- Clinical trial booklet + standard information versus standard information (high risk of bias; Analysis 45.1)
- Educational audiovisual information + help versus standard information + general audiovisual information + help (high risk of bias; Analysis 46.1)
- Educational audiovisual information with written information versus written information (high risk of bias; Analysis 47.1)
- Negative framing of side effects versus neutral framing (high risk of bias; Analysis 48.1)Positive framing of side effects versus neutral framing (high risk of bias; Analysis 49.1)
- Less detailed presentation of risk and other information versus more detailed presentation (high risk of bias; Analysis 50.1)
- Information leaflet with explanation versus information leaflet without explanation (high risk of bias; Analysis 51.1)
- Brief counselling + print materials versus print materials (high risk of bias; Analysis 52.1)
- Interactive computer presentation of trial information versus audio-taped presentation (high risk of bias; Analysis 53.1)
- One new versus both standard (description of intervention) (high risk of bias; Analysis 54.1)
- Coach to support recruitment of minority participants versus no coach (high risk of bias; Fracasso 2013)
- Financial disclosure saying drug company pays investigator versus no disclosure (high risk of bias; Weinfurt 2008a)
- Presenting increasing amounts of financial disclosure information about investigator (high risk of bias; Weinfurt 2008b)
- Video + pamphlet describing the trial versus pamphlet only (high risk of bias; Fureman 1997)
- Multimedia psychoeducational DVD and written information providing trial information versus written information only (high risk of bias; Jacobsen 2012)
- Spanish-language multimedia information versus Spanish-language written information (high risk of bias; Wells 2013)
- Use of Hispanic lay advocates versus no advocates (unclear risk of bias; Larkey 2002)

- **Interventions aimed at the recruiter or recruitment site (Category F)**
  - Teaser campaign using postcards vs no teaser (GRADE: moderate; Analysis 55.1)
  - Additional communication from central trial coordinator to sites versus standard communication (low risk of bias; Monaghan 2007)
  - Site initiation visit versus no initiation visit (low risk of bias; Liénard 2006)
  - Recruitment coordinator plus training vs usual recruitment (high risk of bias; Analysis 56.1)
  - Doctor knows patient preferences about participation vs standard (high risk of bias; Analysis 56.1)
- **Incentives (Category G)**
  - Financial incentive vs no incentive (GRADE: moderate; Analysis 57.1)
  - Variation in information provided about adverse events, participants receiving placebo and payments to participants (high risk of bias; Halpern 2004)
  - Variation in hourly payment plus risk-based bonuses (high risk of bias; Bentley 2004)

FEEDBACK

Michaels, 2 March 2010

Summary

I suggest that the next iteration of this report take into account, assuming it does exist in the literature, researcher relationships with the community. I am not only referring to Community Based Participatory Research (CBPR) in relation to clinical research (see www.communitiespartners.org), but also to researcher relationships with referring physicians and community based organizations. These relationships are critical to the success of clinical research, especially in the community setting.

The review also needs to take into account disease states in terms of recruitment. The patient with controllable diabetes vs the patient needing cancer treatment have very different information needs when it comes to clinical trial participation.

Submitter agrees with default conflict of interest statement:
I certify that I have no affiliations with or involvement in any organization or entity with a financial interest in the subject matter of my feedback.

(Feedback submitted by Margo Micheals March 2010)

Reply

Many thanks for this suggestion, which we would like to build into our review. In terms of managing this, we think the best way to incorporate this comment would be to create a new category of intervention where researchers have specifically evaluated the impact on recruitment of building close collaborative relationships with potential participants, be they patients, healthy volunteers, or health professionals. Here we would be looking to studies that compared such an intervention against what might be called traditional recruitment strategies. We will also add disease as a potential subgroup analysis. We agree that it is highly plausible that disease (especially chronic versus acute) plays a role in recruitment.

As you mention, we may not find primary studies that allow us to act on these suggestions straight away. We did not identify studies that evaluated the kind of interventions mentioned above in our initial search though this may change as the review is updated.

Thanks again for your interest in our review.

Update to the 2010 feedback

We have added disease to our subgroup analysis list although we did not find enough studies to do this analysis, which is what we found for all of our proposed subgroup analyses. We think the new category of intervention we mentioned is nicely covered by Category F (Interventions aimed at the recruiter or recruitment site) as these would include the type of relationship-building interventions mentioned in the feedback. This category also has the advantage of coming from the ORCCA process so matches the categories used elsewhere within the field of trial recruitment.

Contributors

Reply received from the review team, April 2010.

WHAT'S NEW

Date	Event	Description
20 February 2018	New citation required and conclusions have changed	Review updated
9 June 2017	New search has been performed	Review updated: search extended to February 2015; 24 additional included studies, including 6 recent studies identified outside the search (two from 2017) and 1 study missed in earlier searches. One previously included study excluded (it was included in error). Changes to protocol for next update introduced, chiefly linked to hypothetical trials, which will be excluded in future updates. While we added new studies to the review, the overall picture with regard to interventions for improving recruitment to trials remains similar to the previous version of the review.

Date	Event	Description
		We have updated the 'Implications for methodological research' section to suggest interventions that methodological researchers should prioritise for enhanced evaluation, along with protocols for Studies Within A Trial (SWATs) to support these areas.

HISTORY

Protocol first published: Issue 3, 2002
Review first published: Issue 1, 2004

Date	Event	Description
10 June 2011	New search has been performed	Review updated: search extended to April 2010, 18 additional included studies. While new studies were added to the review, the overall picture with regard to interventions to improve recruitment to trials remains similar to the previous version of the review.
16 April 2010	Feedback has been incorporated	Feedback from Margo Michaels added with reply from authors.
10 November 2009	New search has been performed	New search conducted September 2007. Twelve new studies identified.
10 November 2009	New citation required but conclusions have not changed	The title of this review has changed, as have the authors.
27 December 2007	Amended	Converted to new review format.
20 February 2007	New citation required and conclusions have changed	Substantive amendment.

CONTRIBUTIONS OF AUTHORS

For this update, Shaun Treweek, Jonathan Cook, Heidi Gardner, Catherine Jackson, Elizabeth Mitchell, Marie Pitkethly and Frank Sullivan contributed to study design, record screening, full-text review of retrieved records and drafting of the report. Shaun Treweek, Marie Pitkethly and Heidi Gardner extracted the data. Jonathan Cook and Shaun Treweek analysed them. Cynthia Fraser developed and ran the electronic searches. Tyna Taskila contributed to the final report. All authors approved the final version of the review.

DECLARATIONS OF INTEREST

Shaun Treweek and Frank Sullivan are coauthors of Treweek 2012; they were not involved in data extraction or risk of bias assessment for this study for this review. Although Shaun Treweek was not involved in Cockayne 2017, he was involved in the wider START study in which Cockayne 2017 was nested; he was not involved in data extraction or risk of bias assessment for this study for this review. Shaun Treweek was a reviewer for Jennings 2015a; Jennings 2015b; Jennings 2015c; Jennings 2015d; Jennings 2015e (all included in a single article). Shaun Treweek and Frank Sullivan declare no further conflict of interest.

Marie Pitkethly: none known.

Jonathan Cook: none known.

Cynthia Fraser: none known.

Elizabeth Mitchell: none known.

Catherine Jackson: none known.

Tyna Taskila: none known.

Heidi Gardner: none known.

SOURCES OF SUPPORT

Internal sources

- Scottish Funding Council, UK.
- Rigshospitalet, Denmark.

External sources

- Department of Health, Cochrane Review Incentive Scheme 2008, UK.
- Department of Health, Cochrane Review Incentive Scheme 2011, UK.
- Medical Research Council, UK.

Jonathan Cook holds a Medical Research Council UK personal fellowship (G0601938).

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Below we describe the key differences between the protocol used in our previous review and this version. An updated version of the protocol is available describesing the methods used in this version of the review (Appendix 2).

Although we did not exclude studies at high of risk of bias, the low confidence we have in the data they present means that we no longer mention these studies in the text of the Results or Discussion, except where it was possible to include them in a meta-analysis.

Studies at high risk of bias do appear in Data and analyses, but we recommend readers use these data only to make decisions as to whether they would like to evaluate the intervention themselves in a more rigorous way. We do not believe these studies can support judgements about the effects of the tested interventions.

We include data for hypothetical studies in Data and analyses for this version of the review, but we will exclude them from future versions of this review, because:

1. the relevance of the results of hypothetical trials will always be in doubt due to uncertainty as to how people would have reacted had the decision to take part in a trial been a real one, not a hypothetical one;
2. it is possible to study recruitment interventions in real trials, avoiding the above problem;
3. now that the number of evaluations in real trials has increased, we do not think the trade-off between value added and work involved to include hypothetical trials is worthwhile.

INDEX TERMS

Medical Subject Headings (MeSH)

*Patient Selection; *Randomized Controlled Trials as Topic; *Reminder Systems; Patient Education as Topic; Sample Size; Telephone

MeSH check words

Humans