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Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L, Wu JHC

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[Intervention Review]

Decision aids for people facing health treatment or screening decisions

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ABSTRACT

Background

Decision aids are intended to help people participate in decisions that involve weighing the benefits and harms of treatment options often with scientific uncertainty.

Objectives

To assess the effects of decision aids for people facing treatment or screening decisions.

Search methods

For this update, we searched from 2009 to June 2012 in MEDLINE; CENTRAL; EMBASE; PsycINFO; and grey literature. Cumulatively, we have searched each database since its start date including CINAHL (to September 2008).

Selection criteria

We included published randomized controlled trials of decision aids, which are interventions designed to support patients' decision making by making explicit the decision, providing information about treatment or screening options and their associated outcomes, compared to usual care and/or alternative interventions. We excluded studies of participants making hypothetical decisions.

Data collection and analysis

Two review authors independently screened citations for inclusion, extracted data, and assessed risk of bias. The primary outcomes, based on the International Patient Decision Aid Standards (IPDAS), were:

- A) 'choice made' attributes;
- B) 'decision-making process' attributes.

Secondary outcomes were behavioral, health, and health-system effects. We pooled results using mean differences (MD) and relative risks (RR), applying a random-effects model.

Main results

This update includes 33 new studies for a total of 115 studies involving 34,444 participants. For risk of bias, selective outcome reporting and blinding of participants and personnel were mostly rated as unclear due to inadequate reporting. Based on 7 items, 8 of 115 studies had high risk of bias for 1 or 2 items each.

Of 115 included studies, 88 (76.5%) used at least one of the IPDAS effectiveness criteria: A) 'choice made' attributes criteria: knowledge scores (76 studies); accurate risk perceptions (25 studies); and informed value-based choice (20 studies); and B) 'decision-making process' attributes criteria: feeling informed (34 studies) and feeling clear about values (29 studies).

A) Criteria involving 'choice made' attributes:

Compared to usual care, decision aids increased knowledge (MD 13.34 out of 100; 95% confidence interval (CI) 11.17 to 15.51; n = 42). When more detailed decision aids were compared to simple decision aids, the relative improvement in knowledge was significant (MD 5.52 out of 100; 95% CI 3.90 to 7.15; n = 19). Exposure to a decision aid with expressed probabilities resulted in a higher proportion of people with accurate risk perceptions (RR 1.82; 95% CI 1.52 to 2.16; n = 19). Exposure to a decision aid with explicit values clarification resulted in a higher proportion of patients choosing an option congruent with their values (RR 1.51; 95% CI 1.17 to 1.96; n = 13).

B) Criteria involving 'decision-making process' attributes:

Decision aids compared to usual care interventions resulted in:

- a) lower decisional conflict related to feeling uninformed (MD -7.26 of 100; 95% CI -9.73 to -4.78; n = 22) and feeling unclear about personal values (MD -6.09; 95% CI -8.50 to -3.67; n = 18);
- b) reduced proportions of people who were passive in decision making (RR 0.66; 95% CI 0.53 to 0.81; n = 14); and
- c) reduced proportions of people who remained undecided post-intervention (RR 0.59; 95% CI 0.47 to 0.72; n = 18).

Decision aids appeared to have a positive effect on patient-practitioner communication in all nine studies that measured this outcome. For satisfaction with the decision (n = 20), decision-making process (n = 17), and/or preparation for decision making (n = 3), those exposed to a decision aid were either more satisfied, or there was no difference between the decision aid versus comparison interventions. No studies evaluated decision-making process attributes for helping patients to recognize that a decision needs to be made, or understanding that values affect the choice.

C) Secondary outcomes

Exposure to decision aids compared to usual care reduced the number of people of choosing major elective invasive surgery in favour of more conservative options (RR 0.79; 95% CI 0.68 to 0.93; n = 15). Exposure to decision aids compared to usual care reduced the number of people choosing to have prostate-specific antigen screening (RR 0.87; 95% CI 0.77 to 0.98; n = 9). When detailed compared to simple decision aids were used, fewer people chose menopausal hormone therapy (RR 0.73; 95% CI 0.55 to 0.98; n = 3). For other decisions, the effect on choices was variable.

The effect of decision aids on length of consultation varied from 8 minutes shorter to 23 minutes longer (median 2.55 minutes longer) with 2 studies indicating statistically-significantly longer, 1 study shorter, and 6 studies reporting no difference in consultation length. Groups of patients receiving decision aids do not appear to differ from comparison groups in terms of anxiety (n = 30), general health outcomes (n = 11), and condition-specific health outcomes (n = 11). The effects of decision aids on other outcomes (adherence to the decision, costs/resource use) were inconclusive.

Authors' conclusions

There is high-quality evidence that decision aids compared to usual care improve people's knowledge regarding options, and reduce their decisional conflict related to feeling uninformed and unclear about their personal values. There is moderate-quality evidence that decision aids compared to usual care stimulate people to take a more active role in decision making, and improve accurate risk perceptions when probabilities are included in decision aids, compared to not being included. There is low-quality evidence that decision aids improve congruence between the chosen option and the patient's values.

New for this updated review is further evidence indicating more informed, values-based choices, and improved patient-practitioner communication. There is a variable effect of decision aids on length of consultation. Consistent with findings from the previous review, decision aids have a variable effect on choices. They reduce the number of people choosing discretionary surgery and have no apparent adverse effects on health outcomes or satisfaction. The effects on adherence with the chosen option, cost-effectiveness, use with lower literacy populations, and level of detail needed in decision aids need further evaluation. Little is known about the degree of detail that decision aids need in order to have a positive effect on attributes of the choice made, or the decision-making process.

PLAIN LANGUAGE SUMMARY

Decision aids to help people who are facing health treatment or screening decisions

Identifying and making a decision about the best health treatment or screening option can be difficult for patients. Decision aids can be used when there is more than one reasonable option, when no option has a clear advantage in terms of health outcomes, and when each option has benefits and harms that patients may value differently. Decision aids may be pamphlets, videos, or web-based tools. They make the decision explicit, describe the options available, and help people to understand these options as well as their possible benefits and harms. This helps patients to consider the options from a personal view (e.g., how important the possible benefits and harms are to them) and helps them to participate with their health practitioner in making a decision.

The updated review, with searches updated in June 2012, includes 115 studies involving 34,444 participants. Findings show that when patients use decision aids they: a) improve their knowledge of the options (high-quality evidence); b) feel more informed and more clear about what matters most to them (high-quality evidence); c) have more accurate expectations of possible benefits and harms of their options (moderate-quality evidence); and d) participate more in decision making (moderate-quality evidence). Patients who used decision aids that included an exercise to help them clarify what matters most to them, were more likely to reach decisions that were consistent with their values. However, the quality of the evidence was moderate for this outcome, meaning that further research may change these findings. Decision aids reduce the number of patients choosing prostate specific antigen testing and elective surgery when patients consider other options. They have a variable effect on most other actual choices. Decision aids improve communication between patients and their health practitioner. More detailed decision aids are better than simple decision aids for improving people's knowledge and lowering decisional conflict related to feeling uninformed and unclear about their personal values. Decision aids do not worsen health outcomes and people using them are not less satisfied. More research is needed to evaluate adherence with the chosen option, the associated costs, use with patients who have more limited reading skills, and the level of detail needed in a decision aid.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Patient decision aids compared with usual care for adults considering treatment or screening decisions						
Patient or population: adults considering treatment or screening decisions Settings: all settings Intervention: patient decision aid Comparison: usual care						
Outcomes	Illustrative comparative benefits* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed benefit	Corresponding benefit				
	Usual care	Patient decision aid				
Knowledge: decision aid versus usual care - all studies standardized on score from 0 (no knowledge) to 100 (perfect knowledge) [soon after exposure to the decision aid]	The mean knowledge score was 56.9% ranged across control groups from 31% to 85.2%	The mean knowledge score in the intervention groups was 13.34 higher (11.17 to 15.51 higher)		10,842 (42 studies)	⊕⊕⊕⊕ high ¹	Higher scores indicate better knowledge. 41 out of 42 studies showed an improvement in knowledge
Accurate risk perceptions - all studies [soon after exposure to the decision aid]	296 patients per 1000	542 patients per 1000	RR 1.82 (95% CI: 1.52 to 2.16)	5868 (19 studies)	⊕⊕⊕○ moderate ^{1,2}	
Congruence between the chosen option and their values - all studies [soon after exposure to the decision aid]	316 patients per 1000	498 patients per 1000	RR 1.51 (95% CI: 1.17 to 1.97)	4670 (13 studies)	⊕⊕○○ low ^{1,2,3,4}	

<p>Decisional conflict: decision aid versus usual care - all studies - Uninformed sub-scale [soon after exposure to the decision aid]</p>	<p>The mean feeling uninformed ranged across control groups from 12.75 to 49.1. Scores of 25 or lower are associated with follow-through with decisions; whereas scores that exceed 38 are associated with delay in decision making</p>	<p>The mean feeling uninformed in the intervention groups was 7.26 lower (9.73 to 4.78 lower)</p>		<p>4343 (22 studies)</p>	<p>⊕⊕⊕⊕ high¹</p>	<p>Lower scores indicate feeling more informed.</p>
<p>Decisional conflict: decision aid versus usual care - all studies - Unclear values sub-scale [soon after exposure to the decision aid]</p>	<p>The mean feeling unclear values ranged across control groups from 15.5 to 51.29. Scores of 25 or lower are associated with follow-through with decisions; whereas scores that exceed 38 are associated with delay in decision making</p>	<p>The mean feeling unclear values in the intervention groups was 6.09 lower (8.50 to 3.67 lower)</p>		<p>3704 (18 studies)</p>	<p>⊕⊕⊕⊕ high¹</p>	<p>Lower scores indicate feeling more clear about values</p>
<p>Participation in decision making: decision aid versus usual care - all studies - Practitioner controlled decision making [soon after consultation with practitioner]</p>	<p>174 patients per 1000</p>	<p>103 patients per 1000</p>	<p>RR 0.66 (95%CI: 0.53 to 0.81)</p>	<p>3234 (14 studies)</p>	<p>⊕⊕⊕○ moderate^{1,3}</p>	<p>Patient decision aids aim to increase patient involvement in making decisions. Lower proportion of practitioner controlled decision making is better</p>

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group 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.

1. The vast majority of studies measuring this outcome were not at high risk of bias.
2. The GRADE rating was downgraded given the lack of precision.
3. The GRADE rating was downgraded given the lack of consistency.
4. The GRADE rating was downgraded given the lack of directness.

BACKGROUND

Many health treatment and screening decisions have no single 'best' choice. These types of decisions are considered 'preference-sensitive' because there is insufficient evidence about outcomes or there is a need to trade off known benefits and harms. *Clinical Evidence* classified 3000 treatments as: 50% having insufficient evidence, 24% likely to be beneficial, 7% requiring 'trade-offs between benefits and harms', 5% unlikely to be beneficial, 3% likely to be ineffective or harmful, and only 11% being clearly beneficial ([Clinical Evidence 2013](#)). Not only does one have to take into account the strength of the evidence, but even for 11% that show beneficial effects for populations, translating the probabilistic nature of the evidence for patients is necessary to reach an informed value-based decision. Patient decision aids are an intervention that can be used to present evidence ([Brouwers 2010](#)).

According to the International Patient Decision Aids Standards (IPDAS) Collaboration ([Elwyn 2006](#); [IPDAS 2005a](#); [Joseph-Williams 2013](#)), decision aids are evidence-based tools designed to help patients to participate in making specific and deliberated choices among healthcare options. Patient decision aids supplement (rather than replace) clinicians' counselling about options. The specific aims of decision aids and the type of decision support they provide may vary slightly, but in general they:

1. Explicitly state the decision that needs to be considered;
2. Provide evidence-based information about a health condition, the options, associated benefits, harms, probabilities, and scientific uncertainties;
3. Help patients to recognize the values-sensitive nature of the decision and to clarify, either implicitly or explicitly, the value they place on the benefits, harms, and scientific uncertainties. (To accomplish this, patient decision aids may describe the options in enough detail that clients can imagine what it is like to experience the physical, emotional, and social effects and/or guide clients to consider which benefits and harms are most important to them).

Decision aids differ from usual health education materials because decision aids make explicit the decision being considered, and provide detailed, specific, and personalized focus on options and outcomes for the purpose of preparing people for decision making. In contrast, health education materials help people to understand their diagnosis, treatment, and management in general terms, but given their broader perspective these materials do not necessarily help them to participate in decision making. Many decision aids are based on a conceptual model or theoretical framework ([Durand 2008](#); [Mulley 1995](#); [O'Connor 1998b](#); [Rothert 1987](#)).

Decision aids can be used before, during, or after a clinical encounter to enable patients to become active, informed participants. Decision aids can also facilitate shared decision making. Shared decision making is defined as a process by which a healthcare choice

is made by practitioners together with the patient ([Charles 1997](#); [Makoul 2006](#)) and is said to be the crux of patient-centred care ([Weston 2001](#)). However, the way information is provided by the practitioner may strongly affect how patients construct preferences ([Hibbard 1997](#)); thereby suggesting the need for standardized information such as patient decision aids. Patients who are more active in making decisions about their health have better health outcomes and healthcare experiences ([Hibbard 2013](#); [Kiesler 2006](#)).

Decision aids have been developed primarily in Australia, Europe, North America, and the United Kingdom. Since 1999, there has been a rapid proliferation of patient decision aids. For example, decision aids from large-scale producers were accessed over 8 million times in 2006 ([O'Connor 2007](#)). In response to concerns about variability in the quality of patient decision aids, the IPDAS Collaboration reached agreement on criteria for judging their quality ([Elwyn 2006](#)). More than 100 researchers, practitioners, patients, and policy makers from 14 countries participated. Participants addressed three domains of quality: clinical content, development process, and evaluation of a patient decision aid's effectiveness. Subsequently, an international team of researchers reached consensus on a shorter set of qualifying and certifying criteria ([Joseph-Williams 2013](#)). The background papers informing the original IPDAS criteria were updated in 2012 ([IPDAS 2013](#)).

The ultimate goal of patient decision aids is to improve decision making in order to reach a high-quality decision. Over the past decade, there has been considerable debate about the definition of a 'good decision', when there is no single 'best' therapeutic action and choices depend on how patients value benefits versus harms ([Briss 2004](#); [O'Connor 2003a](#); [O'Connor 1997b](#); [Sepucha 2004](#)). IPDAS reached agreement on criteria for judging "the things that you would need to observe in order to say that after using a patient decision aid, the way the decision was made was good and that the choice that was made was good" ([Elwyn 2006](#); [IPDAS 2005b](#); [Sepucha 2013](#)). The criteria were as follows:

- choice made: the patient decision aid improves the match between the chosen option and the features that matter most to the informed patient;
- decision-making process: the patient decision aid helps patients to: recognize that a decision needs to be made; know the options and their features; understand that values affect the decision; be clear about the option-features that matter most; discuss values with their practitioner; and become involved in their preferred ways.

Several individual studies examining the efficacy of decision aids have been published. There are annotated bibliographies, reports, and general reviews of decision aids ([Bekker 1999](#); [Bekker 2003](#); [RTI 1997](#) [Estabrooks 2000](#); [Molenaar 2000](#); [O'Connor 1997a](#); [O'Connor 1999c](#); [RTI 1997](#); [Whelan 2002](#)). We published the first systematic review of 17 randomized trials of decision aids in

1999 (O'Connor 1999b; O'Connor 2001a), followed by updates in 2003 with a total of 35 studies (O'Connor 2003b), in 2009 with a total of 55 studies (O'Connor 2009) and in 2011 with a total of 86 studies (Stacey 2011). Findings from this review have been used to inform clinical practice guidelines such as Patient Experience in Adult NHS Services (NCGC/NICE 2012) and Decision Support for Adults Living with Chronic Kidney Disease (RNAO 2009).

Several systematic reviews focus on the use of patient decision aids as one type of intervention to facilitate shared decision making in clinical practice (Coyne 2013; Duncan 2010; Elwyn 2013; Legare 2010).

OBJECTIVES

To assess the effects of decision aids for people facing treatment or screening decisions.

METHODS

Criteria for considering studies for this review

Types of studies

We included all published studies using a randomized controlled trial (RCT) design comparing decision aids to no intervention, usual care, alternative interventions, or a combination.

Types of participants

We included studies involving people who were making decisions about screening or treatment options for themselves, for a child, or for an incapacitated significant other. We excluded studies in which participants were making hypothetical choices.

Types of interventions

We included studies that evaluated a patient decision aid as part of the intervention. Decision aids were defined as interventions designed to help people make specific and deliberative choices among options (including the status quo), by making the decision explicit and by providing (at the minimum) a) information on the options and outcomes relevant to a person's health status and b) implicit methods to clarify values. The aid also may have included: information on the disease/condition; costs associated with options; probabilities of outcomes tailored to personal health risk factors; an explicit values clarification exercise; information on others' opinions; a personalized recommendation on the basis of clinical characteristics and expressed preferences; and guidance

or coaching in the steps of making and communicating decisions with others.

We excluded studies if interventions focused on: decisions about lifestyle changes, clinical trial entry, or general advance directives (e.g., do not resuscitate); education programs not geared to a specific decision; and interventions designed to promote adherence to or to elicit informed consent regarding a recommended option. We also excluded studies on decision aids that were not available to us, and so we could not determine that they provided the minimum criteria to qualify as a patient decision aid and their characteristics.

Types of outcome measures

To ascertain whether the decision aids achieved their objectives, we examined a broad range of positive or negative effects. Although the decision aids focused on diverse clinical decisions, many had similar objectives such as improving knowledge, accurate risk perceptions and participation in decision making. Many of these evaluation criteria mapped onto the International Patient Decision Aids Standards (IPDAS) criteria for evaluating the effectiveness of decision aids (Elwyn 2006; IPDAS 2005b; Sepucha 2013). A total list of outcomes, specified in advance of the review, included:

Primary outcomes

Evaluation criteria that map onto the IPDAS criteria

- Attributes of the choice made: Does the patient decision aid improve the match between the chosen option and the features that matter most to the informed patient (demonstrated by outcomes such as knowledge, accurate risk perceptions, and chosen option congruent with their values)?
- Attributes of the decision-making process: Does the patient decision aid help patients to: recognize that a decision needs to be made; know the options and their features; understand that values affect the decision; be clear about the option features that matter most; discuss values with their practitioner; and become involved in preferred ways?

Other decision-making process variables

- Decisional conflict
- Patient-practitioner communication
- Participation in decision making
- Proportion undecided
- Satisfaction

Secondary outcomes

Behaviour

- Choice (actual choice implemented; if not reported, the preferred option was used as a surrogate measure)
- Adherence to chosen option

Health outcomes

- Health status and quality of life (generic and condition-specific)
- Anxiety, depression, emotional distress, regret, confidence

Healthcare system

- Costs, cost effectiveness
- Consultation length
- Litigation rates

Search methods for identification of studies

Our search strategy for the review included:

1. searching electronic medical and social science databases; and
2. searching trial registries (World Health Organization, National Institutes of Health, Clinicaltrial.gov), the Internet, reference lists of included trials, and the Decision Aid Library Inventory (<http://decisionaid.ohri.ca>).

For this update, the search strategy (January 2009 to June 2012) was revised with the Trials Search Coordinator at the Cochrane Consumers and Communication Review Group. To validate the new search strategy, we conducted duplicate searches for 2009 and 2010 using the old and the new search strategies.

Therefore, the cumulative search of electronic databases is as follows:

- MEDLINE (Ovid) (1966 to June 2012);
- Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library; Issue 6 of 12, June 2012);
- EMBASE (Ovid) (1980 to June 2012);
- PsycINFO (Ovid) (1806 to June 2012); and
- CINAHL (Ovid) (1982 to September 2008 (then in Ebsco when no longer indexed by Ovid; 2009 to June 2012)).

We present the search strategies in [Appendix 1](#) and [Appendix 2](#).

Data collection and analysis

In the 2009 Cochrane review (O'Connor 2009), the update used the International Patient Decision Aid Standards (IPDAS) criteria; this was a different strategy from that used in the earlier reviews (O'Connor 2001b; O'Connor 2003a). For the 2013 update reported here, we continued to use the IPDAS criteria and we focused only on new publications that had appeared since the previous publication (Stacey 2011).

Two review authors (CB, DS, RT, MB, MHR, NC, KE, BV, DR) screened all reports of randomized controlled trials (RCTs). Two of four research assistants extracted data independently and appraised studies using the Cochrane tool for judging risk of bias (SB, CC, RW, JW) (Higgins 2011, Chapter 8). No review author screened or extracted data from any of his or her own studies in this update or in any other versions of this review. We resolved inconsistencies by discussion with the principal investigator (DS).

First, we described study characteristics individually. According to the original protocol, the planned comparisons between groups were: a) usual care versus decision aids; and b) simple versus detailed decision aids. For studies in which there was more than one intervention group and one control group, we extracted data from the two groups that used a patient decision aid and provided the strongest contrast. For example, the group that used the most detailed decision aid was compared with the group who used the least detailed decision aid (detailed versus simple) or received usual care (decision aid versus control).

We pooled results across studies in cases where: a) similar outcome measures were used; and b) the effects were expected to be independent of the type of decision studied. For example, decision aids were expected to improve knowledge of options, benefits, and harms; to create accurate perceptions of benefits/harms; to reduce decisional conflict; and to enhance active participation in decision making. Therefore, we pooled data from the RCTs for these outcomes, if comparable measures were used. To facilitate pooling of data for some outcomes (e.g., knowledge, decisional conflict), the scores were standardized to range from 0 to 100 points. When analysing the effects of decision aids on choices, we pooled outcomes on more homogenous subgroups of decisions (choice of major surgery versus conservative options; testing or not; menopausal hormone therapy or not; etc.). In addition, we analyzed studies comparing usual care to decision aids separately from studies comparing simple to more detailed decision aids. For this update, we conducted a subgroup analysis of studies comparing decision aids for treatment decisions to usual care separately from studies comparing decision aids for screening decisions to usual care.

We used Review Manager 5.2.6 software (RevMan 2013) to estimate a weighted treatment effect (with 95% confidence intervals). For continuous measures, we used mean differences (MD); for dichotomous outcomes, we calculated pooled relative risks (RR). We analyzed all data with a random-effects model because of the diverse nature of the studies being combined. New for this update,

we summarized all of the findings for the primary outcomes and rated the strength of evidence using GRADE (Andrews 2013), presenting these in a 'Summary of findings' table (Higgins 2011). Funnel plots were used to assess publication bias.

We performed post-hoc sensitivity analyses to examine the effect of excluding trials of lower methodological quality. The first analysis excluded trials that had 'high' risk of bias for any of the seven categories in the 'Risk of bias' assessment (Higgins 2011). The second sensitivity analysis excluded trials that had been rated as 'high' or 'unclear' in three or more of the seven categories.

In the 2009 update, the post-hoc analysis included the IPDAS effectiveness criteria to explore heterogeneity according to the following factors: the type of decision (treatment versus screening), the type of media of the decision aid (video/computer versus audio booklet/pamphlet), and the possibility of a ceiling effect based on usual-care scores (resulting in the removal of studies with lower knowledge and accurate perception scores, and the removal of studies with higher decisional conflict scores for the sub-scales measuring feeling uninformed and unclear values). We analyzed the effect of removing the biggest outlier(s) (defined by visual inspection of forest plots). Given that the post-hoc analysis did not alter the findings in the 2009 update (O'Connor 2009), the post-hoc analysis for the IPDAS effectiveness criteria was not re-conducted.

RESULTS

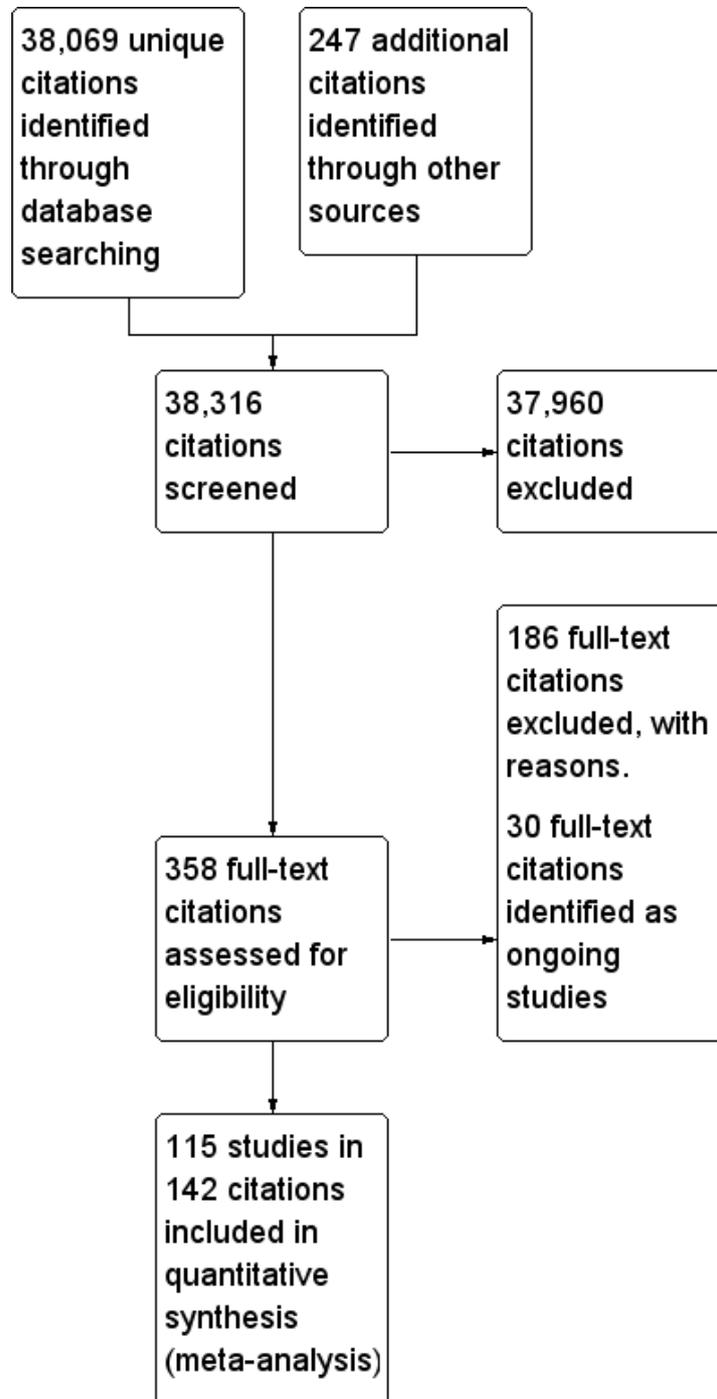
Description of studies

The current version of our review updates our 2011 version (Stacey 2011, which included 86 studies) with 33 new studies: Allen 2010; Arterburn 2011; Berry 2013; Bjorklund 2012; Chambers 2012; de Achaval 2012; Evans 2010; Fagerlin 2011; Hanson 2011; Hess 2012; Jibaja-Weiss 2011; Labrecque 2010; Langston 2010; Legare 2011; Leigh 2011; Lewis 2010; Mann D 2010; Mann E 2010; Marteau 2010; Mathieu 2010; McCaffery 2010; Miller 2011; Montori 2011; Myers 2011; Raynes-Greenow 2010; Rubel 2010; Schroy 2011; Schwalm 2012; Sheridan 2011; Smith 2010; Solberg 2010; Steckelberg 2011; van Peperstraten 2010. We re-assessed four previously-included studies as 'excluded' due to quasi-experimental design (Dunn 1998; Herrera 1983; Phillips 1995) or the same intervention in both arms but delivered using different formats (Frosch 2003).

Results of the search

In total, we identified 38,069 unique citations from the electronic database searches and 247 citations from other sources. Of these, only 2072 citations focused on people's decision making (see Figure 1).

Figure 1. Study flow diagram.



Of the 2072 citations identified, 358 appeared to be evaluations of patient decision aids. We excluded 186 of these upon close perusal of the paper (see [Characteristics of excluded studies](#)). The reasons for exclusion were: a) the study was not a randomized controlled trial; b) the decision was hypothetical, with participants not actually at a point of decision making; c) the intervention was not focused on making a choice; d) the intervention offered no decision support in the form of a decision aid or did not provide enough information about the decision aid; e) no comparison outcome data were provided; f) the study did not evaluate the decision aid; g) the study was a protocol; h) the decision aid was about clinical trial entry, lifestyle choice, or advanced care planning; or i) the study involved testing the presentation of decision aid, but with no difference in the content of the decision aid between study groups.

We also identified 30 ongoing RCTs through trial registration databases, personal contact, and published protocols in the electronic database searches (see references to [Ongoing studies](#) and table [Characteristics of ongoing studies](#)).

Using the old and new search strategies for 2009 and 2010, there was no difference in the included articles identified despite that the newer search strategy yielded fewer citations.

Included studies

The remaining 142 citations provided data on 115 studies that met our inclusion criteria, 33 of which are new for this update. The 115 RCTs, involving 34,444 participants, presented results from 9 countries (Australia (n = 15), Canada (n = 21), China (n = 1), Finland (n = 2), Germany (n = 5), Netherlands (n = 2), Sweden (n = 1), the United Kingdom (n = 14), the United States (n = 53), and Australia plus Canada (n = 1)). Study details are presented below and in the table [Characteristics of included studies](#).

Unit of randomization

One hundred studies randomized individual patients and 15 randomized clusters. [Allen 2010](#) randomized 12 company work sites; [Goel 2001](#) randomized 57 surgeons; [Hamann 2006](#) randomized 12 inpatient psychiatric units; [Legare 2003](#) randomized 40 family physicians; [Legare 2011](#) randomized 4 family medicine group practices; [Lewis 2010](#) randomized 32 family medicine group practices; [Loh 2007](#) randomized 30 general practitioners; [McAlister 2005](#) randomized 102 primary care practices; [Mullan 2009](#) randomized 40 clinicians; [Nagle 2008](#) randomized 60 general practitioners; [Solberg 2010](#) randomized 8 gynaecologist group practices; family-wise randomization was used for [Wakefield 2008](#), [Wakefield 2008a](#), and [Wakefield 2008b](#); and [Whelan 2004](#) randomized 27 surgeons. For 11 studies ([Allen 2010](#); [Goel 2001](#); [Legare 2011](#); [Loh 2007](#); [Mullan 2009](#); [Nagle 2008](#); [Solberg 2010](#);

[Wakefield 2008](#); [Wakefield 2008a](#); [Wakefield 2008b](#); [Whelan 2004](#)), the cluster effect was taken into account in the published outcome data and the meta-analysis used published results. Although [Hamann 2006](#) did not account for the cluster effect in the published outcome data, the way this study was reported did not allow us to include it in the meta-analysis, and, as such, we did not re-analyze the data and the study is reported separately. For [McAlister 2005](#), meta-analysis was done applying the design effect (based on the published intra-cluster correlation coefficient (ICC)). For [Legare 2003](#), the authors stated that for the Decisional Conflict Scale's results, "clustering had no impact on individual scores of women and, therefore, we present the results without adjustment". The analysis in [Lewis 2010](#) did not account for clustering.

Decision aids and comparisons

The 115 included studies evaluating decision aids focused on 46 different decisions ([Table 1](#)). The most common decisions were about prostate cancer screening (n = 15), colon cancer screening (n = 10), menopausal hormone therapy for menopausal women (n = 10), breast cancer genetic testing (n = 7), prenatal screening (n = 6), medication for atrial fibrillation (n = 3), and surgery (mastectomy breast cancer (n = 5), hysterectomy (n = 4), prostatectomy (n = 4)). New decisions included contraception (n = 2), medications for acute respiratory infection (n = 1), bariatric surgery (n = 1), long-term feeding tube placement (n = 1), labour analgesia (n = 1), embryo transplant (n = 1), influenza immunization (n = 1), access site for coronary angiography (n = 1), screening for diabetes (n = 2) or cervical cancer (n = 1), and stress test for chest pain (n = 1).

The decision aids used a variety of formats and were compared to a variety of control interventions (e.g., usual care, no intervention, guideline, placebo intervention). We noted the nature of usual care when reported (see table [Characteristics of included studies](#)). For this review, we have grouped control interventions and refer to them as usual care unless the intervention meets the definition of a patient decision aid.

According to the definition of a patient decision aid, all of the studies evaluated patient decision aids that included information about the options and outcomes, and provided at least implicit values clarification. Most patient decision aids included information on the clinical problem (91.3%) as well as outcome probabilities (87.8%). Fewer patient decision aids provided guidance in the steps of decision making (62.6%), explicit methods to clarify values (59.1%), and/or examples of others' experiences (50.4%) (see table [Characteristics of included studies](#)).

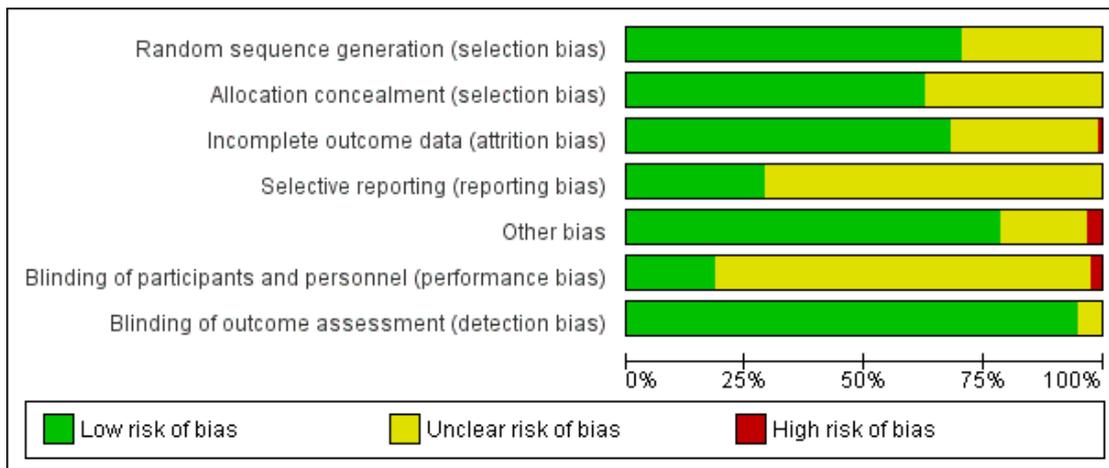
The comparison interventions ranged from no intervention through to usual care, and general information through to simple decision aids that varied in their number of elements. However, a simple decision aid had to meet the minimum definition of a

decision aid (see table [Characteristics of included studies](#)).

Risk of bias in included studies

Details on the ratings and rationale for risk of bias are in the [Characteristics of included studies](#) table and displayed in [Figure 2](#) and [Figure 3](#). The risk of bias was summarized in [Table 2](#) based on the primary outcomes.

Figure 2. Risk of bias summary as percentages across all included studies.



Allocation

For assessing risk of selection bias, random sequence generation was rated as being at low risk of bias in 81 of 115 studies (70.4%) and unclear risk of bias in 34 studies (29.6%). Allocation concealment was rated as being at low risk of bias in 72 of 115 studies (62.6%) and unclear risk of bias in 43 studies (37.4%).

Blinding

Blinding of participants and personnel was rated as being at low risk of bias in 21 studies (18.3%), unclear risk of bias in 91 studies (79.1%), and high risk of bias in 3 studies (2.6%). High risk of bias was due to lack of blinding of physicians who were involved with patients randomized to both the patient decision aid and alternative interventions (Auvinen 2004; Krist 2007; Man-Son-Hing 1999).

Blinding of outcome assessment was low risk of bias in 109 studies (94.8%) and unclear risk of bias in 6 studies (5.2%).

Incomplete outcome data

Incomplete outcome data which could lead to attrition bias were adequately described in 78 studies (67.8%), inadequately described to judge risk of bias in 36 studies (31.3%), and for 1 study (0.9%) there was high risk of bias (Chambers 2012). In Chambers 2012, few participants in the intervention arm compared to usual care completed the study (65% versus 77%).

Selective reporting

Of 115 studies, 33 (28.7%) were rated as low risk of bias because the protocol was registered publicly and 82 (71.3%) were rated as being at unclear risk of bias for this domain.

Other potential sources of bias

Of 115 studies, 90 (78.3%) did not indicate any other potential sources of bias, 21 (18.3%) did not provide an adequate description to judge other potential sources of bias, and 4 (3.4%) discussed other potential risks of bias. Clancy 1988 describes a potential for selection bias, given that non-randomized medical residents were added to the decision analysis group and that there was a low response rate among those offered decision analysis. In a study focused on the decision about menopausal hormone therapy for menopausal women. Rostom 2002 reported that there was a potential for bias, given that there was an uneven balance of premenopausal women who were not appropriate for hormone therapy with more women in the detailed decision aid group. Hamann 2006 and Lewis 2010 did not account for clustering in the analysis.

Effects of interventions

See: [Summary of findings for the main comparison](#)

In addition to [Summary of findings for the main comparison](#), see the [Data and analyses](#) figures for pooled data and Additional tables 3 to 22 for outcome data that were not pooled.

A) Attributes of the choice made:

Does the patient decision aid improve the match between the chosen option and the features that matter most to the informed patient?

The randomized controlled trials (RCTs) used three measures that correspond to this definition: knowledge, accuracy of risk perceptions, and chosen option congruent with their values.

Knowledge

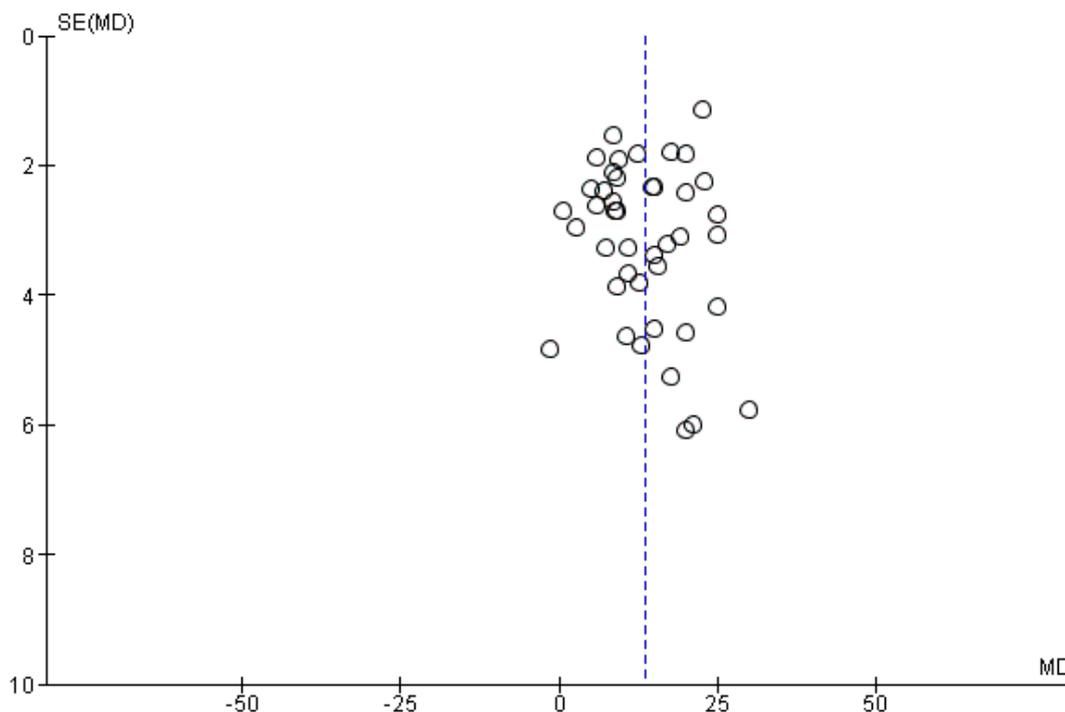
Seventy-six of the 115 studies (66.1%) assessed the effects of decision aids on knowledge; 56 of these compared decision aids to usual care (74%) and 20 compared detailed decision aids to simple decision aids (26%). The studies' knowledge tests were based on information contained in the decision aid. The proportion of accurate responses was transformed to a percentage scale ranging from 0% (no correct responses) to 100% (perfectly accurate responses).

For patient decision aids compared to usual care (n = 42): people exposed to decision aids had higher average knowledge scores (MD 13.34%; 95% CI 11.17 to 15.51; [Analysis 1.1](#)). Fourteen additional studies that compared decision aids to usual care presented knowledge data that could not be included in the pooled outcome (see [Table 3](#)). Six of these studies reported statistically-significantly higher knowledge for those exposed to the decision aid compared to usual care (Evans 2010; Hamann 2006; Nagle 2008; Partin 2004; Trevena 2008; Watson 2006).

One study (Weymiller 2007) reported a higher mean difference when the decision aid was administered during the consultation, but not if administered before the consultation. Mann D 2010 and Miller 2005 reported no difference between groups. Four other studies (Heller 2008; Legare 2008a; Mathieu 2007; Ozanne 2007) reported a change in knowledge from baseline: two found a statistically-significant improvement in the decision aid group (Heller 2008; Mathieu 2007); Ozanne 2007 reported a statistically-significant improvement in the decision aid group (P = 0.01) but not in the control group (P = 0.13); and Legare 2008a reported a statistically-significant improvement in both the decision aid group (P = 0.002) and the control group (P = 0.031) but no difference between groups. Rubel 2010 reported knowledge scores with no

comparisons. The funnel plot for knowledge as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 4).

Figure 4. Funnel plot of comparison: I Knowledge, outcome: I.I Knowledge: DA vs usual care - all studies.



For detailed compared to simple decision aids (n = 19): people exposed to detailed decision aids had higher average knowledge scores but this effect was smaller (MD 5.52%; 95% CI 3.90 to 7.15; Analysis 1.4). One additional study that compared a detailed to simple decision aid (Volk 2008) reported significant improvement in all groups from baseline but no significant differences between groups (see Table 3).

Accurate risk perceptions (i.e. perceived probabilities of outcomes)

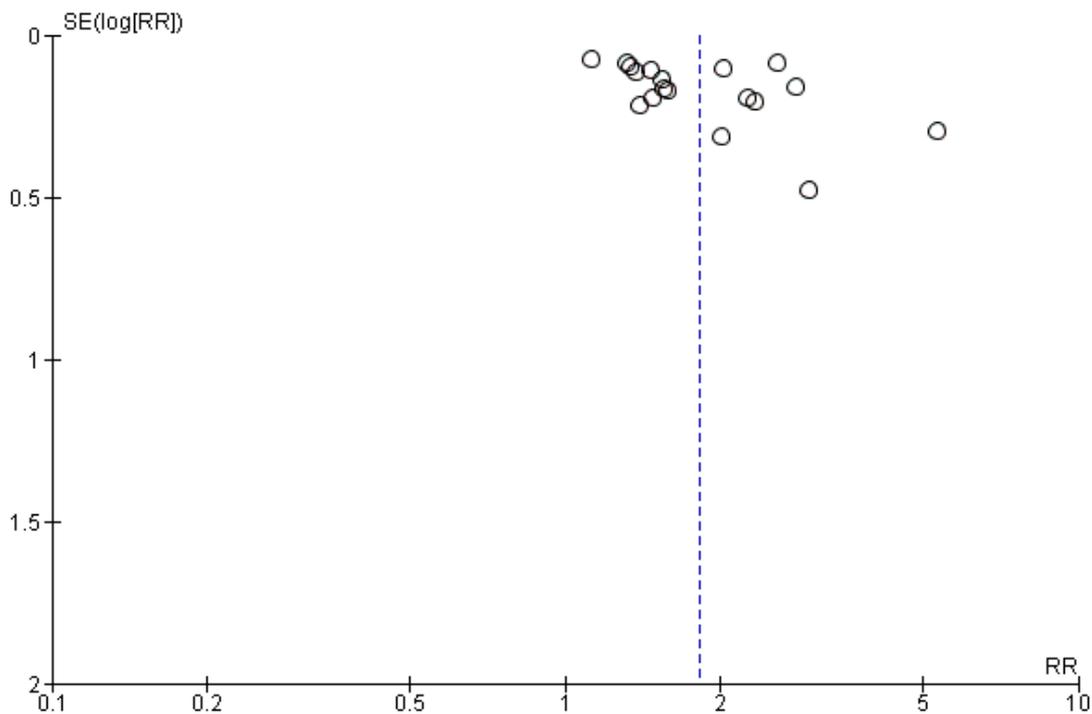
Of 115 studies, 25 (21.7%) examined the effects of including probabilities in decision aids on the accuracy of patients' perceived probabilities of outcomes (see Analysis 2.1; Table 4). Of these 25 studies, 15 measured perceived probabilities as percentages (see Analysis 2.4), 4 gauged probabilities in words (see Analysis 2.5), and 6 were not able to be pooled (Table 4). Perceived outcome probabilities were classified according to the percentage of indi-

viduals whose judgments corresponded to the scientific evidence about the chances of an outcome for similar people. For studies that elicited risk perceptions using multiple items, the proportion of accurate risk perceptions was averaged.

People who received a patient decision aid with descriptions of outcome probabilities were more likely to have accurate risk perceptions than those who did not receive this information; the pooled relative risk (RR) of having accurate risk perceptions was 1.82 (95% CI 1.52 to 2.16, n = 19; Analysis 2.1). The pooled RR for probabilities measured as numbers was 2.00 (95% CI 1.65 to 2.43, n = 15; Analysis 2.4) and the pooled RR for probabilities gauged in words was 1.31 (95% CI 1.13 to 1.52, n = 4; Analysis 2.5). Six studies reported results that could not be pooled (see Table 4). Hanson 2011; Mathieu 2010; and Smith 2010 reported a statistically-significant improvement in accurate perceptions of outcomes for the decision aid group compared to usual care, and

Miller 2005 reported no impact on risk perception. In another study, Weymiller 2007 reported a statistically-significant difference in the accurate perception of baseline risks in the group receiving a decision aid with probabilities compared to the usual care group, when the decision aid was administered during the consultation but not when it was administered before the consultation. The difference in accurate estimations of the potential absolute risk reduction with statin drugs was also statistically significant between the decision aid and usual care groups, and this difference remained significant regardless of the timing of delivery. Although three of eight knowledge test items measured accurate risk perceptions (Mann E 2010), results were presented for total knowledge and not individual items. The funnel plot for accurate risk perception as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 5).

Figure 5. Funnel plot of comparison: 2 Accurate risk perceptions: Decision aid with outcome probabilities vs no outcome probability information, outcome: 2.1 Accurate risk perceptions - all studies.



Chosen option congruent with values

Of 115 studies, 20 (17.4%) measured congruence between with the chosen option and their values; however, 7 did not present

quantitative data to permit pooling across studies (Arterburn 2011; Frosch 2008; Legare 2008a; Lerman 1997; Rothert 1997; Solberg 2010; Vandemheen 2009; see Table 5).

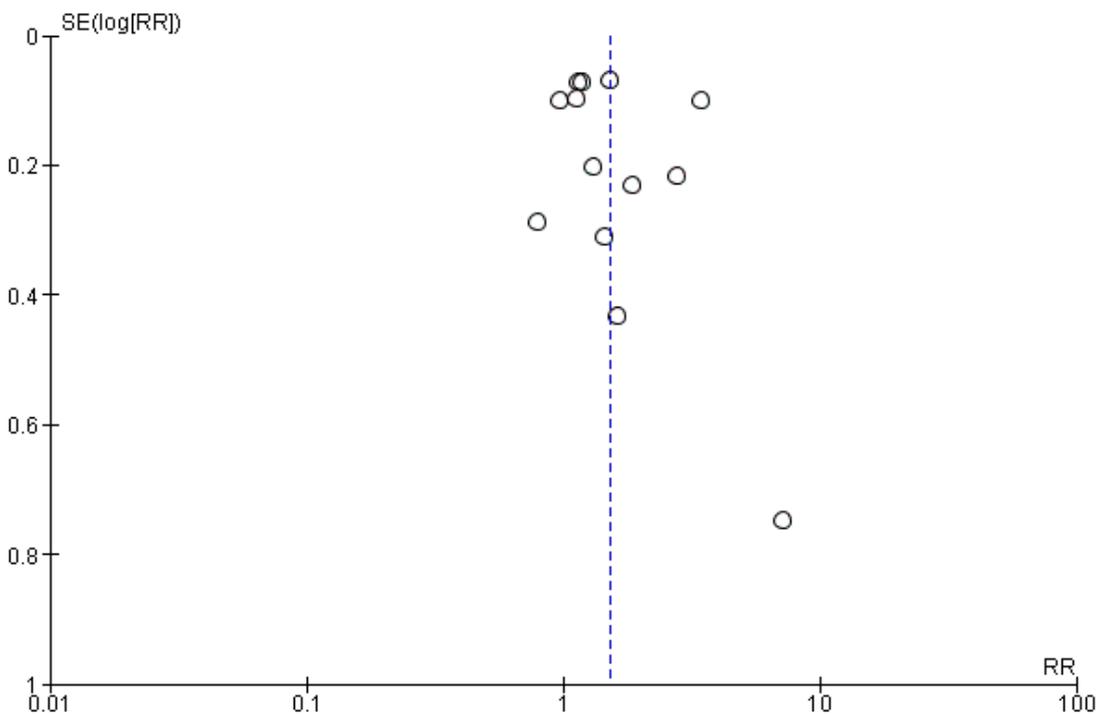
Nine of these studies used the Multi-Dimensional Measure of

Informed Choice (Bjorklund 2012; Mathieu 2007; Mathieu 2010; Nagle 2008; Smith 2010; Trevena 2008; Wakefield 2008; Wakefield 2008a; Wakefield 2008b), which assesses the extent to which the choice is based on relevant knowledge, is consistent with a person's values/attitudes, and is behaviorally implemented (Michie 2002). These studies operationalized the measure in terms of knowledge test scores higher than the mid-point, attitude scale scores higher than the mid-point, and choice being congruent with attitude.

People who received a patient decision aid with an explicit values clarification exercise were more likely to achieve a chosen option congruent with their values: the pooled RR was 1.51 (95% CI 1.17 to 1.96, n = 13; Analysis 3.1). A sub-analysis of studies using the Multi-Dimensional Measure of Informed Choice revealed a pooled RR of 1.35 (95% CI 1.12 to 1.61, n = 9). Of the seven studies that were not pooled, Arterburn 2011 reported that, compared to the control group, those exposed to the decision aid experienced a more rapid early improvement of value concordance

immediately after exposure. Legare 2008a reported that women's valuing of the non-chemical aspect of natural health products was positively associated with their choice of natural health products in managing menopausal symptoms (P = 0.006). Rotherth 1997 reported higher correlations between the expected value of hormones and the likelihood of taking hormones in women exposed to the detailed decision aid compared those exposed to the simple decision aid. No differences between groups were reported in the other studies (Frosch 2008; Lerman 1997; Solberg 2010; Vandemheen 2009; see Table 5). However, Frosch 2008 observed that men exposed to the decision aid who chose not to have a prostate-specific antigen (PSA) test rated their concern about prostate cancer lower than men who requested a PSA test, while men assigned to the usual care group provided similar ratings of concern regardless of their PSA choice. The funnel plot for congruence between the chosen option and their values as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 6).

Figure 6. Funnel plot of comparison: 3 Values congruent with chosen option, outcome: 3.1 Values congruent with chosen option - all studies.



B) Attributes of the decision process:

Does the patient decision aid help patients to: recognize that a decision needs to be made; know the options and their features; understand that values affect the decision; be clear about the option features that matter most; discuss values with their practitioner; and become involved in their preferred ways?

In relation to the International Patient Decision Aids Standards (IPDAS) decision process criteria, no studies evaluated the extent to which patient decision aids helped patients to recognize that a decision needs to be made or understand that values affect the decision.

Some studies measured patients' self-reports about feeling informed and clear about personal values. The measures used to evaluate these two criteria were two sub-scales of the previously validated Decisional Conflict Scale (DCS) (O'Connor 1995).

Decisional conflict

Of 115 studies, 58 (50.4%) evaluated overall decisional conflict using the DCS (O'Connor 1995). The DCS is reliable, discriminates between those who make or delay decisions, is sensitive to change, and discriminates between different decision support interventions (Morgan 2000; O'Connor 1995; O'Connor 1998a). The scale measures the constructs of overall decisional conflict and the particular factors contributing to uncertainty (e.g., feeling uncertain, uninformed, unclear about values, and unsupported in decision making). A final sub-scale measures perceived effective decision making. The scores were standardized to range from 0 (no decisional conflict) to 100 points (extreme decisional conflict). Scores of 25 or lower are associated with follow-through with decisions, whereas scores that exceed 38 are associated with delay in decision making (O'Connor 1998a). When decision aids are

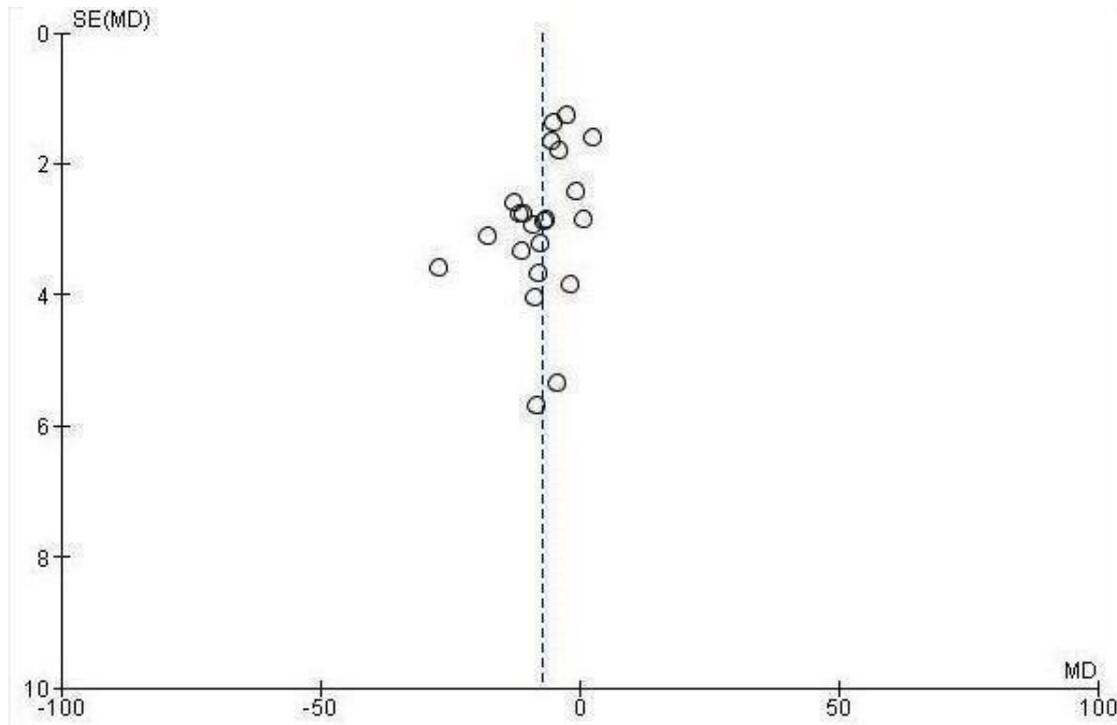
compared to usual care, a negative score indicates a reduction in decisional conflict, which is in favour of the decision aid.

Analysis 4.1.6 summarizes the decisional conflict results for the 28 studies that compared decision aids to usual care, and Analysis 4.4.6 summarizes the results for the 17 studies that compared detailed to simple decision aids. Fifteen studies that were not able to be pooled are reported in Table 6 and Table 7.

The overall MD was -6.22 out of 100 points for decision aid compared to usual care (95% CI -8.00 to -4.44; see Analysis 4.1.6) and -1.77 for detailed compared to simple decision aid (95% CI -2.64 to -0.91; see Analysis 4.4.6). Three studies that could not be pooled (Table 6) reported statistically-significantly less total decisional conflict (Arterburn 2011; Schwartz 2009; Weymiller 2007), three no difference (Krist 2007; Leighl 2011; Ozanne 2007), and one higher decisional conflict (Fagerlin 2011). Smith 2010 used the low literacy version and reported statistically-significant improvement in total decisional conflict in the decision aid group, compared to usual care (Table 7). Rubel 2010 did not report results by group.

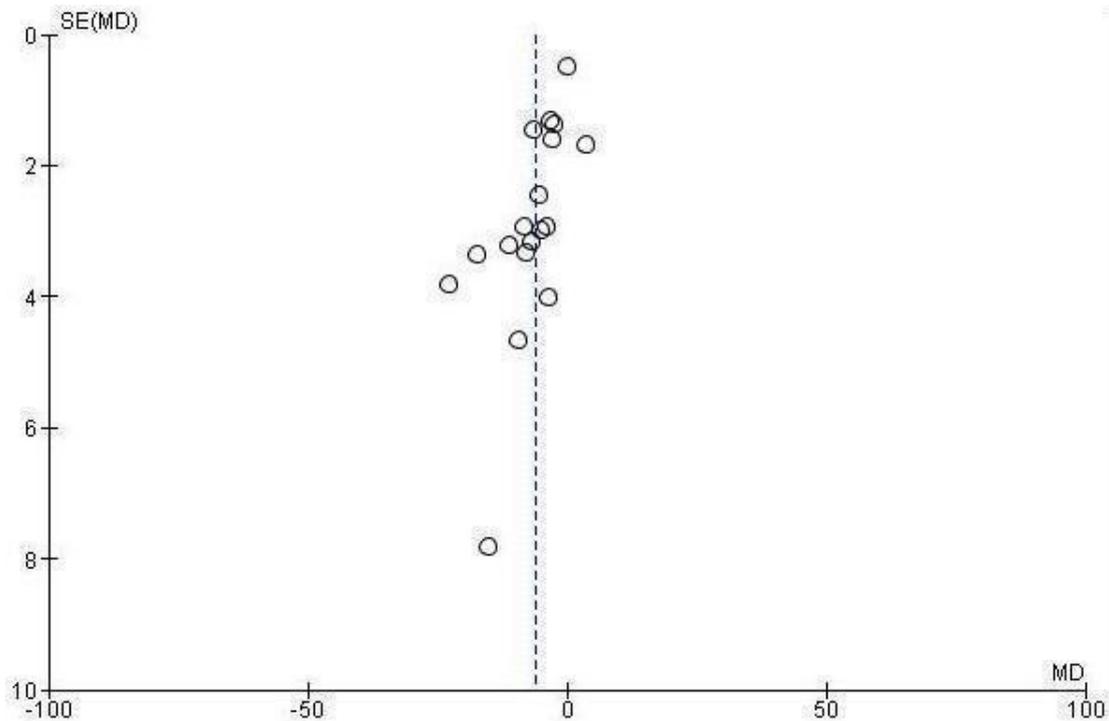
The 'feeling uninformed' sub-scale of the DCS was reported in 32 studies. Because this DCS sub-scale measures self-reported comfort with knowledge and not actual knowledge, we elected to consider it a process measure and to reserve the gold standard of objective knowledge tests for assessing decision quality. The MD for 'feeling uninformed' about options, benefits, and harms was -7.26 (95% CI -9.73 to -4.78) in the 22 studies that compared patient decision aids to usual care (see Analysis 4.1.2). The 10 studies that compared detailed with simple patient decision aids had a MD for 'feeling uninformed' of -2.39 (95% CI -4.39 to -0.39; Analysis 4.4.2). For the studies that could not be pooled (Table 6), compared to usual care, those exposed to the decision aid felt more informed in three studies (Frosch 2008; Mathieu 2010; Weymiller 2007) but were no different in one study (Berry 2013). The funnel plot for feeling uninformed as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 7).

Figure 7. Funnel plot of comparison: 4.1 Decisional conflict: DA vs usual care - all studies, outcome: 4.1.2 Uninformed sub-scale



The 'feeling unclear about values' sub-scale of the DCS was reported in 18 studies comparing patient decision aids to usual care (MD -6.09; 95% CI -8.50 to -3.67; see Analysis 4.1.3). In the 10 studies that compared detailed to simple decision aids, the MD for 'feeling unclear about values' was -2.31 (95% CI -4.67 to -0.05; see Analysis 4.4.3) Compared to usual care, those exposed to the decision aid in all three studies that could not be pooled (Table 6) felt more clear about their values (Berry 2013; Frosch 2008; Weymiller 2007). The funnel plot for feeling unclear about values as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 8).

Figure 8. Funnel plot of comparison: 4.1 Decisional conflict: DA vs usual care - all studies, outcome: 4.1.3 Unclear sub-scale



Volk 2008 compared detailed to simple decision aids and showed improvements in decisional conflict only in lower literacy subgroups of participants. For example, low literacy study participants used the low literacy version of the DCS and their results were reported separately from participants at the higher literacy site. The lower literacy study participants exposed to the more detailed education decision aid reported significantly lower levels of overall decisional conflict and higher levels of 'feeling clear about values', compared to the lower literacy study participants exposed to the simpler audio-booklet decision aid (see Table 7).

Patient-practitioner communication

Of 115 studies, 9 (7.8%) measured the effect of decision aids on patient-practitioner communication. Four studies (Hess 2012; Montori 2011; Mullan 2009; Weymiller 2007) compared the effect of a decision aid used within the clinical encounter (or, in one study, half the decision aid participants were exposed just prior to the encounter) to usual care, and evaluated the extent of shared decision making by analysing the audio-recordings using the OPTION scale. All four studies reported statistically-higher mean OPTION scores when patients were exposed to the decision aid, and this effect was greater when the decision aid was used within the clinical encounter (see Table 8).

Myers 2011 analyzed audio-recorded encounters using the Informed Decision Making observer instrument (Braddock III 1997; Braddock III 1999; Price 2012). Findings reported significantly higher scores in the detailed decision aid group compared to simple decision aid ($P = 0.029$).

For agreement between physicians and women on decisional conflict scores as an indicator of communication about the decision within the consultation, Legare 2003 reported higher agreement for the decision aid group than for the usual care group, but Legare 2011 reported no statistically-significant difference between groups (see Table 8).

Sheridan 2006 and Hanson 2011 found that, of those exposed to the decision aid, a higher proportion compared to usual care reported having discussed the decision with their practitioner (see Table 8)

Participation in decision making

Of 115 studies, 22 (19.1%) measured the effect of decision aids on patient participation in decision making; of these, 20 compared the effects of decision aids to usual care (Analysis 5.1; Table 9) and 2 (Deschamps 2004; Raynes-Greenow 2010) compared a detailed decision aid to a simple one (Analysis 5.4). The Davison 1997

paper used the Control Preferences Scale (Degner 1992). This scale measures the role in decision making using five response statements: two represent an active or patient-controlled role, one a shared or collaborative role, and two response statements represent a passive or practitioner-controlled role. Most other studies used comparable response statements that could be classified within each of the three groupings of the Control Preferences Scale, except for Hamann 2006 which used the COMRADE instrument to measure patient perception of involvement, and two others that used other measures of perceived involvement (Hanson 2011; Loh 2007) (see Table 9).

For patients assuming an active (patient-controlled) role in decision making, the pooled RR for 12 studies compared decision aid to usual care was 1.28 (95% CI 1.02 to 1.60; Analysis 5.1.1). The proportion adopting a shared decision-making role in 12 studies showed no difference between decision aid and usual care (decision aid versus usual care pooled RR 0.96; 95% CI 0.82 to 1.13; Analysis 5.1.2). Given that patient decision aids are hypothesized to increase patient participation in decision making, there was a reduction in practitioner-controlled decision making; the pooled RR based on 14 studies comparing decision aids to usual care was 0.66 (95% CI 0.53 to 0.81; Analysis 5.1.3). For studies that could not be pooled, Allen 2010, Leighl 2011, Rubel 2010, and van Peperstraten 2010 reported no difference in these roles between groups.

For studies that could not be pooled in which a decision aid was compared to usual care, Loh 2007 and Hamann 2006 reported that a statistically-significant proportion of patients exposed to the decision aid described feeling involved in decision making. However, Hamann 2006 did not analyze findings accounting for cluster. Hanson 2011 reported that a higher proportion described feeling involved (83% vs 77%) but that the difference between groups was not statistically significant (Table 9).

There was no statistically-significant difference in patient participation in decision making for the two studies that compared a detailed decision aid to a simple one (Deschamps 2004; Raynes-Greenow 2010) (see Analysis 5.4)

Proportion undecided

Of 115 studies, 21 (18.3%) measured the proportion remaining undecided: of these, 18 pooled studies compared decision aids to usual care, 3 pooled studies compared detailed to simple decision aids, and 1 not able to be pooled compared decision aid to usual care. For 18 studies comparing decision aids to usual care, a statistically-significantly lower proportion of people remained undecided after exposure to a decision aid (RR 0.59; 95% CI 0.47 to 0.72; Analysis 6.1).

None of the studies (Deschamps 2004; Labrecque 2010; Leung 2004) comparing detailed to simple decision aids showed a statistically-significant difference between groups (pooled RR 0.98; 95% CI 0.69 to 1.37; Analysis 6.4).

Kasper 2008 measured progress in decision making using a single item ranging from '0 = completely undecided' to '100 = made my decision'. Given the different measure used, these findings were not included in the meta-analysis. In this study, both the patients exposed to a decision aid and the usual care group progressed in their decision making, with no difference between groups (Table 10).

Satisfaction

Satisfaction was measured as it relates to satisfaction with the choice, satisfaction with the process of decision making, and preparation for decision making. Satisfaction with preparation for decision making was measured in three studies using the Preparation for Decision Making Scale (Bennett 2010). When possible, the scores were standardized to a 0-to-100 point scale, with higher scores reflecting greater satisfaction.

Of 115 studies, 20 (17.4%) measured satisfaction with the choice: 15 compared decision aids to usual care and 5 compared detailed to simple decision aids. Of these 15 studies, 3 (Heller 2008; Laupacis 2006; Montgomery 2007) reported that people exposed to the decision aid had higher satisfaction with their choice compared to usual care, and the other 12 reported no statistically-significant difference (see Analysis 7.1 and Table 11). Of the five studies that compared detailed to simple decision aids, four found no across-group differences in satisfaction with the choice (Deschamps 2004; Raynes-Greenow 2010; Rothert 1997; Schapira 2007), and one reported higher satisfaction with the choice after using the detailed decision aid (Solberg 2010) (Analysis 7.4 and Table 11).

Of 115 studies, 17 (14.8%) measured satisfaction with the decision-making process: 14 compared decision aids to usual care and 3 compared detailed to simple decision aids. Of 14 comparing decision aids to usual care, 10 measured satisfaction with the decision-making process (see Analysis 7.6; Hess 2012; Kennedy 2002; Montori 2011; Vodermaier 2009 in Table 12), 3 measured satisfaction with information received (Laupacis 2006; Miller 2005; Oakley 2006) and 1 (Green 2004) measured satisfaction with genetic counselling. Of the 14 studies, 5 showed statistically-significant improvement in satisfaction with the decision-making process (Barry 1997; Hess 2012; Kennedy 2002; Laupacis 2006; Schroy 2011) and with information provided (Laupacis 2006) when patient decision aids were used compared to usual care, and 9 showed no difference (Bernstein 1998; Green 2004; Jibaja-Weiss 2011; Man-Son-Hing 1999; Miller 2005; Montori 2011; Morgan 2000; Oakley 2006; Vodermaier 2009) (see Analysis 7.6; Table 12). No studies reported that those exposed to patient decision aids were statistically-significantly less satisfied compared to usual care. Although there was no difference in satisfaction with the information between patients in the Montori 2011 study, clinicians had higher satisfaction.

Of three studies comparing detailed and simple decision aids, Deyo 2000 measured satisfaction with the decision-making pro-

cess, [Kuppermann 2009](#) measured satisfaction with involvement in decision making, and [Hunter 2005](#) measured satisfaction with genetic counselling (see [Table 12](#)). [Hunter 2005](#) reported higher satisfaction among those exposed to genetic counselling compared to decision aid alone, and the other two studies reported no difference between groups.

Of 115 studies, 3 (2.6%) measured preparation for decision making ([Table 13](#)). Compared to usual care, two studies reported significant improvements in people's satisfaction with their preparation for making decisions after using decision aids about management of knee osteoarthritis ([Fraenkel 2007](#)) or referral to a lung transplant centre ([Vandemheen 2009](#)) (see [Table 13](#)). The third study ([Deschamps 2004](#)) found no statistically-significant difference between those exposed to the detailed or simple decision aid.

Behaviour

Choice

Choice was defined as the actual choice implemented. However, when the actual choice was not reported, the preferred option was used as a surrogate measure. Ninety-three studies (80.9%) assessed the effects of decision aids on the participants' actual choice implemented (n = 57), their preferred option (n = 33), or used both (n = 3) ([Table 14](#)). Actual choice or preferences were reported as the percentage of individuals actually implementing or stating a preference for the most intensive or most invasive option.

Choice for surgery

Major elective surgery

Eighteen studies (15.3%) focused on choices regarding a more major elective surgery. Fifteen ([Arterburn 2011](#); [Auvinen 2004](#); [Barry 1997](#); [Berry 2013](#); [Bernstein 1998](#); [Morgan 2000](#); [Murray 2001a](#); [Jibaja-Weiss 2011](#); [Kennedy 2002](#); [Protheroe 2007](#); [Schwartz 2009](#); [Solberg 2010](#); [Whelan 2004](#); [Vodermaier 2009](#); [Vuorma 2003](#)) compared decision aids to usual care ([Analysis 8.1](#)), and three ([Deyo 2000](#); [Street 1995](#); [Tiller 2006](#)) compared detailed to simple decision aids ([Analysis 8.2](#)).

Using intention-to-treat analysis, there was a reduction in the number of patients choosing major elective surgery in the group receiving the decision aid compared to usual care (RR 0.79; 95% CI 0.68 to 0.93, n = 15; [Analysis 8.1.2](#)). [Schwartz 2009](#) reported a statistically-significant uptake of prophylactic mastectomy for women who are BRCA1/2 gene carriers (114%). Only three other studies showed statistically-significant changes in surgery rates: -29% for cardiac revascularization ([Morgan 2000](#)), -74% for mastectomy ([Whelan 2004](#)), and -33% for orchiectomy ([Auvinen 2004](#)). Eight other studies ([Arterburn 2011](#); [Barry 1997](#); [Bernstein](#)

[1998](#); [Berry 2013](#); [Jibaja-Weiss 2011](#); [Kennedy 2002](#); [Solberg 2010](#); [Vodermaier 2009](#)) showed reductions in uptake of the more intensive surgical treatment by 14% to 58%, but the results were not statistically significant. Two studies ([Protheroe 2007](#); [Vuorma 2003](#)) showed non-significant higher rates of hysterectomy in the decision aid group compared to usual care. Another study ([Murray 2001a](#)) reported a non-significant five-fold increase in uptake of prostatectomy.

Using intention-to-treat analysis, there was a non-statistically-significant reduction in the number of patients choosing major elective surgery in the group receiving the detailed compared to simple decision aids (RR 0.82; 95% CI 0.63 to 1.08; [Analysis 8.2.2](#)). None of the three studies comparing detailed to simple decision aids reported a statistically-significant difference in surgery rates for mastectomy in women with breast cancer ([Street 1995](#)), back surgery for people with herniated disc or spinal stenosis ([Deyo 2000](#)), prophylactic oophorectomies for women with a family history of breast or ovarian cancer, or non-polyposis colon cancer ([Tiller 2006](#)).

Other elective surgery

Three studies evaluated the effect of decision aids versus usual care on other elective surgical decisions. Decision aids did not significantly influence surgical abortion rates ([Wong 2006](#)), feeding tube insertions ([Hanson 2011](#)), or preference for vasectomy ([Labrecque 2010](#)).

Choice for screening

Prostate-specific antigen screening

The effects of decision aids on prostate-specific antigen (PSA) screening decisions were variable in 13 studies (11.3%): 10 that compared decision aids to usual care and 3 that compared detailed to simple decision aids. The pooled RR for nine studies was 0.87 (95% CI 0.77 to 0.98; [Analysis 8.3.1](#)); [Frosch 2008](#) reported a reduction in screening rates but we were not able to pool the data. Of 10 studies that compared decision aids with usual care, 3 showed significant reductions in screening by 9% to 42% ([Frosch 2008](#); [Volk 1999](#); [Wolf 1996](#)). The results of the other seven studies ([Allen 2010](#); [Evans 2010](#); [Gattellari 2003](#); [Gattellari 2005](#); [Partin 2004](#); [Krist 2007](#); [Watson 2006](#)) were not statistically significant.

Three studies compared a detailed and a simple decision aid and the pooled RR was 0.98 (95% CI 0.82 to 1.17; [Analysis 8.3.2](#)). There were non-significant reductions of 2% and 11% in PSA screening in two studies ([Myers 2011](#); [Schapira 2000](#)). One study reported a non-significant increase in screening of 89% ([Myers 2005a](#)).

Colon cancer screening

Of 10 studies (8.7%) of colon cancer screening, 3 reported statistically-significant changes and 7 showed no difference. Two studies reported that the decision aid, when compared to usual care, significantly increased the uptake of screening by 64% and 70%, respectively (Pignone 2000; Ruffin 2007), and the other study reported a statistically-significant reduction of 21% for screening (Smith 2010). There was an increase in uptake of screening in five studies, by 6% to 39%, but the difference was not statistically significant (Lewis 2010; Miller 2011; Schroy 2011; Steckelberg 2011; Wolf 2000). In two studies (Dolan 2002; Trevena 2008), there was a 73% and 4% decrease in screening rates that was not statistically significant. The pooled RR was 1.12 (95% CI 0.95 to 1.31, n = 10; Analysis 8.3.3).

Cancer genetic screening

Preferences or uptake of cancer genetic screening were reported in 8 studies (7.0%): seven focused on breast cancer and one focused on colorectal cancer genetic testing. Preferences for breast cancer genetic screening were not statistically-significantly affected when a decision aid was compared to usual care. The pooled RR was 1.01 (95% CI 0.83 to 1.22, n = 4; Analysis 8.3.4). One study reported an increased uptake of screening by 14% (Lerman 1997), a second study reported an increase of 18% (Green 2001a), a third study reported a decrease in uptake by 29% (Schwartz 2001), and the other study reported no difference (Green 2004). Miller 2005 reported that women exposed to the decision aid who were at higher risk of breast cancer increased their intention to obtain genetic testing, while those at average risk decreased their intention. When detailed decision aids were compared to simple ones, there was no difference in uptake of genetic testing for breast or colorectal cancer (Wakefield 2008; Wakefield 2008a; Wakefield 2008b).

Breast screening

There was higher uptake of mammography screening among women aged 38 to 45 years of age (Mathieu 2010) but no difference in women aged 70 or older (Mathieu 2007) who were exposed to a decision aid versus usual care.

Prenatal screening

The uptake of prenatal testing was not affected by a decision aid compared to usual care (Bekker 2004; Bjorklund 2012; Nagle 2008), nor by a more detailed decision aid compared to a simple decision aid (Hunter 2005; Leung 2004; pooled RR 0.96, 95% CI 0.90 to 1.03; Analysis 8.3.5).

Stress test for chest pain

Compared to usual care, adults presenting with chest pain in the emergency department who received the decision aid had significantly less stress testing done (58% versus 77%) (Hess 2012).

Screening for diabetes

There was no difference in uptake (Marteau 2010) or preference (Mann E 2010) to be screened for diabetes in adults exposed to a decision aid compared to usual care.

Choice for medication

Antibiotics for upper respiratory infection

There was a decrease in prescriptions for antibiotics for upper respiratory infections when a decision aid was used in the consultation compared to usual care, but this difference was not statistically significant (Legare 2011).

Cardiovascular disease prevention

There was an increase in patient preferences for medication to lower cardiovascular disease risk when a decision aid was used compared to usual care (63% vs 42%) (Sheridan 2011). Three studies evaluated decision aids with people with diabetes considering cardiovascular disease prevention medications and the RR was 1.84 (95% CI 0.77 to 4.39). Compared to usual care, those exposed to the decision aid had increased uptake of statins therapy (Mann D 2010; Weymiller 2007), but the findings were not statistically significant (Analysis 8.4). Mullan 2009 reported that a higher proportion of people with type II diabetes started medications after exposure to the decision aid (33%), compared to usual care (22%).

Breast cancer prevention medication

There was no difference in uptake of medications for women at risk of breast cancer who were exposed to the decision aid versus usual care (Fagerlin 2011).

Chemotherapy for advanced cancer

There was no statistically-significant difference in the uptake of chemotherapy for adults with advanced colorectal cancer (77% versus 71%) (Leighl 2011).

Menopausal hormone therapy

Preferences regarding hormone therapy for menopausal women were affected when a detailed decision aid was compared to a simple decision aid in three studies, with a statistically-significant decrease of 36% (Dodin 2001), a non-statistically-significant decrease of 25% (Deschamps 2004) and non-statistically-significant increase of 12% (O'Connor 1998a) respectively. There was a statistically-significant reduction of 27% in the uptake of hormone therapy when these studies were pooled (RR 0.73; 95% CI 0.55 to 0.98; Analysis 8.5). Schapira 2007 reported no difference in the use of hormone therapy between those exposed to the detailed or simple decision aid. In a single study comparing a decision aid to usual care (Murray 2001b), there was a decrease of 8%, which was not statistically significant.

Natural health products

Preferences for natural health products in women experiencing menopausal symptoms were no different for women exposed to the decision aid compared to women exposed to the usual education materials (Legare 2008a).

Anti-thrombosis medication

Three studies evaluated the effect of a decision aid on the use of anti-thrombotic therapy for atrial fibrillation versus usual care. One study demonstrated a non-significant reduction of uptake of warfarin of 25% (Man-Son-Hing 1999). The second study evaluated the proportions of patients choosing the option that was appropriate relative to their level of risk, and found no significant difference between the groups (McAlister 2005). Thomson 2007 reported that patients in the usual care group (guided by practice recommendations) were much more likely to start warfarin (15/16; 93.8%) compared to the decision aid group (4/16; 25%; RR 0.27; 95% CI: 0.11 to 0.63).

Hypertension medication

Montgomery 2003 found no significant effect of decision aids over usual care on the initiation of medication for hypertension.

Breast cancer medication

Whelan 2003 also found no significant effect on preferences for adjuvant chemotherapy versus no chemotherapy for breast cancer.

Immunotherapy

Kasper 2008 reported no difference in the uptake of immunotherapy in people with multiple sclerosis who were exposed to a decision aid, compared to usual care based on practice guidelines.

Osteoporosis treatment

Montori 2011 found no significant effect of decision aids over usual care on the uptake of medication for osteoporosis treatment.

Schizophrenia treatment

Although Hamann 2006 found no difference in prescriptions for antipsychotic medications but a statistically-significant increase in the uptake in psycho-education (P = 0.003) in people with schizophrenia exposed to the decision aid compared to usual care.

Influenza (flu) vaccine

Compared to usual care, there was a non-statistically-significant increase in intentions to get the flu vaccine in those exposed to the decision aid (46% versus 27%) (Chambers 2012).

Hepatitis B vaccine

Compared to usual care, there was a statistically-significant increase in uptake of Hepatitis B vaccination with decision aids (Clancy 1988).

Blood transfusions

There was no difference in the uptake of pre-operative autologous blood donation when a decision aid was compared to usual care (Laupacis 2006).

Obstetrical choices

Childbirth procedures

Three studies focused on childbirth issues, using a decision aid compared to usual care. There was no difference in preference for (Shorten 2005) or actual vaginal mode of delivery (Montgomery 2007) following previous cesarean section. Another study found no difference in actual choice to undergo external cephalic version for women with breech presentation (Nassar 2007). Raynes-Greenow 2010 reported that there was no difference in uptake of pain relief in labour for those exposed to a detailed versus simple decision aid.

Birth control approaches

There was no difference in the birth control methods chosen for those in the decision aid versus usual care groups (Langston 2010).

Embryo transplantation

Compared to usual care, those in the decision aid group were statistically significantly more likely to choose a single embryo transplant (43% versus 32%) (van Peperstraten 2010).

Other choices

Lung transplant referral

There was no difference in referral rates for consideration of lung transplant in people with advanced cystic fibrosis exposed to a decision aid versus usual care (Vandemheen 2009).

Summary: choice

In summary, patient decision aids decrease the number of patients choosing elective surgical procedures, PSA testing, and use of hormone therapy in multiple studies. Single studies showed that decision aids increased the number of people choosing: hepatitis B vaccination, psycho-educational therapies for schizophrenia, and medication for cardiovascular disease prevention; and decreased cardiac stress testing and the number of embryos being transplanted. The effect on patients' choice in other situations was more variable. There were mixed results for the choice of colon cancer screening, genetic testing, prenatal testing, anti-thrombosis therapy, breast screening, and diabetes medications. There was no difference between groups for choices about natural health products, hypertension therapy, breast cancer chemotherapy, schizophrenia medication, immunotherapy for multiple sclerosis, flu vaccine, diabetes screening, birth control, osteoporosis treatment, chemotherapy for advanced cancer, chemopreventive medications, antibiotics for upper respiratory tract infections, use of blood transfusions, and childbirth procedures.

Adherence (continuance/compliance) with chosen option

Of 115 studies, 13 (11.3%) measured adherence with the chosen option: 10 compared a decision aid to usual care, and 3 compared detailed to simple decision aids (Table 15). Of the 10 that compared a decision aid to usual care, 3 studies showed a statistically-significant difference between groups, with adherence rates reported by Mullan 2009 favouring usual care (97.5% decision aid compared to 100% usual care at 6 months), and with adherence rates reported by Montori 2011 and Sheridan 2011 favouring the decision aid. Montori 2011 reported that 100% of the participants in the decision aid group versus 74% in the usual care group at 6 months had taken their medication on more than 80% of the days for which it was prescribed, based on pharmacy records. Sheridan 2011 found higher adherence in the decision aid group compared to the usual care group for any therapy described in the

decision aid, any therapy whether or not it was described in the decision aid, and aspirin ($P < 0.02$). Although trends appeared positive for decision aids, the Sheridan 2011 study was underpowered to determine if observed differences between decision aid and usual care were statistically significant for adherence to cholesterol medication, blood pressure medication, or smoking cessation. The other seven studies found no difference in adherence to medication for atrial fibrillation (warfarin versus aspirin) at six months (Man-Son-Hing 1999), oral bisphosphonate medication for osteoporosis at four months (Oakley 2006), blood pressure medication at three years (Montgomery 2003), anti-depressant medication at two months (Loh 2007), statins for high cholesterol at three or six months (Mann D 2010; Weymiller 2007), or use of effective contraceptive method (Langston 2010). Three studies that compared a detailed to a simple decision aid reported no difference in adherence to hormone therapy at 12 months (Deschamps 2004; Rothert 1997), or in colorectal cancer screening rates at 1 month (Trevena 2008).

Health outcomes

General health outcomes

Ten studies (8.7%) compared a decision aid to usual care and one study compared detailed to simple decision aids in terms of general health outcomes. Eight of these (Barry 1997; Bernstein 1998; Kennedy 2002; Legare 2011; McCaffery 2010; Morgan 2000; Murray 2001a; Murray 2001b) used the previously validated Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) or the 12-item Short-Form Health Survey (SF-12) (Stewart 1992), and one study (Vuorma 2003) used the RAND-36 (Hays 1993). As shown in Table 16, there were no significant differences for mental health function or social function in any of the seven studies. In one study (Barry 1997), general health and physical function outcome scores were significantly better in the decision aid group compared to usual care for men considering treatments for benign prostatic disease. Of the two studies evaluating the effect of a decision aid for women considering treatment for abnormal uterine bleeding, Kennedy 2002 found a statistically-significant improvement in role physical function, and Vuorma 2003 found a statistically-significant improvement in emotional role functioning for women. Deyo 2000, using the previously validated Roland Disability Questionnaire (Roland 1983) to measure functional status in patients with back pain, found no difference between the detailed decision aid and simple decision aid groups. In two studies measuring health utilities using the Euroqol EQ-5D (Murray 2001a; Murray 2001b), there was no difference between the decision aid and usual care groups.

Condition-specific health outcomes

Twelve studies (10.4%) used various measures to assess condition-specific health outcomes (see Table 17). Ten of these compared decision aids to usual care (Barry 1997; Bernstein 1998; Leighl 2011; Morgan 2000; Murray 2001a; Murray 2001b; Protheroe 2007; Thomson 2007; van Peperstraten 2010; Vuorma 2003), and two compared a detailed decision aid to a simple decision aid (Deyo 2000; Raynes-Greenow 2010). Outcomes included urinary symptoms (Barry 1997; Murray 2001a), angina (Bernstein 1998; Morgan 2000), back pain (Deyo 2000), menopausal symptoms (Murray 2001b), menstrual symptoms (Protheroe 2007; Vuorma 2003), stroke or bleed (Thomson 2007), pregnancies and twin pregnancies (van Peperstraten 2010), and newborn Apgar score and birth weight (Raynes-Greenow 2010). Nine of the 12 studies (Bernstein 1998; Leighl 2011; Morgan 2000; Murray 2001a; Murray 2001b; Raynes-Greenow 2010; Thomson 2007; van Peperstraten 2010; Vuorma 2003) found no significant effects on condition-specific health outcomes. Protheroe 2007 reported statistically-significantly higher menorrhagia-related quality of life in women exposed to the decision aid compared to usual care. Deyo 2000 found no significant differences according to most measures, except for back pain severity -- for which improvement was shown, one year later, in the decision aid group. Barry 1997 showed an improvement in urinary symptoms in favour of the decision aid group, but it was not statistically significant.

Preference-linked health outcomes

None of the 115 studies measured preference-linked health outcomes—that is, whether the patients experienced the outcomes they preferred and avoided the outcomes they wanted to avoid.

Anxiety

Of 115 studies, 30 (26.1%) measured anxiety, with 19 using the previously validated 20-item State Trait Anxiety Inventory (Spielberger 1970) and 1 using a single question on a 7-point Likert scale (Johnson 2006) (see Table 18). Twenty-four of these studies involved decision aid/usual care comparisons, and five (Goel 2001; Hunter 2005; Raynes-Greenow 2010; Tiller 2006; van Roosmalen 2004) involved detailed/simple decision aid comparisons (see Table 18). Of 23 studies that measured anxiety within 1 month, 2 (8.7%) reported that the decision aid group had statistically-significantly lower anxiety scores for people considering birthing options after previous caesarean (Montgomery 2007) and for women considering options for treatment of menorrhagia (Protheroe 2007). Green 2004 reported a greater reduction in anxiety for high-risk women considering genetic testing in the control group and a greater reduction in anxiety for low-risk women considering genetic testing in the decision aid group. None of the studies demonstrated significant differences in effects on people's state anxiety at one month (n = 3 studies), at three

months (n = 6 studies), at six months (n = 5 studies), or at one year (n = 2 studies).

Depression

Of 115 studies, 9 (7.8%) measured the effect of decision aids on depression using various instruments (Table 19). None of the studies reported a statistically-significant difference between groups for decisions about cancer treatment (Davison 1997; Whelan 2004), depression (Loh 2007), prenatal genetic testing (Nagle 2008), people at higher risk of cancer who were considering risk management (Tiller 2006), women considering number of embryos to transplant (van Peperstraten 2010), or genetic testing (Wakefield 2008; Wakefield 2008a; Wakefield 2008b).

Regret

Of 115 studies, 7 (6.1%) measured the effect of decision aids on decision regret, using the 5-item Decisional Regret scale (Brehaut 2003) (see Table 20). Of the seven studies, two compared decision aids to usual care and five studies compared detailed to simple decision aids. There was no statistically-significant difference for any of the seven studies.

Confidence

Of 115 studies, 9 (7.8%) measured the effect of decision aids on confidence levels: 8 compared decision aids to usual care and Rotherth 1997 compared detailed to simple decision aids (see Table 21). Four of these studies used the Decisional Self-efficacy Scale (Allen 2010; Arterburn 2011; Fraenkel 2007; Smith 2010). Of these eight studies, four reported a statistically-significant improvement in confidence or self-efficacy with decision making in the decision aid compared to the usual care groups (Chambers 2012; Fraenkel 2007; Gattellari 2003; McBride 2002) and the other studies reported no difference between groups. The other study comparing detailed to simple decision aids found no difference in confidence scores immediately post decision aid or at 12 months (Rotherth 1997).

Healthcare system effects

Consultation length

Of 115 studies, 10 (8.7%) evaluated the effect of a decision aid compared to usual care (n = 9) or simple decision aid (n = 1) on consultation length, with a range from 8 minutes shorter to 23 minutes longer (median 2.5 minutes longer) (see Table 22). Four studies evaluated decision aids in the form of decision boards used primarily within the consultation (Loh 2007; Vodermaier 2009;

Weymiller 2007; Whelan 2003). Of 9 studies, Bekker 2004 reported consultations about prenatal diagnostic testing were 6 minutes longer for women who prepared for the consultation using a decision aid, Thomson 2007 reported consultations about treatment for atrial fibrillation were 23 minutes longer when using a computerized decision aid with standard gamble method within the consultation compared to guideline driven consultation, and Green 2004 reported that consultations about breast cancer genetic testing were shorter by 8 minutes when women prepared using a decision aid. The other six studies that evaluated decision aids compared to usual care and one study that evaluated detailed compared to simple decision aids reported no statistically-significant difference in consultation length (see Table 22). Results were not pooled given the variability in the way length of time was reported, including many studies that did not include standard deviations.

Cost and resource use

Eight studies (7.0%) evaluated the impact of decision aids compared to usual care on costs (Kennedy 2002; Montgomery 2007; Murray 2001a; Murray 2001b; van Peperstraten 2010; Vuorma 2003) or resource use only (Deyo 2000; Thomson 2007) (see Table 22).

Both studies by Murray involved a cost-minimization economic analysis from the perspective of the healthcare system decision-maker, with less than 4% of resource use items being replaced by conditional means due to missing data. There was no significant difference between the groups in terms of health service resource use. There was a difference in costs, when the additional costs of interactive videodisc equipment was considered in the analysis.

The cost-effectiveness analysis in the Kennedy 2002 study was also conducted from the healthcare system perspective, using 1999 to 2000 US dollars and calculated over two years. The decision aid with nurse coaching demonstrated the lowest mean cost (\$1566) compared to decision aid alone (\$2026) or usual care (\$2751).

In the Vuorma 2003 study, despite the statistically-insignificant trend for fewer diagnostic procedures (55 versus 89; $P = 0.07$) and lower rates for uterine-preserving surgery procedures (16 versus 26; $P = 0.08$) in the intervention group, there was no difference between the intervention and control group when treatment cost and productivity losses were analyzed at one year follow-up.

van Peperstraten 2010 evaluated the costs from a healthcare perspective and determined the difference in total costs per couple between groups. The mean total savings in the decision aid compared to usual care group was EURO169.75 per couple.

Montgomery 2007 evaluated the costs from the United Kingdom National Health Service perspective and reported that there was no difference in mean costs per patient between groups.

For healthcare resource use, there was no difference in most services for Deyo 2000 (except fewer surgeries for herniated disc in the detailed versus simple decision aid group) and no difference in

general practitioner consultations was reported by Thomson 2007.

Litigation rates

None of the 115 studies examined the effect of decision aids on litigation.

Post-hoc analysis

Effects of study quality

To examine the potential bias arising from including trials of low methodological quality, eight trials with a high risk of bias for any of the seven risk of bias criteria were excluded from the analysis (Auvinen 2004; Chambers 2012; Clancy 1988; Hamann 2006; Krist 2007; Lewis 2010; Man-Son-Hing 1999; Rostom 2002). Overall, the results remained the same (Table 23). For a more conservative post-hoc analysis, we also excluded 64 trials with a 'high' risk of bias or 'unclear' risk of bias for at least 3 of the 7 criteria (Figure 3). Overall, the results of this more conservative analysis remained the same (Table 23).

We applied a fixed-effect model for the primary outcomes and compared it to the random-effects model used in the analysis reported earlier. The results were similar. For example, knowledge results were 13.34 (95% CI 11.17 to 15.51) using a random-effects model compared to 13.61 (95% CI 12.83 to 14.38) using a fixed-effect model. Therefore, there is little concern about the impact of small studies being included that could potentially have shown more beneficial effects (Sterne 2011).

Heterogeneity

When patient decision aids were compared to usual care, there was statistically-significant heterogeneity in five of six of the IPDAS effectiveness criteria: knowledge; accurate risk perceptions; values congruence with choice; feeling uninformed; and feeling unclear regarding personal values. There was no statistically-significant heterogeneity for participation in decision making. It should be noted that the heterogeneity of the effect was not manifested in its direction but only in its size. For the 2009 update (O'Connor 2009), we explored the potential factors contributing to heterogeneity (Table 24). Overall, scores for outcomes were similar to the overall effect regardless of sub-analysis conducted as indicated by overlapping confidence intervals.

DISCUSSION

Summary of main results

The addition of 33 studies in this updated review confirms many of the observations reported in the previous versions of our reviews (O'Connor 2003b; O'Connor 2009; Stacey 2011). Based on the GRADE assessment (Summary of findings for the main comparison; Table 2), there is high-quality evidence that decision aids compared to usual care improve people's knowledge regarding options and reduce their decisional conflict related to feeling uninformed and unclear about their personal values. There is moderate-quality evidence that decision aids compared to usual care stimulate people to take a more active role in decision making and that decision aids with probabilities compared to interventions without probabilities increase accurate risk perception. There is low-quality evidence that decision aids improve congruence between the chosen option and their values. For secondary outcomes, there is a decrease in the proportion of people remaining undecided. Compared to simple versions, detailed decision aids improved knowledge only marginally.

The impact of decision aids on increasing or decreasing the numbers of patients choosing particular options continues to be variable. New in this update is pooled evidence indicating a non-significant trend for a 12% increase in colorectal cancer screening in those exposed to a decision aid compared to usual care. The numbers of patients choosing to have major elective surgery continues to be decreased in favour of more conservative options except when base rates are low (e.g., surgery for benign prostate hyperplasia, prophylactic mastectomy for women who are carriers of the BRCA gene). The numbers of patients choosing hormone replacement therapy and prostate-specific antigen (PSA) testing were decreased with exposure to decision aids.

Decision aids do no better than alternative interventions in terms of their effects on people's satisfaction with decision making, anxiety, or health outcomes such as general quality of life or condition-specific quality of life. However, no studies measured preference-linked health outcomes. There continue to be too few studies to determine the effects of decision aids on costs/resource use. Although there may be additional costs of delivering decision aids, an independent review of decision aid trials with economic outcomes concluded that "this was likely to be small relative to the benefit to patients in terms of improved decision quality when effective decision aids are used" (NCGC/NICE 2012). Although several studies have measured adherence, the variability in the measurement makes it difficult to determine the effect of patient decision aids on adherence to the chosen option.

New for this update, we analyzed the pooled data for screening decision aids separately from treatment decision aids, and found that the results were similar.

Quality of the evidence

Risk of bias ratings show the variability in risk of bias across studies. The two criteria for which studies scored the worst were selective outcome reporting, and blinding of participants and personnel.

When a post-hoc analysis was conducted that involved removing studies at high risk of bias, there was no effect on the results. The conclusions of this review are limited by: a) inadequate power to detect important differences in effectiveness in subgroups; and b) the wide variability in the decision contexts, the elements within the patient decision aids, the type of comparison interventions, the targeted outcomes, and the evaluation procedures. The small number of studies for most outcomes did not allow for analysis of publication bias due to failure to publish negative studies. Moreover, there may have been publication bias due to failure to report all negative findings in a published study. Several of the outcomes demonstrated statistically-significant heterogeneity. For the outcome of knowledge, for example, heterogeneity would be expected, given that the knowledge tests themselves were not standardized. Furthermore, the heterogeneity found in the various outcomes reflects differences across clinically-diverse studies; therefore, the pooled effect size and confidence intervals should be interpreted as a range across conditions, which may not be applicable to a specific condition.

Main effects of decision aids

The largest and most consistent benefits of decision aids, relative to usual care, are better knowledge of options and outcomes, more accurate perceptions of outcome probabilities, and congruence between the chosen option and the person's values. These observations are clinically important because the usual care group's knowledge and understanding of probable outcomes were less than the intervention group; both knowledge and understanding of probable risk are important for ensuring informed decision making. These effects on knowledge and risk perceptions suggest that current 'usual care' may not be good enough when informing people about these complex, values-sensitive decisions. People need to comprehend the options and probable outcomes in order to consider and communicate to their practitioners the personal value they place on the benefits versus the harms. As well, in this update there is a significant increase in values-based choice when decision aids with explicit values clarification exercises were compared to a simple decision aid without explicit values clarification or usual care.

Decision aids, when compared to usual care, also help people feel more comfortable with their choices. This is revealed by the reduced scores for the decisional conflict sub-scales. People who use decision aids generally feel more informed about options and clearer regarding their personal values.

Compared to usual care strategies, decision aids improve individuals' involvement in decision making. This observation suggests that the International Patient Decision Aids Standards criterion of helping patients participate 'in ways that they prefer' needs to be assessed after a patient has adequate information about what involvement means. People may have a mistaken preference for passivity because they believe that the best choice relies on the

expertise of the clinician (which option is medically reasonable?) rather than the opinions of the person who will experience the outcomes (which outcomes matter most to me?).

Evidence continues to build that decision aids have a positive effect on the patient-practitioner consultation in all nine studies that measured it, and have a variable effect on the length on these consultations. Of the studies that measured patient-practitioner communication, five involved using decision aids within the consultation and in three decision aids were used in preparation for the consultation. Interestingly, most studies of consultation length were conducted on decision aids intended to be used within the consultation, and fewer studies were focused on consultation length when decision aids were used in preparation for the consultation. Of the 10 studies that measured consultation length, 2 that also measured patient-practitioner communication reported that there was increased patient participation in the consultation for those exposed to the patient decision aid within the consultation compared to usual care (Weymiller 2007) but there was no difference when the detailed compared to simple decision aid was used in preparation for the consultation (Myers 2011). However, few studies have evaluated the impact of patient decision aids in clinical practice and further research is underway to better evaluate outcomes when the trial was conducted within clinical practice versus as another research study.

Variable effects of decision aids

There may be several reasons for the variable impact of decision aids on choices. First, most studies were under-powered to detect important differences in choices. Second, in the five studies reporting choices at baseline and post decision aid, some options may have been under-used and others over-used, relative to the choices individuals would make if they were more fully informed. Under these circumstances, one could expect to observe directional effects on choices once people become better informed and more involved in decision making. Examples of relatively under-used options at baseline were colon cancer screening and hepatitis B vaccination. Another illustration lies in the non-significant five-fold increase in the number of people choosing prostate surgery in the UK study and uptake in prophylactic mastectomy in women who were carriers of the BRCA gene. For the prostate example, there was a shortage of urologists and low referral rates for benign prostatic hyperplasia; whereas the breast example reflects the growing number of women who test gene positive who are aware of their options for preventing breast cancer. This situation may have resulted in under-use of a chosen option, which was corrected with exposure to a decision aid. In contrast, the other surgical decision aid studies had higher numbers of people choosing surgery in the control group. The procedure may have been chosen due to people's inflated perceptions of the probabilities of benefits, lack of appreciation of the probabilities of harms, and lack of awareness of alternatives. Exposure to the decision aid reduced the number

of people choosing surgery in favour of more conservative alternatives.

Limited effects of decision aids

The limited effects of decision aids on reported satisfaction with the decision-making process and with the actual choice made may indicate that decision aids have a limited effect on satisfaction. The null effects may also be due to measurement insensitivity. This is especially likely when satisfaction with usual care is already quite high (e.g., ceiling effects) and when choices are inherently difficult to make because of competing benefits and harms. Furthermore, once the decision is made, people may find it psychologically more comforting to say that they are satisfied rather than entertain doubts about what they have chosen (Gruppen 1994). Interestingly, in the two studies that used the Preparation for Decision Making Scale to compare the decision aid to usual care, both reported positive outcomes for satisfaction in the patient decision aid group.

The small differences in knowledge and decisional conflict scores between detailed and simple versions of decision aids are likely due to the overlapping information presented in the two interventions. This raises questions about the minimum information needed for the decision aid to be effective. For example, in the study by Goel 2001, a simple pamphlet describing options and outcomes of mastectomy versus lumpectomy was comparable to a detailed audio-workbook for women newly diagnosed with breast cancer. However, a post-hoc analysis revealed that women who were uncertain about their choice at baseline or were leaning toward mastectomy, appeared to benefit more from the detailed aid. These observations indicate a need to establish the 'essential ingredients' in decision aids and to identify the people who are most likely to benefit from more detailed versions. As the body of available research grows, it will become easier and more important to assess the usefulness of different components of decision support for different clinical contexts, decision problems, and groups of people. The IPDAS Collaboration is trying to establish the evidence for the various components in decision aids in the recent set of reviews underlying the IPDAS checklist (IPDAS 2013). At a minimum, the IPDAS collaboration proposes criteria for defining the intervention as a patient decision aid and certifying criteria (Joseph-Williams 2013).

It is not surprising that decision aids had limited effects on health outcomes. One reason for using a decision aid is that there is often no option with a clear health outcome advantage. For example, when men with localized prostate cancer consider active treatment options, their health outcomes can be different, depending on whether they choose surgery with higher risks of longer term urinary incontinence, or radiation therapy with higher risks of longer term bowel irritation. Therefore, if health outcomes are used in future investigations of decision aids in situations in which there is clearly no health outcome advantage, the key question to pose is:

do patients experience the health outcomes they prefer and avoid the outcomes to which they are averse?

More recently, decision aids are being used in situations in which there may be a longer-term health advantage; for example, in preventive decisions about the management of type II diabetes (Mann D 2010; Mullan 2009; Weymiller 2007) and/or hypertension (Montgomery 2003), when the longer-term health outcome maybe to avoid may be stroke. Interestingly, of these studies one reported a statistically-significant difference in medication initiation when exposed to the decision aid compared to alternative interventions (Mullan 2009), thereby highlighting tensions between outcome and process measures (Bekker 2010; Thomson 2005).

Unknown effects of decision aids

The effect of patient decision aids on adherence is an area of uncertainty. The adherence results are difficult to interpret due to incomplete data, varying length of follow-up (4 to 36 months), and small sample size ($n = 33$ in one study). Moreover, studies such as Man-Son-Hing 1999 had very little variation in choice (over 90% of long-term aspirin users decided to stay on aspirin). When examining adherence, it would be important to do so: a) in the early phase, when presumably the issue is actually decisional in nature (e.g., filling the prescription, picking up the prescription, refilling the prescription) rather than involving the management of side effects; and b) in a manner that separates those choosing to change versus those remaining with the status quo.

Despite the positive effects of decision aids on patient-practitioner communication, some authors are concerned about the potential negative influence that decision aids may have on the relational aspects of the decision-making process; this concern highlights the need for further evaluation when decision aids are implemented as part of the routine process of care (Charles 2010; LeBlanc 2010). Cost-effectiveness, health utilities, and preference-linked health outcomes are other secondary outcomes about which little is known and further evaluation is required. It is unlikely that we will observe the effect of decision aids on litigation rates in trials of decision aids, given the time delay to litigation and the rareness of this type of event. In fact, a mock trial that used a patient decision aid for prostate-specific antigen testing found that the majority of jurors (94%) would indicate that the standard of care had been met (Barry 2008).

Limitations

This systematic review is limited by inadequate power to detect important differences in effectiveness in subgroups and the wide variability in the decision contexts, the elements within the patient decision aid, the type of comparison interventions, the targeted outcomes, and the evaluation procedures. Several of the outcomes demonstrated statistically-significant heterogeneity. This reflects

differences across clinically-diverse studies; therefore, the pooled effect size and confidence intervals should be interpreted as a range across conditions, which may not be applicable to a specific condition. A sub-analysis to explore three potential sources of heterogeneity (e.g. type of control intervention, decision aid IPDAS quality score, patients' baseline accurate risk perception) found that patients' baseline accurate risk perception was an important variable for explaining heterogeneity (Gentles 2013). When patients' baseline scores for accurate risk perception are lower, there is great improvement observed. Furthermore, we limited the study data to only two comparison groups (e.g. most intensive and least intensive).

AUTHORS' CONCLUSIONS

Implications for practice

The positive effects of decision aids on improving people's knowledge of risks and benefits, feeling informed and feeling clear about their values provides sufficient evidence for using them in clinical practice. As well they can facilitate accurate risk perception and active participation in decision making. However, several conditions may be necessary for successful implementation: a) good quality decision aids to meet the needs of the population; b) practitioners willing to use decision aids in their practice; c) effective systems for delivering decision support; and d) practitioners and health-care consumers who are skilled in shared decision making. Although some strides have been made in achieving these conditions (O'Connor 2007), the use of patient decision aids will not occur without adequate attention to the barriers to implementation and consideration of effective interventions for implementing them as part of routine clinical practice (Gravel 2006; Legare 2008b; Legare 2010).

Implications for research

Studies are needed to deepen our understanding of: interactions between patient decision aid use and the patterns of patient-practitioner communication; the effect of decision aids on lower health literacy and low numeracy populations; various cultural groups; format issues such as web-based delivery of patient decision aids; timing issues regarding most effective use of decision aids before or during a consultation; and downstream effects on cost, resource use, and adherence.

With the addition of more studies in the systematic review, it may be possible to tease out the reasons for heterogeneity of results, including variability in: a) study quality; b) comparison intervention; c) elements within patient decision aids; d) decision type; and e) format of decision aid (e.g., video, Internet, booklet). The degree of detail in patient decision aids that is required for positive effects on IPDAS criteria should also be explored. In particular,

evaluation is needed to determine the effect of those that meet the minimal IPDAS criteria for certification versus those that also meet the IPDAS quality criteria (Joseph-Williams 2013).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Allen 2010

Methods	Randomised to decision aid vs usual care	
Participants	398 + 414 men considering prostate cancer screening in the USA	
Interventions	DA: computer tailored program on clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step by step process for making the decision; interactive computer program: inherently guided the patient through the decision aid and decision making process), tailored print out given to patients to promote discussion with others (practitioner, significant others) COMPARE: received no intervention	
Outcomes	decisional status* (pre, post DA), knowledge* (pre, post DA), *decision self-efficacy(pre, post DA), decisional consistency* (pre, post DA), desire for involvement in decision making (pre, post DA), decisional conflict(pre, post DA), preferred options	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.2173 (Setting): "Sites were blocked on size and percent of male employees and randomly assigned by computer-generated random numbers to condition within blocks."
Allocation concealment (selection bias)	Unclear risk	The study does not address this criterion.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data.
Selective reporting (reporting bias)	Unclear risk	No mention of protocol.
Other bias	Low risk	pg.2175 (Intervention delivery): mention of money incentive to complete paperwork, but was judged to have no effect on outcomes measured
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The study does not address this criterion.

Allen 2010 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes measured were not subjective to interpretation
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Arterburn 2011

Methods	Randomised to decision aid vs usual care
Participants	75 + 77 participants considering bariatric surgery in the USA
Interventions	DA: booklet + video on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (list of questions to discuss with clinician) COMPARE: usual care (general information pamphlets on clinical problem)
Outcomes	knowledge* (pre, immediately post and 3 month follow-up), values (pre, immediately post and 3 month follow-up), values concordance* (pre, immediately post and 3 month follow-up), treatment preference (pre and immediately post), decisional conflict (pre and immediately post), decisional self efficacy (pre and immediately post), proportion undecided
Notes	*primary outcomes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.1670 (Participants and randomization): "used computer-assisted, block randomisation process to ensure balanced allocation of participants"
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment and no mention of impact on study
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg.1671 (measures): mentioned 4 choices for treatment preference (surgery, drug therapy, diet and/or exercise program and unsure) but only reported on surgery and unsure options
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol or trial registration; all pre-specified outcomes included
Other bias	Low risk	The study appears to be free of other sources of bias

Arterburn 2011 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg.1670 (Participants and randomization) : “study was not blinded”; no mention of impact on study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subject to interpretation

Auvinen 2004

Methods	Randomised to decision aid vs usual care
Participants	103 + 100 men newly diagnosed with prostate cancer in Finland
Interventions	DA: pamphlet patient decision aid created for study on options’ outcomes, outcome probability, guidance COMPARE: usual care by clinical guideline
Outcomes	Uptake of options*, participation in decision making
Notes	*primary outcome

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Auvinen, 2001, BJU International: pg. 2 “randomized centrally, using software based on a random number generator” No blocking used Auvinen, 2004, BJU International (Primary Study): pg. 1 “randomized using a computer algorithm based on random numbers”
Allocation concealment (selection bias)	Unclear risk	Auvinen, 2001, BJU International: pg. 2 - Patients and Methods randomized centrally at the Finnish Cancer Registry Auvinen, 2004, BJU International (Primary Study): pg. 1 - randomized centrally I think central allocation is considered as low risk
Incomplete outcome data (attrition bias) All outcomes	Low risk	Auvinen, 2001, BJU International: pg. 3 flow-chart; pg. 4 “imbalance in the numbers of patients between the arms within two hospitals. Not expected to affect the results in any way” “some participants refused to give informed consent, health deterioration,

Auvinen 2004 (Continued)

		not seen by urologist” Auvinen, 2004, BJU International (Primary Study): pg. 2 - flow diagram & results; Base-line data not included
Selective reporting (reporting bias)	Unclear risk	No indication that trial registered in central trials registry. Auvinen, 2001, BJU International: Protocol mentioned pg. 2 “The study protocol was approved by an ethical committee in each participating hospital”; Auvinen, 2004, BJU International (Primary Study): pg. 1 “The study protocol was approved by the institutional review board at each participating hospital”
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	High risk	Auvinen, 2001, BJU International: pg. 3 “recognized carry-over effect because same physician in charge for intervention and control groups, diminish contrast between groups, as these physicians were more motivated to inform patients than those physicians not participating”; Auvinen, 2004, BJU International (Primary Study): No blinding but primary outcome is choice of treatment for prostate, objectively recorded. But unsure how physicians may have influenced decisions
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but primary outcome is choice of treatment for prostate, objectively recorded

Barry 1997

Methods	Randomised to decision aid vs usual care
Participants	104 + 123 patients considering benign prostatic hyperplasia treatment in the USA
Interventions	DA: Health Dialog interactive videodisc on options’ outcomes, clinical problem, outcome probability, others’ opinion COMPARE: usual care using general information on the clinical problem
Outcomes	uptake of option; knowledge*; satisfaction with DM process; satisfaction with decision; interest in DM; general health outcomes; condition specific health outcomes
Notes	*primary outcome

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "Stratified by study site in concealed blocks of 10"
Allocation concealment (selection bias)	Low risk	pg. 2 - study coordinator opening serially numbered, opaque, sealed envelopes
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - patient accrual and follow-up; Reasons for withdrawal mentioned; pg. 4 Base-line characteristics included
Selective reporting (reporting bias)	Unclear risk	No indication that trial registered in central trials registry
Other bias	Low risk	Appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding but phase 1 eliminated risk of contamination
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but phase 1 eliminated risk of outcome assessor interfering with decision

Bekker 2004

Methods	Randomised to detailed vs routine consultation
Participants	59 + 58 pregnant women who have received a maternal serum screening positive test result for Down syndrome in the UK
Interventions	DA: decision analysis plus routine consultation on options' outcomes, clinical problem, outcome probability, values clarification, guidance/coaching COMPARE: routine consultation on options' outcomes, outcome probability
Outcomes	uptake of option; knowledge; decisional conflict; anxiety*; informed decision making; satisfaction with consultation; consultation length
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
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Bekker 2004 (Continued)

Random sequence generation (selection bias)	Unclear risk	Bekker, 2003, Pt Ed & Counseling: pg. 2 - section 2.3 Sample and Procedure “randomly allocated... using previously numbered... envelopes” Bekker, 2004, Prenat Diagn (Primary Study): pg. 3 “Participants were randomly allocated by previously numbered envelopes”; Does not mention how sequence was generated
Allocation concealment (selection bias)	Low risk	Bekker, 2003, Pt Ed & Counseling: pg. 2 - section 2.3 Sample and Procedure “using previously numbered, sealed, opaque envelopes” Bekker, 2004, Prenat Diagn (Primary Study): pg. 3 - previously numbered, sealed, opaque envelopes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Bekker, 2003, Pt Ed & Counseling; Bekker, 2004, Prenat Diagn (Primary Study): pg. 4 - results/flow diagram; Baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	Bekker, 2003, Pt Ed & Counseling: The coding frame was developed from literature. Does not mention protocol Bekker, 2004, Prenat Diagn (Primary Study): no information provided about central trials registry
Other bias	Unclear risk	Bekker, 2003, Pt Ed & Counseling: does not directly address baseline characteristics of participants; Bekker, 2004, Prenat Diagn (Primary Study): appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants blinded, personnel not blinded. Same personnel did control & intervention. Tape recorded sessions to ensure no bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured

Bernstein 1998

Methods	Randomised to decision aid vs usual care
Participants	65 + 53 patients with coronary artery disease considering revascularization surgery in the USA
Interventions	DA: Health Dialog video on options' outcomes, clinical problem, outcome probability, others' opinion COMPARE: usual care (no information provided)
Outcomes	uptake of option, knowledge, satisfaction with care, satisfaction with decision and decision making process*, general health outcomes, condition specific health outcomes
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 "Randomization was stratified by study site in blocks of 10"
Allocation concealment (selection bias)	Low risk	pg. 3 "randomization performed by a study coordinator opening opaque, sealed envelopes at study headquarters"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - flow diagram; Baseline data comparison included.
Selective reporting (reporting bias)	Unclear risk	No information provided indicating trial was included in central trials registry
Other bias	Low risk	Appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Neither subjects nor study staff were blinded to treatment assignment - could lead to different satisfaction ratings based on knowing the treatment received
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured

Berry 2013

Methods	Randomised to decision aid vs usual care
Participants	266 + 228 men considering prostate cancer treatment in the USA
Interventions	DA: interactive web based video on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (list of questions to ask doctor and automated summary) COMPARE: usual care
Outcomes	decisional conflict*, preferred/actual treatment choice (pre and post DA), proportion undecided
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.3 (Methods section- second paragraph) "Participants were randomized automatically by the P3P application to study groups (1:1 using a simple randomization scheme with no blocking")
Allocation concealment (selection bias)	Low risk	pg.3 (Methods section) "Participants were randomized automatically by the P3P application to study groups"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg.4: used ITT analysis and low dropout
Selective reporting (reporting bias)	Low risk	Protocol made available
Other bias	Unclear risk	Was a multicentre trial which could have lead to contamination, protocol violation and biased questionnaire completion
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were not blinded and study does not address the effect on the results
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear whether outcome assessors are blinded, but outcomes are not subject to interpretation

Bjorklund 2012

Methods	Randomised to decision aid vs usual care
Participants	236 + 247 women less than 11 weeks pregnant considering Down syndrome screening in Sweden
Interventions	DA: linear video on options' outcomes, clinical problem, outcome probabilities, others' opinion, and guidance (step by step process for making the decision) COMPARE: usual care using pamphlet
Outcomes	knowledge* (post DA), values congruent with chosen option (post DA), attitude* (post DA), uptake of CUB* (post DA)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 391: "The midwife allocated the participants randomly by sealed envelopes..." but does not state the actual sequence generation method
Allocation concealment (selection bias)	Low risk	pg. 391: used sealed envelopes, "prepared, sequentially coded and distributed to the maternity units by the research group"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of why some participants' data were excluded in Tables 2, 3 and 4
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	Low risk	Appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	p. 395: 'It was not possible to blind neither [sic] the midwives nor the participants due to the characteristics of the intervention.'
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but outcomes were objectively measured and not subjective to interpretation

Chambers 2012

Methods	Randomised to DA vs usual care
Participants	74 + 77 healthcare workers who did not receive the influenza vaccine considering receiving the vaccine in Canada
Interventions	DA: web based DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance COMPARE: usual care using pamphlet
Outcomes	confidence in decision* (post DA), impact on immunization intent (post DA), proportion undecided
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 199 - "The randomization list was generated using the randomization function in Excel 2002 (version 10.6856.6856 SP3)."
Allocation concealment (selection bias)	Low risk	pg. 199 - "The list was imported from Excel into a Microsoft SQL Server database. The online application would sequentially assign a random identification number and their decision aid status (seeing the decision aid or not) from the randomization list when users logged into the survey."
Incomplete outcome data (attrition bias) All outcomes	High risk	65% completion rate in intervention arm and 77% completion rate in control arm: attrition could be different where the respondents and non-respondents are different
Selective reporting (reporting bias)	Low risk	protocol available
Other bias	Unclear risk	Figure 1 numbers for exclusion are not logical
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported whether or not they were blinded during the course of the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	questionnaire scores are objective and not subject to interpretation

Clancy 1988

Methods	Randomised to decision aid vs usual care	
Participants	753 + 263 Health physicians considering Hep B vaccine in the USA	
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification (personal decision analysis), guidance/coaching COMPARE: usual care (no information provided)	
Outcomes	uptake of option*	
Notes	*primary outcome	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - random numbers table; all incoming residents were assigned to Group 2 (non-randomised residents identified as Subgroup)
Allocation concealment (selection bias)	Unclear risk	No information provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 2 "35 physicians excluded because already received vaccine" Flow chart not included. Baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	High risk	pg. 287 - potential selection bias - non-randomised residents were added to group 2 and therefore potential unbalanced distribution; Plus low response rate among those offered decision analysis
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding of participants or personnel. Not clear how this may affect their decision
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but decisions for screening were retrieved from health records

Davison 1997

Methods	Randomised to decision aid + audio-taped consultation vs usual care
Participants	30 + 30 men with prostate cancer considering treatment in Canada
Interventions	DA: written + audiotape consultation of options' outcomes, clinical problem, outcome probability, others' opinion COMPARE: usual care (general information pamphlets on clinical problem)
Outcomes	role in decision making*, anxiety, depression
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 5 - Data Collection "The group to which subjects were assigned was predetermined by a block randomization procedure. This ensured there were an equal number of subjects in both groups for each physician."
Allocation concealment (selection bias)	Unclear risk	Not mentioned; pg. 5 - group assignment predetermined by block randomisation procedure
Incomplete outcome data (attrition bias) All outcomes	Low risk	no flow diagram; pg. 12 explains why certain men did not listen to audiotape. Baseline characteristics included. All men approached by study investigator agreed to participate, only one man refused to complete the second set of questionnaires
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other sources of bias. Similar baseline characteristics,
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding. Unclear how participant's willingness to participate was affected by knowing they received the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding, and whether outcomes could be affected by not blinding the assessor

de Achaval 2012

Methods	Randomised to detailed vs simple vs usual care
Participants	70 + 70 + 71 patients diagnosed with knee OA considering OA treatment in the USA
Interventions	COMPLEX DA: videobooklet + interactive conjoint analysis on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (list of questions) COMPARE DA: videobooklet on options' outcomes, clinical problem, outcome probabilities, others' opinion and guidance (list of questions) COMPARE: usual care receiving generic booklet
Outcomes	decisional conflict* (pre and post DA)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 231: computer generated list with un-even blocks
Allocation concealment (selection bias)	Low risk	pg. 231 (procedure): numbered, sealed and opaque envelopes
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 dropouts; missing data effect size unlikely to have significant impact on study outcome
Selective reporting (reporting bias)	Unclear risk	protocol not available
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg. 231 (procedures): likely not blinded, but low threat to causality in study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg. 231: patients were not blinded but outcome was objectively measured

Deschamps 2004

Methods	Randomised to detailed decision aid vs pharmacist consultation
Participants	67 + 61 women considering hormone replacement therapy in Canada

Deschamps 2004 (Continued)

Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance/coaching (Ottawa Decision Support Framework) COMPARE: 40-minute pharmacist consultation on options' outcomes, outcome probability
Outcomes	preferred option*, decisional conflict*, role in decision making*, satisfaction with preparation for decision making, satisfaction with decision*, adherence*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 4 - flow diagram; pg.3 reasons for attrition mentioned. Baseline characteristics included
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured

Deyo 2000

Methods	Randomised to detailed vs simple decision aid
Participants	190 + 203 adults with herniated disc or spinal stenosis considering back surgery in the USA
Interventions	DA: Health Dialog interactive videodisc on options' outcomes, clinical problem, outcome probability, other's opinions COMPARE: simple DA pamphlet with clinical problem, options outcomes

Deyo 2000 (Continued)

Outcomes	uptake of option*, satisfaction with DM process, satisfaction with care, condition specific health outcomes	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 "computer generated simple randomization sequence"; Phelan - pg. 2 computer generated
Allocation concealment (selection bias)	Low risk	pg. 3 "series of numbered opaque envelopes"; Phelan - pg. 2 - concealed in serially marked, opaque envelopes
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 5 - flow diagram; Reasons for attrition mentioned and participants balanced across study groups. Baseline data not included; Phelan - Flow of participants not included. Baseline characteristics included
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	pg. 4 - There were no significant group differences; appears to be free of other potential biases; Phelan - appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured

Dodin 2001

Methods	Randomised to detailed vs simple decision aid
Participants	52 + 49 women considering hormone replacement therapy in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance/coaching (Ottawa Decision Support Framework)

Dodin 2001 (Continued)

	COMPARE: simple decision aid pamphlet with options' outcomes, clinical problem	
Outcomes	preferred option, knowledge, decisional conflict*, accurate risk perceptions, congruence between values and choice	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 2 - eligible women randomly assigned - no information on how sequence was generated
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline characteristics included. pg. 3 "Toutes les 101 femmes recrutées ont complété l'étude" [all 101 women recruited completed the study]
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Unclear risk	women of 50-59 years and married were significantly more numerous in the experimental group
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg. 2 - a research assistant met the women during a debriefing of 20 minutes in small groups of 4-5 women assigned to the same intervention to avoid inter-group contact, thus ensuring blinding. Not sure if the physicians were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured

Dolan 2002

Methods	Randomised to decision aid vs usual care
Participants	50 + 47 average risk for colorectal cancer considering screening in the USA
Interventions	DA: computer with analytic hierarchy process on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance/coaching COMPARE: usual care with information on options, clinical problem

Dolan 2002 (Continued)

Outcomes	uptake of option*, decisional conflict*, role in decision making	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 (Study Interventions) "randomization schedules were created using a computer random number generator"
Allocation concealment (selection bias)	Low risk	pg. 2 (Study Interventions) - computer-based
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram and description in results
Selective reporting (reporting bias)	Unclear risk	Nothing specifically mentioned re: study protocol
Other bias	Low risk	Appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding of participants. All patient interviews in both the experimental and control groups were done by the same investigator, unclear on how this could contribute to risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Evans 2010

Methods	Randomised to online decision aid vs paper decision aid vs questionnaire vs usual care
Participants	129 + 126 + 127 + 132 men considering PSA screening in Wales
Interventions	DA: online program on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer program; summary) COMPARE: paper version of online DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer program; summary) COMPARE: received a questionnaire COMPARE: received nothing

Outcomes	Knowledge* (post DA), attitude (post DA), intention to undergo PSA testing (post DA), anxiety (post DA), uptake of PSA test (post DA), total decisional conflict
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg.4 (recruitment process): "a random sample of 100 men was selected from the list." "The process ensured individual level randomization"
Allocation concealment (selection bias)	Low risk	pg.4 (recruitment process): "affirmative consent forms from each practice were transferred to the research officer who allocated each participant with a number provided remotely by the trial statistician to ensure concealment"
Incomplete outcome data (attrition bias) All outcomes	Low risk	see Figure 1 for flow diagram and Table 1 for baseline characteristics of participants
Selective reporting (reporting bias)	Low risk	registered as a trial
Other bias	Low risk	the study appears free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	the study does not address this outcome
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were objectively measured and not subjective to interpretation

Fagerlin 2011

Methods	Decision aid vs delayed intervention vs control
Participants	382 + 159 + 100 women with an elevated five year risk of breast cancer considering breast cancer prevention medication in the USA
Interventions	DA: tailored DA on options' outcomes, clinical problem, outcome probabilities, and explicit values clarification COMPARE: given DA after 3-month follow-up COMPARE: given DA after all outcome measures were taken

Fagerlin 2011 (Continued)

Outcomes	decisional conflict (post DA), behavioural intent (post DA), actual behaviour (post DA), proportion undecided, perception of benefits (post DA), perception of risk (post DA)	
Notes	primary outcome was not specified	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	random sequence generation was provided by the author
Allocation concealment (selection bias)	Low risk	central and web-based allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	does not report exclusions
Selective reporting (reporting bias)	Unclear risk	no mention of study protocol
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	unclear blinding - study does not address this outcome
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were objectively measured and not subjective to interpretation

Fraenkel 2007

Methods	Randomised to decision aid vs usual care	
Participants	47 + 40 patients with knee pain considering treatment options in the USA	
Interventions	DA: interactive computer tool options' outcomes, outcome probability, explicit values clarification COMPARE: usual care using the Arthritis Foundation information pamphlet	
Outcomes	Decisional self-efficacy, preparation for decision making	
Notes	primary outcome was not specified	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Fraenkel 2007 (Continued)

Random sequence generation (selection bias)	Low risk	pg. 2 - computer-generated randomisation sequence
Allocation concealment (selection bias)	Unclear risk	no information provided; computer generated
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - results; baseline characteristics included and balanced
Selective reporting (reporting bias)	Unclear risk	no information provided; no indication of trial was registered centrally
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding but unclear if it has impact on the outcomes measured
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Frosch 2008

Methods	Randomised to decision aid vs. decision aid + chronic disease trajectory vs chronic disease trajectory vs usual care (Internet information)	
Participants	155 + 152 + 153 + 151 men considering prostate cancer screening	
Interventions	DA: information on options' outcomes, clinical problem, outcome probabilities, others' opinions COMPARE: information on options' outcomes, clinical problem, outcome probabilities, others' opinions, explicit values clarification (utilities for outcomes associated with prostate cancer) COMPARE: explicit values clarification (utilities for outcomes associated with prostate cancer) COMPARE: usual care using public information on prostate cancer screening on American Cancer Society and Centers for Disease Control and Prevention websites 2005-2006	
Outcomes	knowledge*, actual option*, decisional conflict*, concern about prostate cancer, treatment preference if prostate cancer diagnosed	
Notes	*primary outcome	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Frosch 2008 (Continued)

Random sequence generation (selection bias)	Low risk	computer algorithm randomly assigned participants to the 4 study groups
Allocation concealment (selection bias)	Low risk	revealed after signed consent and completed baseline measures
Incomplete outcome data (attrition bias) All outcomes	Low risk	used intention to treat analysis; imputed missing data for participants who did not complete follow-up assessments
Selective reporting (reporting bias)	Unclear risk	no indication of published protocol
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	accessed a secure Internet site that hosted all study materials; participants had unlimited access to assigned intervention, unclear blinding of personnel
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were measured via questionnaires and not subjective to interpretation

Gattellari 2003

Methods	Randomised to decision aid vs usual care
Participants	126 + 122 men considering PSA testing in Australia
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification COMPARE: usual care using brief information on screening test and chances of false-positive results
Outcomes	preferred option, knowledge, decisional conflict, accurate risk perceptions, perceived ability to make an informed choice
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 1 - pre-randomised code - no further information

Gattellari 2003 (Continued)

Allocation concealment (selection bias)	Low risk	pg. 1 - pre-randomised code unobtrusively marked on envelopes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pre-test characteristics included. Flow chart not included and reasons for attrition not mentioned
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	consenting men were blinded to allocation, but unclear if personnel were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were objectively measured and not subjective to interpretation

Gattellari 2005

Methods	Randomised to decision aid booklet vs decision aid video vs usual care	
Participants	140 + 141 + 140 men considering PSA testing in Australia	
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification COMPARE: video on clinical problem, outcome probability, others' opinion COMPARE: usual care using brief information on screening test and chances of false-positive results	
Outcomes	preferred option, knowledge, decisional conflict, perceived ability to make an informed choice	
Notes	primary outcome was not specified	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - 2.3.1. Unique identification codes assigned to participants according to date and time enrolled into the interventional component of the study. Block randomisation of identification codes then performed via computer software

Gattellari 2005 (Continued)

Allocation concealment (selection bias)	Low risk	pg. 2 - 2.3.1. "Allocation concealment was ensured as the interviewers, responsible for enrolling participants onto the trial, were blinded to the randomised study design while one of the authors (MG) was responsible for randomisation. Hence, it was not possible for either participants or interviewers to be aware of the randomisation sequence."
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 5 (172) "interviews terminated, call times exhausted, one man with prostate cancer accidentally included, but data is excluded from results" pg. 7 baseline characteristics equally distributed; pg. 6 fig. 1 - flow diagram
Selective reporting (reporting bias)	Unclear risk	pg.13 (180)par. 5 "success of study protocol" "limitation to protocol: men not confronted with actual decision to undergo PSA screening; No indication that trial registered in central trials registry
Other bias	Low risk	pg. 13 (180) par. 5 "high follow-up rate and allocation concealment; study not subjected to selection bias" Appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants & interviewers were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	At post-test, it was not possible to blind the interviewers but outcomes were objectively measured and not subjective to interpretation

Goel 2001

Methods	Randomised to detailed vs simple decision aid Cluster randomised trial
Participants	86 + 50 women considering surgery for breast cancer (cluster RCT with 57 surgeons randomised) in Canada
Interventions	DA: audiotape + booklet on options' outcomes, clinical problem, outcome probability, values clarification, other's opinions, coaching/guidance (Ottawa Decision Support Framework)

Goel 2001 (Continued)

	COMPARE: simple DA pamphlet with clinical problem, options outcomes	
Outcomes	knowledge, decisional conflict*, decisional regret, anxiety	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "blocks of 8 based on a random number generator"
Allocation concealment (selection bias)	Unclear risk	pg. 2 - Prerandomisation was done to eliminate opportunities to select into the study intervention arm. The allocation was not revealed to the surgeon until after agreement to participate in the study was obtained
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - Baseline characteristics included. pg. 3 - results
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg. 2 - unclear on whether participants were blinded. The allocation was not revealed to the surgeon until after agreement to participate in the study was obtained
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were objectively measured and not subjective to interpretation

Green 2001a

Methods	Randomised to decision aid + counselling vs counselling alone vs usual care
Participants	29 + 14 women with a first degree relative with breast cancer interested in learning about genetic testing in the USA
Interventions	DA: CD-ROM plus counselling on options' outcomes, clinical problem, others' opinions, guidance/coaching COMPARE: counselling COMPARE: usual care

Green 2001a (Continued)

Outcomes	knowledge, preferred options*	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "block randomization schedule to one of 3 groups in a 2:2:1 ratio"
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 5 table "Values do not always add up to the number of participants due to missing data" Reasons not mentioned. pg. 4 "Participants' baseline knowledge was reflected in the control group's answers" Participants balanced in study groups
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg. 2 "genetic counsellor blinded to randomization until just prior to the session", unclear if participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were objectively measured and not subjective to interpretation

Green 2004

Methods	Randomised to detailed decision aid + genetic counselling vs routine genetic counselling
Participants	106 + 105 women with first degree relative with breast cancer considering genetic testing in the USA
Interventions	DA: CD-ROM plus counselling on options' outcomes, clinical problem, others' opinions, guidance/coaching COMPARE: genetic counselling
Outcomes	preferred option, knowledge*, decisional conflict, satisfaction with decision, anxiety, counsellor/participant rating of effectiveness of counselling session, consultation length
Notes	*primary outcome

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Green, 2004, JAMA (Primary Study):pg. 2 - used separate computer generated randomisation lists for low-risk and high-risk individuals at each study site; Green, 2005, Genet Med: no information provided
Allocation concealment (selection bias)	Unclear risk	Green, 2004, JAMA (Primary Study): no information provided; Green, 2005, Genet Med: no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Green, 2004, JAMA (Primary Study):pg. 4 figure; flow chart. Reasons for attrition/loss to follow-up not included. p.5 Baseline characteristics included; Green, 2005, Genet Med:pg. 4 - flow diagram; reasons for attrition mentioned and participants balanced in study groups. Baseline characteristics included
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Green, 2004, JAMA (Primary Study): appears to be free of other potential biases; Green, 2005, Genet Med: appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Green, 2005, Genet Med: pg. 8 - this was not a blinded study "counselor's responses may have been biased" but primary outcome was objective, so it is unlikely to introduce bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Hamann 2006

Methods	Cluster randomised trial of decision aid vs usual care
Participants	54 + 59 patients with schizophrenia considering treatment options (cluster RCT with 12 wards paired and randomised) in Germany
Interventions	DA: 16-page booklet on options' outcomes, outcome probabilities, explicit values clarification, coaching/guidance COMPARE: usual care
Outcomes	knowledge, participation in decision making (COMRADE - doctor gave me a chance to decided which treatment I thought was best for me), uptake of psycho education, rehospitalization, adherence, satisfaction with care, severity of illness (baseline only), attitudes about drug use, decision making preference
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p266 "one member of each pair being randomly assigned to the control or to the interventional condition." Sequence generation method was not stated
Allocation concealment (selection bias)	Unclear risk	no mention of allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Low risk	reasons for attrition mentioned
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	High risk	clustering was not accounted for in the analysis
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	no information provided

Hanson 2011

Methods	Randomised to decision aid vs usual care
Participants	127 + 129 patients diagnosed with advanced dementia and eating problems considering long term feeding tube placement in the USA
Interventions	DA: booklet or audio recording on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (steps in decision making, worksheet, summary) COMPARE: usual care
Outcomes	surrogate knowledge, risk perceptions, decisional conflict* (3 months post DA), frequency of communication with providers (3 months post DA), feeding treatment use (3, 6 and 9 months post DA), participation in decision making, satisfaction with the decision, decisional regret
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.2010 (randomization): computerized random number generation
Allocation concealment (selection bias)	Unclear risk	pg.2010 (randomization): no description of method used to conceal allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	table 3: intervention group missing data for 1 participant, reason for omission not reported table 4: no explanation for number of participants in each group (127) given- numbers vary from those in 'recruitment and retention' figure
Selective reporting (reporting bias)	Low risk	registered with clinicaltrials.gov, protocol on website
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg.2014 (discussion) "Cluster randomization prevented double blinding and may have introduced bias due to site effects", study authors unsure of effect on study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg.2010 (randomization) "because of cluster randomization, data collectors were not blinded to group assignment", authors be-

	lieve has little impact on study
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Heller 2008

Methods	Randomised to decision aid vs usual care
Participants	66 + 67 breast cancer patients eligible for breast reconstruction in the USA
Interventions	DA: interactive software program on options' outcomes, others' opinions COMPARE: standard patient education
Outcomes	knowledge, anxiety, satisfaction with treatment choice, satisfaction with decision making ability
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - "upon study entry, the participants were randomized (computer generated) to one of two groups"
Allocation concealment (selection bias)	Unclear risk	not enough information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline anxiety and knowledge included in graphs. pg. 3 Participant numbers between study groups balanced. Reasons for incomplete questionnaires and study withdrawals mentioned
Selective reporting (reporting bias)	Unclear risk	no information provided re: protocol
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	no information provided

Hess 2012

Methods	Randomised to decision aid vs usual care
Participants	103 + 105 patients in the the emergency department with primary symptoms of nontraumatic chest pain and were being considered of admission to the emergency department observation unit for monitoring and cardiac stress testing within 24 hours
Interventions	DA: one page printout on options' outcomes, clinical problem, and outcome probabilities COMPARE: usual care
Outcomes	knowledge*, risk perceptions, decisional conflict, actual choice, satisfaction with decision making process, patient-practitioner communication
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg 253 - "Patients were randomized to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion"
Allocation concealment (selection bias)	Low risk	pg 253 - "Patients were randomized to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Some of the numbers of patients reported in the results did not match the flow chart
Selective reporting (reporting bias)	Low risk	Protocol is available
Other bias	Low risk	appears to be free of other biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg 253. outcome measures. Personnel were blinded, but unclear if patients were blinded. However, the primary outcome is unlikely to be biased
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg 253. outcome measures. Investigators assessing outcomes were blinded.

Hunter 2005

Methods	Randomised to decision aid with option to speak to genetic counsellor vs individual genetic counselling vs group counselling
Participants	116 + 126 + 110 women of advanced maternal age considering prenatal diagnostic testing in Canada
Interventions	DA: audiotape workbook on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance/coaching (Ottawa Decision Support Framework) COMPARE: individual counselling session on options' outcomes, outcome probability, values clarification COMPARE: group counselling session on options' outcomes, outcome probability, others' opinions
Outcomes	uptake of option, knowledge*, decisional conflict*, satisfaction with decision making process*, anxiety*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 4 - randomised in blocks of 30, 10 to each intervention group
Allocation concealment (selection bias)	Low risk	pg. 4 - "the allocations were provided in opaque envelopes"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	outcomes reported on fewer participants but no rationale provided for missing data
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were objectively measured and not subjective to interpretation

Jibaja-Weiss 2011

Methods	Randomised to decision aid vs usual care
Participants	51 + 49 women diagnosed with breast cancer considering surgical treatment in the USA
Interventions	DA: computer program on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step by step process for making the decision) COMPARE: usual care + breast cancer treatment educational materials normally provided to patients
Outcomes	surgical treatment preference (post DA), breast cancer knowledge (pre, post DA, post DA and consult), satisfaction with surgical decision (post DA), satisfaction with decision making process (post DA), decisional conflict (pre, post DA, post DA and consult), proportional undecided
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.42 (Methods section): "Patients at each hospital were randomized using permuted blocks"
Allocation concealment (selection bias)	Unclear risk	not addressed in the study
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	there is no way to know if the plots are including all of the participants' data since they do not specify what was the number of patients used to obtain these mean scores
Selective reporting (reporting bias)	Unclear risk	no mention of protocol
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	not addressed in the study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were objectively measured and not subjective to interpretation

Johnson 2006

Methods	Randomised to decision aid vs usual care
Participants	32 + 35 patients considering endodontic treatment options in the USA
Interventions	DA: decision board on options' outcomes, clinical problem, outcome probability, guidance COMPARE: usual care
Outcomes	knowledge*, satisfaction with decision making process*, anxiety*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p.3 "four computerized random generation lists to assign to one of two groups"
Allocation concealment (selection bias)	Unclear risk	NO for residents: pg. 3 - 4 computer-generated randomisation lists (1 for each resident) were prepared by the PI; therefore residents would have had pre-generated lists; but UNCLEAR for patients p.3 "Allocation was concealed from patients" but does not explained how
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 6 fig. 3 - flow diagram; pg. 5 - all 40 patients agreed to participate in the study, but only 32 questionnaires were useable several residents did not understand need for entering data on the envelope and placing matched questionnaire in it
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Unclear risk	p.5 "baseline data obtained because possible that clinicians training in the EndoDB would alter usual care discussions" Mentions taking baseline characteristics, but not included in article
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not mentioned. pg. 3 - allocation was concealed from patients only

Johnson 2006 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
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Kasper 2008

Methods	Randomised to decision aid vs usual care
Participants	150 + 147 multiple sclerosis patients considering immunotherapy in Germany
Interventions	DA: booklet and worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification (based on IPDAS) COMPARE: information material on immunotherapy (80 pages)
Outcomes	role in decision making*, choice, feeling undecided, helpfulness with making a decision, attitudes toward immunotherapy, expectations of side effects realized at 6 months
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - "allocation using computer generated random numbers"
Allocation concealment (selection bias)	Unclear risk	pg. 2 - Assignment - randomisation was carried out by concealed allocation, but method of concealment was not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 2 - Fig 1 flow of participants; baseline data/characteristics included
Selective reporting (reporting bias)	Low risk	pg. 2 "The protocol of this study has been published with the trial registration at http://controlled-trials.com/ISRCTN25267500 "
Other bias	Unclear risk	pg. 5 - difference in preferred interaction style between groups at baseline (P value 0.04)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg. 3 - Masking - Participants were not told whether the information they received was standard information or the newly developed DA

Kasper 2008 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg. 3 - Masking - assessors were not told whether the information they received was standard information or the newly developed DA
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Kennedy 2002

Methods	Randomised to decision aid + coaching vs decision aid only vs usual care	
Participants	215 + 206 + 204 women considering treatment for menorrhagia in the UK	
Interventions	DA: video + booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance/coaching COACHING: ~20 minute coaching with explicit values clarification by a registered nurse prior to see physician COMPARE: usual care	
Outcomes	uptake of option, satisfaction, general quality of life*, menorrhagia severity, cost effectiveness	
Notes	*primary outcome	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 - allocation sequence was generated by computer and stratified by consultant and the age at which the woman left full-time education
Allocation concealment (selection bias)	Low risk	pg. 3 "Secure randomization ensured by using a central telephone randomization system"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 4-5 - see Table 1 and Figure 1 flow diagram.
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free from other risks of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg. 6 possibility of contamination bias, clinicians could have applied the experience gained from consultations with the interventions groups in their consultations with the control group

Kennedy 2002 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear if blinding used but most outcomes were objectively measured and not subjective to interpretation
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Krist 2007

Methods	Randomised to decision aid booklet vs decision aid web-based vs usual care
Participants	196 + 226 + 75 patients considering prostate cancer screening in the USA
Interventions	DA: 4 page pamphlet with options' outcomes, clinical problem, outcome probability COMPARE: web-site with same information as paper based DA COMPARE: usual care
Outcomes	role in decision making*, knowledge, decisional conflict, time spent discussing screening, choice (PSA test ordered)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "coordinator referred to pre-generated randomisation tables to inform the participant to which arm he was randomised"
Allocation concealment (selection bias)	Low risk	pg. 2 - At the time of enrolment, the allocation was concealed from the coordinator
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - results; pg. 4 - flow diagram
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Unclear risk	uneven groups but done intentionally, ration of 1:3:3 but appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	High risk	physicians were not blinded - could affect decision making process and uptake of screening
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Kuppermann 2009

Methods	Randomised to decision aid vs simple decision aid
Participants	244 + 252 pregnant women considering prenatal testing in the USA
Interventions	DA: computerized tool on options' outcomes, clinical problem, outcome probability, explicit values clarification COMPARE: education booklet on the computer on options' outcomes, clinical problem
Outcomes	knowledge*, decisional conflict*, accurate risk perception* (procedure related miscarriage, DS affected fetus), decision regret, satisfaction with the intervention*, satisfaction with involvement in decision making
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided
Allocation concealment (selection bias)	Low risk	pg. 3 - Materials and Methods - interviewer opened an opaque envelope containing the randomisation assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - Fig 1 flow diagram
Selective reporting (reporting bias)	Low risk	pg. 1 - Abstract CLINICAL TRIAL REGISTRATION: Clinicaltrials.gov, www.clinicaltrials.gov, NCT00686062
Other bias	Unclear risk	appears to be free of other potential biases p.10 "The effect of these potential selection biases not determined"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Labrecque 2010

Methods	Randomised to decision aid vs simple decision aid
Participants	32 + 31 men considering vasectomy as an option for contraception in Quebec, Canada
Interventions	DA: booklet on options outcomes, clinical problem, outcome probability, explicit values clarification, guidance (step by step process for making the decision; one or more questions that asked patients to clarify their preferences; encourages patients to communicate with their practitioners) COMPARE: booklet on options outcomes, clinical problem, outcome probability
Outcomes	knowledge (pre and post DA), decisional conflict* (pre and post DA), preferred option (pre and post DA), proportion undecided
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 557 (section 2.1): "computer-generated list"
Allocation concealment (selection bias)	Low risk	pg. 557 (section 2.1): "Randomization was stratified according to method of recruitment" "Each participant received either the full or the abridged PtDA inside an opaque, sealed, unmarked envelope"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg.559 (Fig 1 flow diagram): p.560 Table 2 results
Selective reporting (reporting bias)	Unclear risk	no mention of examination of selective outcome reporting or study protocol
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg. 557 (section 2.1): single-blinded- "researcher in charge of recruitment remained blind to the participants' group assignment". Participants were given an intervention but not aware of the alternative intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg.558 (section 2.4): "researcher blinded to the participant's group allocation when conducting the interviews", outcomes were objectively measured

Lalonde 2006

Methods	Randomised to decision aid + pharmacist consultation vs simple decision aid + pharmacist consultation
Participants	13 + 13 patients considering lifestyle changes and drug therapy to improve cardiovascular health in Canada
Interventions	DA: booklet and worksheet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinion, guidance/coaching (Ottawa Decision Support Framework) COMPARE: personal risk profile with clinical problem, outcome probabilities
Outcomes	knowledge, risk perception, decisional conflict, satisfaction with decision making process
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p. 2 "research nurse randomly assigned participant" "stratified by community pharmacy" Does not indicate how randomisation occurred
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	p. 4 does not indicate why participants did not complete post-intervention interview and post follow-up interview. Pre-intervention characteristics included on p. 6 in paragraphs
Selective reporting (reporting bias)	Unclear risk	protocol not mentioned
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	unclear blinding, interviews used open-ended question, do not know whether this contributes to risk of bias

Langston 2010

Methods	Randomised to decision aid + coaching vs. usual care
Participants	114 + 108 women pregnant women in their first trimester considering use of contraceptives in the USA
Interventions	DA: double-sided flip chart on clinical problem, outcome probabilities, guidance (administered by a research assistant), coaching (structured, standardized, non-directive contraceptive counselling) + usual care COMPARE: usual care
Outcomes	proportion of participants choosing very effective contraceptive method* (post DA and consult), actual choice on day of procedure (post DA and consult), adherence of very effective and/or effective methods at 3 months and at 6 months (post DA and consult)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.363 (Methods-study procedures): "Using a random-number table, we determined the sequence for 1:1 allocation constrained by blocks of 10"
Allocation concealment (selection bias)	Low risk	pg.363 (Methods-study procedures): "Randomization assignments were sealed inside numbered, opaque envelopes"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	for "method initiation on the day of the procedure" it is only said that the "Participants in the intervention group were not more likely to initiate the requested method immediately compared to those in the usual care group"; possible that the results contradicted the hypothesis and were excluded for this reason
Selective reporting (reporting bias)	Unclear risk	no mention of study protocol; not enough information to permit judgement
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg.363 (Methods-study procedures): "No blinding of participants or coordinators was feasible due to the nature of the intervention. Physician-providers did not know the participant's allocation group, did not discuss the study with patients, and were

Langston 2010 (Continued)

		asked not to change their counselling”
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Laupacis 2006

Methods	Randomised to decision aid vs usual care	
Participants	60 + 60 patients undergoing elective open heart surgery considering pre-operative autologous blood donation in Canada	
Interventions	DA: audiotape booklet on options’ outcomes, clinical problem, outcome probability, explicit values clarification, guidance (Ottawa Decision Support Framework) COMPARE: usual care	
Outcomes	uptake of option, knowledge*, decisional conflict*, satisfaction with decision making process, satisfaction with decision, accurate risk perceptions	
Notes	*primary outcome	

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 “Randomization envelopes were prepared centrally by a statistician”
Allocation concealment (selection bias)	Low risk	pg. 2 “The envelopes were labeled with identification numbers and contained a card specifying the patient’s group assignment. The envelopes were opened by the interviewer after completion of the baseline interview.”
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 4 results, fig 1 flow diagram
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	no information provided

Laupacis 2006 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding but outcomes were objectively measured and not subjective to interpretation
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Legare 2003

Methods	Cluster randomised to decision aid vs simple decision aid
Participants	97 + 87 post-menopausal women considering hormone replacement therapy (Cluster RCT with 40 family physicians randomised) in Canada
Interventions	DA: audiotape, booklet and worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) COMPARE: general information pamphlet on risks, benefits and side-effects of HRT
Outcomes	decisional conflict, satisfaction with decision making process, agreement between physicians' and patients' decisional conflict
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg.5 fig 1 flow chart. Reasons for attrition not mentioned. pg.6 Demographic characteristics included
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Legare 2008a

Methods	Randomised to decision aid vs usual care
Participants	45 + 45 women considering use of natural health products for managing menopausal symptoms
Interventions	DA: booklet with worksheet on options' outcomes, clinical problem, explicit values clarification, guidance/coaching (Ottawa Decision Support Framework) COMPARE: general information brochure on the clinical problem (did not address risks and benefits)
Outcomes	knowledge of natural health products in general (not specific option outcomes), preferred choice, decisional conflict*, values-choice agreement, proportion undecided
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomisation schema was carried out by a biostatistician using computer-generated unequal blocks
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes containing one or the other documents (a PDA in the intervention group and a general information brochure in the control group) were prepared by another individual, external to the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	See Figure 1 for flow diagram, reason for lost to follow up was described
Selective reporting (reporting bias)	Low risk	trial registration identifier is NCT00325923
Other bias	Low risk	There was no statistically significant difference in women's characteristics between groups (Table 1)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The investigators were blinded but no mention of blinding of participants
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Legare 2011

Methods	randomised to decision aid vs usual care
Participants	245 + 214 patients with non-emergent acute respiratory infections considering using antibiotics in Canada
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance and coaching COMPARE: delayed intervention
Outcomes	Patient Outcomes: actual choice* (pre and post DA), perceived decision quality* (pre and post DA), decisional conflict* (pre and post DA), intention to engage in future SDM (pre and post DA), decision regret* (pre and post DA), participation in decision making, general health outcomes* Practitioner Outcomes: decision*, perceived decision quality*, decisional conflict*, intention to engage in future SDM and comply with clinical practice guidelines
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 99 : "A biostatistician simultaneously randomised all FMGs and allocated them to groups using Internet-based software."
Allocation concealment (selection bias)	Low risk	pg. 99 : "using Internet-based software."
Incomplete outcome data (attrition bias) All outcomes	Low risk	there appears to be no missing data
Selective reporting (reporting bias)	Low risk	no missing pre-specified outcomes
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	unclear blinding of participants and personnel; pg.99: only biostatistician was blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg. 99: biostatistician who assesses the outcomes is blinded, outcomes were objectively measured

Leighl 2011

Methods	Randomised to DA + usual care vs usual care
Participants	107 + 100 patients diagnosed with metastatic CRC considering advanced chemotherapy in Australia and Canada
Interventions	DA: booklet and audiotape on option' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance (steps in decision making + worksheet) COMPARE: usual care
Outcomes	anxiety (pre and post DA), knowledge* (post DA), satisfaction with consultation (post DA), choice leaning (post DA), decisional conflict (post DA). achievement of their information preference (post DA), participation in decision making (post DA), acceptability (post DA), satisfaction with decision* (post DA), quality of life (post DA)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2078 (study design): computer generated randomised lists
Allocation concealment (selection bias)	Low risk	pg. 2078 (study design): code concealed in sealed envelopes until time of random assignment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	31% drop out, but similar losses across all groups
Selective reporting (reporting bias)	Unclear risk	protocol not available
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	patients not blinded and subjective outcomes may be affected by them knowing their assignment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	all outcomes are not subjected to interpretation

Lerman 1997

Methods	Randomised to decision aid vs waiting list control
Participants	122 + 114 + 164 women considering BRCA1 gene testing in the USA
Interventions	DA: education and counselling on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance/coaching COMPARE: no intervention
Outcomes	preferred option*, knowledge, accurate risk perceptions, perceived personal risk / benefits / limitations, agreement between values and choice
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 2 - of these 440 women, 400 completed 1-month follow-up interviews; no reasons provided; Baseline data/characteristics included
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Leung 2004

Methods	Randomised to decision aid vs simple decision aid
Participants	100 + 101 women considering prenatal diagnostic testing in China
Interventions	DA: interactive multimedia decision aid on options' outcomes, clinical problem, outcome probability, guidance COMPARE: video and leaflet on options' outcomes, clinical problem, outcome proba-

Leung 2004 (Continued)

	bility	
Outcomes	Preferred option, proportion remaining undecided, uptake of option*	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "women randomised at a 1:1 ratio." "Allocation was made by a nurse specialist opening consecutive, sealed opaque envelopes"
Allocation concealment (selection bias)	Low risk	pg. 2 "Allocation was made by a nurse specialist opening consecutive, sealed opaque envelopes"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 2 Baseline demographic data collected. pg. 3 Acknowledges non-compliant woman
Selective reporting (reporting bias)	Unclear risk	no mention of protocol
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Lewis 2010

Methods	Randomised to decision aid vs usual care
Participants	211 + 232 patients considering CRC screening in the USA
Interventions	DA: web-based, DVD and VHS videotape formats + stage targeted brochures (and booster kit if patients had not been screened) on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (encouraged patients to communicate with their practitioners by asking questions and sharing preferences; summary) COMPARE: usual care using Aetna annual reminders to obtain CRC screening

Outcomes	<p>knowledge of the age at which screening should begin (post DA), completion of colorectal cancer screening (pre, post DA), intrusive thoughts (pre, post DA), interest in CRC screening (pre, post DA), intent to ask provider about screening (pre, post DA), readiness to be screened (pre, post DA), perceived risk of colon cancer (pre, post DA), general beliefs about colon cancer (pre, post DA), fears about colorectal cancer screening (pre, post DA), perceptions about whether participants had enough information (post DA), whether participants had enough information about specific screening tests (post DA), willingness to pay for screening tests (post), desire to participate in medical decision (post)</p> <p>Practice level measures: assess CRC screening practices (pre, post DA), referrals (pre, post DA), quality improvement initiatives</p>	
Notes	primary outcome was not specified	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 (Practice recruitment and randomisation section): "Randomisation was done using matched pairs and a blocking procedure."
Allocation concealment (selection bias)	Unclear risk	pg. 3 (Practice recruitment and randomisation section): "Thus, purposive assignment to treatment group was used, resulting in a hybrid randomisation" There is no mention of the effect of this purposive assignment on the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appears to be no missing outcome data
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	High risk	unadjusted cluster analysis
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	As mentioned above, staff used purposive assignment and were therefore not blinded, but there is no mention of the effect on the study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The study did not address this outcome, but outcomes were objectively measured

Loh 2007

Methods	Cluster randomised to decision aid vs usual care
Participants	263 + 142 patients with physician diagnosed depression (cluster RCT with 30 general practitioners randomised) in Germany
Interventions	DA: decision board on options' outcomes, clinical problem, explicit values clarification, guidance/coaching COMPARE: usual care
Outcomes	participation in decision making, adherence, satisfaction with clinical care, depression severity, consultation length
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 "two-thirds of the general practitioners were randomly assigned to the intervention group by drawing blinded lots under the supervision of the principal investigator and two researchers"
Allocation concealment (selection bias)	Low risk	pg. 3 - 2.1 drawing blinded lots
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	'pg.5 fig p.3 "Further results resting on the baseline phase of this trial were already presented elsewhere" p. 3 "Unequal distribution of physicians was due to possibility of higher dropout rate in intervention group because of additional time and effort"
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	appears to be free of other potential biases - pg. 5 & 6 details pt and physician baseline characteristics. Stat sig differences were controlled for in outcome analyses
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding, not enough information provided to assess whether this contributes to bias on outcomes not measured by using a scale (e.g. consultation time was doc-

		umented in minutes by the physicians following each consultation)
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Man-Son-Hing 1999

Methods	Randomised to decision aid vs usual care
Participants	139 + 148 patients on atrial fibrillation trial considering continuing on aspirin vs change to Warfarin in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) COMPARE: usual care
Outcomes	uptake of options*, help with making a decision, knowledge, accurate risk perceptions, decisional conflict, satisfaction with decision making process, role in decision making, adherence*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - computer-generated scheme
Allocation concealment (selection bias)	Low risk	pg. 2 - administered from a central location
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 4 fig 2 flow chart. Reasons for attrition not mentioned. Baseline data not included
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	no other potential risks of bias
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear blinding however, pg. 7 "contamination, physicians may have provided DA information to patients receiving usual care"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Mann D 2010

Methods	Randomised to decision aid vs usual care
Participants	80 + 70 participants diagnosed with diabetes considering the use of statins to reduce coronary risk
Interventions	DA: healthcare provider led discussion using developed tool (Statin Choice) on options' outcomes, outcome probabilities, guidance (step by step process for making the decision; administered by the physician in the consultation) COMPARE: usual primary care visit + pamphlet
Outcomes	knowledge (post consult and DA), decisional conflict (post consult and DA), risk estimation (post consult and DA), beliefs (post consult and DA), adherence (3 and 6 months post consult and DA)
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p.138 (methods section) told that participants were randomised but there is no mention of method used
Allocation concealment (selection bias)	Unclear risk	not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline data was provided
Selective reporting (reporting bias)	Unclear risk	only reports on improvement (i.e. decisional conflict scale); does not present outcome data to fullest (no numerical data on knowledge results between groups, only describes in words)
Other bias	Unclear risk	p.139 (Analysis section): "We did not adjust the clustering of effects given that few participants received care by the same clinicians." No mention of magnitude in change of data due to this choice
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were not subjective to interpretation

Mann E 2010

Methods	Randomised to decision aid vs usual care
Participants	278 + 139 participants considering diabetes screening in the UK
Interventions	DA: screening invitation on clinical problem, outcome probabilities and explicit values clarification COMPARE: usual care using screening invitation on clinical problem
Outcomes	preferred option* (post DA), whether invitation type impacts on intention (post DA), impact on knowledge (post DA), impact on attitude (post DA), risk perception
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 2-3 (Methods- Participants section): "Invitation taken from the top of a randomly ordered pile (either standard or one of two versions of an informed decision choice invitation). The materials were ordered in a way that the invitation type was hidden until the recruitment process was completed" Unclear how invitation type was hidden
Allocation concealment (selection bias)	Low risk	pg. 2-3 (Methods- Participants section): invitation taken from the top of a randomly ordered pile; materials were ordered in a way that the invitation type was hidden until the recruitment process was completed
Incomplete outcome data (attrition bias) All outcomes	Low risk	no missing outcome data
Selective reporting (reporting bias)	Unclear risk	no mention of protocol; insufficient information to permit judgment
Other bias	Unclear risk	pg.6 (Discussion section [end of page]): "present sample was [...] not necessarily representative of the highest risk individuals in this age group"; "£5 incentive might have also added a selection bias"; "Lack of anonymity with verbally delivered questionnaire might encourage socially desirable responding"

Mann E 2010 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg.3 (methods, participants section): interviewers were not aware of the direction of anticipated effect of materials, and materials were dummy-coded so that no sense of intervention or control would have been communicated to interviewers or participants
Blinding of outcome assessment (detection bias) All outcomes	Low risk	study did not address this outcome, but outcomes were objectively measured and not subject to interpretation

Marteau 2010

Methods	randomised to decision aid vs usual care
Participants	633 + 639 patients considering diabetes screening in England
Interventions	DA: screening invitation on clinical problem, outcome probabilities and explicit values clarification COMPARE: usual care using screening invitation on clinical problem
Outcomes	attendance for screening* (post DA and consult), intention to make changes to lifestyle (post DA and consult), satisfaction with decisions made among attenders (post DA and consult)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.2 (randomisation section): "generated simultaneously in a batch by random numbers using Excel spreadsheet software, stratifying by number of participants in household"
Allocation concealment (selection bias)	Low risk	pg.2 (randomisation section): "Randomisation [...] was undertaken by the study statistician from a central site"
Incomplete outcome data (attrition bias) All outcomes	Low risk	no missing outcome data
Selective reporting (reporting bias)	Low risk	pg.2 (methods section): they published a protocol
Other bias	Low risk	the study appears free of other potential biases

Marteau 2010 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg.2 (randomisation section): personnel were blinded and appears that patients were unaware which arm they were in (members of the same household received the same intervention)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg.2 (randomisation section): clinical and trial staff taking measurements and entering data were unaware of the study arm to which participants had been assigned

Mathieu 2007

Methods	Randomised to decision aid versus usual care
Participants	367+367 women aged 70 to 71 years and considering a subsequent screening mammography in Australia
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance with worksheet (Ottawa Decision Support Framework) COMPARE: BreastScreen NSW brochure - includes information for women 70+ but no numeric information about the outcomes of screening
Outcomes	knowledge (includes 5 questions about risk perceptions), anxiety, decisional conflict, breast cancer worry, preference/intension, actual decision*, informed choice*, attitudes about screening, relationship between objective and perceived risk of breast cancer
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - Methods - computer program, which assigned allocations in accordance with a simple randomisation schedule
Allocation concealment (selection bias)	Low risk	'pg. 2 - Methods - randomised by interview staff who accessed a previously concealed computer program
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 2 - fig 1 flow diagram
Selective reporting (reporting bias)	Low risk	pg. 5 "The trial was registered with the Australian Clinical Trials Registry and the Clin-

Mathieu 2007 (Continued)

		ical Trials Registration System”
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	interviewers [at follow-up] were blinded, outcomes were objectively measured and not subjective to to interpretation

Mathieu 2010

Methods	Randomised to decision aid vs usual care
Participants	189 + 223 women considering mammography screening
Interventions	DA: Internet program + worksheet on options’ outcomes, clinical problem, outcome probabilities, explicit values clarification, others’ opinions, guidance (worksheet with questions relevant to decision making process; one or more questions that asked patients to clarify their preferences; summary) COMPARE: delayed intervention
Outcomes	knowledge* (post DA), intention (post DA), values (post DA), informed choice (post DA), risk perception*, proportion undecided
Notes	*primary outcome

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 66 (randomization and baseline questions section): “computer generated simple randomization schedule”
Allocation concealment (selection bias)	Unclear risk	pg. 66 “randomization was conducted in a concealed manner.” The method of allocation concealment was not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg.68 (Table 2) all outcomes mentioned in outcome measures section were reported in the results section (information for intention as well as anxiety and acceptability can be found in text format in the secondary outcomes section on pg.67-68)

Mathieu 2010 (Continued)

Selective reporting (reporting bias)	Unclear risk	no mention of protocol
Other bias	Low risk	appears to be free of other potential sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were not subjective to interpretation

McAlister 2005

Methods	Cluster randomised to decision aid vs usual care
Participants	219 + 215 patients considering antithrombotic therapy for nonvalvular atrial fibrillation (Cluster RCT with 102 primary care practices randomised) in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) COMPARE: usual care
Outcomes	uptake of (appropriate) option*, knowledge, decisional conflict, accurate risk perceptions
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "cluster randomization at level of primary care practice to minimize contamination; randomization was done centrally to preserve allocation concealment using a computer generated sequence."
Allocation concealment (selection bias)	Low risk	pg. 2 - Methods - randomisation was done centrally to preserve allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - Results & Fig 1 - flow diagram

McAlister 2005 (Continued)

Selective reporting (reporting bias)	Low risk	pg. 1 - Methods - DAAFI Trial protocol, including copies of the various questionnaires we employed, has been published
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded, but not sure whether the lack of blinding would affect the outcomes
Blinding of outcome assessment (detection bias) All outcomes	Low risk	outcome assessors blinded

McBride 2002

Methods	Randomised to decision aid vs usual care	
Participants	289 + 292 peri-menopausal women considering hormone replacement therapy in the USA	
Interventions	DA: options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: delayed intervention	
Outcomes	accurate risk perceptions*, satisfaction with decision, confidence with knowledge & making/discussing decision	
Notes	*primary outcome	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided; Bastian 2002 - no information provided - pg. 4 - Study design is described elsewhere
Allocation concealment (selection bias)	Unclear risk	no information provided; Bastian 2002 - no information provided - pg. 4 - Study design is described elsewhere
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 2 Complete data are available for 520 (90%) of the women. Reasons why not mentioned; Bastian - pg. 5 - results; pg. 6 Base-line characteristics/data included

McBride 2002 (Continued)

Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	appears to be free of other potential biases; Bastian - pg. 8 - Eligible participants were willing to consider HRT and this may have favoured recruitment of women with higher SES and those who had prior experience with HRT
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

McCaffery 2010

Methods	Randomized to decision aid + informed choice vs HPV testing vs repeat smear	
Participants	104 + 104 + 106 women screened as HPV indeterminate considering HPV testing in Australia	
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (worksheet) COMPARE: no decision support, received immediate HPV testing COMPARE: no decision support, received a repeat cervical smear at 6 months	
Outcomes	waiting time anxiety (post DA), quality of life* (post DA), perceived risk (post DA), perceived seriousness of cancer (post DA), worriedness (post DA), intrusive thoughts (post DA), satisfaction with care (post DA), anxiety (post DA), distress and concerns (post DA), self-esteem (post DA), effect on sexual behaviour (post DA), help seeking behaviour (post DA), knowledge (post DA)	
Notes	*primary outcome	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.2 (design): "Participants were randomised centrally by the research team within each clinic in blocks of three"

McCaffery 2010 (Continued)

Allocation concealment (selection bias)	Low risk	pg.2 (design): “Participants were randomised centrally by the research team within each clinic in blocks of three”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Figure 3: sensitivity analysis was done to include most of the patients
Selective reporting (reporting bias)	Low risk	protocol available
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	patients and staff were unblinded, but objective outcomes were used
Blinding of outcome assessment (detection bias) All outcomes	Low risk	all outcomes are on questionnaires; not subject to interpretation

Miller 2005

Methods	Randomised to decision aid vs usual care
Participants	279 women considering BRCA1 BRCA2 gene testing in the USA
Interventions	DA: educational intervention on options’ outcomes, personal family cancer history; clinical problem, outcome probability, explicit values clarification, others’ opinions, guidance/coaching COMPARE: provision of general information about cancer risk
Outcomes	Preferred option, knowledge, perceived risk, satisfaction
Notes	primary outcome was not specified

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 4 “randomized by the CATI system” Randomized after self initiated telephone contact
Allocation concealment (selection bias)	Low risk	pg. 4 “computerized assisted telephone interview system (CATI)”
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 8 reasons stated for initial drop-out of study participants. Patients contacted offered reasons for dropping-out. Study pro-

Miller 2005 (Continued)

		tocol allowed patients to be reached up to 13 times at follow-up; but still not able to be reached
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding was not addressed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Miller 2011

Methods	decision aid vs attention placebo
Participants	132 + 132 participants considering colon cancer screening in the USA
Interventions	DA: computer-based web program on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (encourages patient-practitioner communication, summary) COMPARE: computer-based web program on prescription drug refills and safety
Outcomes	Receipt of CRC screening* (post DA); ability to state a preference; change in readiness to receive screening (pre and post DA); CRC test ordering (post DA), proportion undecided
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.609 (methods): block randomised, stratified by literacy level
Allocation concealment (selection bias)	Unclear risk	study does not address this domain
Incomplete outcome data (attrition bias) All outcomes	Low risk	no missing outcome data
Selective reporting (reporting bias)	Low risk	protocol on clinical trials.gov

Miller 2011 (Continued)

Other bias	Unclear risk	\$10 gift card for participation could affect participant pool
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg.609 (methods): health care providers were not notified of patients' enrolment in the study at any time ; pg.613 (discussion): RAs that administered post-DA questionnaire were not blinded but believed to be a low risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg.613 (discussion): "clinical outcome assessors were [blinded]"

Montgomery 2003

Methods	Randomised to decision aid + decision analysis vs decision analysis vs decision aid vs usual care
Participants	51 + 52 + 55 + 59 newly diagnosed hypertensive patients considering drug therapy for blood pressure in the UK
Interventions	DA: decision analysis plus information video and leaflet on options' outcomes, clinical problem, outcome probability, explicit values clarification COMPARE: decision analysis on options' outcomes, outcome probability, explicit values clarification COMPARE: video and leaflet on options' outcomes, clinical problem COMPARE: usual care
Outcomes	uptake of option, knowledge, decisional conflict*, anxiety
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - allocation schedule was computer-generated by an individual not involved in the study
Allocation concealment (selection bias)	Low risk	pg. 2 "allocation was concealed to the author in advance by the nature of the minimization procedure"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 5 - flow diagram

Montgomery 2003 (Continued)

Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Montgomery 2007

Methods	Randomised to decision aid with values clarification vs decision aid without values clarification vs usual care
Participants	245 + 250 + 247 women with previous caesarean section in the UK
Interventions	DA: options' outcomes, clinical problem, outcome probability, explicit values clarification COMPARE: options' outcomes, clinical problem, outcome probability COMPARE: usual care
Outcomes	decisional conflict*, choice, anxiety, knowledge, satisfaction with decision
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 Methods Randomization: blocked by using randomly permuted and selected blocks of sizes 6, 9, 12, and 15 generated by computer
Allocation concealment (selection bias)	Low risk	pg. 2 Methods Randomization: one member of the study team generated the randomisation sequence by computer, and another member of staff with no other involvement in the trial performed the allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	see flow of women through the study

Montgomery 2007 (Continued)

Selective reporting (reporting bias)	Low risk	Trials registry ISRCTN84367722
Other bias	Low risk	Recruited more than planned to account for lost data (Sample Size pg. 4); Baseline characteristics were balanced
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Montori 2011

Methods	Randomised to decision aid vs usual care+booklet	
Participants	52 + 48 women with low bone mass or osteoporosis considering taking bisphosphonates in the USA	
Interventions	DA: worksheet on options' outcomes, clinical problem, outcome probabilities, guidance (administered by physician) COMPARE: usual care + general information booklet on osteoporosis	
Outcomes	patient knowledge (post DA), satisfaction with knowledge transfer (post DA), decisional conflict (post DA), patient-clinician communication (OPTION), trust with physician (during intervention), clinician's perception of decision quality (post DA), clinician's satisfaction with knowledge transfer (post DA), uptake(post DA), adherence (post DA), fidelity (post DA), contamination (post DA), risk perception	
Notes	primary outcome was not specified	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.551(Randomization):“computer generated allocation ”
Allocation concealment (selection bias)	Low risk	pg.551(Randomization): patients randomised “in a concealed fashion (using a secure study website)”
Incomplete outcome data (attrition bias) All outcomes	Low risk	no missing outcome data

Montori 2011 (Continued)

Selective reporting (reporting bias)	Low risk	pg.550 (design):“The protocol for this trial has been reported in full”
Other bias	Unclear risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg.551 (Randomization): no mention of participants being blinded to their allocation; only mention of data collectors and analysts blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg.551 (Randomization): “After randomization, data collectors and data analysts were blind to allocation”, outcomes were not subject to interpretation

Morgan 2000

Methods	Randomised to decision aid vs usual care
Participants	120 + 120 patients with Ischemic heart disease considering revascularization surgery in Canada
Interventions	DA: Health Dialog interactive videodisc on options’ outcomes, clinical problem, outcome probability, others’ opinions COMPARE: usual care
Outcomes	uptake of option, knowledge, satisfaction with the decision making process*
Notes	*primary outcome

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Morgan, 1997, Thesis: pg. 29 - all randomisation enrolment was performed by telephone at which time the pt was assigned; Morgan, 2000, JGIM (Primary Study):pg. 2 - Methods (Patient Pop) “Only the statistician was privy to the two randomisation schedules and blocking factor used”
Allocation concealment (selection bias)	Low risk	Morgan, 1997, Thesis:pg. 29 - only the statistician was privy to the two randomisation schedules and blocking factor; Morgan, 2000, JGIM (Primary Study):pg. 2 - Methods (Patient Pop) “only the statistician was

Morgan 2000 (Continued)

		privity to the two randomisation schedules and blocking factor used. All randomization enrolment was performed by telephone”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Morgan, 1997, Thesis: pg. 39 - patient accrual & follow-up, Baseline characteristics included; Morgan, 2000, JGIM (Primary Study): no reason indicated, but judgement of YES
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Unclear risk	Morgan, 1997, Thesis: pg. 56 - significant number of patients were lost to follow-up (25%); Morgan, 2000, JGIM (Primary Study): baseline data imbalance (High school grad, income, # of diseased arteries) Drop-out group reported lower incomes, may have affected results. (discussion par. 6) “Selection bias was minimized by enrolling available consecutive patients”
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	“due to nature of trial, neither patients or investigators were blinded to the study” - may introduce bias to subjective outcomes such as satisfaction
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Mullan 2009

Methods	Cluster randomised to decision aid vs usual care
Participants	48 + 37 patients with type 2 diabetes considering treatment options (cluster RCT with 40 clinicians randomised) in the USA
Interventions	DA: decision cards with information on options, outcomes, outcome probability, explicit values clarification Compare: 12-page pamphlet on oral antihyperglycaemic medications
Outcomes	knowledge, decisional conflict, participation in decision making, acceptability of the information, change in medication, adherence, HA1C levels, trust in physician, OPTION to analyse audio-taped encounters
Notes	primary outcome was not specified

Mullan 2009 (Continued)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	computer generated
Allocation concealment (selection bias)	Low risk	central allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	reasons for attrition not included
Selective reporting (reporting bias)	Low risk	trial registration # at clinicaltrials.gov reported
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients were blinded, the clinicians were not, but each session was recorded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Murray 2001a

Methods	Randomised to decision aid vs usual care
Participants	57 + 55 men considering treatment for benign prostatic hypertrophy in the UK
Interventions	DA: Health Dialog interactive videodisc on options, outcomes, clinical problem, outcome probability, others' opinions COMPARE: usual care
Outcomes	uptake of option*, decisional conflict, role in decision making, prostate symptoms*, costs, anxiety*, general health status, utility
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 4 "randomisation schedule, stratified according to recruitment centre, was generated by computer"

Murray 2001a (Continued)

Allocation concealment (selection bias)	Low risk	pg. 4 "Allocation were sealed in opaque numbered envelopes, opened by the study nurse"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 5 - flow diagram; Baseline data/characteristics included and balanced
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded but not sure how this would introduce bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Murray 2001b

Methods	Randomised to decision aid vs usual care
Participants	102 + 102 women considering hormone replacement therapy in the UK
Interventions	DA: Health Dialog interactive videodisc on options outcomes, clinical problem, outcome probability, other's opinion COMPARE: usual care
Outcomes	preferred option*, help with making a decision, decisional conflict, role in decision making anxiety, menopausal symptoms, costs, utility, general health status
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 Methods (Randomization) "randomisation schedule, stratified according to recruitment centre, was generated by computer"
Allocation concealment (selection bias)	Low risk	pg. 3 Methods (Randomization) "Allocations were sealed in opaque numbered envelopes, opened by the study nurse after col-

Murray 2001b (Continued)

		lection of the baseline data“
Incomplete outcome data (attrition bias) All outcomes	Low risk	See page 3 figure for Progress of patients through trial
Selective reporting (reporting bias)	Unclear risk	protocol is not mentioned
Other bias	Low risk	similar baseline characteristics, appears to be free of other potential biases. Educational achievement was higher in control group. quote ”Subsequent analysis showed that educational level not related to use of HRT nor was there an interaction between ed
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation

Myers 2005a

Methods	Randomised to detailed decision aid vs simple decision aid
Participants	121 + 121 African-American men considering prostate cancer screening in the USA
Interventions	DA: information booklet on options’ outcomes + decision education session with clinical problem, explicit values clarification, guidance/coaching COMPARE: information booklet on clinical problem, options’ outcomes
Outcomes	uptake of option*
Notes	*primary outcome

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 4 - flow diagram; Reasons for not receiving intervention or completing endpoint chart mentioned. Baseline characteristics

Myers 2005a (Continued)

		included
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Unclear risk	pg. 8 - The mode of delivery of the decision education might have modified a potential intervention effect; baseline characteristics similar except Enhanced Intervention group consisted of more men who were educated beyond high school and who were married
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Myers 2011

Methods	Randomised to detailed vs simple DA
Participants	156 + 157 men considering prostate cancer screening in the USA
Interventions	DA: 12 page informational brochure (options, outcomes, clinical problem, outcome probability) + coaching (structured decision counselling session with nurse educator) COMPARE: 12 page informational brochure
Outcomes	Participants: knowledge* (pre, post DA and consult), decisional conflict* (post DA and consult), actual choice(post DA and consult), patient-clinician communication, consult length Physician: knowledge(pre), orientation to talking with patients(pre), preferred role in shared decision making(pre)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no mention of how sequence was generated
Allocation concealment (selection bias)	Low risk	pg.241 (section 2.1): "Using a system of sealed envelopes"

Myers 2011 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg.243 (section 3.3): does not account for why 24 audio-recordings were excluded
Selective reporting (reporting bias)	Unclear risk	no mention of study protocol; not enough information to permit judgement
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	no mention of blinding of either personnel or participants; all patient charts had a generic note placed in them by the nurse educator to prompt physician to discuss prostate cancer screening
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were not subjective to interpretation

Nagle 2008

Methods	Cluster randomised to decision aid vs usual care
Participants	167 + 172 women in early pregnancy considering genetic testing (26 + 29 general physicians) (cluster RCT with 60 general practitioners randomised) in Australia
Interventions	DA: 24-page booklet and worksheet on options, benefits and risks, test limitations, outcomes; clinical problem, outcome probability, explicit values clarification, opinions of others', guidance (Ottawa Decision Support Framework) COMPARE: standard pamphlet on prenatal testing
Outcomes	informed choice*, decisional conflict*, anxiety, depression, attitudes toward pregnancy, acceptability of the intervention, choice
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 computer-generated random numbers
Allocation concealment (selection bias)	Low risk	pg. 3 - computer-generated random numbers by an independent statistician; allocation concealment was achieved

Nagle 2008 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 4 - results & pg. 5 fig 1 - flow diagram
Selective reporting (reporting bias)	Low risk	pg. 4 - Trial Registration - The ADEPT trial was registered in the UK with Current Controlled Trials [ISRCTN22532458] and with the Australian Clinical Trials Registry (No: 012606000234516)
Other bias	Low risk	appears to be free of other potential biases - pg. 8 - selection bias but was adjusted for in analysis
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg. 3 "Due to the nature of the intervention, it was not possible to blind women, GP's or researchers"; unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	researchers were not blinded but outcomes were objectively measured and not subjective to interpretation

Nassar 2007

Methods	Randomised to decision aid vs usual care
Participants	102 + 98 women diagnosed with a breech presentation from 34 weeks gestation considering external cephalic version in Australia
Interventions	DA: 24-page booklet, 30-minute audio-CD and worksheet; clinical problem, outcome probability, explicit values clarification, opinions of others', guidance (Ottawa Decision Support Framework) COMPARE: usual care counselling and information on the management of breech presentation
Outcomes	knowledge*, decisional conflict*, anxiety*, satisfaction with the decision*, preferred role in decision making, preferred choice
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "randomly generated using computer and stratified by parity and center using random variable block sizes"

Allocation concealment (selection bias)	Low risk	pg. 2 "participants were randomized by telephoning a remote, central location"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 Lost to follow-up because of onset of labour or incomplete data forms. Baseline characteristics are included and equal. Minimum of 84 participants in each study group achieved; pg. 4 - flow diagram
Selective reporting (reporting bias)	Low risk	ISRCTN14570598
Other bias	Low risk	pg. 3 Results "Maternal characteristics and baseline measures of cognitive and affective outcomes were comparable between groups (Table 1); pg.6 "Blinding clinicians and employment of a research midwife to interact with women"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Womens were not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

O'Connor 1999a

Methods	Randomised to decision aid with values clarification vs simple decision aid without values clarification
Participants	101 +100 women considering long term hormone therapy in Canada
Interventions	DA: audiotape booklet on options outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (Ottawa Decision Support Framework) COMPARE: options outcomes, clinical problem, outcome probabilities, others' opinion, guidance/coaching
Outcomes	decisional conflict, congruence with values*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
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O'Connor 1999a (Continued)

Random sequence generation (selection bias)	Unclear risk	Based on centrally handled randomisation, randomly assigned but sequence generation method was not stated
Allocation concealment (selection bias)	Low risk	pg. 4 - Methods (Design) "randomization was handled centrally; RA called research office"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Appears to account for outcome data
Selective reporting (reporting bias)	Unclear risk	Does not mention protocol
Other bias	Low risk	similar baseline characteristics, appear to be free of any other potential biases. No baseline measures to avoid exposing groups to value measurement before the decision aid
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	participants were blinded but RA was not (trained to remain neutral)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding, outcomes were objectively measured and not subjective to interpretation and data analyst was blinded to assignment of intervention

O'Connor 1998a

Methods	Randomised to detailed decision aid vs simple decision aid	
Participants	81 + 84 women considering long term hormone therapy in Canada	
Interventions	DA: audiotape booklet on options outcomes, clinical problem, outcome probability, explicit values clarification, others' opinion, guidance (Ottawa Decision Support Framework) COMPARE: simple DA pamphlet on options outcomes, clinical problem	
Outcomes	preferred option, knowledge, decisional conflict*, accurate risk perceptions*	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement

O'Connor 1998a (Continued)

Random sequence generation (selection bias)	Unclear risk	no information provided; pg.3 "RA called research office with screening info and given participant's id number and intervention assignment"
Allocation concealment (selection bias)	Low risk	pg.3 "randomization was handled centrally"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg.8 "in future studies it would be important to collect baseline predispositions" Flow chart not included
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	participants were blinded but RA was not (trained to remain neutral)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding, outcomes were objectively measured and not subjective to interpretation and data analyst was blinded to assignment of intervention

Oakley 2006

Methods	Randomised to decision aid vs usual care
Participants	16 + 17 postmenopausal women with osteoporosis considering treatment options to prevent further bone loss in the UK
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) COMPARE: usual care
Outcomes	satisfaction with information, decisional conflict (intervention group only), improvement in adherence
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided

Oakley 2006 (Continued)

Allocation concealment (selection bias)	Low risk	pg. 1 - group allocation was done by a third party, unconnected to the study and blinded to the identity of the patients
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Sample characteristics not included. Baseline satisfaction score included. pg. 2 “No evaluation was carried out to determine the reasons for non-participation”
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Unclear risk	no baseline characteristics; pg. 2 Only 16 patients in intervention group and 17 in control group. Small sample size
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding, some outcomes were assessed by open-ended questions, do not know whether this contributes to risk of bias

Ozanne 2007

Methods	Randomised to decision aid + standard counselling vs usual care (standard counselling)
Participants	15 + 15 women considering breast cancer prevention in the USA
Interventions	DA: interactive computer decision aid on options outcomes, outcome probability COMPARE: standard counselling
Outcomes	consultation length*, knowledge, decisional conflict, satisfaction with the decision, acceptability of the decision aid, physician satisfaction with the consultation
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 149 patients were randomised evenly between groups; no information provided about generation
Allocation concealment (selection bias)	Unclear risk	no information provided

Ozanne 2007 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	demographic data included; reasons for attrition mentioned
Selective reporting (reporting bias)	Unclear risk	no reference to study protocol
Other bias	Unclear risk	small sample size, does not say how many physicians participated in study, mentions that there were observed changes in physician behaviour (based on doing both intervention and control)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Partin 2004

Methods	Randomised to decision aid with others' opinions vs decision aid without others' opinions vs usual care
Participants	384 + 384 + 384 men considering PSA testing in the USA
Interventions	DA: Health Dialog video on options' outcomes, clinical problem, outcome probability, others' opinions COMPARE: pamphlet on options' outcomes, clinical problem, outcome probability COMPARE: usual care
Outcomes	preferred option, help with making a decision, knowledge*, decisional conflict
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - Using a computer-generated algorithm
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 2 - flow diagram; Reasons for attrition mentioned and participants balanced across study groups. Sample characteristics included

Partin 2004 (Continued)

Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg. 5 “providers were blinded to the fact that their patients were participating in a trial” “coordinator did not have direct contact with subjects”
Blinding of outcome assessment (detection bias) All outcomes	Low risk	“follow-up interviewers blinded, statisticians were not”. Outcomes were objectively measured and not subjective to interpretation

Pignone 2000

Methods	Randomised to decision aid vs usual care
Participants	125 + 124 adults considering colon cancer screening in the USA
Interventions	DA: video of options’ outcomes, clinical problem, others’ opinion COMPARE: video on car safety
Outcomes	uptake of options*
Notes	*primary outcome

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - Methods (Group Assignment) “computerized random number generator”
Allocation concealment (selection bias)	Low risk	pg. 2 - Methods (Group Assignment) “randomization was performed centrally and was not balanced among centers. Assignments were placed in sealed, opaque, sequentially numbered envelopes and were distributed to the three sites”
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 4 Because of an administrative error, 18 controls did not complete the second and third questionnaires
Selective reporting (reporting bias)	Unclear risk	Protocol was not mentioned

Pignone 2000 (Continued)

Other bias	Low risk	baseline characteristics similar, appear to be no other potential sources of biases. minimized bias from repeated measurements by administering the same questionnaires to the intervention and control participants
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg 2. "The providers and staff were not blinded to intervention status" "3 to 6 months after, different RA blinded to participant intervention examined clinic records" -Does not mention whether patients were blinded; Unclear if lack of blinding contributed to potential risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	a different research assistant who was blinded to participants' intervention status examined participants' clinic records in a standardized and validated manner to determine whether colon cancer screening tests were actually completed within 3 months of the index visit

Protheroe 2007

Methods	Randomised to decision aid vs usual care
Participants	60 + 56 women considering treatment options for menorrhagia in the UK
Interventions	DA: interactive computerized DA on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance COMPARE: information leaflet
Outcomes	knowledge, decisional conflict*, anxiety, condition specific health outcomes, treatment preference, undecided
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - Methods - computer generated randomisation, stratified by practice and minimized according to age
Allocation concealment (selection bias)	Unclear risk	pg. 2 - Methods - Random allocation was concealed from the individual who was making judgments of eligibility, but the

Protheroe 2007 (Continued)

		method of concealment was not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 5 - fig 6 flow diagram; pg. 4 Baseline data/characteristics included and balanced
Selective reporting (reporting bias)	Low risk	ISRCTN72253427
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Raynes-Greenow 2010

Methods	Randomised to detailed vs simple decision aid	
Participants	395 + 201 primiparous women in final trimester considering pain relief for labour in Australia	
Interventions	DA: booklet (and/or audiotape) and worksheet on options' outcomes, clinical problem, outcome probabilities, other's opinion, explicit values clarification, guidance (steps by step process for making the decision; worksheet with questions relevant to decision making process; encouraged patients to communicate with their practitioner by asking questions and sharing preferences; one or more questions that asked patients to clarify their preferences; summary) COMPARE: pamphlet on certain options' outcomes, clinical problem, outcome probabilities	
Outcomes	knowledge* (pre, post DA and consult), decisional conflict* (pre, post DA, and consult), anxiety* (pre, post DA and consult), satisfaction with decision (post DA and consult), actual choice (post DA and consult), participation in decision making (post DA and consult), condition-specific health outcomes	
Notes	*primary outcome	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 (procedures section): computer generated; randomly allocated via a remote location

Raynes-Greenow 2010 (Continued)

Allocation concealment (selection bias)	Low risk	pg.5 (bias section): “we also used remote telephone randomisation”, made use of central allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	all of the aforementioned outcome measures are included in the outcome data
Selective reporting (reporting bias)	Low risk	pg. 2 (study setting section): study’s protocol was published
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	no blinding, but review authors judge that the outcome is not likely to be influenced by lack of blinding pg. 5 (bias section):“it was not possible to conceal allocation once randomised; however to minimise contamination a number of methods were utilized.”, “most women who received the pamphlet were unaware that it was not the intervention”
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg.5 (bias section):“used forms based on standardised instruments that used highly objective closed ended questions, researchers were kept blinded to women’s intervention as much as possible”; authors believe that lack of blinding did not affect the measurements

Rostom 2002

Methods	Randomised to detailed decision aid vs simple decision aid
Participants	25 + 26 women considering hormone replacement therapy in Canada
Interventions	DA: computer version of same information with feedback to reinforce and correct participant knowledge COMPARE: audiotape booklet on options’ outcomes, clinical problem, outcome probabilities, explicit values clarification, others’ opinions, guidance (Ottawa Decision Support Framework)
Outcomes	knowledge, accurate risk perceptions*, satisfaction with decision aid
Notes	*primary outcome
<i>Risk of bias</i>	

Rostom 2002 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - randomisation was performed using a table of random numbers
Allocation concealment (selection bias)	Low risk	pg. 2 "Allocation concealment was maintained through the use of consecutively numbered sealed envelopes"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 2 - all randomised participants completed the study
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	High risk	pg. 69 - on average, participants in the computer group were more likely to be still menstruating and therefore not taking HRT; see limitations section too
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Rothert 1997

Methods	Randomised to detailed decision aid vs simple decision aid	
Participants	83 + 89 peri-menopausal women considering hormone replacement therapy in the USA	
Interventions	DA: lecture with personal decision exercise on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance/coaching COMPARE: simple DA pamphlet with clinical problem, options' outcomes	
Outcomes	knowledge, decisional conflict, satisfaction with decision, satisfaction with provider, self-efficacy, adherence, likelihood to take HRT, consistency with values	
Notes	primary outcome was not specified	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Rothert 1997 (Continued)

Random sequence generation (selection bias)	Unclear risk	pg. 4 “370 were women randomly assigned”, no information on method of sequence generation
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 4 Reasons for attrition mentioned. Table 1 demonstrates participant balance in each study group
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Unclear risk	no specific comparisons reported for baseline characteristics
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	not blinded but outcomes were objectively measured and not subjective to interpretation

Rubel 2010

Methods	Randomised to pretest + decision aid + posttest vs decision aid + posttest vs pretest + posttest vs posttest
Participants	50 + 50 + 50 + 50 men considering prostate cancer screening in the USA
Interventions	DA: booklet on options’ outcomes, clinical problem, outcome probabilities, others’ opinions + pretest and posttest COMPARE: booklet on options’ outcomes, clinical problem, outcome probabilities, others’ opinions + posttest COMPARE: pretest + posttest COMPARE: posttest
Outcomes	knowledge (pre, post DA), decisional anxiety (post DA), decisional conflict (post DA), participation in decision making (pre, post DA), schema for PSA testing (pre, post DA), perception of quality and interpretation of recommendation (post DA)
Notes	primary outcome was not specified

Risk of bias

Bias	Authors’ judgement	Support for judgement
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Rubel 2010 (Continued)

Random sequence generation (selection bias)	Low risk	pg.309 (study design section): electronically generated random number sequence
Allocation concealment (selection bias)	Low risk	pg.309 (study design section): they were given sealed, sequentially numbered packets
Incomplete outcome data (attrition bias) All outcomes	Low risk	no missing outcome data
Selective reporting (reporting bias)	Low risk	pg. 310 (study design section): protocol followed CONSORT checklist
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	no mention of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding, but the outcomes were objectively measured and not subject to interpretation

Ruffin 2007

Methods	Randomised to decision aid vs usual care
Participants	87 + 87 community dwelling adults not previously screened for CRC in the USA
Interventions	DA: Interactive Web site with information on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinion, guidance COMPARE: Non-interactive Web site with information on clinical problem
Outcomes	uptake of option*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 "A block randomisation process programmed by the study computer support staff and verified by a statistician was used including two strata, race and gender"
Allocation concealment (selection bias)	Unclear risk	no information provided

Ruffin 2007 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - flow diagram
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Both blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The investigators, data collectors, data entry, and data analyst were all blinded to study arm assignment

Schapira 2000

Methods	Randomised to detailed decision aid vs simple decision aid
Participants	122 + 135 men considering PSA testing in the USA
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability COMPARE: simple DA pamphlet with clinical problem, options' outcomes
Outcomes	uptake of option*, knowledge, accurate risk perceptions
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3-4 Reasons for exclusion of participants and not participating mentioned. Participants in study groups balanced
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	acknowledges potential for volunteer bias in limitations section

Schapira 2000 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Schapira 2007

Methods	Randomised to detailed decision aid vs simple decision aid
Participants	89 + 88 post-menopausal women considering hormone therapy use in the USA
Interventions	DA: computer-based decision aid on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinion COMPARE: educational pamphlet on options' outcomes, clinical problem
Outcomes	knowledge*, satisfaction with the decision*, decisional conflict*, choice*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - Assignments were made by randomisation. The allocation sequence and assignments were made at a central site
Allocation concealment (selection bias)	Low risk	pg. 2 "Assignments were concealed by an envelope that was opened after informed consent was obtained" "The allocation sequence and assignments were made at a central site"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 3 fig 1 Flow chart. Reasons for not completing follow-up not mentioned. p.4 baseline characteristics included
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg. 2 - Those administering the intervention and assessing outcomes were not

Schapira 2007 (Continued)

		blinded to the group assignment; Unclear if lack of blinding contributed to potential risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Those administering the assessing outcomes were not blinded to the group assignment but outcomes were objectively measured and not subjective to interpretation

Schroy 2011

Methods	Randomised to detailed vs simple decision aid vs control
Participants	223 + 212 + 231 average-risk patients considering CRC screening in the USA
Interventions	DETAILED DA: CRC risk assessment + web-based interactive audio-visual DA on options' outcomes, clinical problem, outcome probabilities, others' opinion and guidance COMPARE: web-based decision aid only COMPARE: usual care using pamphlet
Outcomes	knowledge (pre and post DA), satisfaction with decision making process (pre and post DA), preferred choice (pre and post DA)
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no mention of randomisation process
Allocation concealment (selection bias)	Unclear risk	no mention of allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Low risk	no data appears to be missing
Selective reporting (reporting bias)	Unclear risk	no mention of examination of selective outcome reporting or study protocol
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Providers were not blinded, subjective outcomes such as satisfaction with decision making process could have been affected, unclear is participants were blinded

Schroy 2011 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors not blinded but outcome measures not believed to be influenced by it
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Schwalm 2012

Methods	Randomised to decision aid vs usual care
Participants	76 + 74 patients undergoing coronary angiography
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance COMPARE: usual care
Outcomes	knowledge, decisional conflict*, risk perception, value congruent with chosen option
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	p261 study design - computerized random number generator
Allocation concealment (selection bias)	Low risk	p261 study design - sealed envelopes
Incomplete outcome data (attrition bias) All outcomes	Low risk	Did not seem to have incomplete data
Selective reporting (reporting bias)	Low risk	Protocol is available
Other bias	Low risk	Appeared to be free of other biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	p261 study design - patients and physicians were not blinded to the allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear if DCS score assessed by unblinded individuals, but outcomes were objectively measured and not subjective to interpretation

Schwartz 2001

Methods	Randomised to decision aid vs usual care
Participants	181 + 190 Ashkenazi Jewish women considering genetic testing in the USA
Interventions	DA: 16-page booklet on genetic testing with options' outcomes, clinical problem COMPARE: general information on breast cancer "Understanding Breast Changes: A Health Guide for all Women published by the National Cancer Institute
Outcomes	preferred option*, knowledge, accurate risk perceptions
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 - computer-generated
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 2 - participants section - high retention rate, baseline data and reasons for lost to follow up were provided
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Schwartz 2009

Methods	Randomised to decision aid + genetic counselling vs genetic counselling alone
Participants	100 + 114 women considering prophylactic mastectomy for being BRCA1/2 mutation carriers in the USA
Interventions	DA: CD-Rom on options' outcomes, clinical problem, risk communication with individually tailored risk graphs, explicit values clarification, others' opinion; guidance/ counselling - genetic counselling as usual care (Ottawa Decision Support Framework COMPARE: Genetic counselling on benefits and risks of testing, clinical problem (risk

Schwartz 2009 (Continued)

	assessment, cancer risks associated with mutations, process of testing and interpretation of results) plus written letter outlining all guidelines and recommendations
Outcomes	decisional conflict*, satisfaction with decision*, remaining undecided, actual choice* (risk reduction mastectomy)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 - Procedure - randomised via computer-generated random number in a 1:1 ratio
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - fig. 1 - flow diagram
Selective reporting (reporting bias)	Unclear risk	protocol not mentioned
Other bias	Low risk	appears to be free of other sources of bias. p.8 "when variable for not watching DA cd was considered in multivariate models, the results did not change substantively (data not shown)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Sheridan 2006

Methods	Randomised to decision aid vs usual care (list of risk factors)
Participants	49 + 38 adults with no history of cardiovascular disease in the USA
Interventions	DA: computerized decision aid on options' outcomes, outcome probabilities COMPARE: list of CHD risk factors to present to doctor
Outcomes	patient-practitioner communication (e.g. discussion with doctor, specific plan to reduce risk discussed with doctor)

Sheridan 2006 (Continued)

Notes	primary outcome was not specified	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "computerized random number generator"
Allocation concealment (selection bias)	Low risk	pg. 2 "sealed in security envelopes"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 5 - results; pg. 10 - flow diagram; Base-line characteristics/data included
Selective reporting (reporting bias)	Low risk	pg. 1 - ClinicalTrials.gov NCT00315978
Other bias	Low risk	appears to have no other potential risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients were blinded but the doctors who saw both group were not
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcome was patient reported

Sheridan 2011

Methods	Randomised to decision aid + tailored messages vs usual care	
Participants	81 + 79 patients with moderate or high risk for CHD considering CHD prevention strategies in the USA	
Interventions	DA: web-based decision aid on options' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance COMPARE: usual care using computer program	
Outcomes	preferred choice (post DA), adherence.	
Notes	primary outcome was not specified	
Risk of bias		
Bias	Authors' judgement	Support for judgement

Sheridan 2011 (Continued)

Random sequence generation (selection bias)	Unclear risk	pg.2 "Patients were randomised by study staff who accessed an online randomised schedule." Sequence generation method was not stated
Allocation concealment (selection bias)	Low risk	pg.2 "Patients were randomised by study staff who accessed an online randomised schedule."
Incomplete outcome data (attrition bias) All outcomes	Low risk	there appears to be no missing data
Selective reporting (reporting bias)	Low risk	protocol made available
Other bias	Low risk	appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Low risk	patients blinded and physicians unblinded but objective outcomes are not likely affected by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	outcomes deemed objective therefore lack of blinding did not influence assessment

Shorten 2005

Methods	Randomised to decision aid vs usual care
Participants	85 + 84 pregnant women who have experienced previous cesarean section considering birthing options in Australia
Interventions	DA: decision aid booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (Ottawa Decision Support Framework) COMPARE: usual care
Outcomes	preferred option, help with making a decision, knowledge*, decisional conflict*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 - procedure - computer-based randomised generation

Shorten 2005 (Continued)

Allocation concealment (selection bias)	Low risk	pg. 3 “opaque envelopes containing a random allocation for each participant code number”
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 4 - results - 16 women were lost to follow-up from the intervention group and 18 from the control group (no reasons listed)
Selective reporting (reporting bias)	Low risk	reference to published protocol
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants/midwives/ doctors were blinded to patients’ allocation. However, women who used the decision-aid as specified and in a process of consultation with their midwife or doctor would have negated the blinding of their clinicians, and perhaps of the women themselves. For the intervention group, this may have affected the level and type of information exchanged between them and their caregivers
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Smith 2010

Methods	Randomised to detailed vs simple decision aid vs usual care
Participants	196 + 188 + 188 socio-economically disadvantaged participants diagnosed with average or slightly above average risk of bowel cancer considering bowel cancer screening in Australia
Interventions	DA: booklet + DVD + worksheet + question prompt list on options’ outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step-by-step process for making the decision; worksheet; encourages patients to communicate with practitioners by asking questions; summary) COMPARE: booklet + DVD + worksheet on options’ outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step-by-step process for making the decision; worksheet; encourages patients to communicate with practitioners by asking questions; summary) COMPARE: usual care using standard information booklet
Outcomes	values congruent with chosen option* (post DA), knowledge (pre, post DA), attitude, actual choice (post DA), participation in decision making* (pre, post DA), decisional conflict (post DA), decision satisfaction (post DA), confidence in decision making (post

	DA), general anxiety (post DA), worry about developing bowel cancer (pre, post DA), risk perception	
Notes	*primary outcome	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.3 (Participants and recruitment section) : "Participants who verbally consented to take part were then randomised to one of the three groups using random permuted blocks of size 6 and 9 for each sex stratum"
Allocation concealment (selection bias)	Low risk	pg.3 (participants and recruitment section) : central allocation; "interviewers responsible for recruiting participants were not aware of the randomization sequence or allocation and therefore did not know which intervention respondents would receive"
Incomplete outcome data (attrition bias) All outcomes	Low risk	explanation for the missing data reported at base of tables
Selective reporting (reporting bias)	Low risk	study protocol available (ClinicalTrials.gov NCT00765869 and Australian New Zealand Clinical Trials Registry 12608000011381)
Other bias	Low risk	appears to be free of other potential sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg.3 (outcome measures section): "It was not possible for the reviewers to be blinded to the group allocation. However, all questions used standardised wording with pre-coded responses and were asked within a supervised environment, where interviewer performances were regularly monitored to ensure scripts were read as written"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg.5 (statistical analysis section): "analyses were by intention to treat and carried out blinded to intervention", outcomes measured were not subject to interpretation

Solberg 2010

Methods	Randomised to detailed vs simple decision aid
Participants	136 + 164 women diagnosed with uterine fibroids considering treatment options in the USA
Interventions	DA: DVD + booklet + worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (worksheet with questions relevant to decision making process; one or more questions that asked patients to clarify their preferences; summary), coaching (nurse coach access) COMPARE: Simple DA pamphlet on options' outcomes, clinical problem, outcome probabilities, others' opinion
Outcomes	knowledge (post DA and consult); values congruent with chosen option (post DA and consult); satisfaction with decision (post DA and consult); actual choice (post DA and consult), patient-clinician communication Survey of physicians, midwives, nurse practitioners, nurses, and medical assistants to obtain their impressions of the approaches used in their clinic (post DA and consult)
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	p.445 (participants and data collection section) random allocation stratified by patient population size and type. First the 2 large central city sites were sorted into opposite study arms, followed by random allocation of the other sites to end up with similar patient sizes and characteristics. Patient allocation to intervention (n = 3 clinics) or control arm (n = 5 clinics) depended on the specific clinic where they received care
Allocation concealment (selection bias)	Unclear risk	not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	all of the outcomes mentioned in p.446 (measures section) are either found in Tables 2, 3 and 4 or in the text in the results/staff survey sections
Selective reporting (reporting bias)	Unclear risk	no mention of a protocol or a list of pre-specified outcomes
Other bias	Low risk	appears to be free of other potential sources of bias

Solberg 2010 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	unclear blinding, but outcomes were objectively measured and not subject to interpretation

Steckelberg 2011

Methods	Randomised to decision aid vs usual care
Participants	785 + 792 patients with no CRC history considering CRC screening in Germany
Interventions	DA: brochure on options' outcomes, clinical problem, and outcome probabilities COMPARE: usual care using pamphlet
Outcomes	values congruent with chosen option* (post DA), knowledge (post DA), combination of actual and planned uptake (post DA), risk perception
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg.2 (randomisation and blinding): computer generated sequence
Allocation concealment (selection bias)	Low risk	pg.2 (randomisation and blinding): Allocation was concealed. Identity numbers were independent of allocation, and study members did not have access to the data
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg.2 : 12% missing one or both questionnaires in intervention group vs 9.2% in control; judged to have low impact on study outcome
Selective reporting (reporting bias)	Low risk	protocol available
Other bias	Unclear risk	participants who completed the trial do not add up
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg.2 (randomisation and blinding): trial staff who sent out questionnaires and reminders were not aware of study arm, un-

		clear if participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	pg.2 (randomisation and blinding): trial staff and statistician who entered data were blinded

Street 1995

Methods	Randomised to detailed decision aid vs simple decision aid
Participants	30 + 30 women considering breast cancer surgery in the USA
Interventions	DA: interactive multimedia on options' outcomes, clinical problem, others' opinion, guidance COMPARE: simple DA pamphlet with clinical problem, options' outcomes
Outcomes	uptake of option, *knowledge, *optimism
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 3 "Patients were randomly assigned to one of two pre consultation education conditions"; sequence generation method was not stated
Allocation concealment (selection bias)	Unclear risk	Does not mention how allocation occurred and the concealment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline data included. Flow diagram not included. Unsure how/why n = 60. pg. 3 "Only four patients chose not to participate" without reason why
Selective reporting (reporting bias)	Unclear risk	no mention of protocol
Other bias	Low risk	pg. 3 - Table 1 & text - no sig. differences between groups; appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding

Street 1995 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
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Thomson 2007

Methods	Randomised to decision aid vs usual care by clinical guidelines
Participants	69 + 67 patients with atrial fibrillation considering treatment options in the UK
Interventions	DA: computerized decision on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance/coaching by physician COMPARE: guidelines applied as direct advice
Outcomes	decisional conflict*, anxiety, knowledge, resource use, choice, health outcomes (stroke, TIA, bleeding events)
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - Recruitment and randomisation - "electronically-generated random permuted blocks via a web-based randomisation service"
Allocation concealment (selection bias)	Low risk	pg. 2 - Recruitment and randomisation - "electronically-generated random permuted blocks via a web-based randomisation service"
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram
Selective reporting (reporting bias)	Low risk	ISRCTN24808514
Other bias	Low risk	Baseline characteristics similar, sample size similar, not stopped early
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Physicians were blinded. Unclear if patients are blinded and how that may affect the outcome
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Tiller 2006

Methods	Randomised to detailed decision aid vs simple decision aid
Participants	68 + 63 women at increased risk of developing ovarian cancer considering risk management options in Australia
Interventions	DA: decision aid booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance/coaching (Ottawa Decision Support Framework) COMPARE: general education pamphlet with information contained in decision aid but "does not include the strategies commonly used in decision aids, such as a values clarification exercise"
Outcomes	knowledge, decisional conflict, anxiety, depression, choice, acceptability of the intervention, Intrusive thoughts sub-scale of Impact of Event scale, others influencing the decision
Notes	primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 - Participants - Eligibility criteria and recruitment are outlined in detail elsewhere. Table of random numbers per author
Allocation concealment (selection bias)	Low risk	pg. 3 - Participants - Eligibility criteria and recruitment procedures are outlined in detail elsewhere. Randomisation done centrally per author
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline data included. p. 5 flow chart; Reasons for attrition not mentioned. Participants balanced in each study group
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	pg. 3 "Participants blinded to study, told the purpose of the study was to compare two types of education materials, not told how types differed or which one received"; Unclear if lack of blinding of others may have contributed to potential risk of bias

Tiller 2006 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
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Trevena 2008

Methods	Randomised to decision aid vs usual care by consumer guidelines
Participants	157 + 157 patients not previously screened for colorectal cancer in Australia
Interventions	DA: age-gender-family history specific DA booklet with information on options, outcome probabilities, explicit values clarification, guidance (personal worksheet with steps in decision making) (Theory of planned behaviour) COMPARE: consumer guidelines recommending faecal occult blood testing
Outcomes	Informed choice*: knowledge, values, screening intention (choice); test uptake, anxiety, acceptability of the intervention, satisfaction with the decision
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 "Sequential ID numbers were randomly assigned by computer program to DA or Guidelines (G) in blocks of four"
Allocation concealment (selection bias)	Low risk	pg. 3 "Allocation was concealed via the password-protected program"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 3 Baseline characteristics included. pg. 5 fig 2 flow chart. Reasons for loss to follow up not mentioned
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov - NCT00148226.
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	participants were blinded to the intervention type - not sure about GPs
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers were blinded to allocation for all telephone interviews, outcomes were objectively measured

van Peperstraten 2010

Methods	Randomised to decision aid vs usual care	
Participants	152 + 156 infertile women on wait list for in vitro fertilisation in the Netherlands	
Interventions	DA: self-administered booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step by step process for making decision, worksheet with questions relevant to decision making process; one or more questions that asked patients to clarify their preferences; summary to be shared with practitioner), coaching (by trained in vitro fertilization nurse) + standard in vitro fertilisation care COMPARE: standard in vitro fertilisation care, including a session in which the number of embryos transferred was discussed	
Outcomes	knowledge (pre, post DA and consult), actual choice* (post DA and consult), empowerment (pre, post DA and consult), participation in decision making, decisional conflict (post DA and consult), levels of anxiety (pre, post DA and consult), depression (pre, post DA and consult), cost evaluation of empowerment strategy (post DA and consult), condition-specific health outcomes (pregnancies) (post DA and consult)	
Notes	*primary outcome	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 (methods section): computer generated list
Allocation concealment (selection bias)	Low risk	pg. 2 (methods section): central allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg.3 (Table 1), there are categories in each column where the denominators do not match the number of people in the group and no reason was given to explain why this would be or if this affects the study
Selective reporting (reporting bias)	Low risk	outcomes same as those registered with ClinicalTrials.gov
Other bias	Low risk	The study appear to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Low risk	pg.2 (methods section): "because of the nature of the intervention it was not possible to blind the participants or in vitro fertilisation doctors to the allocation. Participation in our trial did not change the normal in vitro routine."

van Peperstraten 2010 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes assessed were not subjective to interpretation
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van Roosmalen 2004

Methods	Randomised to detailed decision aid with decision analysis vs simple decision aid
Participants	44 + 44 women diagnosed with BRCA 1/2 mutation considering prophylactic surgery in the Netherlands
Interventions	DA: video and brochure patient decision with decision analysis on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance/coaching COMPARE: same video and brochure on options' outcomes, clinical problem, outcome probability, guidance/coaching
Outcomes	decision uncertainty*, perceived weighing pros/cons, perceived participation, anxiety, health outcomes
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	van Roosmalen, 2004, J Clin Onco (Primary Study): pg. 4 - randomisation schedule, stratified by medical history of breast/ovarian cancer and by timing of the informative DA, was generated by computer in blocks of 10; van Roosmalen, 2004, Brit J Cancer: p.2 "computer generated in blocks of 10" "stratified by personal medical history of breast/ovarian cancer"
Allocation concealment (selection bias)	Unclear risk	Roosmalen, 2004, Brit J Cancer: randomisation was performed after obtaining informed consent, no mention of allocation concealment
Incomplete outcome data (attrition bias) All outcomes	Low risk	van Roosmalen, 2004, J Clin Onco (Primary Study):p.3 fig 1; van Roosmalen, 2004, Brit J Cancer: Fig 1 flow diagram
Selective reporting (reporting bias)	Unclear risk	van Roosmalen, 2004, J Clin Onco (Primary Study): no information provided; van Roosmalen, 2004, Brit J Cancer: no information provided

van Roosmalen 2004 (Continued)

Other bias	Unclear risk	van Roosmalen, 2004, J Clin Onco (Primary Study):appears to be free of other potential biases; van Roosmalen, 2004, Brit J Cancer:Between the DA and control groups, significant differences were found for being religiously affiliated, anxiety, and general health; apart from that appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding , unclear if this contributes to bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but outcomes were objectively measured and not subjective to interpretation

Vandemheen 2009

Methods	Randomised to decision aid vs usual care
Participants	70 + 79 patients with cystic fibrosis considering referral for lung transplantation in Canada
Interventions	DA: booklet with clinical problem, outcome probability, explicit values clarification, guidance (Ottawa Decision Support Framework) COMPARE: blank pages
Outcomes	knowledge*, accurate risk perceptions*, decisional conflict*, preparation for decision making, choice, durability of decision, undecided
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "computer-generated random listing of two treatment allocations blocked in blocks of 2 or 4, stratified by site and infection status of Burkholderia cepacia"
Allocation concealment (selection bias)	Low risk	pg. 2 - central allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 2 - flow diagram; Baseline characteristics included.

Vandemheen 2009 (Continued)

Selective reporting (reporting bias)	Low risk	Clinical trial registered with www.clinical-trials.gov (NCT00345449)
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single blinded RCT; patients and researchers were blinded but physicians were not because they were involved with patients before being randomized
Blinding of outcome assessment (detection bias) All outcomes	Low risk	research staff, who were blinded to treatment allocation, telephoned each patient and had them complete a follow-up questionnaire, other outcomes reported are objectively measured

Vodermaier 2009

Methods	Randomised to decision aid vs usual care
Participants	74 + 78 women with breast cancer considering treatment options in Germany
Interventions	DA: Decision board and booklet on options' outcomes, clinical problem, outcome probability COMPARE: booklet on clinical problem
Outcomes	decisional conflict*, choice, length of consultation, satisfaction with decision making, participation in decision making
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 2 "Randomisation after the patient gave written informed consent" "Random assignment was performed by means of numbered cards in envelopes" "stratified by age group";
Allocation concealment (selection bias)	Low risk	pg. 2 "numbered cards in envelopes"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	pg. 5 - flow diagram; Baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	no information provided

Vodermaier 2009 (Continued)

Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded but outcomes were objectively measured and not subjective to interpretation

Volk 1999

Methods	Randomised to decision aid vs usual care
Participants	80 + 80 men considering PSA testing in the USA
Interventions	DA: Health Dialog videotape and brochure on options' outcomes, clinical problem, outcome probability, others' opinion COMPARE: usual care
Outcomes	knowledge*, preferred/uptake of option*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Volk, 1999, Arch Fam Med (Primary Study): p.3 "Randomization by permuted blocks" "Each block included the numbers 1 through 4"; Volk, 2003, Ann Fam Med: pg. 2 - Methods - Randomization by permuted blocks was used to balance the number of subjects in each arm of the study
Allocation concealment (selection bias)	Unclear risk	Volk, 1999, Arch Fam Med (Primary Study) : no information provided; Volk, 2003, Ann Fam Med: p.2 "Details of the study procedures, subjects, and 2-week follow-up results can be found elsewhere"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Volk, 1999, Arch Fam Med (Primary Study) : pg. 2 - procedures; Baseline values included. p.4 fig 1 flow chart; Volk, 2003, Ann Fam Med:pg. 4 fig 1 - flow diagram; Baseline data not included

Volk 1999 (Continued)

Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	Volk, 1999, Arch Fam Med (Primary Study) : appears to be free of other potential biases; Volk, 2003, Ann Fam Med: appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Low risk	subjects was not blinded to the treatment assignment, but the physicians were, therefore outcomes were unlikely to be biased
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers were not blinded but outcomes were objectively measured and not subjective to interpretation

Volk 2008

Methods	Randomised to detailed decision aid vs simple decision aid
Participants	224 + 226 men with no history of prostate cancer in the USA
Interventions	DA: edutainment decision aid with tailored computerized program with information options' outcomes, clinical problem, explicit values clarification, others' opinion, guidance COMPARE: audio-booklet information on options' outcomes
Outcomes	knowledge*, decisional conflict, self-advocacy, acceptability of the intervention, length of the intervention
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "randomized separately in each setting using permuted blocks"
Allocation concealment (selection bias)	Unclear risk	not mentioned
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline data not included. pg. 4 reasons for not completing evaluation and recognizes difference in participant characteristics across sites
Selective reporting (reporting bias)	Unclear risk	no mention of protocol

Other bias	Unclear risk	Participant imbalance across study sites. Low Literacy = 89 completing follow-up and High Literacy = 263 completing follow-up
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	does not mention blinding apart from pg. 2 - 2.3 - "Research assistants were not blinded to the study" (but unlikely to introduce bias patient outcomes). Therefore, unclear blinding of participants and physicians
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research assistants were not blinded to the study but outcomes were objectively measured and not subjective to interpretation

Vuorma 2003

Methods	Randomised to decision aid vs usual care
Participants	184 + 179 women considering treatment for menorrhagia in Finland
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability COMPARE: usual care
Outcomes	uptake of option*, knowledge, proportion remaining undecided, anxiety, satisfaction, health outcomes, use and cost of healthcare services
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Vuorma, 2003 (Primary Study): pg. 2 - Randomization - computer-generated; done by a researcher who did not participate in the planning or concealment procedures pg. 2 "done in STAKES, by researcher separately for each hospital in computer-generated varying clusters"; Vuorma, 2004 no information provided
Allocation concealment (selection bias)	Low risk	Vuorma, 2003 (Primary Study):pg. 2 "sequentially numbered, opaque and sealed envelopes"; Vuorma, 2004: pg.2 "sequentially numbered, opaque, sealed envelopes"

Vuorma 2003 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Vuorma, 2003 (Primary Study): Flow chart balanced. p. 4-5 reasons for non-eligibility. "One women on HRT was randomized by mistake and included in analyses." Baseline characteristics included and balanced across groups; Vuorma, 2004: pg. 3 - flow diagram
Selective reporting (reporting bias)	Unclear risk	Vuorma, 2003 (Primary Study): no mention of study protocol; Vuorma, 2004: no information provided
Other bias	Low risk	Vuorma, 2003 (Primary Study): pg. 7 "increase in knowledge in both study groups, carry-over effect; change in decision-making process of intervention group may have altered physician's negotiation with patients" appears to be free of other potential biases; Vuorma, 2004: p.5 "comparison of the baseline characteristics presented elsewhere" In the pre-trial group compared with the control group, there was a greater increase in the dimensions of physical role functioning and emotional role functioning of the RAND-36
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding, unclear if measurements could be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study staff were not blinded but outcomes were objectively measured and not subjective to interpretation

Wakefield 2008

Methods	Cluster randomised to detailed decision aid vs simple decision aid
Participants	69 + 84 individuals considering genetic testing for colorectal cancer (cluster RCT with family-wise randomisation) in Australia
Interventions	DA: detailed 40-page decision aid booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) COMPARE: simple 4-page pamphlet with benefits and risks, no values clarification
Outcomes	knowledge, decisional conflict*, informed choice, anxiety, depression, regret, actual choice, family involvement, Impact of event scale

Wakefield 2008 (Continued)

Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 3 "agreeing to participate, given a pre-randomised envelope containing a DA or control pamphlet, a consent form, first questionnaire, and a reply-paid envelope" - unclear how pre-randomisation was generated
Allocation concealment (selection bias)	Low risk	Opaque envelope
Incomplete outcome data (attrition bias) All outcomes	Low risk	Demographic variables similar in both groups. pg. 9 "not possible to collect baseline data"; pg. 5 fig. 2 - flow diagram
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	No baseline data (pg. 9, however characteristics equally distributed because randomisation) pg. 9 "potential for contamination because lack of blinding clinicians" Participants completed questionnaire before reading info. materials
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Wakefield 2008a

Methods	Cluster randomised to detailed decision aid vs simple decision aid
Participants	73 + 72 women considering genetic testing for breast and ovarian cancer (cluster RCT with family-wise randomisation) in Australia
Interventions	DA: detailed 40-page decision aid booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) COMPARE: simple 4-page pamphlet with benefits and risks, no values clarification

Wakefield 2008a (Continued)

Outcomes	knowledge, decisional conflict*, informed choice, anxiety, depression, genetic testing decision, decision regret, family involvement, impact of event	
Notes	*primary outcome	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 3 "pre-randomized envelope containing the DA or the control pamphlet, a consent form, the first questionnaire and a reply-paid envelope" pg. 4 "Participants were randomized according to family-wise randomization"
Allocation concealment (selection bias)	Low risk	pg. 4 - all patients who were the first of their family to attend the clinic were randomly allocated to the control or DA condition. pg. 3 - Those who agreed were given a pre-randomised opaque envelope containing the DA or the control pamphlet
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 11 "It was not possible to collect a baseline assessments" pg. 6 fig 2 Flow chart. Reasons for withdrawal not mentioned
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	Appears to be free of other sources of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Wakefield 2008b

Methods	Cluster randomised to detailed decision aid vs simple decision aid
Participants	73 + 75 women considering genetic testing for breast and ovarian cancer (cluster RCT with family-wise randomisation) in Australia

Wakefield 2008b (Continued)

Interventions	DA: detailed 40-page decision aid booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) COMPARE: simple 4-page pamphlet with benefits and risks, no values clarification
Outcomes	knowledge, decisional conflict*, informed choice, anxiety, depression, genetic testing decision, decision regret, impact of event, family involvement
Notes	The study procedure was identical for the 2008a trial except that the decision aid was given to women at the beginning of their first consultation with a genetic counsellor, used during counselling, and then taken home by the women *primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Details provided in Wakefield 2008a : pg. 3 "pre-randomized envelope containing the DA or the control pamphlet, a consent form, the first questionnaire and a reply-paid envelope" pg. 4 "Participants were randomized according to family-wise randomization"
Allocation concealment (selection bias)	Low risk	Details provided in Wakefield 2008a pg. 4 - all patients who were the first of their family to attend the clinic were randomly allocated to the control or DA condition. pg. 3 - Those who agreed were given a pre-randomised opaque envelope containing the DA or the control pamphlet
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 5 - fig 2 - flow diagram
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	no baseline characteristics, but author states that due to randomisation should be evenly distributed across both groups
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias)	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to inter-

Wakefield 2008b (Continued)

All outcomes	pretation
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Watson 2006

Methods	Randomised to decision aid vs usual care
Participants	475 + 522 men considering prostate cancer screening in the UK
Interventions	DA: leaflet on options' outcomes, clinical problem, outcome probability COMPARE: usual care
Outcomes	knowledge*, screening intention*, attitudes*, preferred role in decision making
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 3 "random numbers generated centrally by Stata v8.2"
Allocation concealment (selection bias)	Low risk	pg. 3 "random numbers generated centrally by Stata v8.2"
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 2 - flow diagram; Reason for exclusion from analysis mentioned. Sample characteristics of risk included
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Unclear risk	pg. 3 "Adjustment for multiple testing was not accounted for and hence a degree of caution with interpretation is required, particularly in relation to findings with a P-value close to 0.05"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	no information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Weymiller 2007

Methods	Cluster randomised to decision aid vs usual care
Participants	51 + 46 patients with type 2 diabetes in the USA
Interventions	DA: 1-page decision aid options' outcomes, clinical problem, tailored outcome probability, guidance/coaching COMPARE: booklet on cholesterol management
Outcomes	knowledge*, decisional conflict*, consultation length, acceptability of the intervention, adherence, estimated personal risk, trust, patient participation (OPTION), choice
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 - computer-generated allocation sequence; Nannenga - no information provided
Allocation concealment (selection bias)	Low risk	computer-generated allocation sequence, unavailable to personnel enrolling patients. Abstract: "with concealed allocation" pg. 5 "maintained allocation concealment" Nannenga - pg. 2 - randomised by concealed central allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	pg. 3 - flow diagram; Reasons for attrition mentioned. pg.4 Baseline characteristics included; Nannenga - pg. 3 - flow diagram; Reasons for attrition mentioned and study groups balanced. Baseline characteristics included
Selective reporting (reporting bias)	Low risk	clinical trials.gov Identifier: NCT00217061
Other bias	Low risk	Enrollment of patients already receiving statin therapy and limited statin uptake decreased the precision of our results; results should best be interpreted as preliminary and requiring verification; Nannenga - appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and clinicians blinded to the study objectives, providers and patients were naive to this study objective

Weymiller 2007 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data analysts and statisticians blinded to allocation; intervention and outcomes; adequate blinding wherever possible
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Whelan 2003

Methods	Randomised to decision aid vs usual care
Participants	82 + 93 women with node negative breast cancer considering adjuvant chemotherapy in Canada
Interventions	DA: Decision board and booklet on options' outcomes, clinical problem, outcome probability, guidance/coaching COMPARE: booklet on clinical problem
Outcomes	preferred option, knowledge*, anxiety, accurate risk perceptions, satisfaction of patient*, participation in decision making
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no information provided
Allocation concealment (selection bias)	Low risk	pg. 3 - randomisation, which was performed at a central location
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram not included. pg. 4 "one patient excluded from analysis, determined by physician not to be candidate for chemotherapy" Baseline data/characteristics included
Selective reporting (reporting bias)	Unclear risk	Unclear if lack of blinding contributed to potential risk of bias
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	unable to blind participants in our trial for practical reasons, measures were taken to minimize bias in the design of the study and the assessment of outcomes

Whelan 2003 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
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Whelan 2004

Methods	Cluster randomised to decision aid vs usual care
Participants	94 + 107 women with Stage 1 or 2 breast cancer considering surgery (Cluster RCT with 27 surgeons randomised) in Canada
Interventions	DA: decision board on options' outcomes, outcome probability, guidance/coaching COMPARE: usual care
Outcomes	preferred option*, knowledge*, accurate risk perceptions, decisional conflict*, anxiety, satisfaction*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	does not specify how the sequence was generated - pg. 2 - study design and procedures - a paired cluster randomisation process was used
Allocation concealment (selection bias)	Unclear risk	pg. 2 - study design and procedures - they were then randomly assigned in a concealed fashion, but method of concealment was not stated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics not included. Reasons given for loss of participants
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	'appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	p. 6 "chose cluster randomization method to avoid contamination that might have occurred if surgeons used decision board for some patients and not others", unclear if this would introduce bias

Whelan 2004 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
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Wolf 1996

Methods	Randomised to decision aid vs usual care
Participants	103 + 102 men considering PSA testing in the USA
Interventions	DA: script of options' outcomes, clinical problem, outcome probability, others' opinions COMPARE: usual care (single sentence)
Outcomes	preferred option*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Wolf, 1996, Arch Intern Med (Primary Study): no information provided Wolf, 1998, J Ger Ser A-Bio Sc & Med Sc: p.2 "The methodology of the randomized trial has been reported previously"
Allocation concealment (selection bias)	Unclear risk	Wolf, 1996, Arch Intern Med (Primary Study): no information provided; Wolf, 1998, J Ger Ser A-Bio Sc & Med Sc: p.2 "The methodology of the randomized trial has been reported previously"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Wolf, 1996, Arch Intern Med (Primary Study): pg. 2 needed a minimum sample size of 150 participants, and was achieved with total sample size of 205. Reasons for attrition mentioned. Baseline characteristics included; Wolf, 1998, J Ger Ser A-Bio Sc & Med Sc: 'no information provided pg. 2 - methodology of the randomised trial and the content of the informational intervention have been reported previously p.2 Baseline characteristics included. Flow of participants not included

Wolf 1996 (Continued)

Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Wolf, 1996, Arch Intern Med (Primary Study): pt population was lower SES therefore external validity of the findings limited, but overall appears to be free of other potential biases; Wolf, 1998, J Ger Ser A-Bio Sc & Med Sc: appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Wolf 2000

Methods	Randomised to decision aid vs usual care
Participants	266 + 133 elderly (65+) considering CRC screening in the USA
Interventions	DA: script of options' outcomes, clinical problem, outcome probabilities COMPARE: usual care (5 sentences)
Outcomes	preferred option*, accurate risk perceptions
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	pg. 2 "patients were randomised" Does not indicate how.
Allocation concealment (selection bias)	Unclear risk	no information provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline data not included; pg. 2 - Results
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other potential biases

Wolf 2000 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Wong 2006

Methods	Randomised to decision aid vs placebo control leaflet
Participants	162 + 164 women referred for pregnancy termination in the UK
Interventions	DA: decision aid leaflet on options' outcomes, clinical problem, outcome probability, explicit values clarification COMPARE: placebo leaflet on contraception use post pregnancy termination
Outcomes	uptake of option*, knowledge*, decisional conflict*, anxiety*
Notes	*primary outcome

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	pg. 2 "1:1 ratio, balanced block of 10" "envelope preparation by drawing slips of paper labelled either control or intervention" "the slip determined leaflet placed into envelope"
Allocation concealment (selection bias)	Low risk	pg. 2 - Methods - consecutive numbered, opaque trial envelope
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics not included. pg. 3 Reasons for attrition and incompleteness mentioned
Selective reporting (reporting bias)	Unclear risk	no information provided
Other bias	Low risk	appears to be free of other potential biases
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding

Wong 2006 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
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CHD: coronary heart disease; CRC: colorectal cancer; DA: decision aid; HPV: human papilloma virus; OA: osteoarthritis; PSA: prostate-specific antigen; RCT: randomized controlled trial; UK: United Kingdom; USA: United States of American;

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Abadie 2009	study did not evaluate the decision aid (evaluated clinician use of the decision aid in one arm of a study only)
Adab 2003	hypothetical choice, not at a point of decision making
Al Saffar 2008	study not focused on making a choice; adhering to medications only
Altiner 2007	not a patient decision aid
Anderson 2011	not a randomised controlled trial
Arimori 2006	not a patient decision aid (not including benefits and harms)
Armstrong 2005	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid. Additional information requested from author but not provided
Au 2011	not a randomised controlled trial
Becker 2009	hypothetical choice, not at the point of decision making
Bellmunt 2010	not a patient decision aid
Bieber 2006	study did not evaluate the patient decision aid (evaluated SDM process)
Breslin 2008	not a randomised controlled trial
Brown 2004	Not focused on making a choice (no specific decision to be made)
Brundage 2001	Not a randomised controlled trial
Burton 2007	not a patient decision aid (general patient education only)

(Continued)

Carling 2008	Hypothetical choice, not at point of decision making
Chadwick 1991	Not a randomised controlled trial
Chan 2011	not a patient decision aid
Chewning 1999	Not a randomised controlled trial
Chiew 2008	Not a randomised controlled trial
Col 2007	Unable to ascertain characteristics of the patient decision aid. Additional information requested from author but not provided (e.g. values clarification)
Colella 2004	Not a patient decision aid (Describes model of care)
Costanza 2011	not a randomised controlled trial
Coulter 2003	Not a randomised controlled trial (editorial)
Crang-Svalenius 1996	Not a randomised controlled trial
Davison 1999	Unable to ascertain whether intervention meets criteria (values clarification) to qualify as a patient decision aid
Davison 2007	Not a patient decision aid
Deen 2012	not a patient decision aid
Deinzer 2009	Not a patient decision aid
Diefenbach 2012	not a patient decision aid
Dobke 2008	Not focused on making a choice
Driscoll 2008	not a patient decision aid
Dunn 1998	Quasi-RCT: randomization was by days of the week
Eaton 2011	not a decision aid (no decision support)
Eden 2009	Hypothetical choice, not at point of decision making
El-Jawahri 2010	end of life decision
Ellison 2008	Not a randomised controlled trial (Quasiexperimental design); unclear whether at point of decision making
Elwyn 2004	No difference in intervention between arms. Risk communication did not have value clarification

(Continued)

Emery 2007	not a patient decision aid
Emmett 2007	Not a randomised controlled trial
Feldman-Stewart 2006	hypothetical choice, not at point of decision making
Flood 1996	Non-randomized allocation; waiting list control
Francis 2009	not a patient decision aid
Frosch 2001	Not a randomised controlled trial
Frosch 2003	Same decision aid delivered on the Internet versus on DVD plus booklet
Frosch 2008a	Not a randomised controlled trial
Frost 2009	qualitative study for an included RCT
Graham 2000	Not a patient decision aid (General information)
Gray 2009	hypothetical choice, not at the point of decision making
Green 2001b	Not a patient decision aid (Educational intervention)
Greenfield 1985	Not focused on making a choice (Intervention to increase patient involvement in care)
Griffith 2008a	Hypothetical choice, not at the point of decision making
Griffith 2008b	Not a randomised controlled trial
Gruppen 1994	Not a patient decision aid
Hall 2007	Not about evaluating a patient decision aid
Hall 2011	Not a patient decision aid
Harwood 2011	not a randomised controlled trial
Healton 1999	Not a patient decision aid (education to promote compliance)
Herrera 1983	Quasi-RCT: assigned to 1 of 2 alternating groups
Hewison 2001	Not a patient decision aid; no values clarification
Hickish 1995	Not a randomised controlled trial (letter)
Hochlehnert 2006	Not a patient decision aid (General information; no values clarification)

(Continued)

Hofbauer 2008	Not a randomised controlled trial
Hoffman 2009	Not a patient decision aid
Holbrook 2007	hypothetical choice, not at the point of decision making
Holloway 2003	not focused on making a choice (Promotes complying with a recommended option)
Holmes-Rovner 2011	not a randomised controlled trial
Holt 2009	study does not evaluate a decision aid; evaluation of spiritual versus non-spiritual framework
Hope 2010	Same content
Hunt 2005	not focused on making a choice (Promotes complying with a recommended option)
Hunter 1999	Not focused on making a choice (no specific decision)
Huyghe 2009	hypothetical choice, not at point of decision making for all participants
Ilic 2008	No difference in content of interventions - testing mode of delivery
Isebaert 2007	Not a randomised controlled trial (English paper published in 2008 Urologia Internationalis)
Jackson 2011	not a patient decision aid
Jerant 2007	Not focused on making a choice - adherence to screening
Jibaja-Weiss 2006	no comparison outcome data provided (only presents data for intervention group)
Joosten 2009	not a patient decision aid
Joosten 2011	not a patient decision aid
Jorm 2003	hypothetical choice, not at point of decision making - community sample asked to evaluate information booklet on depression
Kakkilaya 2011	hypothetical choice, not at point of decision making
Kellar 2008	hypothetical choice, not at point of decision making
Kobelka 2009	not a randomised controlled trial; not a patient decision aid
Kopke 2009	not a patient decision aid
Kripalani 2007	not a patient decision aid

(Continued)

Krones 2008	Not a patient decision aid - no benefits and harms
Kurian 2009	not a randomised controlled trial; not a patient decision aid
LaCroix 1999	inadequate comparison outcome data provided, Secondary report of pilot study
Lairson 2011	not a patient decision aid (to increase uptake of screening)
Lancaster 2009	not a patient decision aid
Lazcano Ponce 2000	not a patient decision aid (No values clarification)
Levin 2011	not a patient decision aid
Lewis 2003	Hypothetical choice, not at the point of decision making
Loon 2009	lifestyle only
Lurie 2011	not a randomised controlled trial (all patients received DA)
Maisels 1983	not a patient decision aid (No values clarification)
Mancini 2006	not about evaluating a patient decision aid
Manne 2009	not focused on making a choice (about adherence not decision making)
Manns 2005	not focused on making a choice (Promotes complying with a recommended option)
Markham 2003	Not a patient decision aid (Review of patient information pamphlets on pre-operative fasting)
Martin 2012	hypothetical choice, not at the point of decision making
Maslin 1998	Insufficient outcome data provided in publication. Requested from author but not provided
Matloff 2006	Not a patient decision aid - genetic counselling only
Mazur 1994	Hypothetical choice, not at the point of decision making
McCaffery 2007	not a patient decision aid
McGinley 2002	Not a patient decision aid (No values clarification)
McGowan 2008	not a patient decision aid
McInerney-Leo 2004	Not a patient decision aid (No risk/benefit information; no values clarification)

(Continued)

Mclaren 2012	not a patient decision aid; hypothetical choice, not at point of decision making
Michie 1997	Unable to ascertain whether intervention meets criteria (values clarification) to qualify as a patient decision aid. Additional information requested but author was unable to provide the intervention
Mishel 2009	not a patient decision aid (information only)
Molenaar 2001	Not a randomised controlled trial
Mulley 2006	Not a randomised controlled trial (Editorial)
Myers 2005b	Not a randomised controlled trial (Editorial)
Myers 2007	not a patient decision aid
Neubeck 2008	study protocol, does not appear to be patient decision aid
Newton 2001	Not a randomised controlled trial
O’Cathain 2002	Suite of 8 decision aids (not an efficacy trial)
O’Connor 1996	No patient decision aid - framing effects
O’Connor 2009	Not patient decision aid
O’Connor 2011	not a patient decision aid
Pearson 2005	Not a patient decision aid (Focus on provision of information)
Peele 2005	Not a patient decision aid (Decision aid only supplies mortality risk information; no risk info; no values clarification)
Philip 2010	not a randomised controlled trial, not a patient decision aid (Promotes complying with a recommended option)
Phillips 1995	Quasi-RCT: alternating order based on patients’ initial appointment sequence
Pinto 2008	about clinical trial entry
Powers 2011	not a patient decision aid
Proctor 2006	Not a patient decision aid (General patient education resource)
Prunty 2008	about a lifestyle choice - whether or not to have a child or have another child if I have multiple sclerosis
Rapley 2006	Not a randomised controlled trial

(Continued)

Raynes-Greenow 2009	No difference in intervention content; Comparison of presentation formats; audio-guided decision aid versus booklet only
Rimer 2001	Not focused on making a choice (Promotes complying with a recommended option)
Rimer 2002	Not focused on making a choice (Promotes complying with a recommended option)
Rovner 2004	Not a randomised controlled trial
Rubinstein 2011	not a patient decision aid
Ruddy 2009	Not a patient decision aid
Ryser 2004	Not focused on making a choice (Promotes complying with a recommended option)
Saver 2007	Not a patient decision aid - general information; not a specific decision
Sawka 2011	Not a randomised controlled trial
Schwartz 2009a	hypothetical choice, not at the point of decision making
Sears 2007	about do not resuscitate versus initiating cardiopulmonary resuscitation decision
Sequist 2011	not a patient decision aid (Promotes complying with a recommended option)
Sheppard 2012	Not a randomised controlled trial
Sheridan 2004	Not a randomised controlled trial
Sheridan 2010	hypothetical choice, not at point of decision making
Silver 2012	hypothetical choice, not at point of decision making
Siminoff 2006	Not a patient decision aid (no discussion of harms)
Simon 2012	not a patient decision aid
Smith 2011	no decision regarding treatment or screening to be made (decision regarding full disclosure)
Sorenson 2004	Not a randomised controlled trial
Sparano 2006	not a patient decision aid
Stalmeier 2009	Not a randomised controlled trial (about instrument development)
Steiner 2003	not a patient decision aid (Only effectiveness not cons of options; not at point of decision making)

(Continued)

Stephens 2008	not a randomised controlled trial
Stiggelbout 2008	not a patient decision aid
Street 1998	Not focused on making a choice (Promotes complying with a recommended option)
Sundaresan 2011	hypothetical choice, not at the point of decision making, not a randomised controlled trial
Tabak 1995	Not a randomised controlled trial
Ten 2008	not a patient decision aid; about stopping medication use
Thomson 2006	Not a randomised controlled trial; not at point of decision making
Thornton 1995	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid. Additional information requested from author but not provided
Valdez 2001	Not a randomised controlled trial; not focused on making a choice (complying with a recommended option)
van Steenkiste 2008	Not a randomised controlled trial
van Til 2009	hypothetical choice, not at the point of decision making
Veroff 2012	not a patient decision aid
Volandes 2009	advanced care planning options
Volandes 2011	hypothetical choice, end-of-life decision
von Wagner 2011	not a randomised controlled trial (commentary)
Wagner 1995	Not a randomised controlled trial
Wallston 1991	Not a patient decision aid - patient preference study
Wang 2004	Not a patient decision aid - Intent of intervention to facilitate genetic counselling process, no focused decision
Wennberg 2010	Same decision aid in both groups
Wilhelm 2009	not a patient decision aid
Wilkins 2006	Not a randomised controlled trial
Willemsen 2006	Lifestyle change
Williams-Piehot 2008	Not a randomised controlled trial

(Continued)

Woltmann 2011	not a patient decision aid
Wroe 2005	Not focused on making a choice - Promotes complying with a recommended option
Yun 2011	end-of-life decision
Zapka 2004	Not focused on making a choice - Promotes complying with a recommendation
Zikmund-Fisher 2008	No difference in intervention content - comparison of presentation of probabilities
Zoffman 2012	not a randomised controlled trial, not a patient decision aid

Characteristics of studies awaiting assessment [ordered by study ID]

Hamm prostate

Methods	
Participants	Men considering prostate cancer screening
Interventions	2 decision aids on prostate cancer screening
Outcomes	
Notes	<p>Weinrich SP, Seger RE, Rao GS, Chan EC, Hamm RM, Godley PA, Moul JW, Powell IJ, Chodak GW, Taylor KL, Weinrich MC. A decision aid for teaching limitations of prostate cancer screening. <i>Journal Natl Black Nurses Association</i>, 2008 Jul, 19(1): 1-11</p> <p>There is minimal research regarding men's knowledge of the limitations of prostate cancer screening. This study measured knowledge of prostate cancer screening based on exposure to one of two decision aids that were related to prostate cancer screening (enhanced versus usual care). The sample consisted primarily of low income (54%) African-American men (81%) (n = 230). The enhanced decision aid was compared against the usual care decision aid that was developed by the American Cancer Society. The enhanced decision aid was associated with higher post-test knowledge scores, but statistically-significant differences were observed only in the men who reported having had a previous DRE (P = 0.013) in the multivariable analyses. All the men were screened, regardless of which decision aid they received. This study highlights the impact of previous screening on education of the limitations of prostate screening, and challenges the assumption that increased knowledge of the limitations of prostate cancer screening will lead to decreased screening</p>

Unable to obtain a copy of this paper.

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

Allen 2012

Trial name or title	Evaluation of DVD and Internet decision aids for hip and knee osteoarthritis: focus on health literacy
Methods	RCT
Participants	Osteoarthritis patients
Interventions	DVD decision aid vs Internet based decision aid
Outcomes	Decisional conflict, decision self-efficacy, knowledge
Starting date	January 2012
Contact information	Kelli D Allen, Duke University
Notes	Trial #: NCT01618097

Bozic 2011

Trial name or title	Shared decision making in patients with osteoarthritis of the hip and knee
Methods	RCT
Participants	Patients with hip or knee osteoarthritis
Interventions	Participating in a share decision program with help from trained research nurse versus usual care
Outcomes	Choice of treatment, satisfaction, knowledge, length of office visit
Starting date	Not yet assessed
Contact information	Kevin Bozic
Notes	Trial #: NCT01492257

Brazell 2012

Trial name or title	Effect of a decision aid on decision making for the treatment of pelvic organ prolapse
Methods	RCT
Participants	Scheduled for consultation visit for pelvic organ prolapse of any type
Interventions	Decision aid prior to initial visit vs usual care
Outcomes	Decisional conflict, proportion patient that choose surgery or conservative management

Brazell 2012 (Continued)

Starting date	December 2012
Contact information	Hema Brazell, Hartford Hospital
Notes	Trial #: NCT01798082

Carroll 2012

Trial name or title	Development of and feasibility testing of decision support for patients who are candidates for an implantable defibrillator
Methods	RCT
Participants	Referred for consideration of an ICD(non-CRT) for a primary prevention indication
Interventions	Patient decision aid provided prior to the consultation with the physician, which provides a lay summary that outlines the facts, risks, benefits (including probabilities), specific to the option of an implantable defibrillator or the option of medical management vs usual care
Outcomes	Decision aid development and evaluation, decisional conflict and decision quality, sure test, reparation for decision-making scale, medical outcomes trust short form (SF-36v2)
Starting date	June 2012
Contact information	Sandra Carroll, McMaster University
Notes	Trial #: NCT01876173

Chambers 2008

Trial name or title	ProsCan for Men: Randomized controlled trial of a decision support intervention for men with localised prostate cancer
Methods	RCT
Participants	700 men newly diagnosed with localised prostate cancer
Interventions	A tele-based nurse delivered five session decision support/psychosocial intervention vs usual care
Outcomes	Cancer threat appraisal; decision-related distress and bother from treatment side effects; involvement in decision making; satisfaction with health care; health care utilisation; use of health care resources; and a return to previous activities
Starting date	Not yet assessed
Contact information	Suzanne K Chambers

Chambers 2008 (Continued)

Notes	Trials # ACTRN012607000233426
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Denig 2009

Trial name or title	Risk management in patients with diabetes mellitus: development and evaluation of a treatment oriented decision aid [DUTCH]
Methods	Not yet assessed
Participants	Not yet assessed
Interventions	Not yet assessed
Outcomes	Not yet assessed
Starting date	Not yet assessed
Contact information	P Denig
Notes	Trials # NTR1942

Geiger 2011

Trial name or title	Investigating a training supporting Shared Decision Making (IT'S SDM 2011): study protocol for a randomized controlled trial
Methods	RCT
Participants	40 physicians that contribute a sequence of four medical consultations including a diagnostic or treatment decision
Interventions	A training curriculum for the doctors - intend to stimulate efforts to involve their patients in the decision-making process
Outcomes	Physician-patient communication, effect of SDM on perceived quality of the decision process and on the elaboration of the decision, decisional conflict
Starting date	Not yet assessed
Contact information	Friedemann Geiger
Notes	Trials #ISRCTN78716079

Goossens 2008

Trial name or title	Decision aid evaluation by a clinical trial in abdominal aortic aneurysms: Improving decision making
Methods	Not yet assessed
Participants	Not yet assessed
Interventions	Not yet assessed
Outcomes	Not yet assessed
Starting date	November 2008
Contact information	A. Goossens
Notes	Trials # NTR1524

Ibrahim 2010

Trial name or title	Behavioral & social science research on understanding and reducing health disparities: African American preference for knee replacement: a patient-centred intervention (ACTION)
Methods	RCT
Participants	African-American patient referred to orthopedic doctor with presence of knee OA
Interventions	Decision aid video + communication, skill-building intervention vs educational program (an NIH-developed booklet) that summarizes how to live with knee OA but does not mention joint replacement
Outcomes	Recommendation and receipt of knee joint replacement
Starting date	July 2010
Contact information	Said A Ibrahim
Notes	Trial #: NCT01851785

Ickenroth 2012

Trial name or title	A single-blind randomized controlled trial of the effects of a web-based decision aid on self-testing for cholesterol and diabetes
Methods	RCT
Participants	Men and women with an intention to use a diabetes and/or cholesterol self-test
Interventions	Patient decision aid versus control pamphlet
Outcomes	Knowledge; intention; attitude; ambivalence; psychosocial determinants; behaviour

Ickenroth 2012 (Continued)

Starting date	Not yet assessed
Contact information	Martine Ickenroth
Notes	Trial # NTR3149 (Dutch trial register)

Jimbo 2012

Trial name or title	Decision aid to technologically enhance shared decision making
Methods	RCT
Participants	Patients who are not current with colorectal cancer screening
Interventions	Web based decision aid + interactive component (preferences and risk assessment) vs web based decision aid only
Outcomes	Uptake of screening on patient determinants/preference/intention before the patient-physician encounter, and on shared decision making, concordance and patient intention during/after the patient-physician encounter
Starting date	May 2012
Contact information	Mary Rapai
Notes	Trial# :NCT01514786

Juraskova 2009

Trial name or title	Improving communication about treatment options for asymptomatic ovarian cancer patients with rising CA125: RCT of patient decision aid
Methods	RCT
Participants	Not yet assessed
Interventions	Not yet assessed
Outcomes	Not yet assessed
Starting date	April 2009
Contact information	Ilona Juraskova
Notes	Trials # ACTRN12609001035213

Kuppermann 2011

Trial name or title	Development and pilot test of an elective bilateral salpingo-oophorectomy (BSO) decision support guide
Methods	RCT
Participants	Patients plans to undergo an elective hysterectomy for symptomatic fibroids, abnormal bleeding, pelvic pain, or pelvic organ prolapse OR hysterectomy via any route
Interventions	Not yet assessed
Outcomes	Decisional conflict, regret, anxiety
Starting date	May 2011
Contact information	Miriam Kuppermann
Notes	Trial #: NCT01369654

Leighl 2007

Trial name or title	Breast cancer metastatic decision aid
Methods	Not yet assessed
Participants	Women with metastatic breast cancer considering treatment options
Interventions	Decision aid versus usual care
Outcomes	Treatment decision; satisfaction with decision; knowledge; anxiety; decisional conflict; physician satisfaction with decision-making
Starting date	Sept. 2002
Contact information	Natasha Leighl, Princess Margaret Hospital, 5-222 610 University Avenue, Toronto, Ontario M5G 2M9, Canada; Telephone; 416-946-2399, Fax; 416-946-6546, email; natasha.leighl@uhn.on.ca
Notes	Chiew KS, Shepherd H, Vardy J, Tattersall MH, Butow P, Leighl NB. Development and evaluation of a decision aid for patients considering first line chemotherapy for metastatic breast cancer. Health Expectations 2008 March 11(1): 35-45. Indicates trial in process Trials #ACTRN12607000084482

Lurie 2010

Trial name or title	Helping patients with spinal stenosis make a treatment decision: a randomized study assessing the benefits of health coaching
Methods	RCT
Participants	Spinal stenosis patients

Lurie 2010 (Continued)

Interventions	Decision aid + coaching vs decision aid only
Outcomes	Decisional conflict, decision self-efficacy, number of treatment decision-related clinical contacts, treatment follow-through and decision regret
Starting date	November 2010
Contact information	Jon D Lurie
Notes	Trial #: NCT01263678

Mann 2012

Trial name or title	Increasing efficacy of primary care-based counselling for diabetes prevention: rationale and design of the ADAPT (Avoiding Diabetes Thru Action Plan Targeting) trial
Methods	RCT
Participants	Primary care providers
Interventions	Using the ADAPT (Avoiding Diabetes Thru Action Plan Targeting) system to enhance providers' effectiveness to counsel about lifestyle behaviour changes
Outcomes	Outcome measurements are designed to detect changes in patient behaviours that are most likely to result from the use of ADAPT tool: difference between intervention and control patients in the change in mean steps per day at baseline and after six months, and six month difference of differences in haemoglobin A1C and self reported diet between the two groups
Starting date	Not yet assessed
Contact information	Devin Mann
Notes	Trial #NCT01473654

Montori 2011b

Trial name or title	Translating comparative effectiveness of depression medications into practice by comparing the depression medication choice decision aid to usual care: study protocol for a randomized controlled trial
Methods	RCT
Participants	Presumed diagnosis of depression (PHQ-9 of 10 or greater) and those need to initiate drug treatment for depression as judged by clinician
Interventions	DEPRESSION CHOICE decision aid is provided to clinician to share with patient vs usual care

Montori 2011b (Continued)

Outcomes	Impact of the decision aid on patient involvement in decision making, decision making quality, patient knowledge, and 6-month measures of medication adherence and mental health compared to usual depression care
Starting date	December 2011
Contact information	Victor Montori, Mayo Clinic
Notes	Trial #: NCT01502891

Neilan 2008

Trial name or title	Use of a patient decision aid for gastrologic endoscopy in a paediatric setting
Methods	Not yet assessed
Participants	Not yet assessed
Interventions	Not yet assessed
Outcomes	Not yet assessed
Starting date	December 2008
Contact information	Nancy Neilan
Notes	Trials # NCT00813033

Oostendorp 2011

Trial name or title	Assessing the information desire of patients with advanced cancer by providing information with a decision aid, which is evaluated in a randomized trial: a study protocol
Methods	RCT
Participants	Patients with advanced colorectal, breast, or ovarian cancer and have started treatment with first-line palliative chemotherapy
Interventions	Patients are randomized to receive either usual care or usual care + decision aid
Outcomes	Not yet assessed
Starting date	Not yet assessed
Contact information	Linda JM Oostendorp

Oostendorp 2011 (Continued)

Notes	Netherlands Trial Register (NTR): NTR1113
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Parow 2007

Trial name or title	Testing the helpfulness of 2 decision aids for prostate cancer
Methods	Not yet assessed
Participants	Not yet assessed
Interventions	Not yet assessed
Outcomes	Not yet assessed
Starting date	February 2007
Contact information	Julie Parow
Notes	Trials # NCT00432601

Patel 2011

Trial name or title	Study protocol: Improving patient choice in treating low back pain (IMPACT - LBP): A randomized controlled trial of a decision support package for use in physical therapy
Methods	RCT
Participants	Physiotherapists
Interventions	Physiotherapists are randomized to receive either training for the Decision Support Package or not. Patients are randomly allocated to treatment for non specific low back pain to either a physiotherapist trained in decision support or to receive usual care
Outcomes	Satisfaction with treatment, health-related quality of life, health utility, anxiety, depression, attitude to movement in pack pain, attendance, satisfaction with decision
Starting date	Not yet assessed
Contact information	Shilpa Patel
Notes	Current Controlled TRials ISRCTN46035546

Sawka 2010

Trial name or title	Decision aid on radioactive iodine treatment for early stage papillary thyroid cancer--a randomized controlled trial
Methods	RCT
Participants	Patients with early stage papillary thyroid carcinoma
Interventions	Computerized decision aid (DA) relative to a control group receiving usual care
Outcomes	Knowledge about papillary thyroid carcinoma and radioactive iodine treatment, decisional conflict, decisional regret, client satisfaction with information received about RAI treatment, final decision to accept or reject adjuvant RAI treatment and rationale
Starting date	Not yet assessed
Contact information	Not yet assessed
Notes	Trials #NCT01083550

Schroy 2012

Trial name or title	Impact of risk stratification on shared decision making for colorectal cancer screening
Methods	RCT
Participants	Due for CRC screening based on current recommendations
Interventions	Risk Assessment tool + web based decision aid vs web based decision aid only
Outcomes	Screening test ordered, test completion rate, concordance between patient and test preference, satisfaction with decision making progress and provider satisfaction
Starting date	April 2012
Contact information	Paul C Schroy III, Boston medical center
Notes	Trial #: NCT01596582

Sepucha 2010a

Trial name or title	Measuring quality of decisions about treatment of menopausal symptoms
Methods	RCT
Participants	Patients talked with health care provider about ways to manage menopause or seriously considered taking medicine or supplement to manage menopause

Sepucha 2010a (Continued)

Interventions	Decision aid (DVD/booklet) vs usual care
Outcomes	Knowledge, value concordance
Starting date	June 2010
Contact information	Karen R Sepucha
Notes	NCT01152294

Sepucha 2010b

Trial name or title	Measuring quality of decisions about treatment of depression
Methods	RCT
Participants	Patients that talked to a health care provider about starting or stopping a treatment (prescription medicine for depression or counselling)
Interventions	Decision aid (DVD/booklet) vs usual care
Outcomes	Knowledge, value concordance
Starting date	June 2010
Contact information	Karen R Sepucha
Notes	NCT01152307

Shah 2011

Trial name or title	Study to test use of a decision aid in a clinical visit to help patients choose a diabetes medication. Translating Information on Comparative Effectiveness Into Practice (TRICEP)
Methods	RCT
Participants	Type 2 diabetes mellitus patients
Interventions	Diabetes Medication Decision Aid vs usual care
Outcomes	Patient satisfaction and knowledge. Physician adoption and satisfaction with the decision aid
Starting date	January 2011
Contact information	Nilay D. Shah, Mayo Clinic

Shah 2011 (Continued)

Notes	NCT01293578
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Sherman 2009

Trial name or title	Evaluating an online decision aid for women considering breast reconstruction following mastectomy
Methods	Not yet assessed
Participants	Not yet assessed
Interventions	Not yet assessed
Outcomes	Not yet assessed
Starting date	May 2009
Contact information	Kerry Sherman
Notes	Trials # ACTRN12609000363280

Smits 2009

Trial name or title	Shared decision making: the effects of a decision aid for Turkish and Moroccan mental health care clients with depression on the client-caregiver relationship
Methods	Not yet assessed
Participants	Not yet assessed
Interventions	Not yet assessed
Outcomes	Not yet assessed
Starting date	May 2009
Contact information	C. Smits
Notes	RTN 1822

Stacey 2009

Trial name or title	Comparison of ways to prepare patients for decisions about joint replacement surgery
Methods	RCT
Participants	Patients considering joint replacement surgery

Stacey 2009 (Continued)

Interventions	Patient decision aid versus usual care
Outcomes	Wait times, decision quality, knowledge, choice, disease specific quality of life
Starting date	Not yet assessed
Contact information	Not yet assessed
Notes	Trial Registry NCT00911638

Zayed 2009

Trial name or title	Decision aid in veterans with PTSD
Methods	Not yet assessed
Participants	Not yet assessed
Interventions	Not yet assessed
Outcomes	Not yet assessed
Starting date	May 2009
Contact information	Maha Zayed
Notes	Trials # NCT00908440

OA: osteoarthritis; RCT: randomized controlled trial

DATA AND ANALYSES

Comparison 1. Knowledge

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Knowledge: DA vs usual care - all studies	42	10842	Mean Difference (IV, Random, 95% CI)	13.34 [11.17, 15.51]
2 Knowledge: DA vs usual care - treatment only	23	3977	Mean Difference (IV, Random, 95% CI)	13.75 [11.08, 16.43]
3 Knowledge: DA vs usual care - screening only	19	6865	Mean Difference (IV, Random, 95% CI)	12.76 [9.66, 15.86]
4 Knowledge: Detailed vs simple decision aids - all studies	19	3531	Mean Difference (IV, Random, 95% CI)	5.52 [3.90, 7.15]
5 Knowledge: Detailed vs simple decision aids - treatment only	12	1930	Mean Difference (IV, Random, 95% CI)	4.98 [2.64, 7.33]
6 Knowledge: Detailed vs simple decision aids - screening only	7	1601	Mean Difference (IV, Random, 95% CI)	6.33 [4.49, 8.17]

Comparison 2. Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Accurate risk perceptions - all studies	19	5868	Risk Ratio (M-H, Random, 95% CI)	1.82 [1.52, 2.16]
2 Accurate risk perceptions - treatments only	12	2435	Risk Ratio (M-H, Random, 95% CI)	1.72 [1.47, 2.01]
3 Accurate risk perceptions - screening only	7	3433	Risk Ratio (M-H, Random, 95% CI)	2.03 [1.40, 2.93]
4 Accurate risk perceptions - numbers	15	4776	Risk Ratio (M-H, Random, 95% CI)	2.00 [1.65, 2.43]
5 Accurate risk perceptions - words	4	1092	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.13, 1.52]

Comparison 3. Values congruent with chosen option

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Values congruent with chosen option - all studies	13	4670	Risk Ratio (M-H, Random, 95% CI)	1.51 [1.17, 1.96]
2 Values congruent with chosen option - treatment only	3	452	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.80, 2.30]
3 Values congruent with chosen option - screening only	10	4321	Risk Ratio (M-H, Random, 95% CI)	1.56 [1.16, 2.11]

Comparison 4. Decisional conflict

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Decisional conflict: DA vs usual care - all studies	32		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Uncertainty sub-scale	23	4837	Mean Difference (IV, Random, 95% CI)	-2.47 [-4.28, -0.66]
1.2 Uninformed sub-scale	22	4343	Mean Difference (IV, Random, 95% CI)	-7.26 [-9.73, -4.78]
1.3 Unclear values sub-scale	18	3704	Mean Difference (IV, Random, 95% CI)	-6.09 [-8.50, -3.67]
1.4 Unsupported sub-scale	19	3851	Mean Difference (IV, Random, 95% CI)	-4.77 [-6.86, -2.69]
1.5 Ineffective choice sub-scale	19	3878	Mean Difference (IV, Random, 95% CI)	-4.86 [-7.04, -2.68]
1.6 Total decisional conflict score	28	5830	Mean Difference (IV, Random, 95% CI)	-6.22 [-8.00, -4.44]
2 Decisional conflict: DA vs usual care - treatment only	23		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Uncertainty sub-scale	16	3020	Mean Difference (IV, Random, 95% CI)	-3.06 [-5.33, -0.79]
2.2 Uninformed sub-scale	17	3007	Mean Difference (IV, Random, 95% CI)	-8.06 [-10.52, -5.60]
2.3 Unclear values sub-scale	14	2474	Mean Difference (IV, Random, 95% CI)	-6.31 [-9.01, -3.61]
2.4 Unsupported sub-scale	15	2621	Mean Difference (IV, Random, 95% CI)	-5.28 [-7.74, -2.82]
2.5 Ineffective choice sub-scale	15	2746	Mean Difference (IV, Random, 95% CI)	-6.07 [-8.41, -3.72]
2.6 Total decisional conflict score	22	3783	Mean Difference (IV, Random, 95% CI)	-6.14 [-7.78, -4.50]
3 Decisional conflict: DA vs usual care - screening only	9		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 Uncertainty sub-scale	7	1817	Mean Difference (IV, Random, 95% CI)	-1.32 [-4.47, 1.83]
3.2 Uninformed sub-scale	5	1336	Mean Difference (IV, Random, 95% CI)	-4.67 [-10.61, 1.27]
3.3 Unclear values sub-scale	4	1230	Mean Difference (IV, Random, 95% CI)	-5.94 [-13.44, 1.56]
3.4 Unsupported sub-scale	4	1230	Mean Difference (IV, Random, 95% CI)	-2.94 [-6.90, 1.02]
3.5 Ineffective choice sub-scale	4	1132	Mean Difference (IV, Random, 95% CI)	-0.17 [-1.88, 1.55]
3.6 Total decisional conflict score	6	2047	Mean Difference (IV, Random, 95% CI)	-6.83 [-12.64, -1.03]
4 Decisional conflict: Detailed vs simple decision aid - all studies	19		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.1 Uncertainty sub-scale	14	2130	Mean Difference (IV, Random, 95% CI)	-2.15 [-4.42, 0.12]
4.2 Uninformed sub-scale	10	1264	Mean Difference (IV, Random, 95% CI)	-2.39 [-4.39, -0.39]

4.3 Unclear values sub-scale	10	1260	Mean Difference (IV, Random, 95% CI)	-2.31 [-4.67, 0.05]
4.4 Unsupported sub-scale	10	1268	Mean Difference (IV, Random, 95% CI)	-2.05 [-5.37, 1.27]
4.5 Ineffective choice sub-scale	9	1541	Mean Difference (IV, Random, 95% CI)	-1.06 [-2.83, 0.71]
4.6 Total decisional conflict score	17	3277	Mean Difference (IV, Random, 95% CI)	-1.77 [-2.64, -0.91]
5 Decisional conflict: Detailed vs simple decision aid - treatment only	12		Mean Difference (IV, Random, 95% CI)	Subtotals only
5.1 Uncertainty sub-scale	9	1101	Mean Difference (IV, Random, 95% CI)	-2.02 [-6.65, 2.61]
5.2 Uninformed sub-scale	6	672	Mean Difference (IV, Random, 95% CI)	-1.16 [-4.40, 2.09]
5.3 Unclear values sub-scale	6	669	Mean Difference (IV, Random, 95% CI)	-0.46 [-3.72, 2.80]
5.4 Unsupported sub-scale	6	674	Mean Difference (IV, Random, 95% CI)	-0.65 [-3.09, 1.79]
5.5 Ineffective choice sub-scale	7	849	Mean Difference (IV, Random, 95% CI)	-0.27 [-2.97, 2.44]
5.6 Total decisional conflict score	10	1732	Mean Difference (IV, Random, 95% CI)	-0.96 [-2.30, 0.38]
6 Decisional conflict: Detailed vs simple decision aid - screening only	7		Mean Difference (IV, Random, 95% CI)	Subtotals only
6.1 Uncertainty sub-scale	5	1029	Mean Difference (IV, Random, 95% CI)	-2.16 [-4.20, -0.12]
6.2 Uninformed sub-scale	4	592	Mean Difference (IV, Random, 95% CI)	-3.42 [-5.81, -1.02]
6.3 Unclear values sub-scale	4	591	Mean Difference (IV, Random, 95% CI)	-4.54 [-6.77, -2.32]
6.4 Unsupported sub-scale	4	594	Mean Difference (IV, Random, 95% CI)	-3.65 [-9.74, 2.44]
6.5 Ineffective choice sub-scale	2	692	Mean Difference (IV, Random, 95% CI)	-2.18 [-3.60, -0.75]
6.6 Total decisional conflict score	7	1545	Mean Difference (IV, Random, 95% CI)	-2.26 [-3.33, -1.19]

Comparison 5. Participation in decision making

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participation in decision making: DA vs usual care - all studies	14		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Patient controlled decision making	12	2438	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.02, 1.60]
1.2 Shared decision making	12	2402	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.82, 1.13]
1.3 Practitioner controlled decision making	14	3234	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.53, 0.81]
2 Participation in decision making: DA vs usual care - treatment only	11		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Patient controlled decision making	10	2147	Risk Ratio (M-H, Random, 95% CI)	1.33 [1.05, 1.68]
2.2 Shared decision making	10	2111	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.78, 1.15]
2.3 Practitioner controlled decision making	11	2318	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.54, 0.90]
3 Participation in decision making: DA vs usual care - screening only	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only

3.1 Patient controlled decision making	3	887	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.82, 1.20]
3.2 Shared decision making	3	887	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.89, 1.45]
3.3 Practitioner controlled decision making	4	1512	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.44, 1.01]
4 Participation in decision making: Detailed vs simple decision aid - all studies	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 Patient controlled decision making	2	687	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.68, 1.64]
4.2 Shared decision making	2	687	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.63, 1.81]
4.3 Practitioner controlled decision making	2	687	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.56, 2.23]
5 Participation in decision making: Detailed vs simple decision aid - treatment only	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1 Patient controlled decision making	2	687	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.68, 1.64]
5.2 Shared decision making	2	687	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.63, 1.81]
5.3 Practitioner controlled decision making	2	687	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.56, 2.23]

Comparison 6. Proportion undecided

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Proportion undecided: DA vs usual care - all studies	18	4753	Risk Ratio (M-H, Random, 95% CI)	0.59 [0.47, 0.72]
2 Proportion undecided: DA vs usual care - treatment only	14	2830	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.51, 0.78]
3 Proportion undecided: DA vs usual care - screening only	4	1923	Risk Ratio (M-H, Random, 95% CI)	0.52 [0.30, 0.90]
4 Proportion undecided: Detailed vs simple decision aids - all studies	3	352	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.69, 1.37]
5 Proportion undecided: Detailed vs simple decision aids - treatment only	2	151	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.71, 1.47]
6 Proportion undecided: Detailed vs simple decision aids - screening only	1	201	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.21, 1.86]

Comparison 7. Satisfaction

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Satisfaction with the choice: DA vs usual care - all studies	10		Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Satisfaction with the choice: DA vs usual care - treatment only	9		Mean Difference (IV, Random, 95% CI)	Totals not selected
3 Satisfaction with the choice: DA vs usual care - screening only	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
4 Satisfaction with the choice: Detailed vs simple DA - all studies	3		Mean Difference (IV, Random, 95% CI)	Totals not selected
5 Satisfaction with the choice: Detailed vs simple DA - treatment only	3		Mean Difference (IV, Random, 95% CI)	Totals not selected
6 Satisfaction with the decision making process: DA vs usual care - all studies	6		Mean Difference (IV, Random, 95% CI)	Totals not selected
7 Satisfaction with the decision making process: DA vs usual care - treatment only	5		Mean Difference (IV, Random, 95% CI)	Totals not selected
8 Satisfaction with the decision making process: DA vs usual care - screening only	1		Mean Difference (IV, Random, 95% CI)	Totals not selected

Comparison 8. Choice

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Choice: Surgery over conservative option: DA vs usual care	15		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 As treated analysis	15	2915	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.67, 0.95]
1.2 Intention to treat analysis	15	3553	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.68, 0.93]
2 Choice: Surgery over conservative option: Detailed vs simple decision aid	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 As treated analysis	3	513	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.63, 1.08]
2.2 Intention to treat analysis	3	584	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.63, 1.08]
3 Choice for screening	28		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 PSA screening: DA vs usual care	9	3565	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.77, 0.98]
3.2 PSA screening: detailed DA vs simple decision aid	3	782	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.82, 1.17]

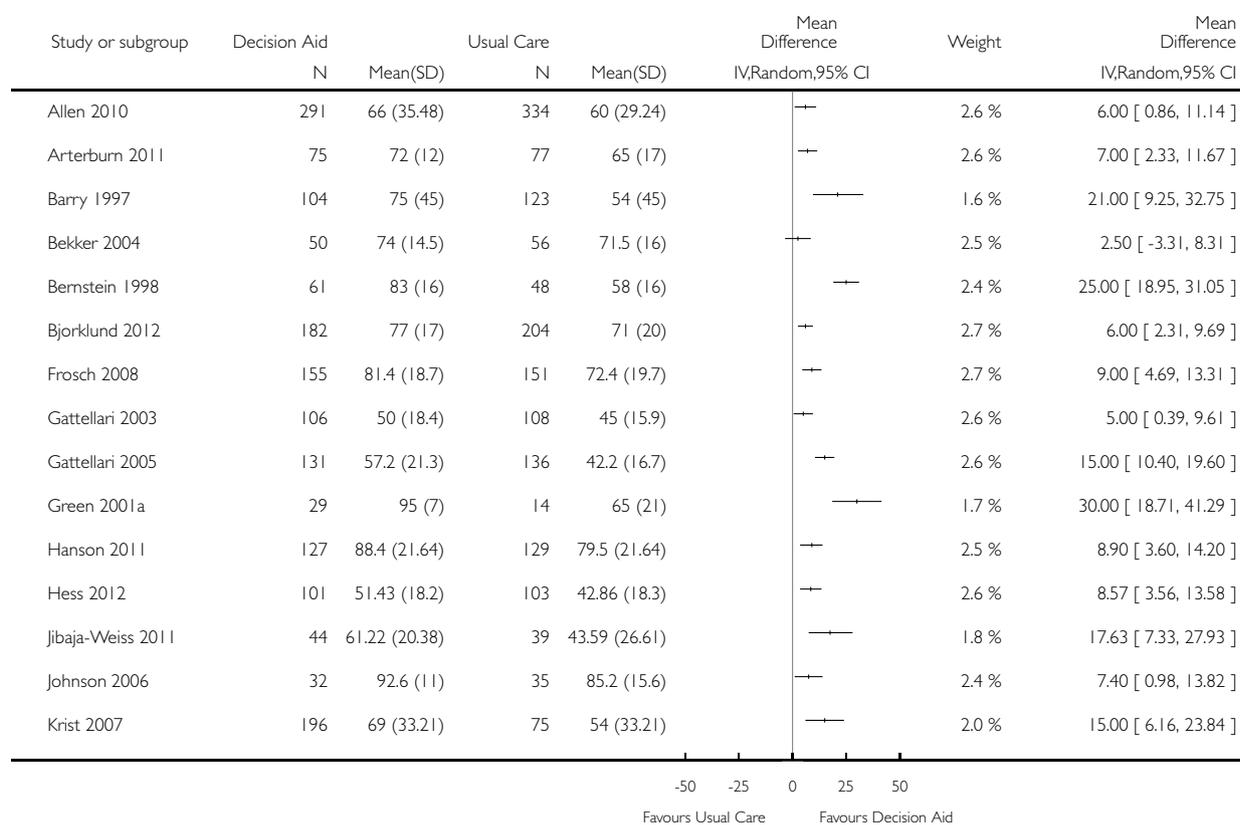
3.3 Colorectal cancer screening: DA vs usual care	10	4529	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.95, 1.31]
3.4 Breast cancer genetic testing: DA vs usual care	4	949	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.83, 1.22]
3.5 Prenatal diagnostic testing: Detailed vs simple decision aid	2	443	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.90, 1.03]
4 Choice: Diabetes medication (uptake new medication): DA vs usual care	3	277	Risk Ratio (M-H, Random, 95% CI)	1.84 [0.77, 4.39]
5 Choice: Menopausal hormone therapy: Detailed vs simple decision aid	3	357	Risk Ratio (M-H, Random, 95% CI)	0.73 [0.55, 0.98]

Analysis 1.1. Comparison 1 Knowledge, Outcome 1 Knowledge: DA vs usual care - all studies.

Review: Decision aids for people facing health treatment or screening decisions

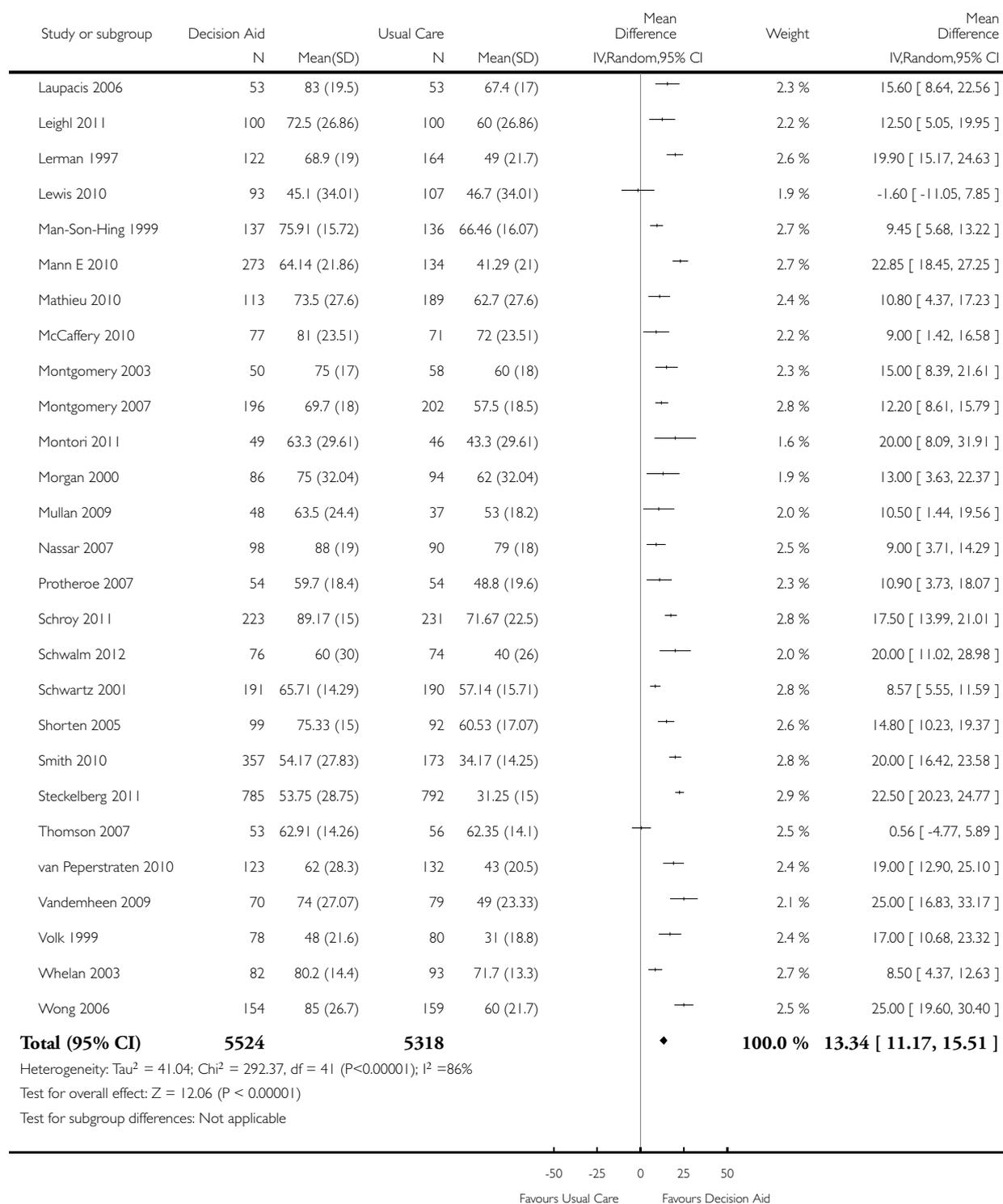
Comparison: 1 Knowledge

Outcome: 1 Knowledge: DA vs usual care - all studies



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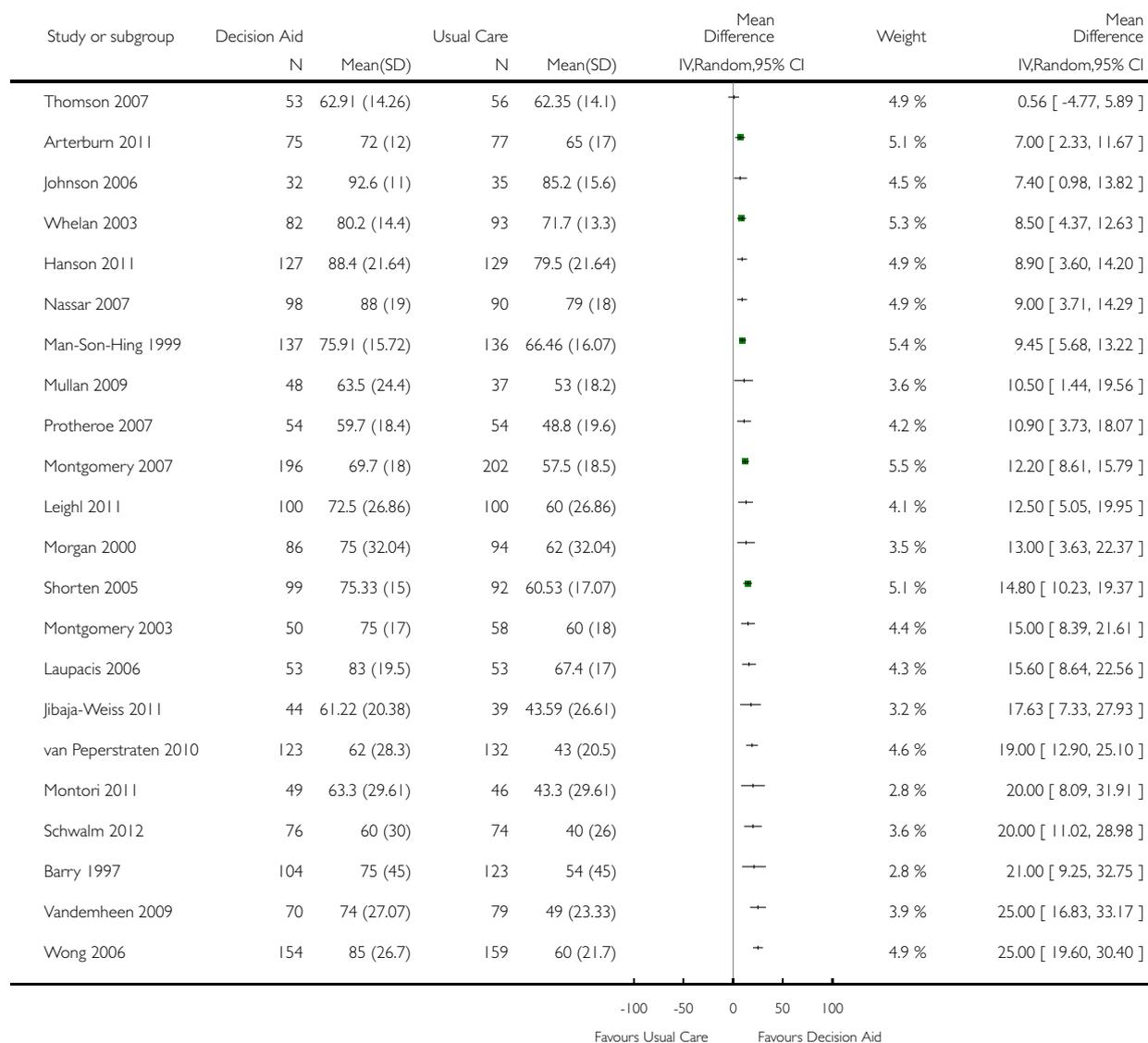


Analysis 1.2. Comparison 1 Knowledge, Outcome 2 Knowledge: DA vs usual care - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

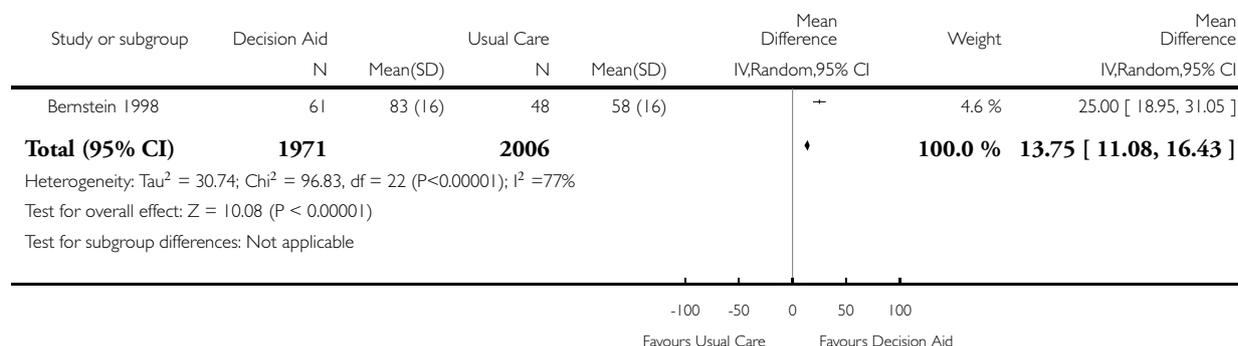
Comparison: 1 Knowledge

Outcome: 2 Knowledge: DA vs usual care - treatment only



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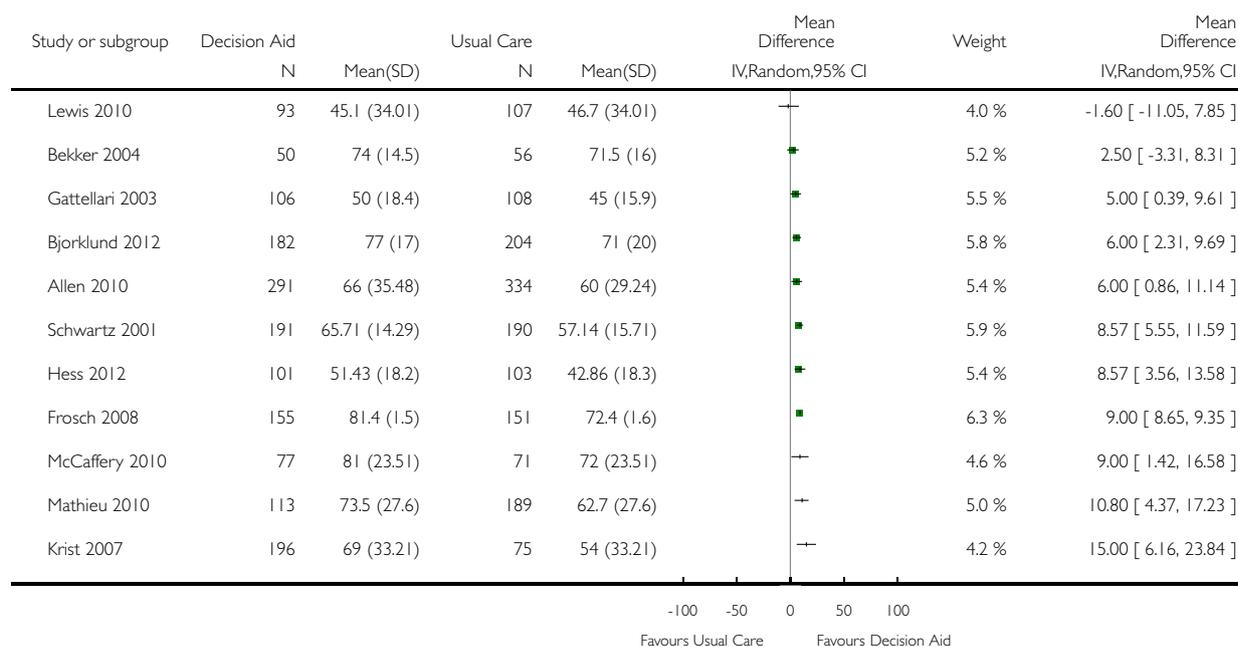


Analysis 1.3. Comparison 1 Knowledge, Outcome 3 Knowledge: DA vs usual care - screening only.

Review: Decision aids for people facing health treatment or screening decisions

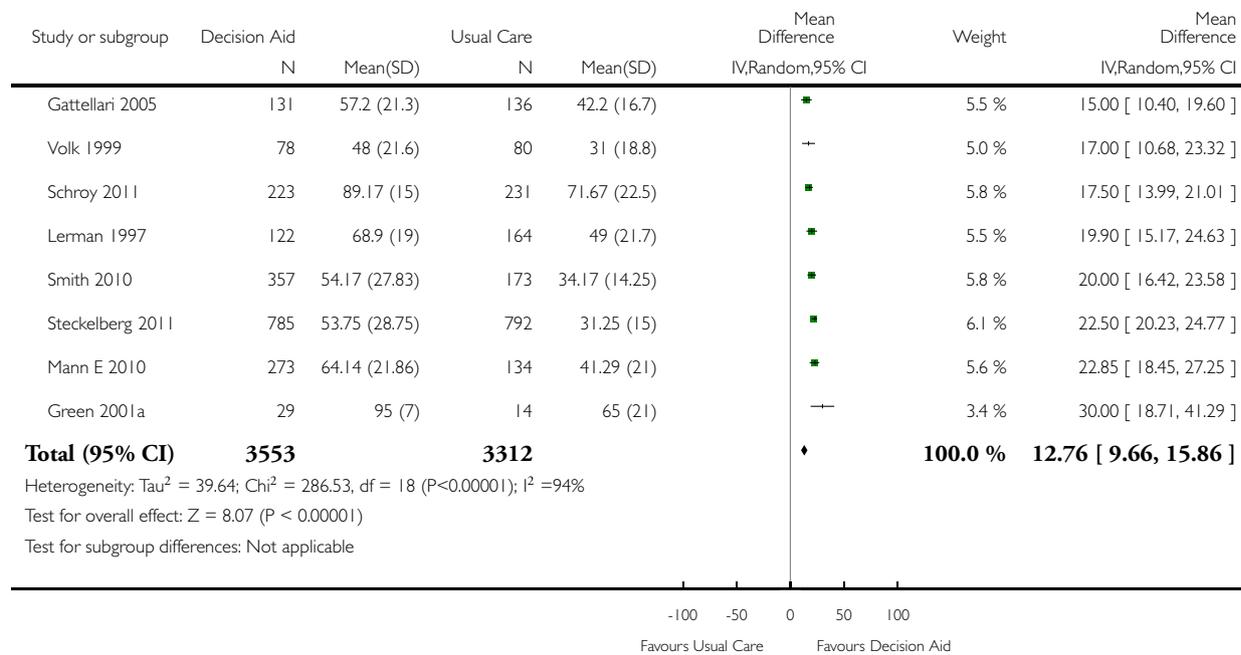
Comparison: 1 Knowledge

Outcome: 3 Knowledge: DA vs usual care - screening only



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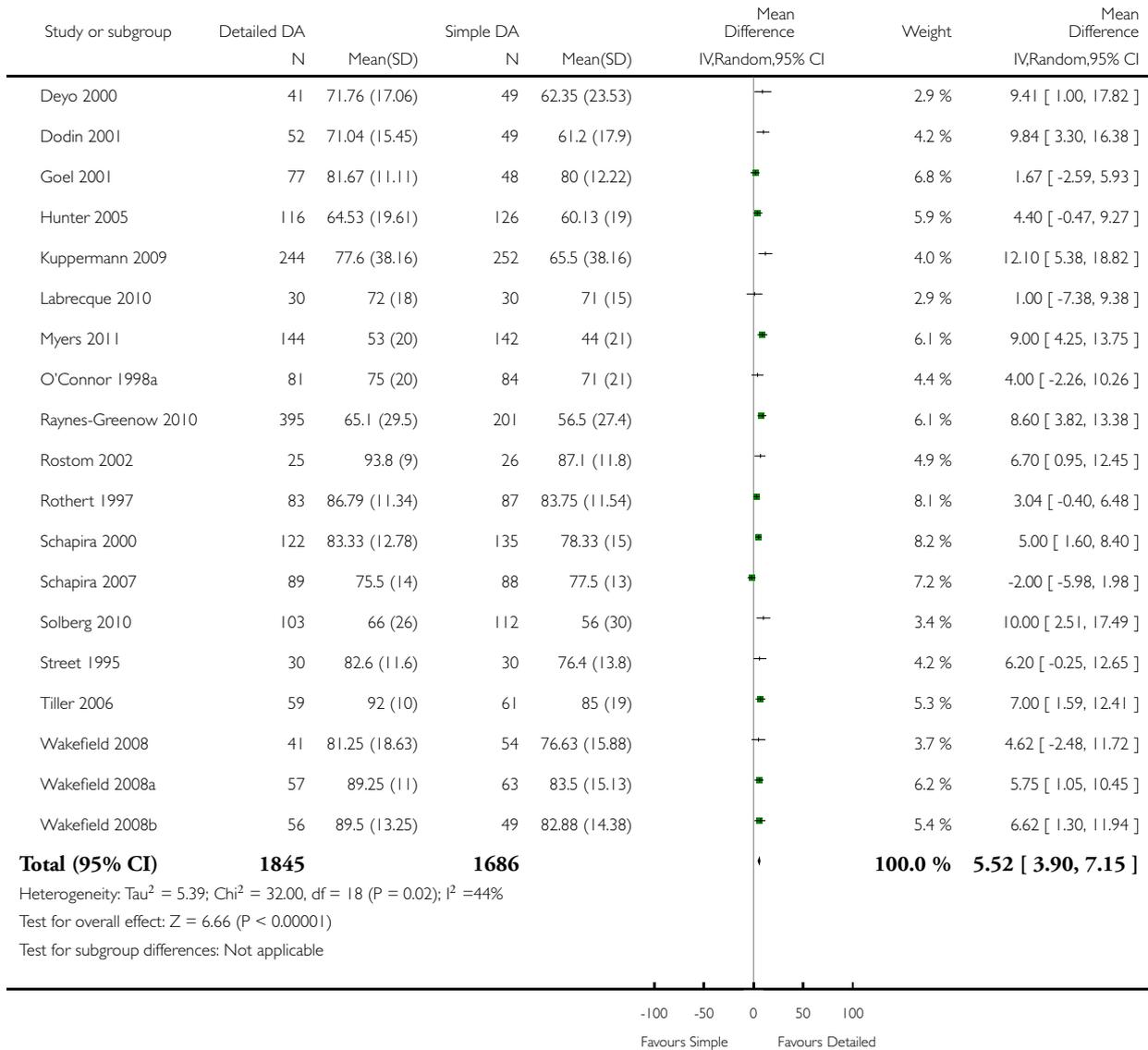


Analysis 1.4. Comparison 1 Knowledge, Outcome 4 Knowledge: Detailed vs simple decision aids - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Knowledge

Outcome: 4 Knowledge: Detailed vs simple decision aids - all studies

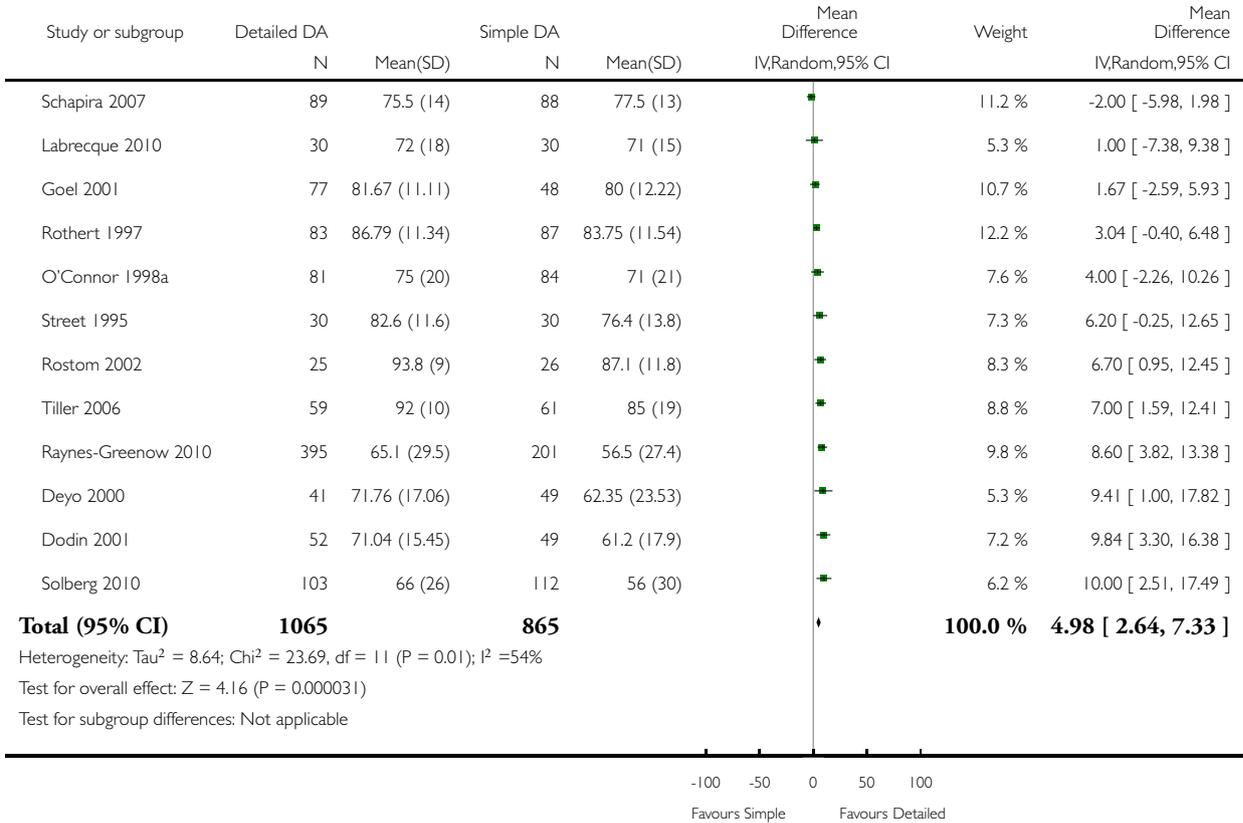


Analysis 1.5. Comparison 1 Knowledge, Outcome 5 Knowledge: Detailed vs simple decision aids - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Knowledge

Outcome: 5 Knowledge: Detailed vs simple decision aids - treatment only

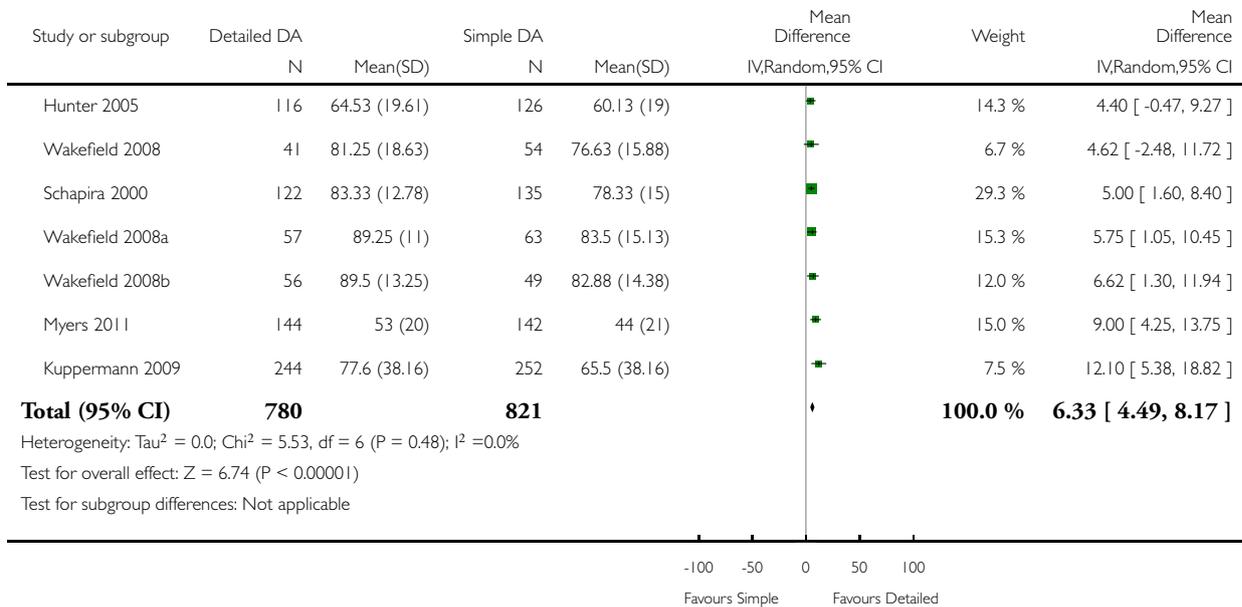


Analysis 1.6. Comparison 1 Knowledge, Outcome 6 Knowledge: Detailed vs simple decision aids - screening only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Knowledge

Outcome: 6 Knowledge: Detailed vs simple decision aids - screening only

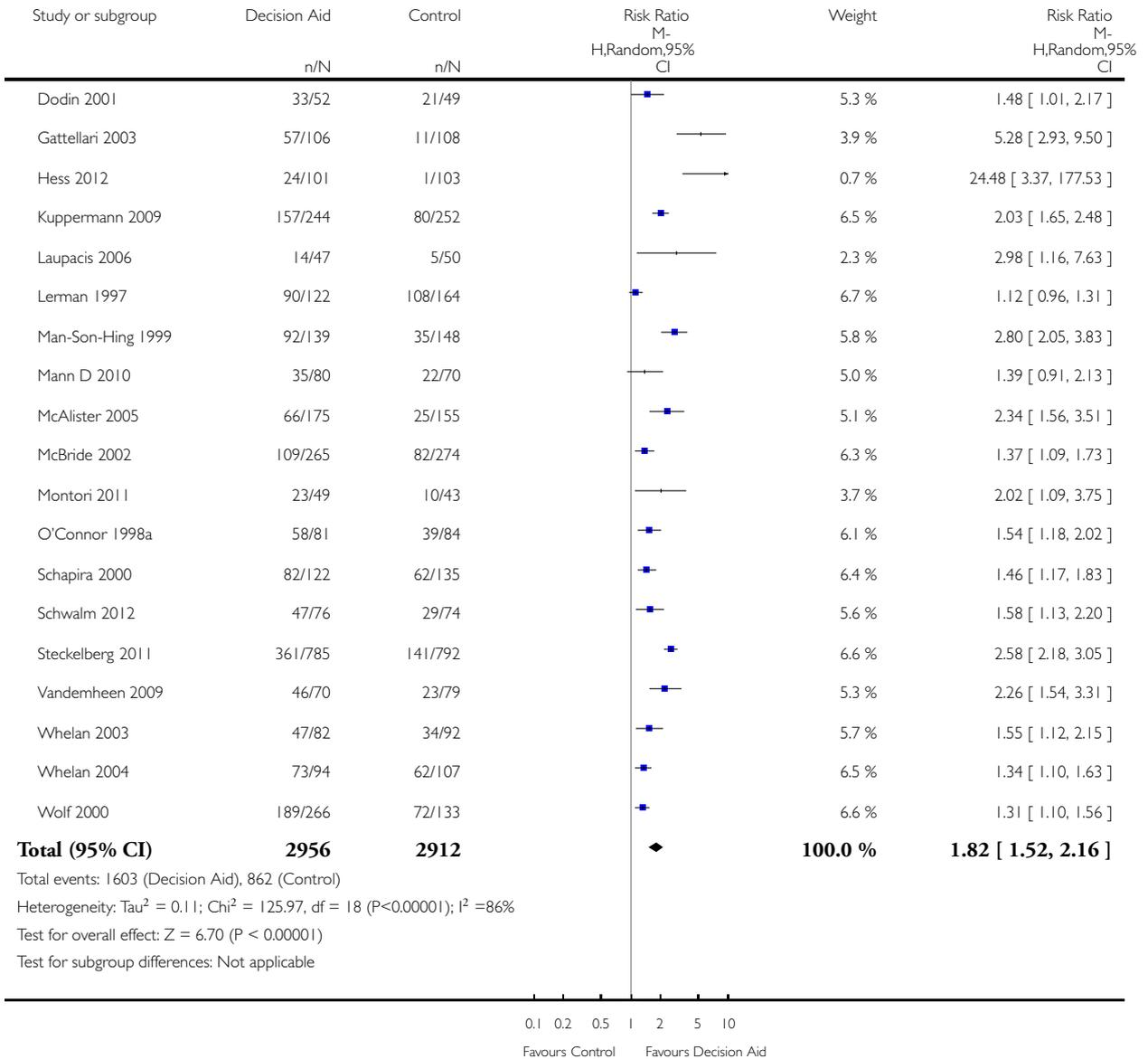


Analysis 2.1. Comparison 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information, Outcome 1 Accurate risk perceptions - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information

Outcome: 1 Accurate risk perceptions - all studies

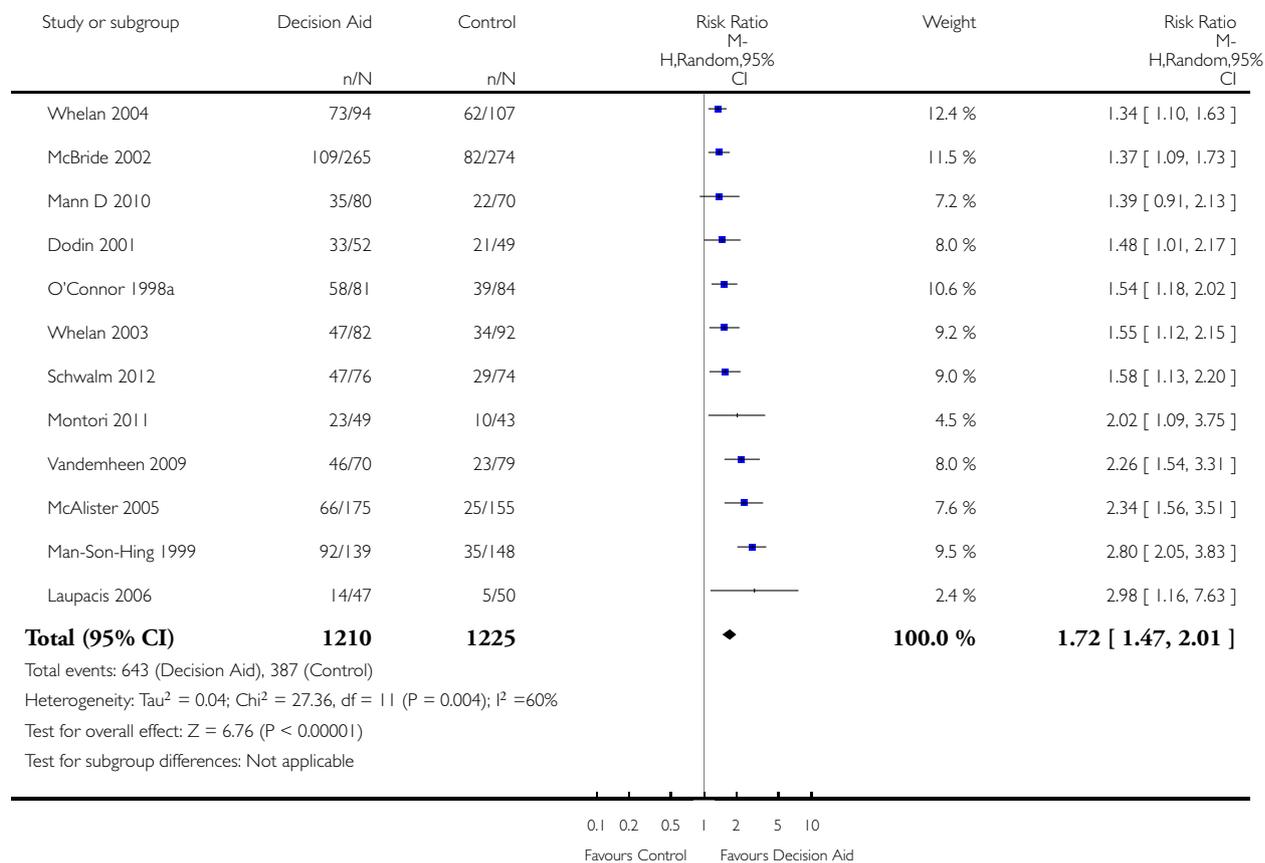


Analysis 2.2. Comparison 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information, Outcome 2 Accurate risk perceptions - treatments only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information

Outcome: 2 Accurate risk perceptions - treatments only

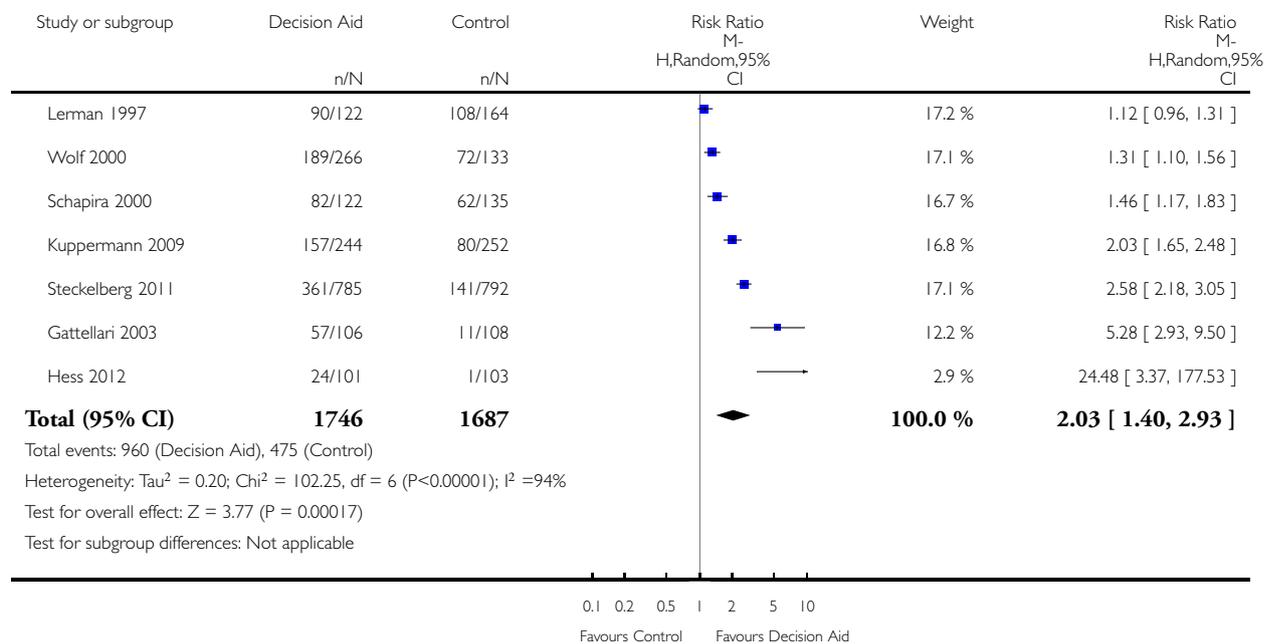


Analysis 2.3. Comparison 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information, Outcome 3 Accurate risk perceptions - screening only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information

Outcome: 3 Accurate risk perceptions - screening only

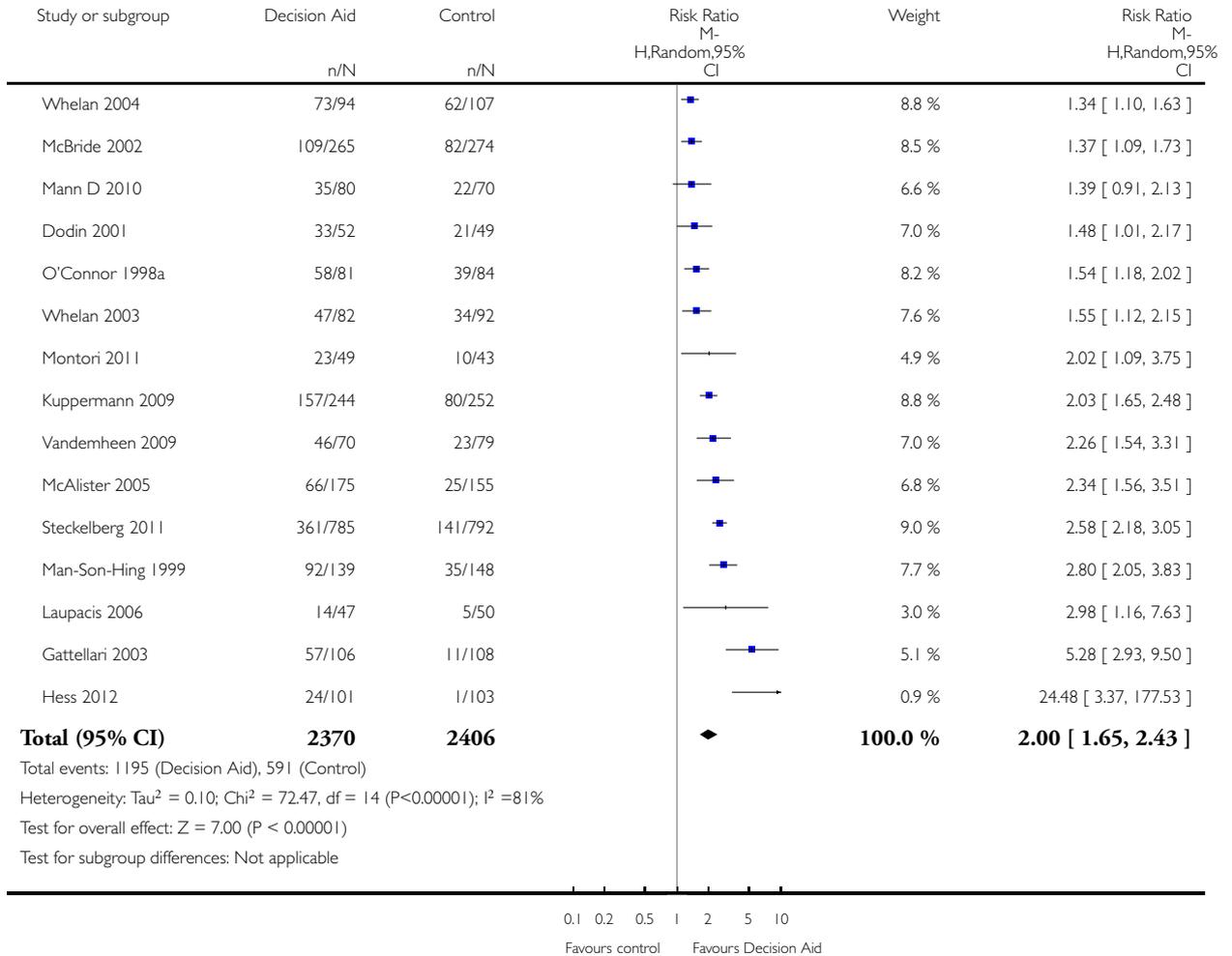


Analysis 2.4. Comparison 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information, Outcome 4 Accurate risk perceptions - numbers.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information

Outcome: 4 Accurate risk perceptions - numbers

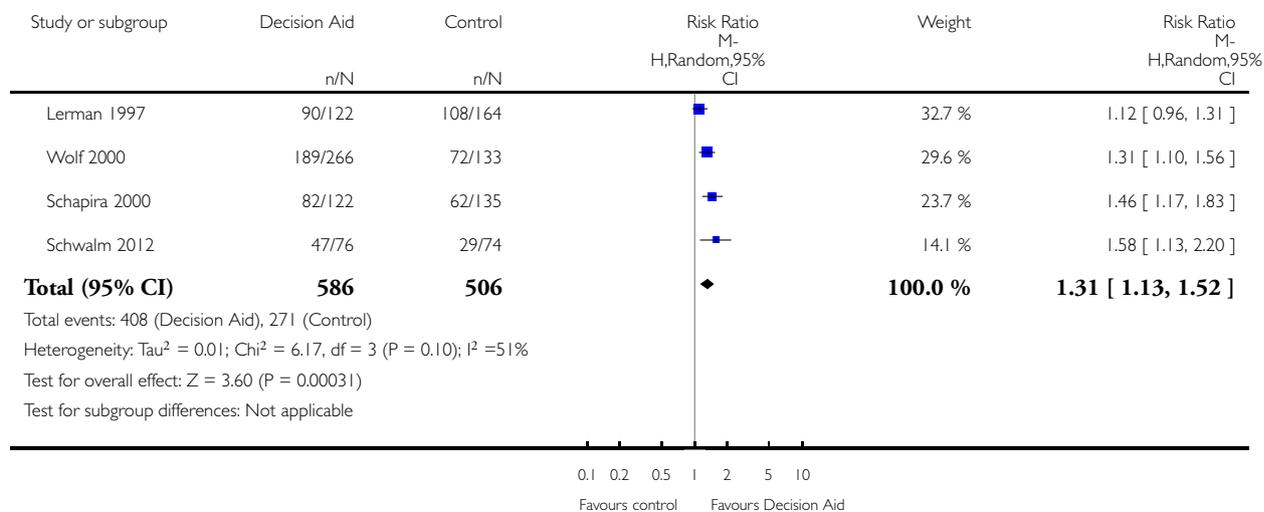


Analysis 2.5. Comparison 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information, Outcome 5 Accurate risk perceptions - words.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Accurate risk perceptions: decision aid with outcome probabilities vs no outcome probability information

Outcome: 5 Accurate risk perceptions - words

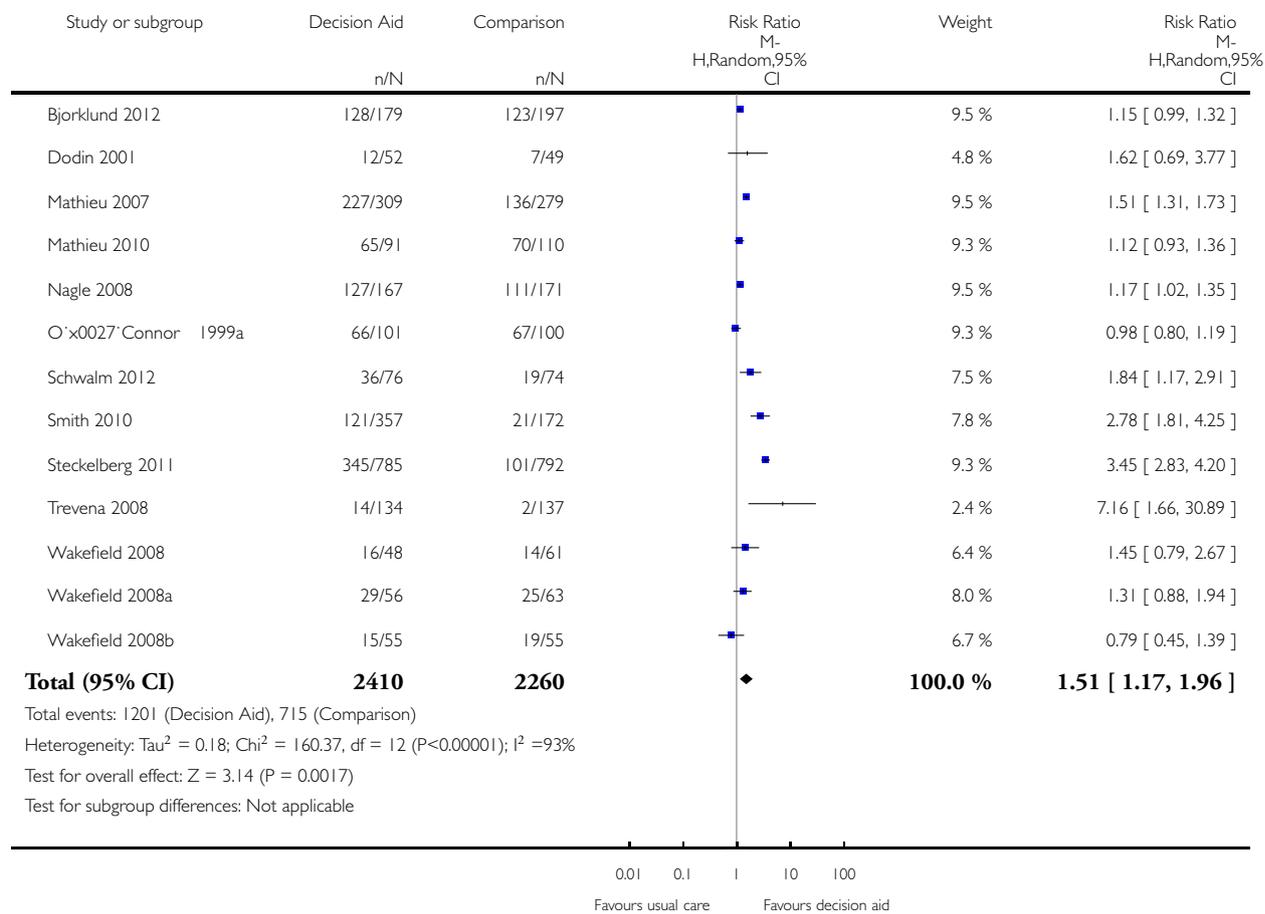


Analysis 3.1. Comparison 3 Values congruent with chosen option, Outcome 1 Values congruent with chosen option - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 3 Values congruent with chosen option

Outcome: 1 Values congruent with chosen option - all studies

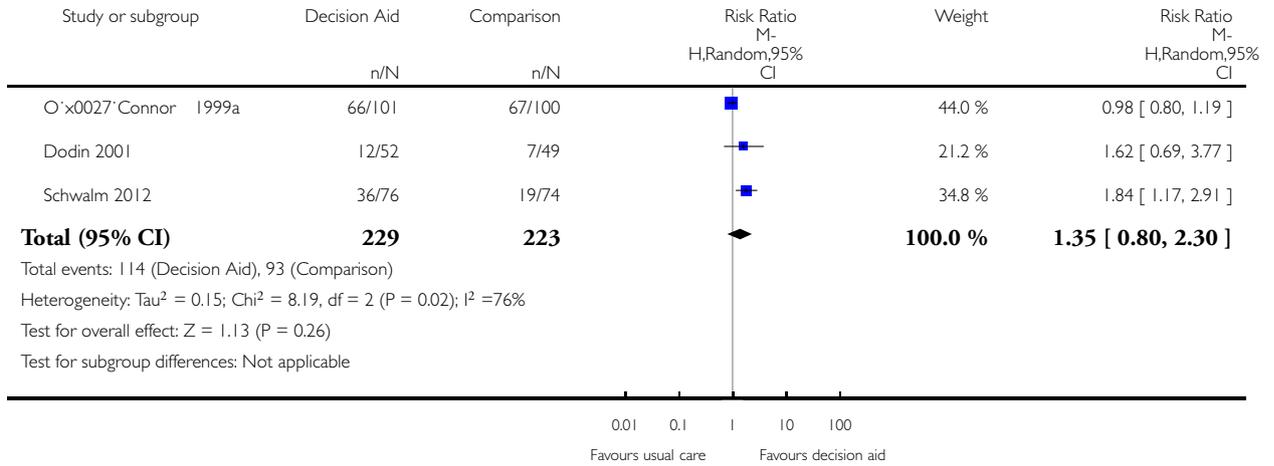


Analysis 3.2. Comparison 3 Values congruent with chosen option, Outcome 2 Values congruent with chosen option - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 3 Values congruent with chosen option

Outcome: 2 Values congruent with chosen option - treatment only

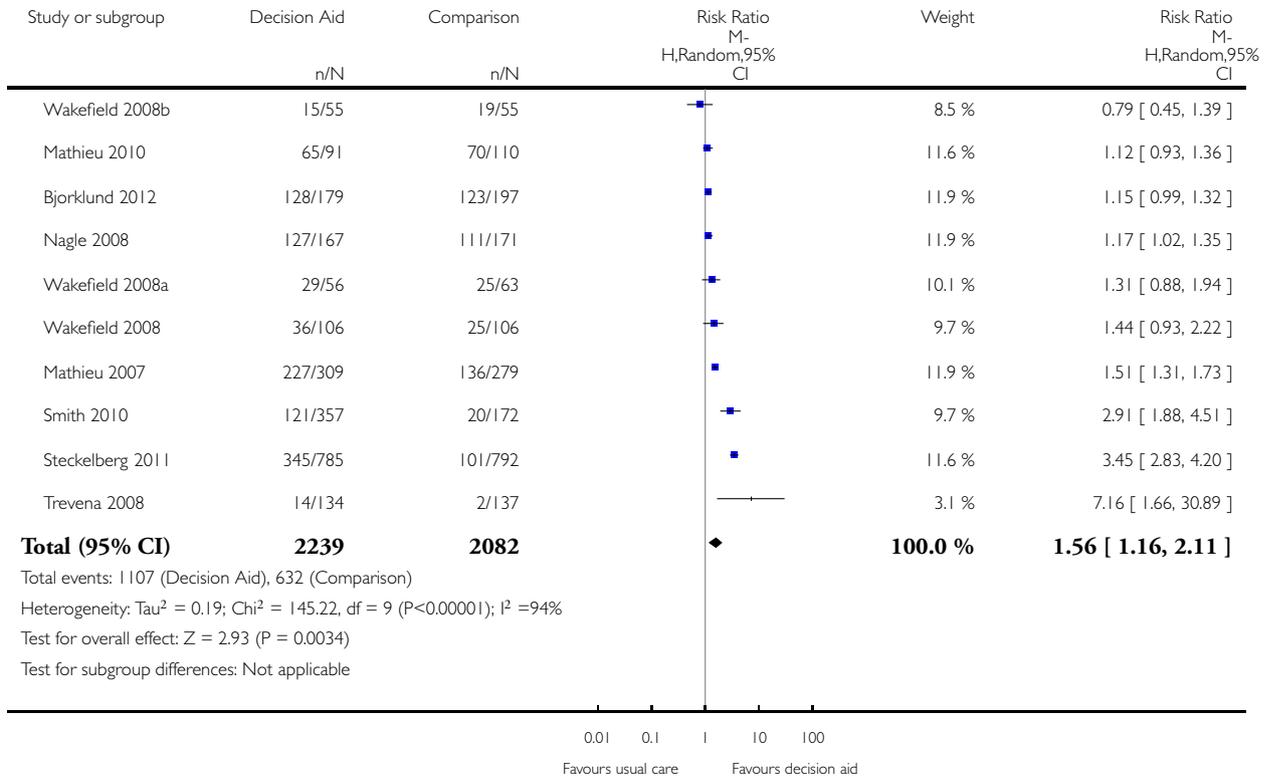


Analysis 3.3. Comparison 3 Values congruent with chosen option, Outcome 3 Values congruent with chosen option - screening only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 3 Values congruent with chosen option

Outcome: 3 Values congruent with chosen option - screening only

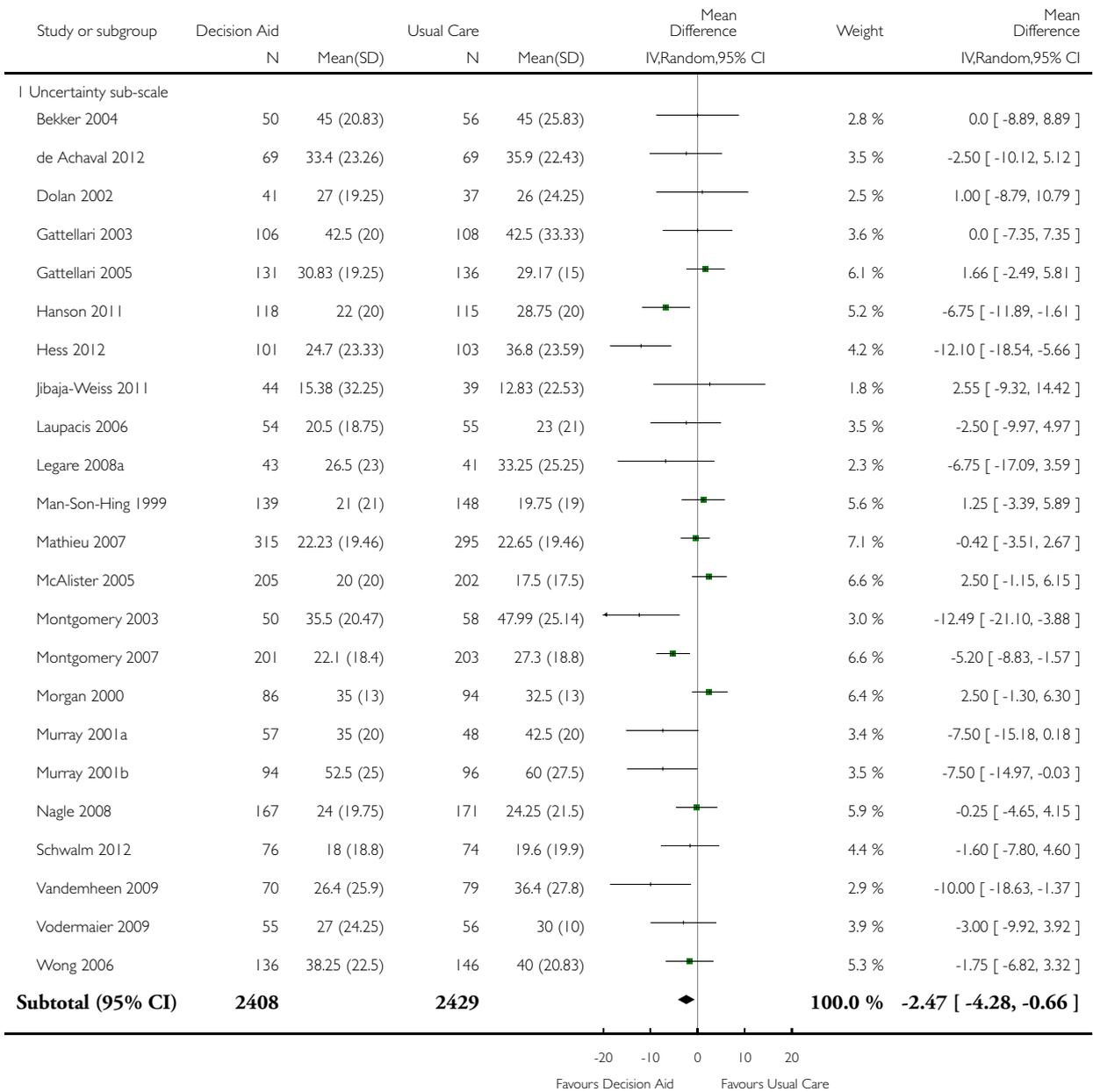


Analysis 4.1. Comparison 4 Decisional conflict, Outcome 1 Decisional conflict: DA vs usual care - all studies.

Review: Decision aids for people facing health treatment or screening decisions

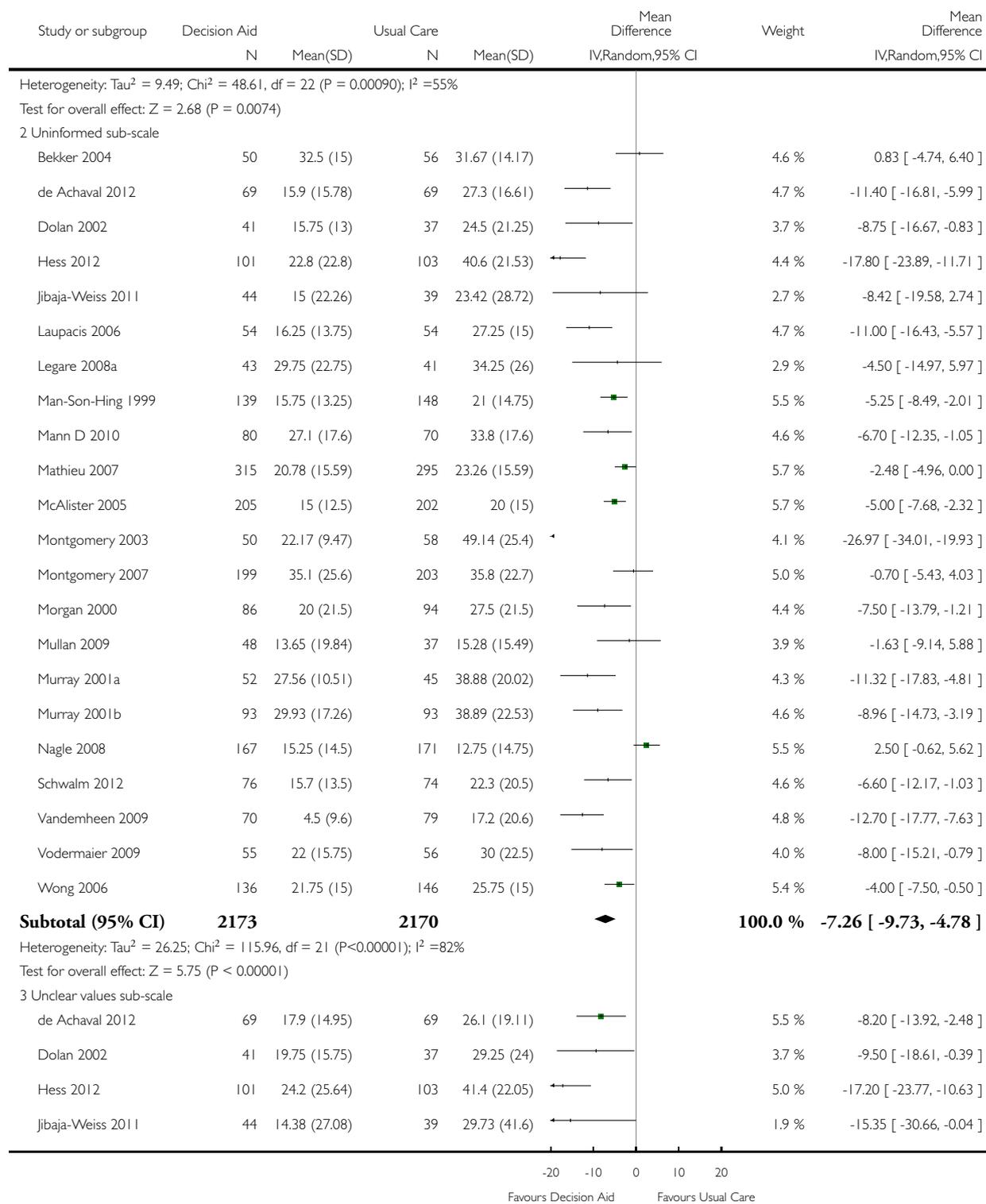
Comparison: 4 Decisional conflict

Outcome: 1 Decisional conflict: DA vs usual care - all studies



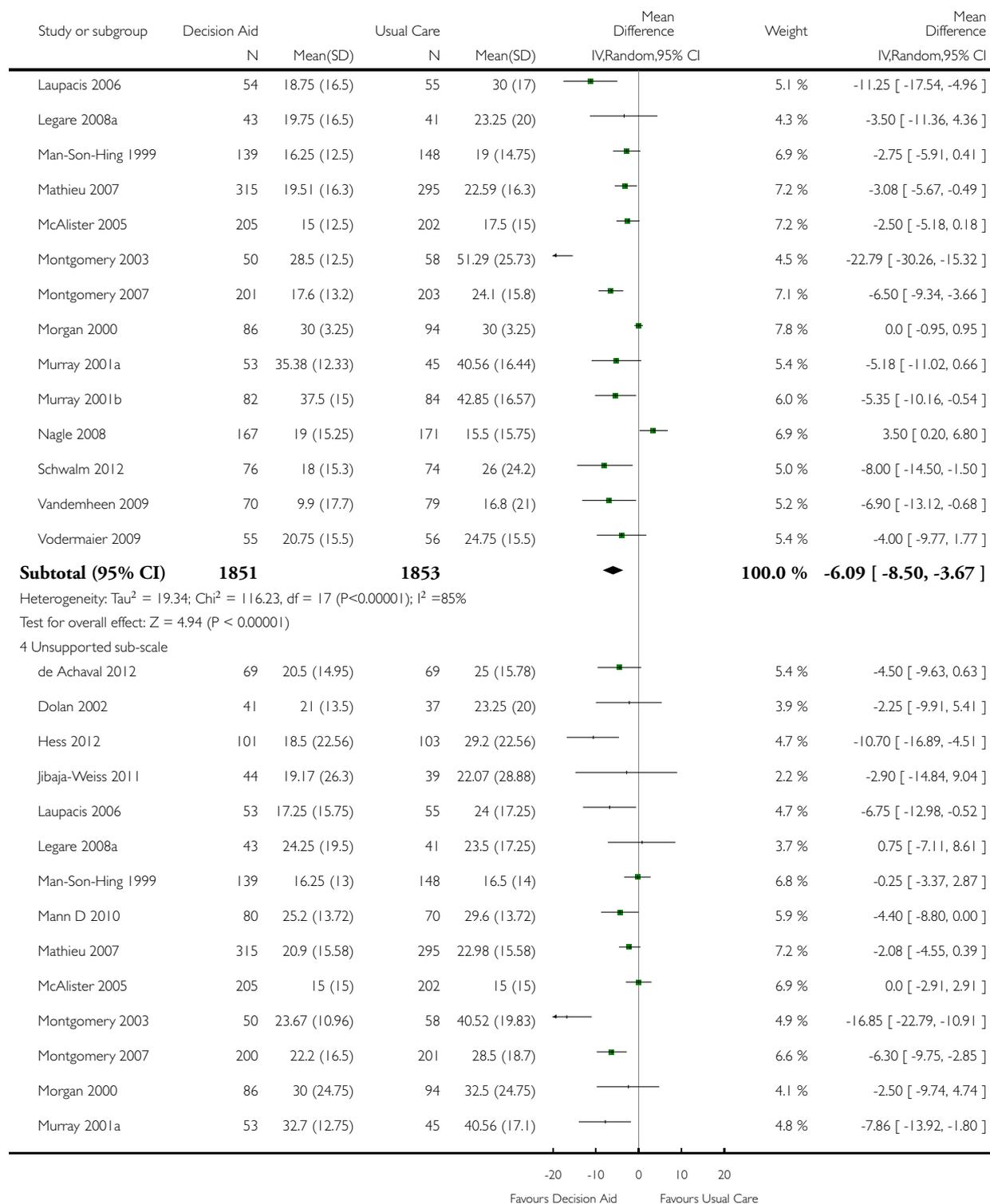
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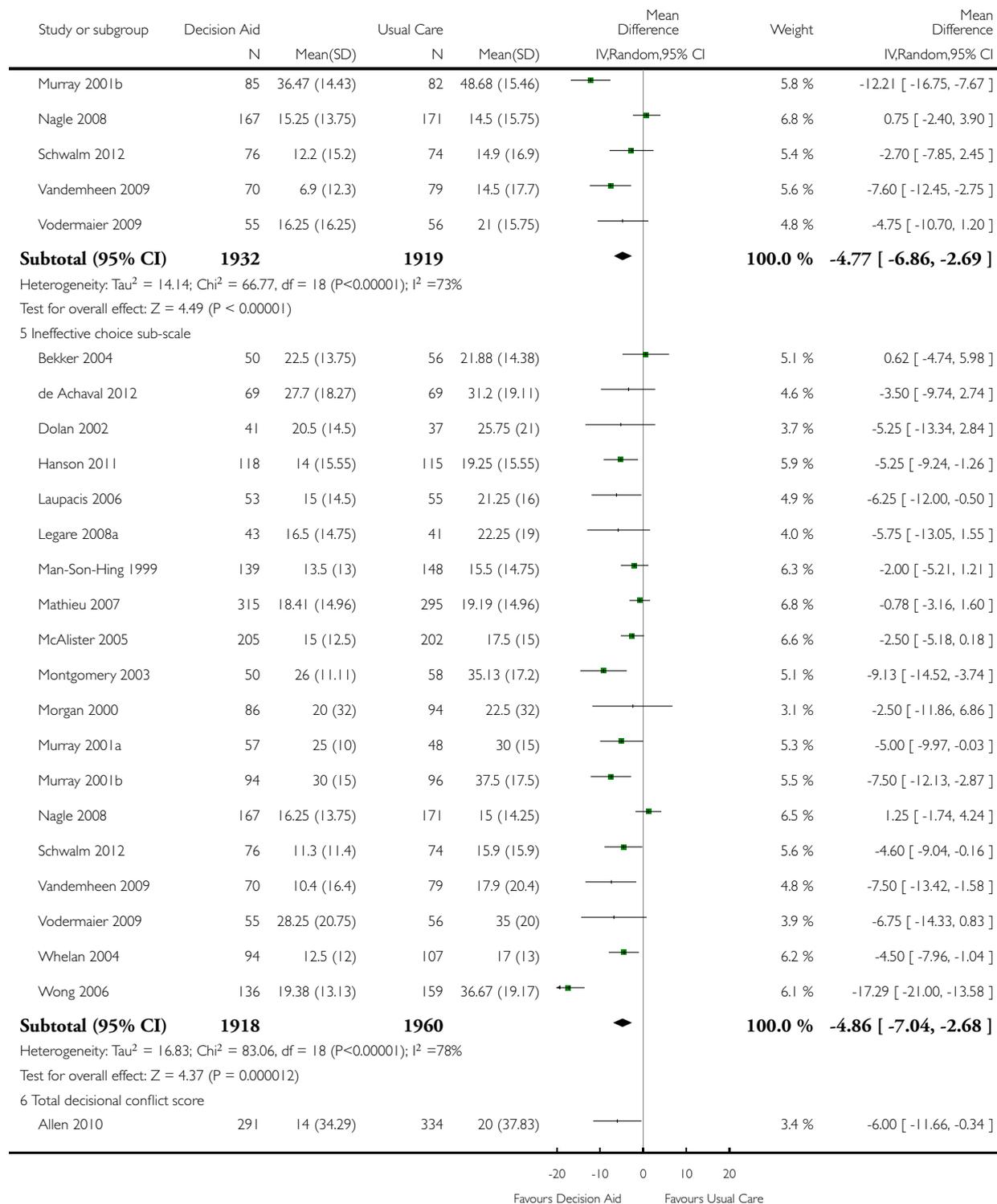
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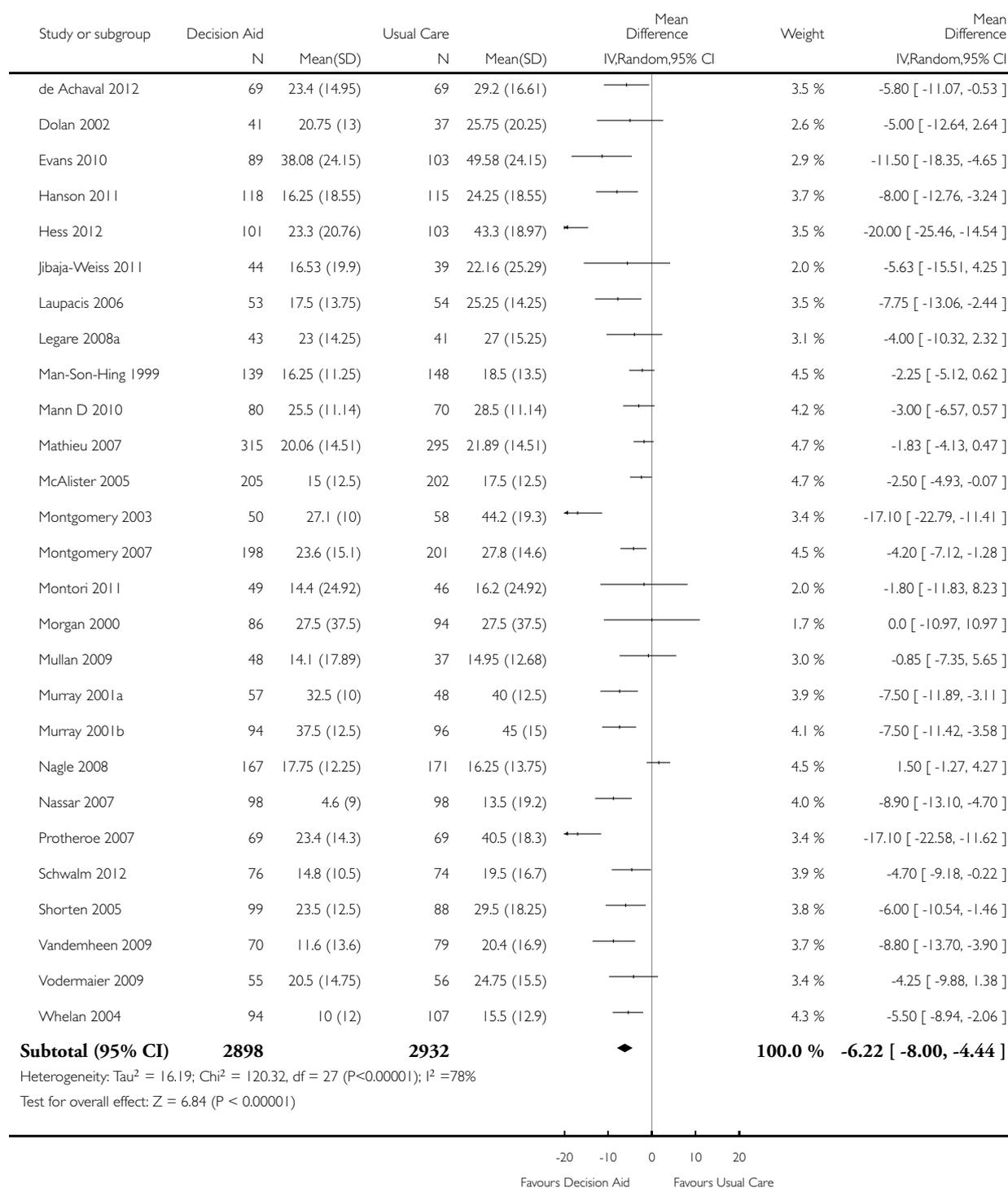
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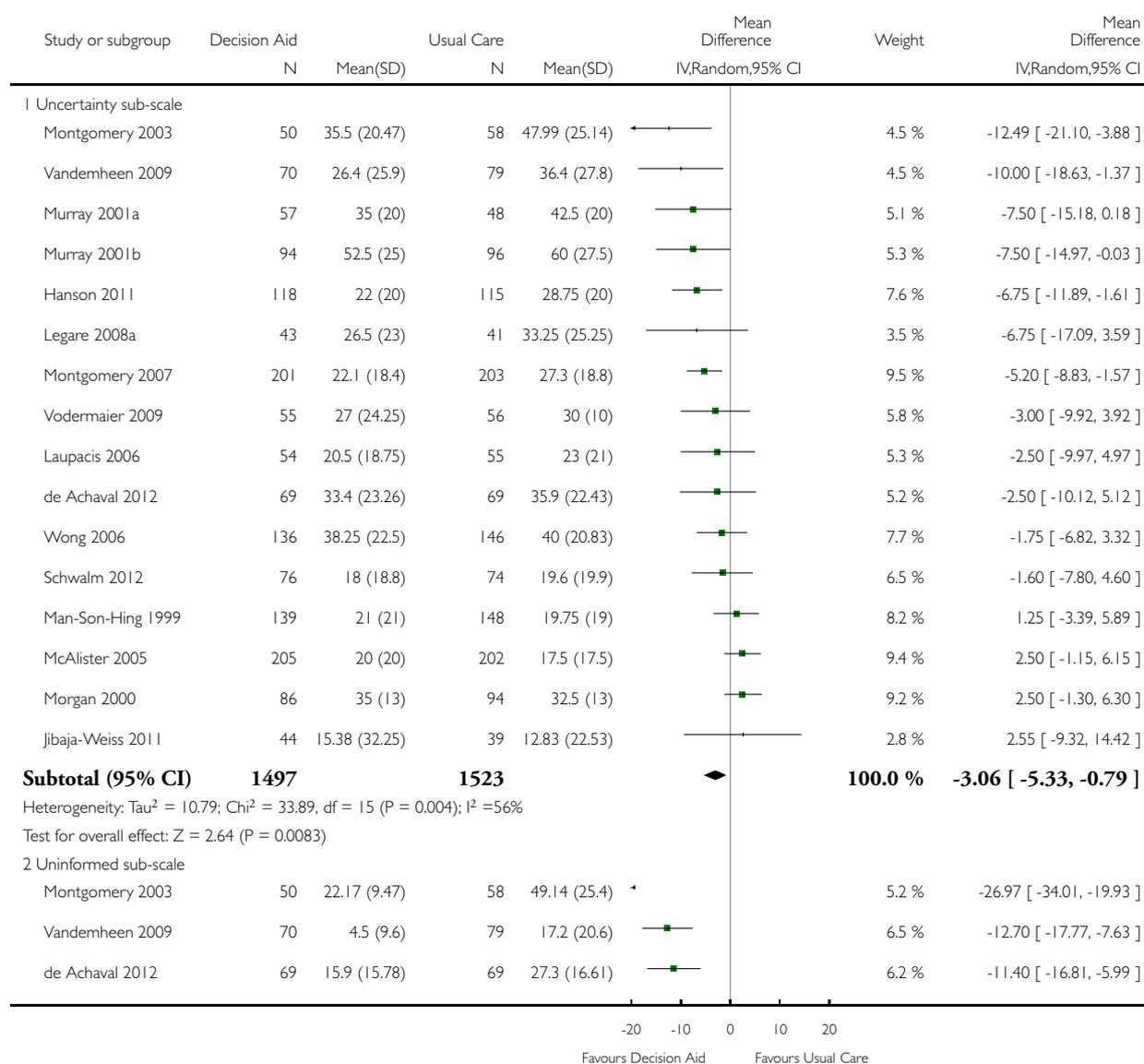


Analysis 4.2. Comparison 4 Decisional conflict, Outcome 2 Decisional conflict: DA vs usual care - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

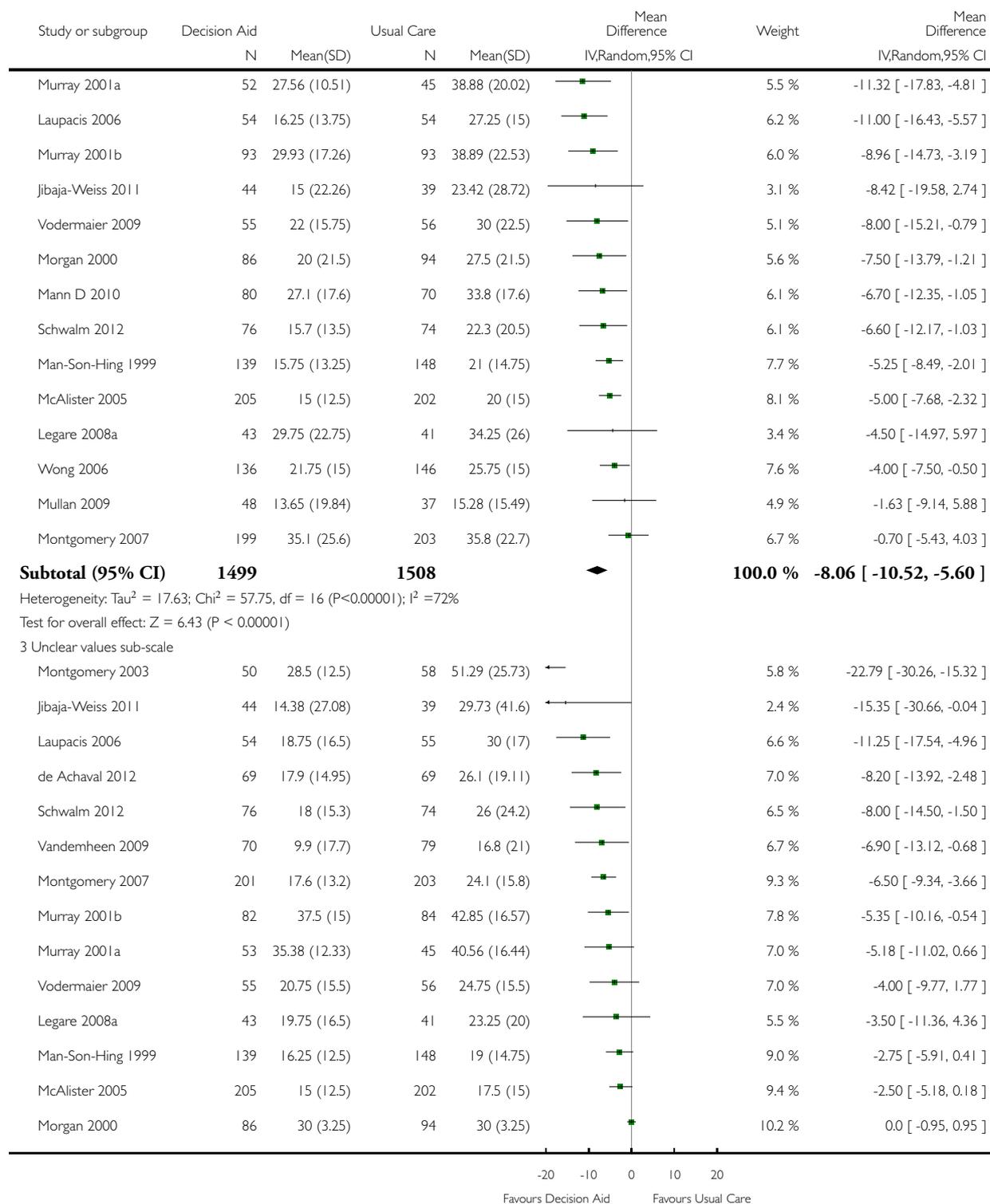
Comparison: 4 Decisional conflict

Outcome: 2 Decisional conflict: DA vs usual care - treatment only



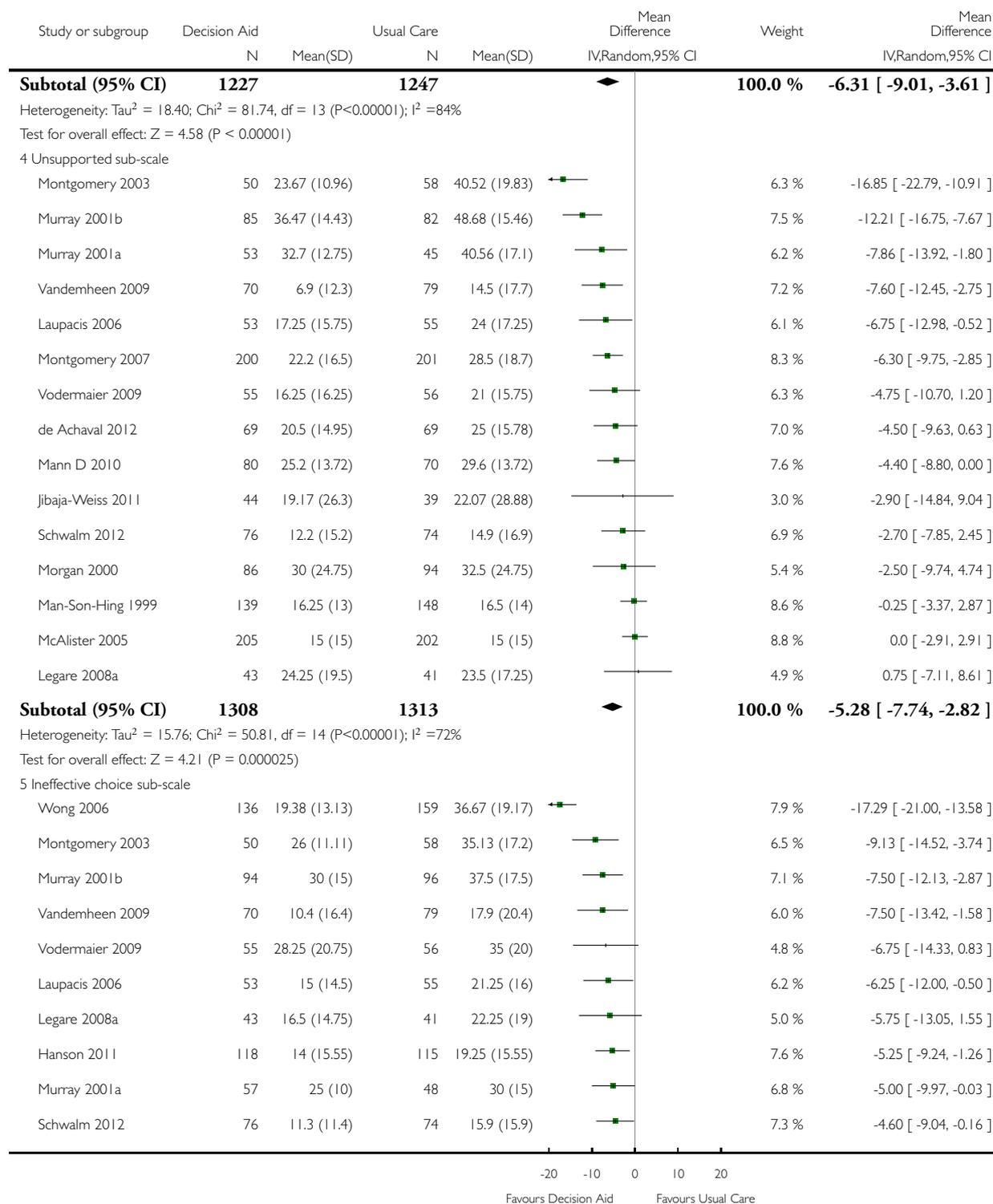
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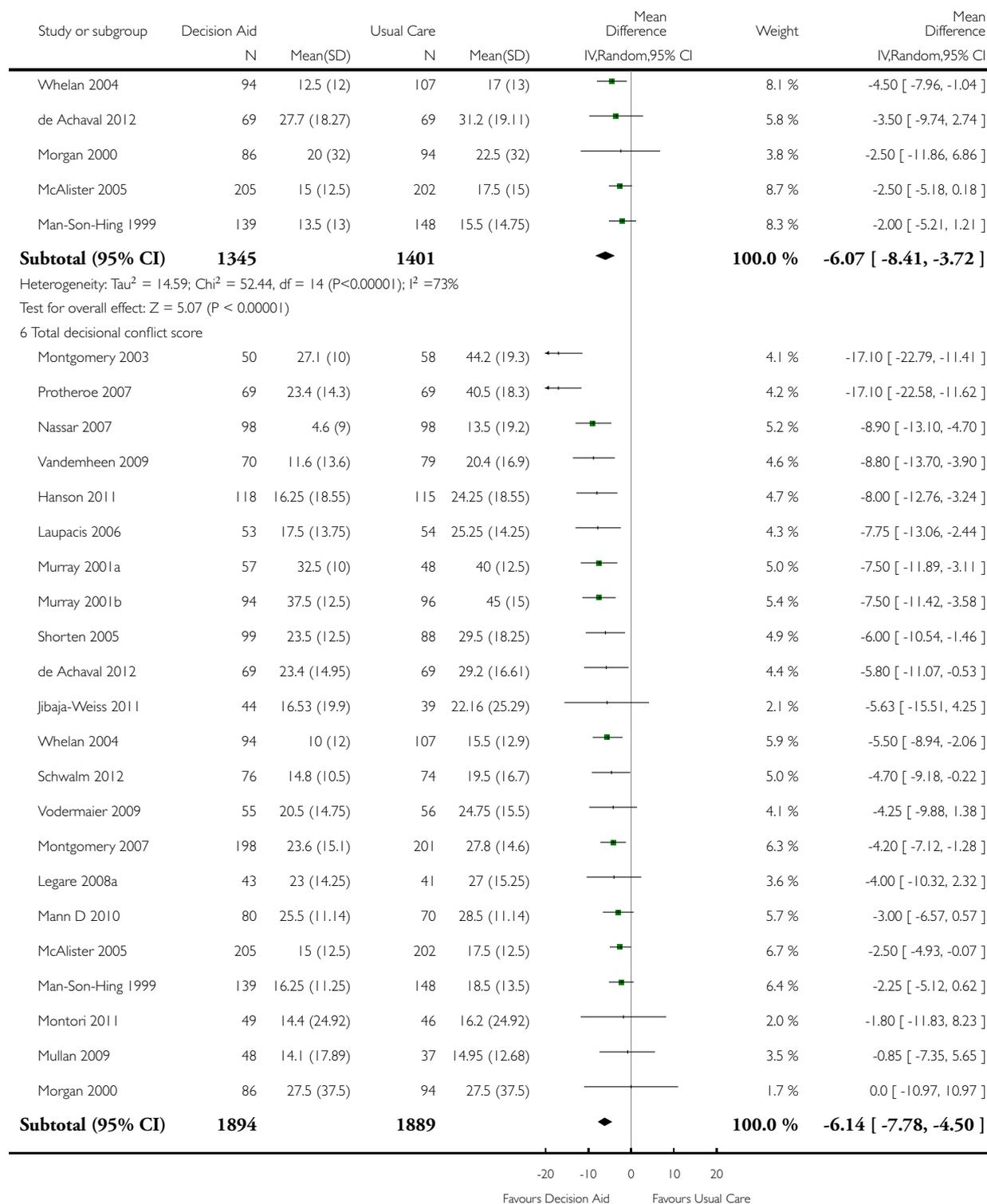
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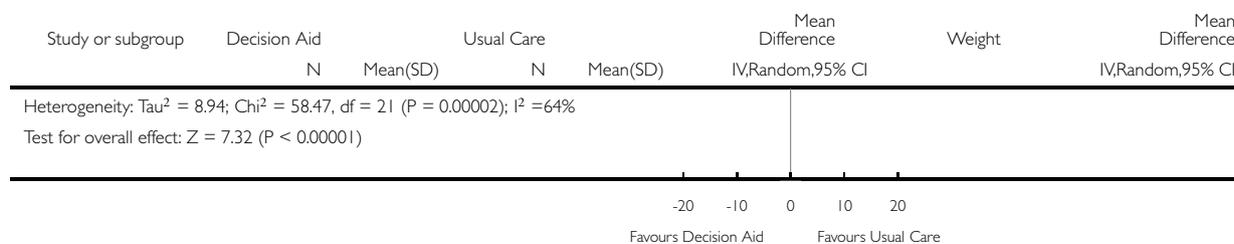
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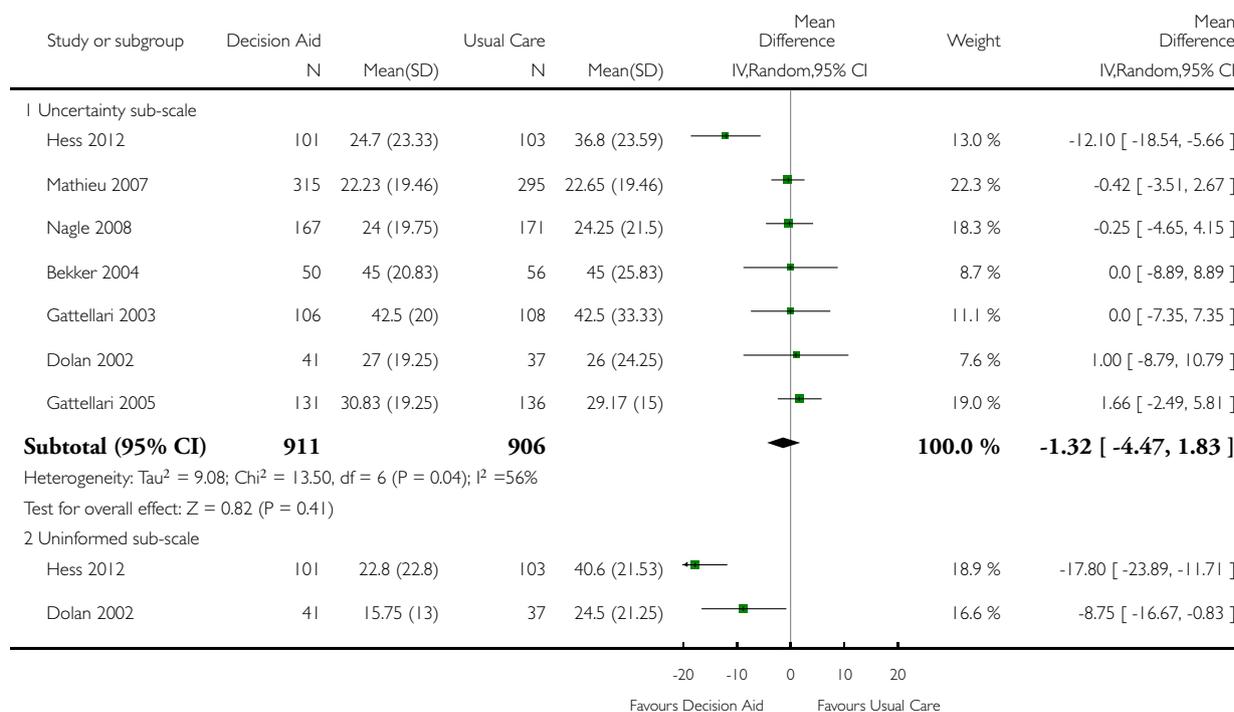


Analysis 4.3. Comparison 4 Decisional conflict, Outcome 3 Decisional conflict: DA vs usual care - screening only.

Review: Decision aids for people facing health treatment or screening decisions

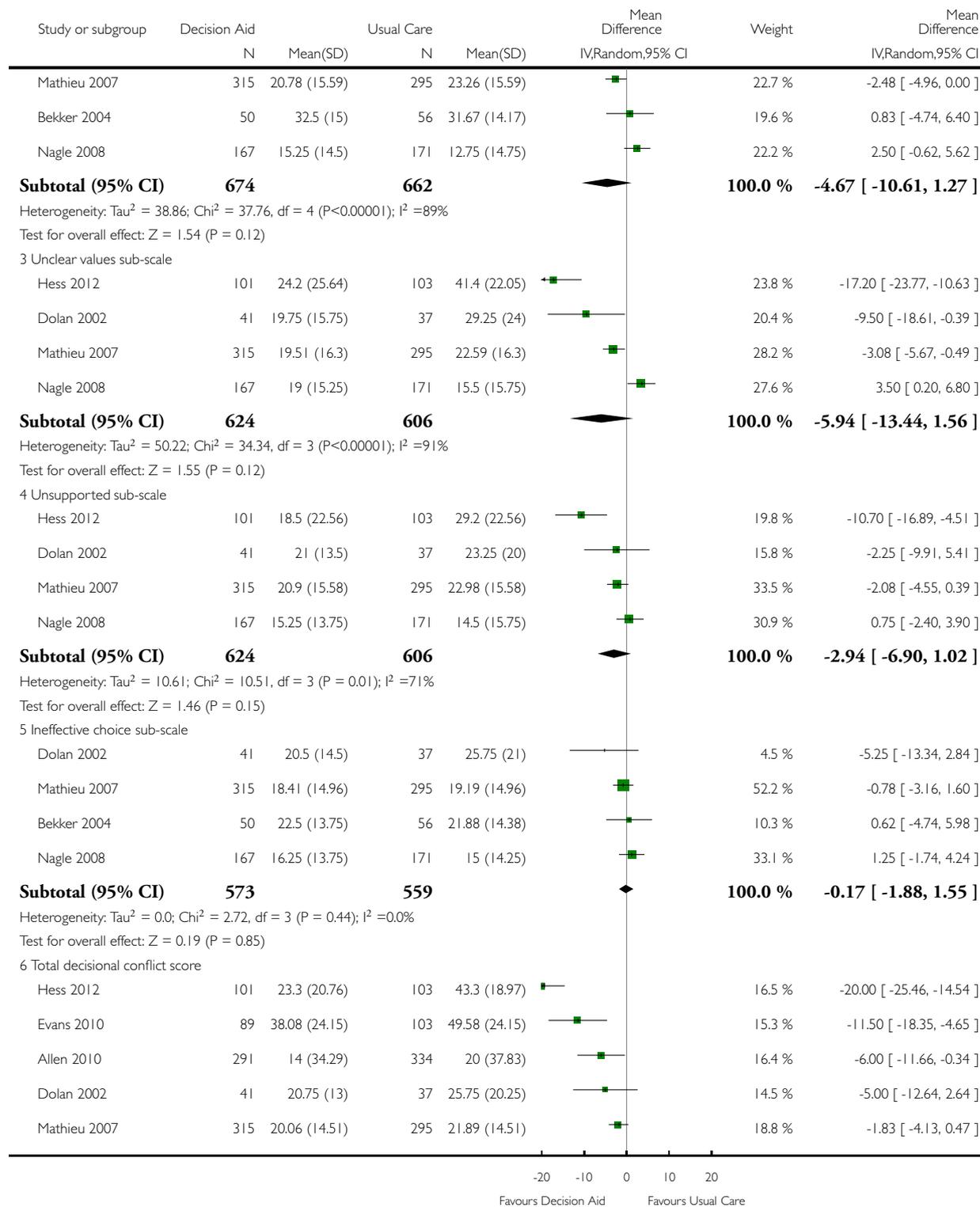
Comparison: 4 Decisional conflict

Outcome: 3 Decisional conflict: DA vs usual care - screening only



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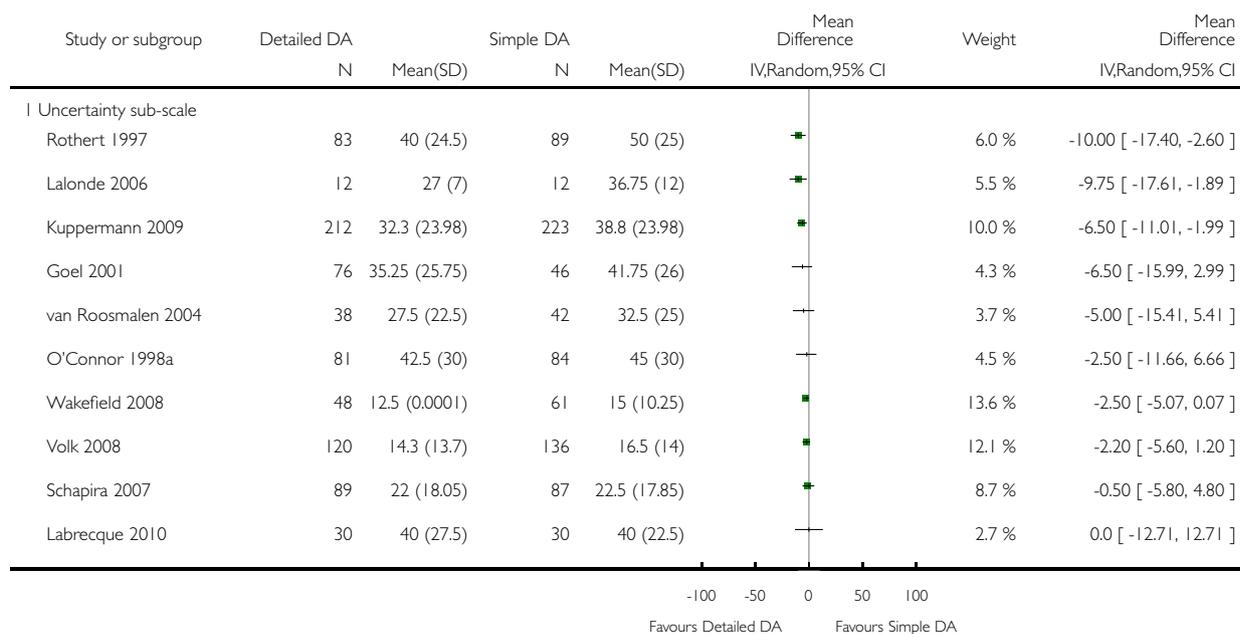


Analysis 4.4. Comparison 4 Decisional conflict, Outcome 4 Decisional conflict: Detailed vs simple decision aid - all studies.

Review: Decision aids for people facing health treatment or screening decisions

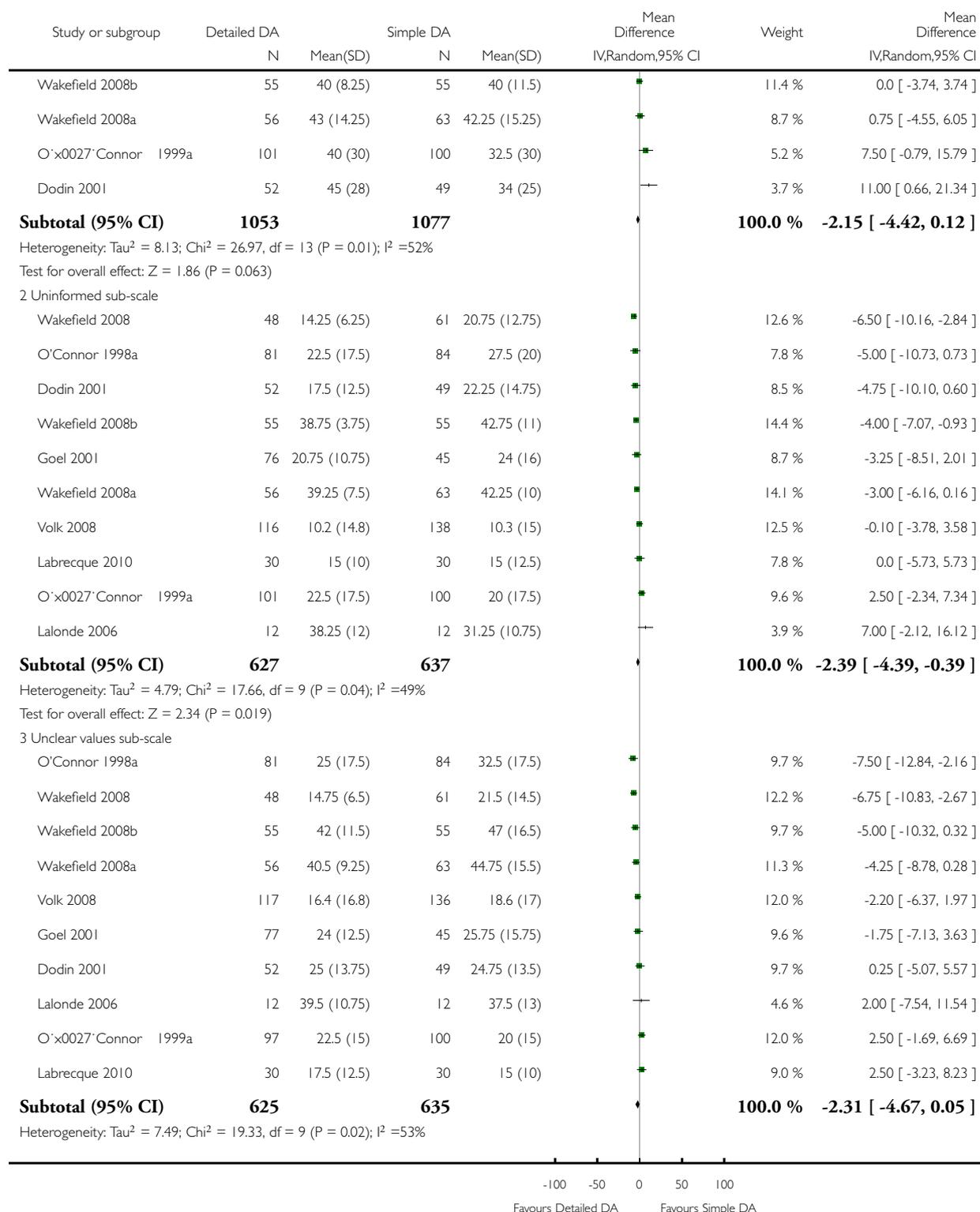
Comparison: 4 Decisional conflict

Outcome: 4 Decisional conflict: Detailed vs simple decision aid - all studies



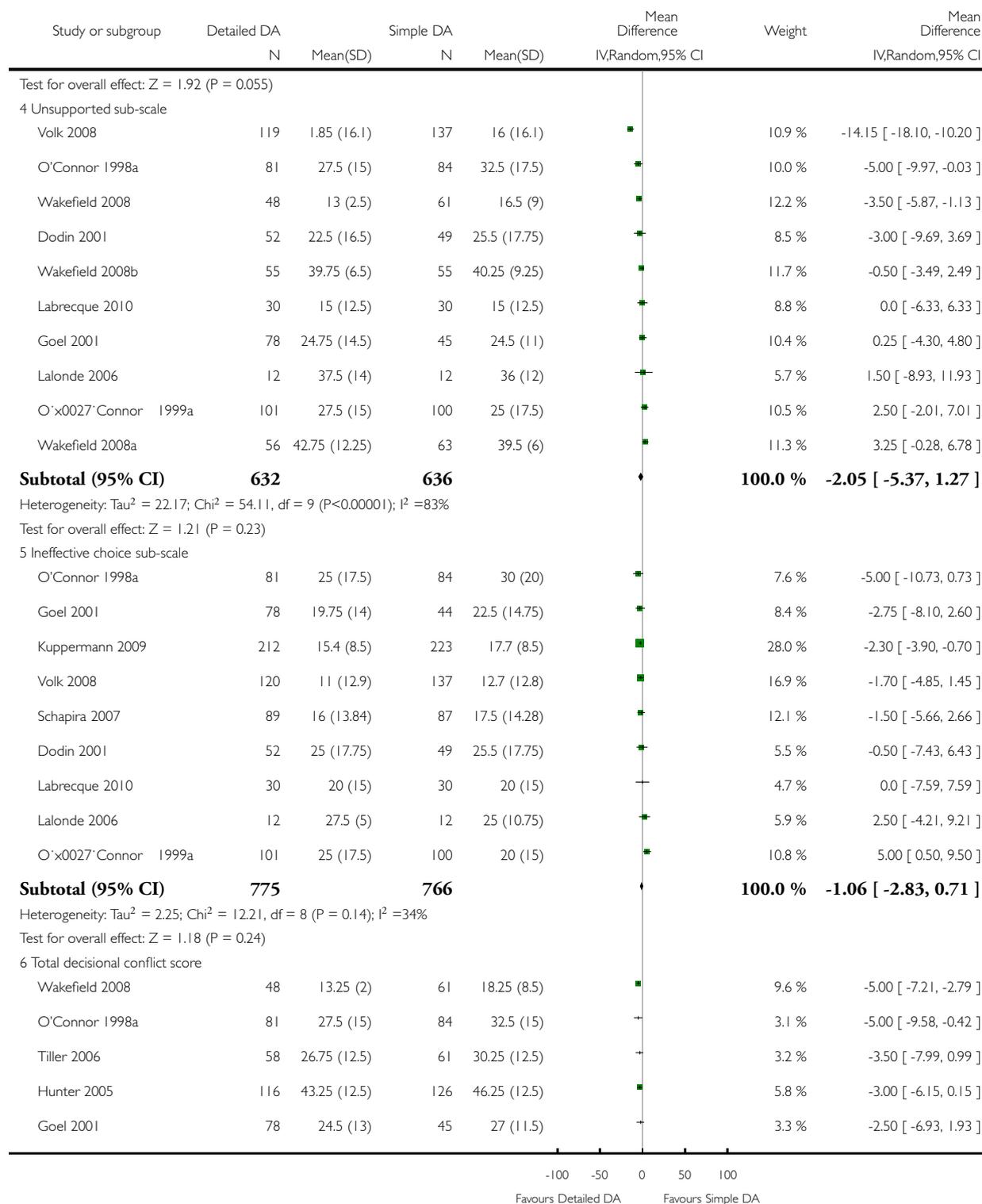
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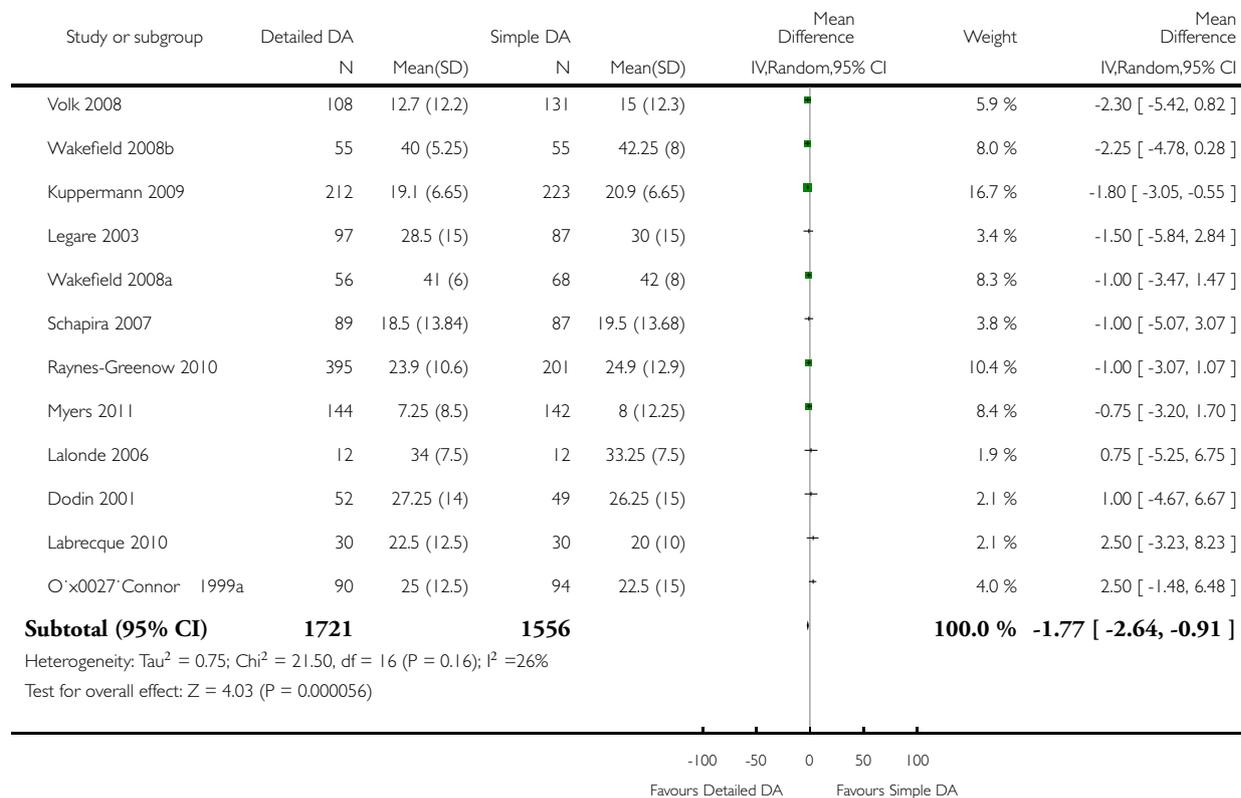
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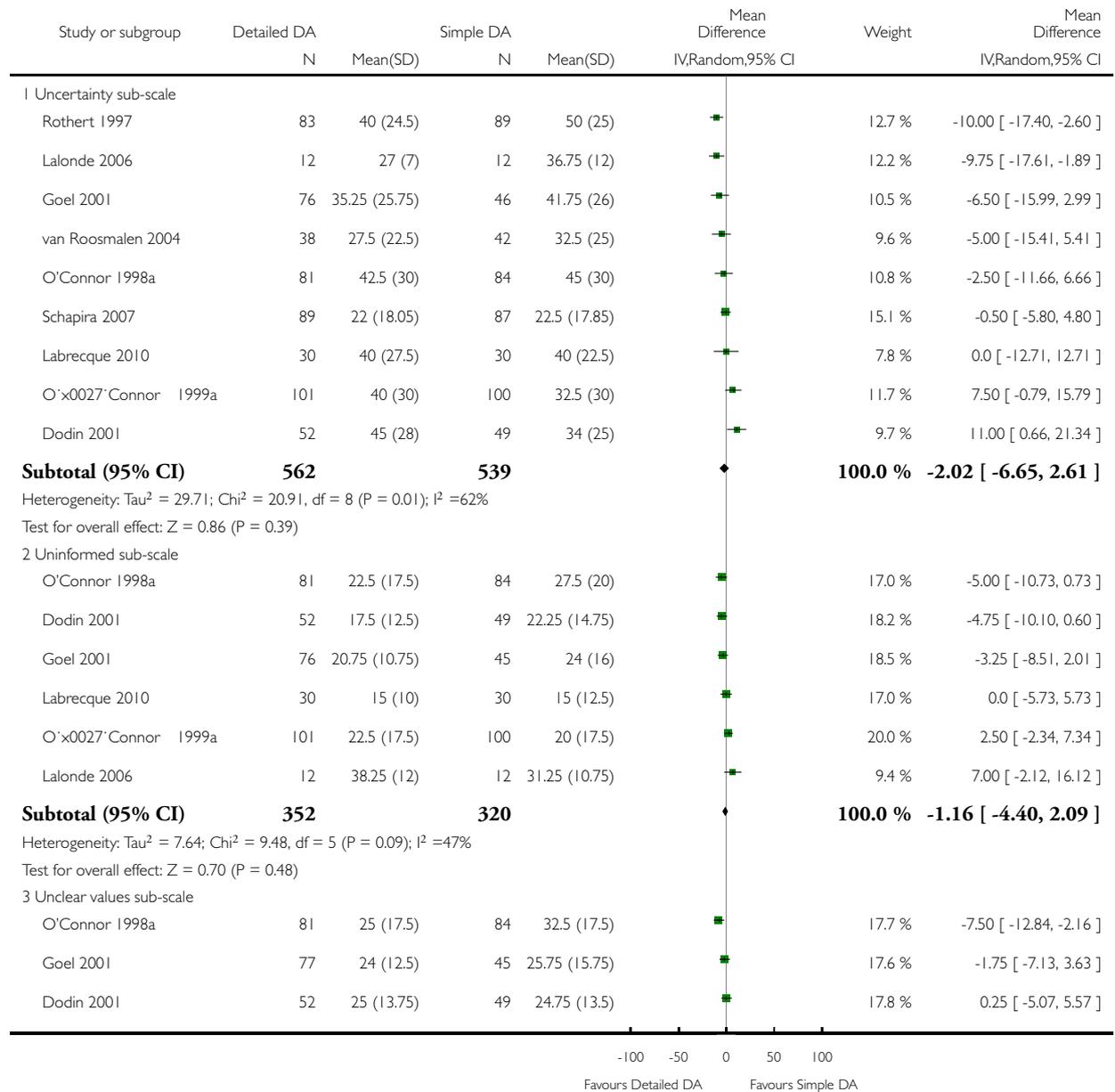


Analysis 4.5. Comparison 4 Decisional conflict, Outcome 5 Decisional conflict: Detailed vs simple decision aid - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

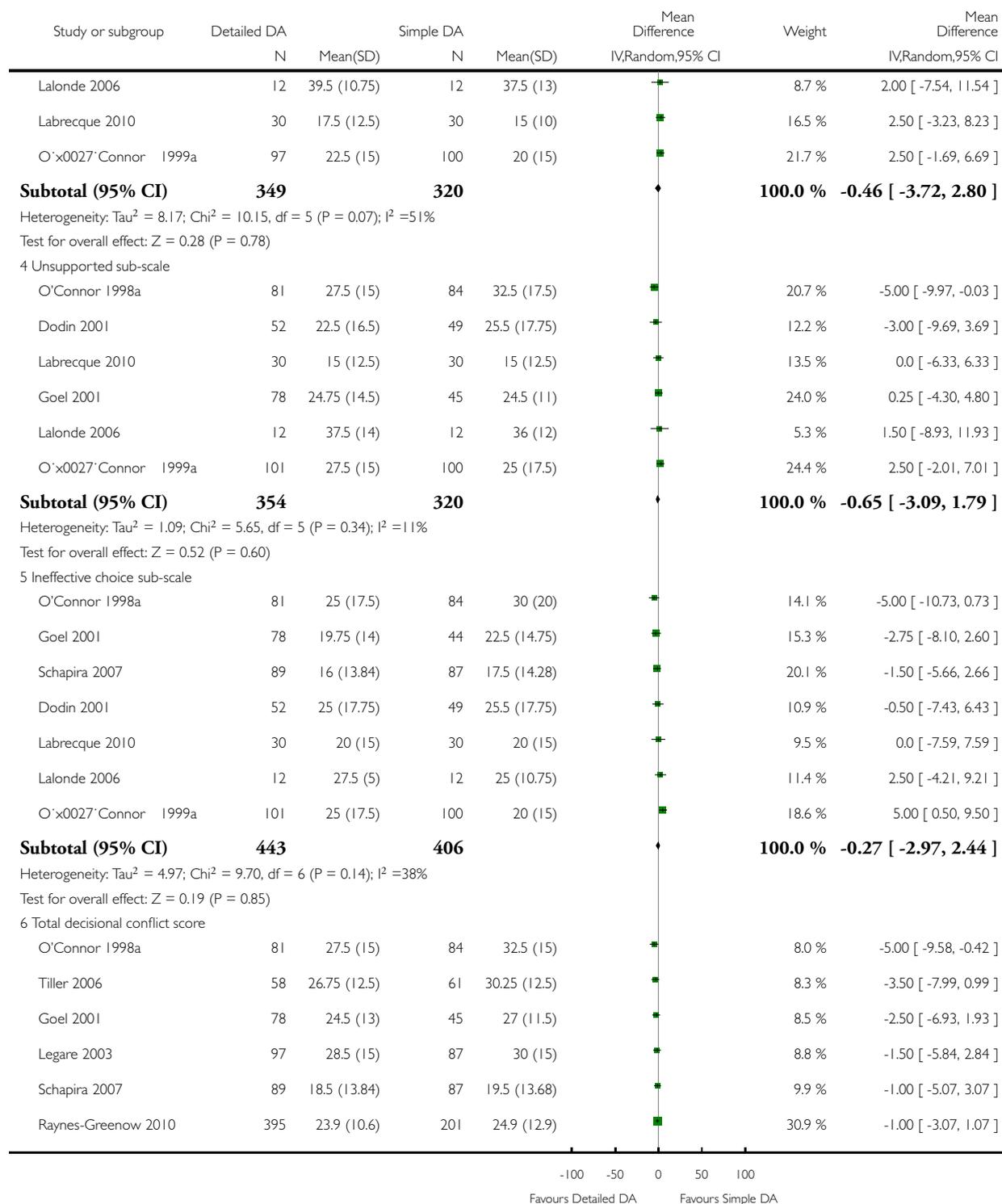
Comparison: 4 Decisional conflict

Outcome: 5 Decisional conflict: Detailed vs simple decision aid - treatment only



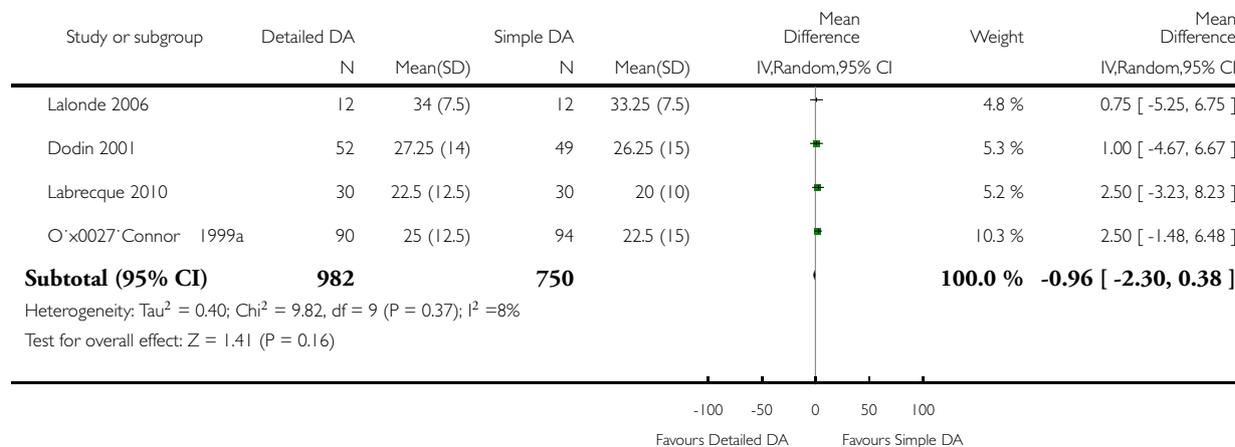
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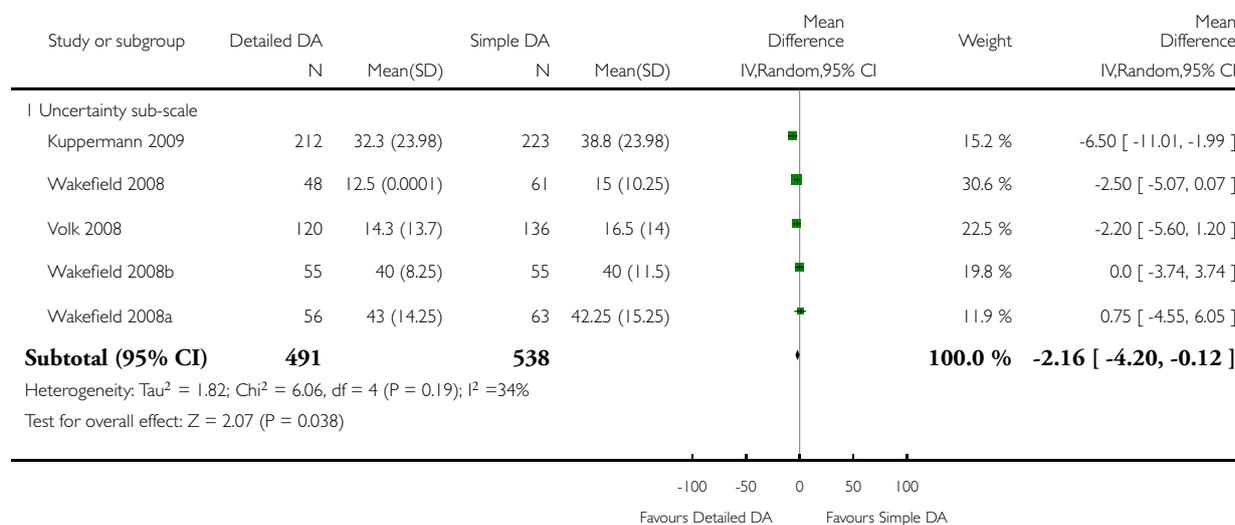


Analysis 4.6. Comparison 4 Decisional conflict, Outcome 6 Decisional conflict: Detailed vs simple decision aid - screening only.

Review: Decision aids for people facing health treatment or screening decisions

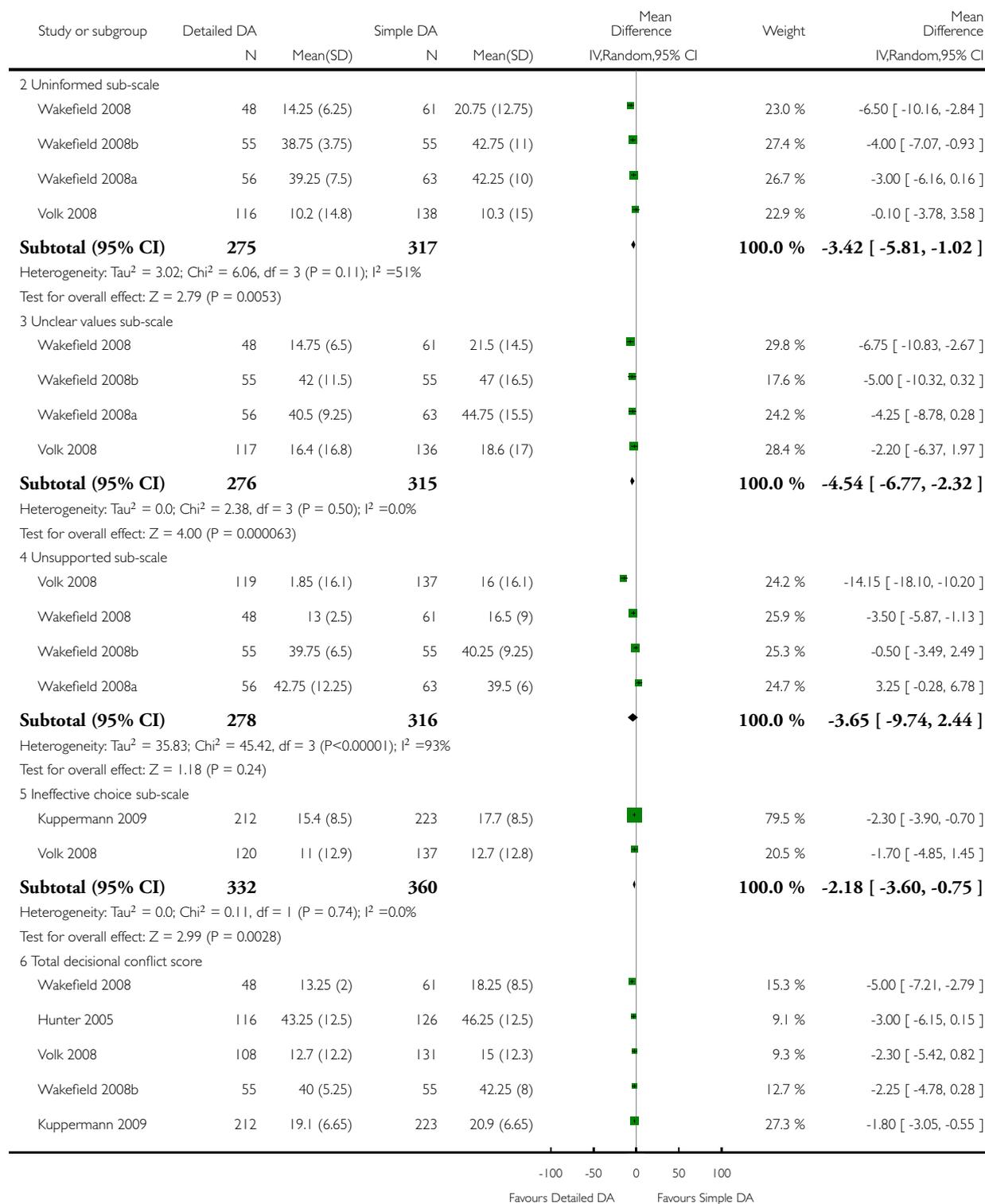
Comparison: 4 Decisional conflict

Outcome: 6 Decisional conflict: Detailed vs simple decision aid - screening only



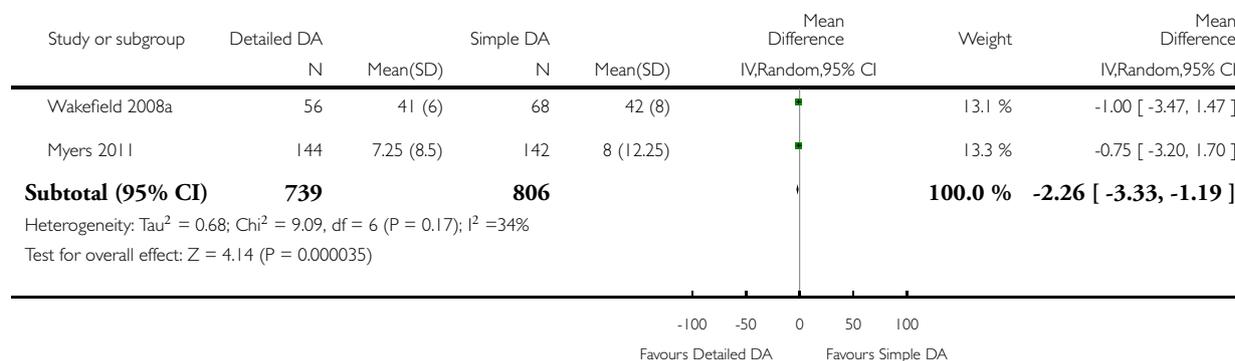
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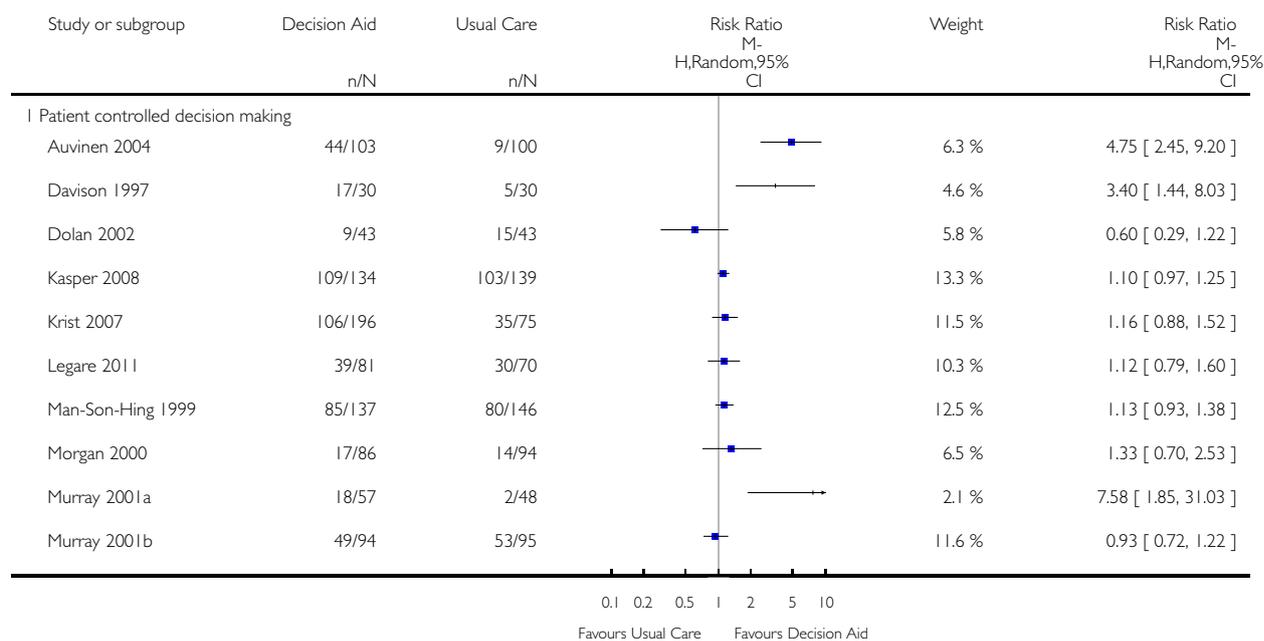


Analysis 5.1. Comparison 5 Participation in decision making, Outcome 1 Participation in decision making: DA vs usual care - all studies.

Review: Decision aids for people facing health treatment or screening decisions

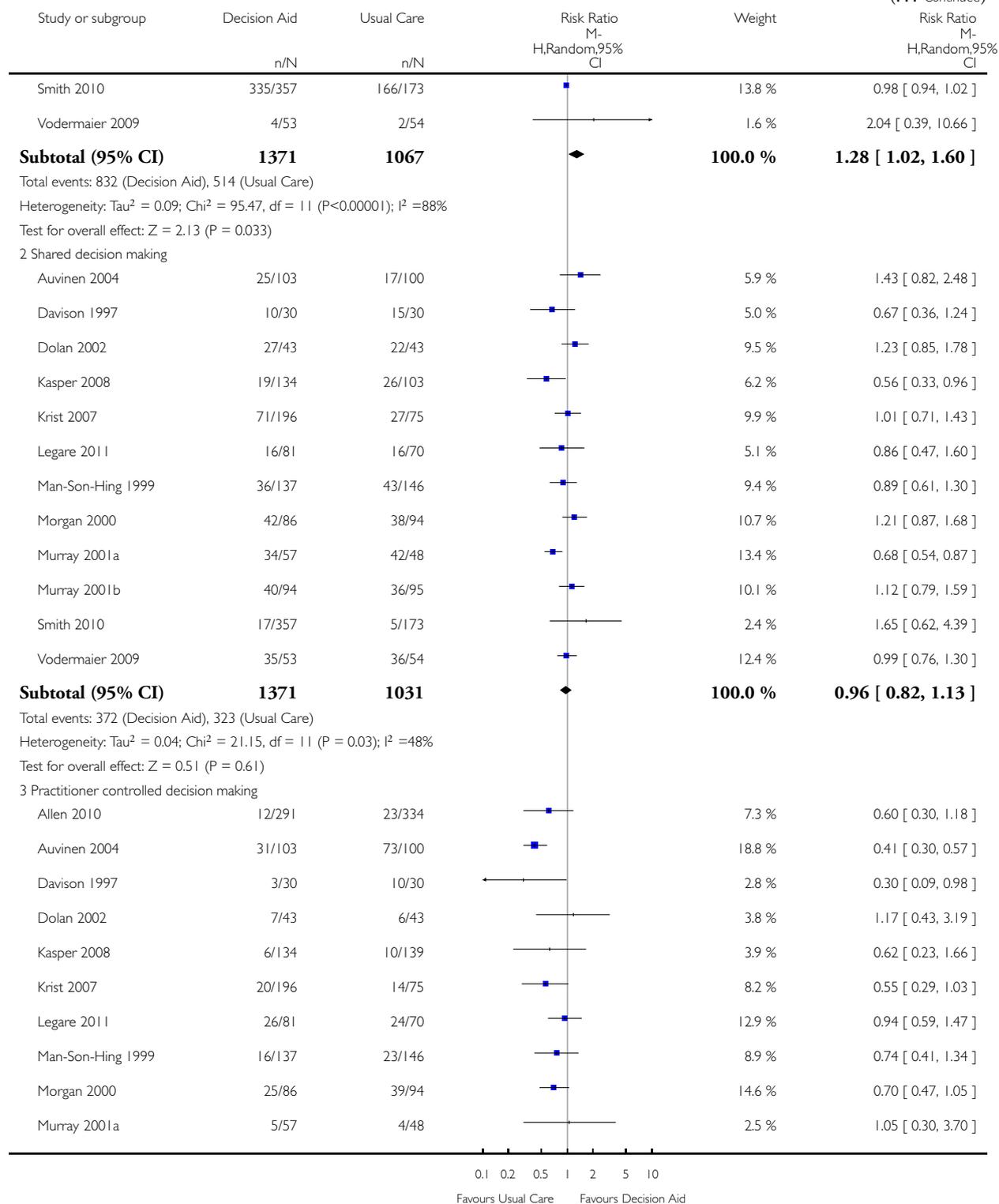
Comparison: 5 Participation in decision making

Outcome: 1 Participation in decision making: DA vs usual care - all studies

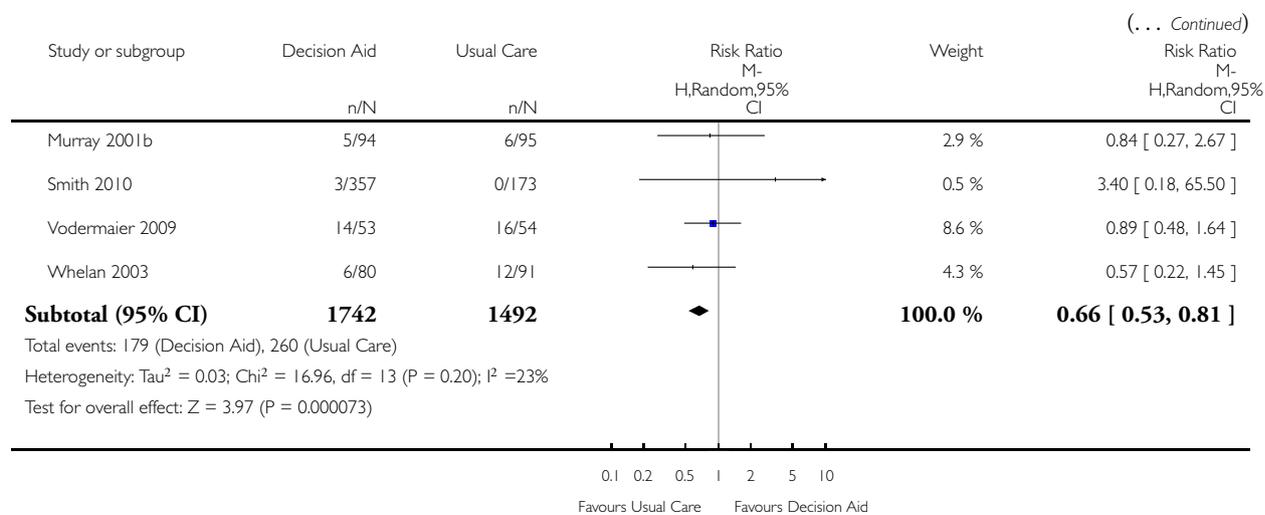


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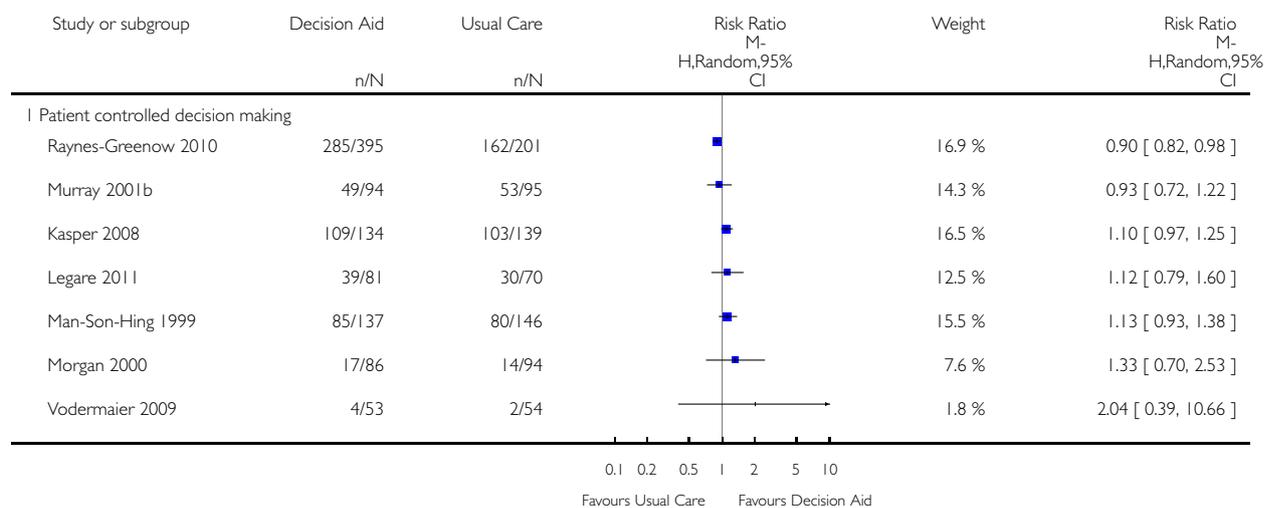


Analysis 5.2. Comparison 5 Participation in decision making, Outcome 2 Participation in decision making: DA vs usual care - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

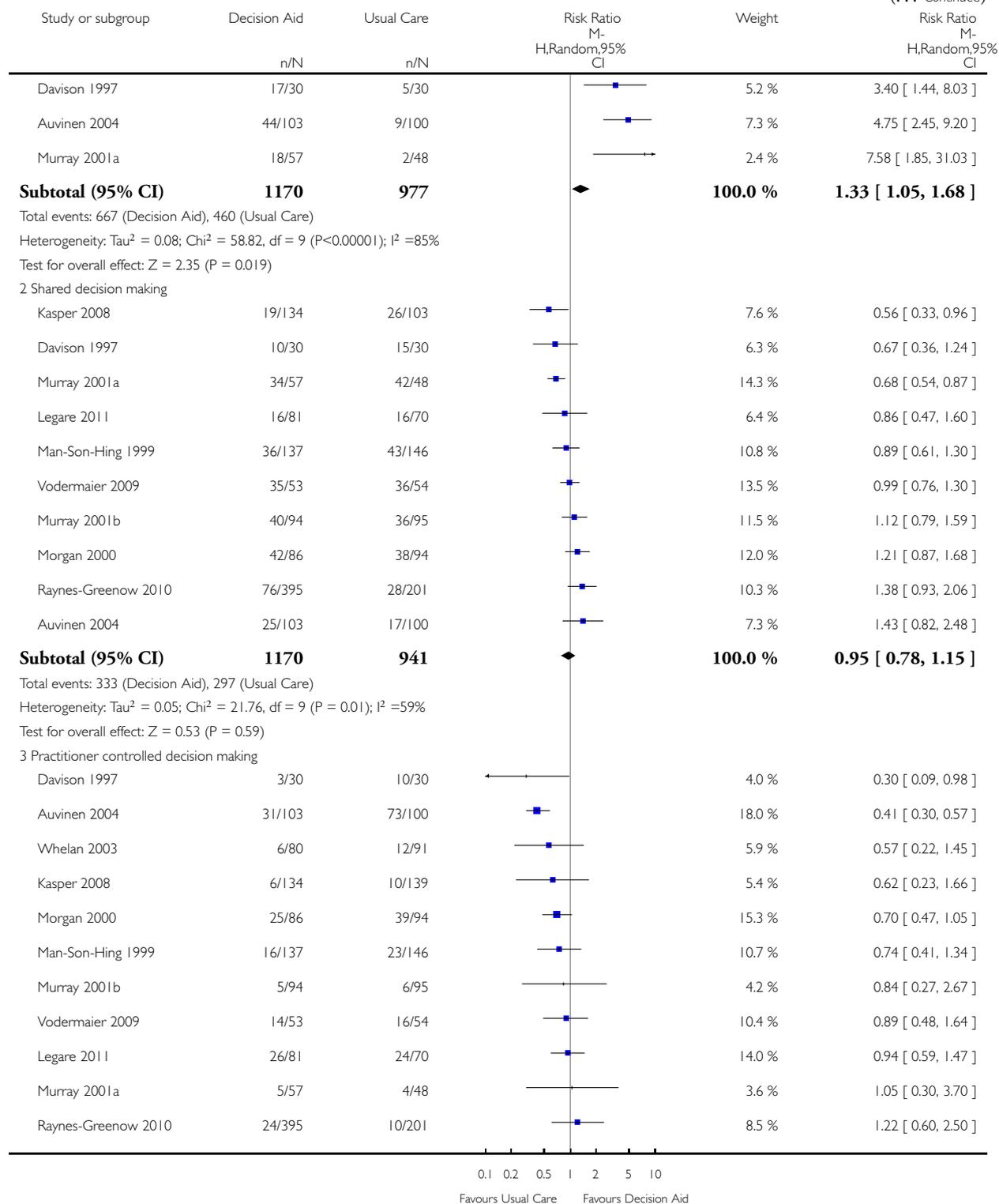
Comparison: 5 Participation in decision making

Outcome: 2 Participation in decision making: DA vs usual care - treatment only

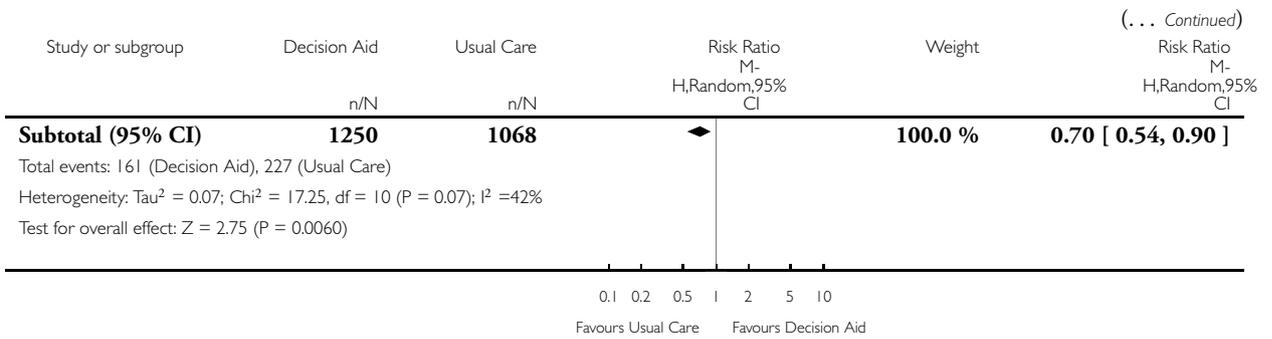


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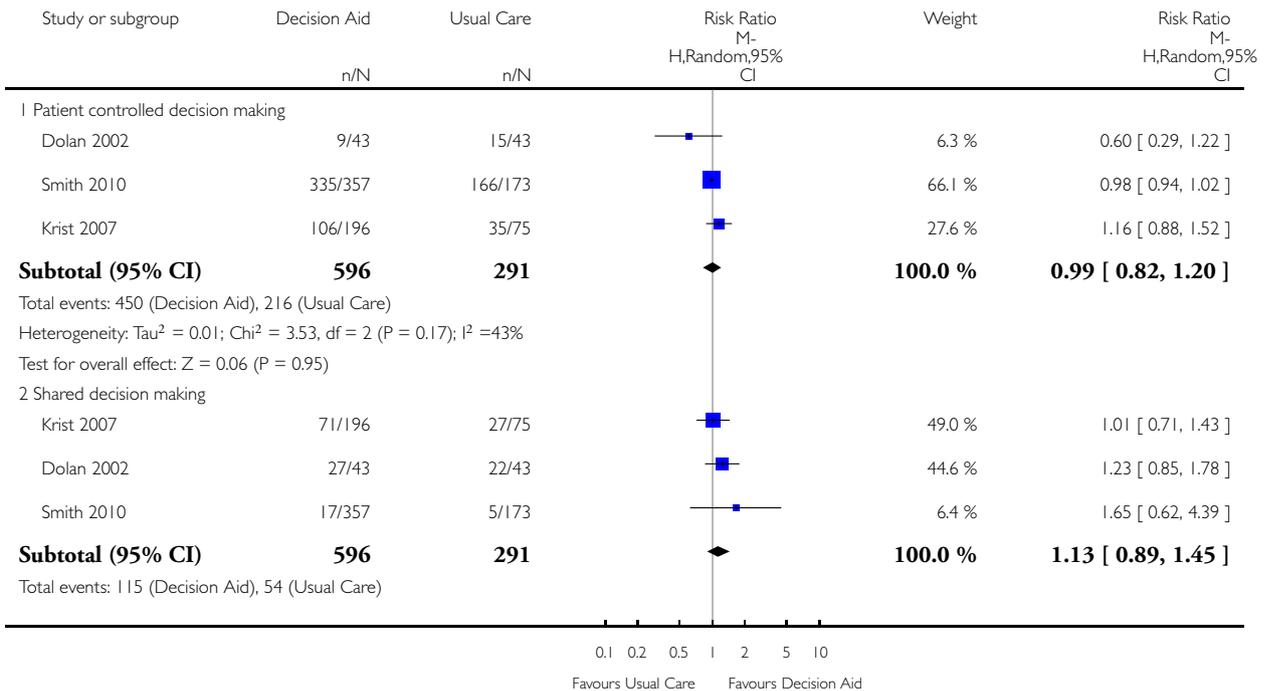


Analysis 5.3. Comparison 5 Participation in decision making, Outcome 3 Participation in decision making: DA vs usual care - screening only.

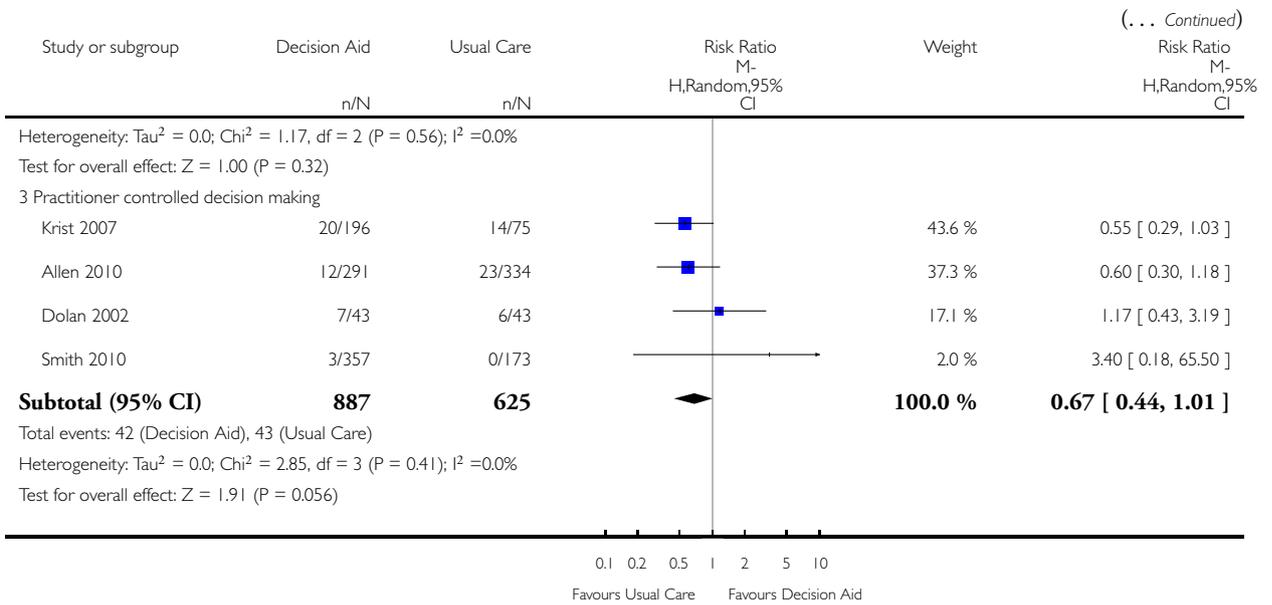
Review: Decision aids for people facing health treatment or screening decisions

Comparison: 5 Participation in decision making

Outcome: 3 Participation in decision making: DA vs usual care - screening only



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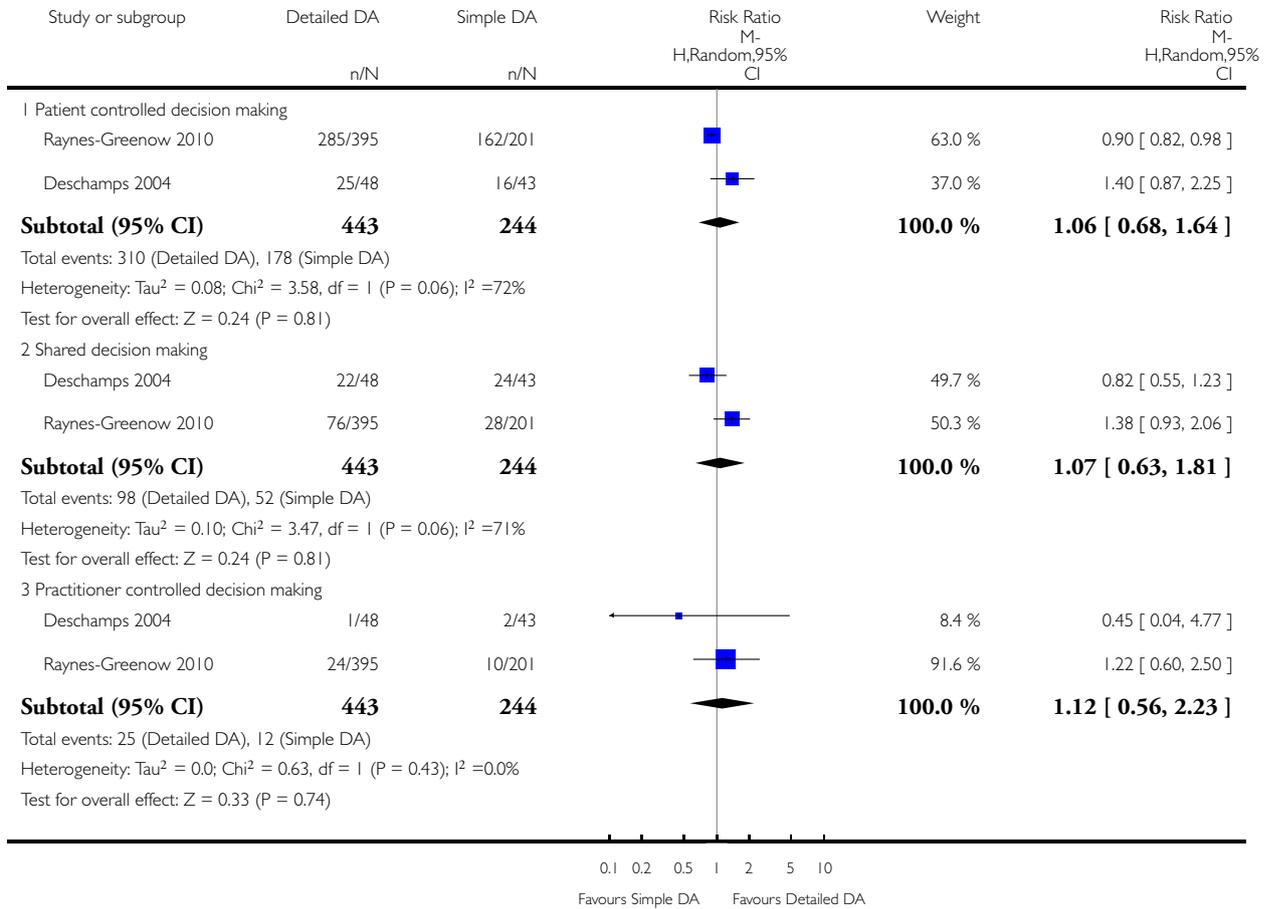


Analysis 5.4. Comparison 5 Participation in decision making, Outcome 4 Participation in decision making: Detailed vs simple decision aid - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 5 Participation in decision making

Outcome: 4 Participation in decision making: Detailed vs simple decision aid - all studies

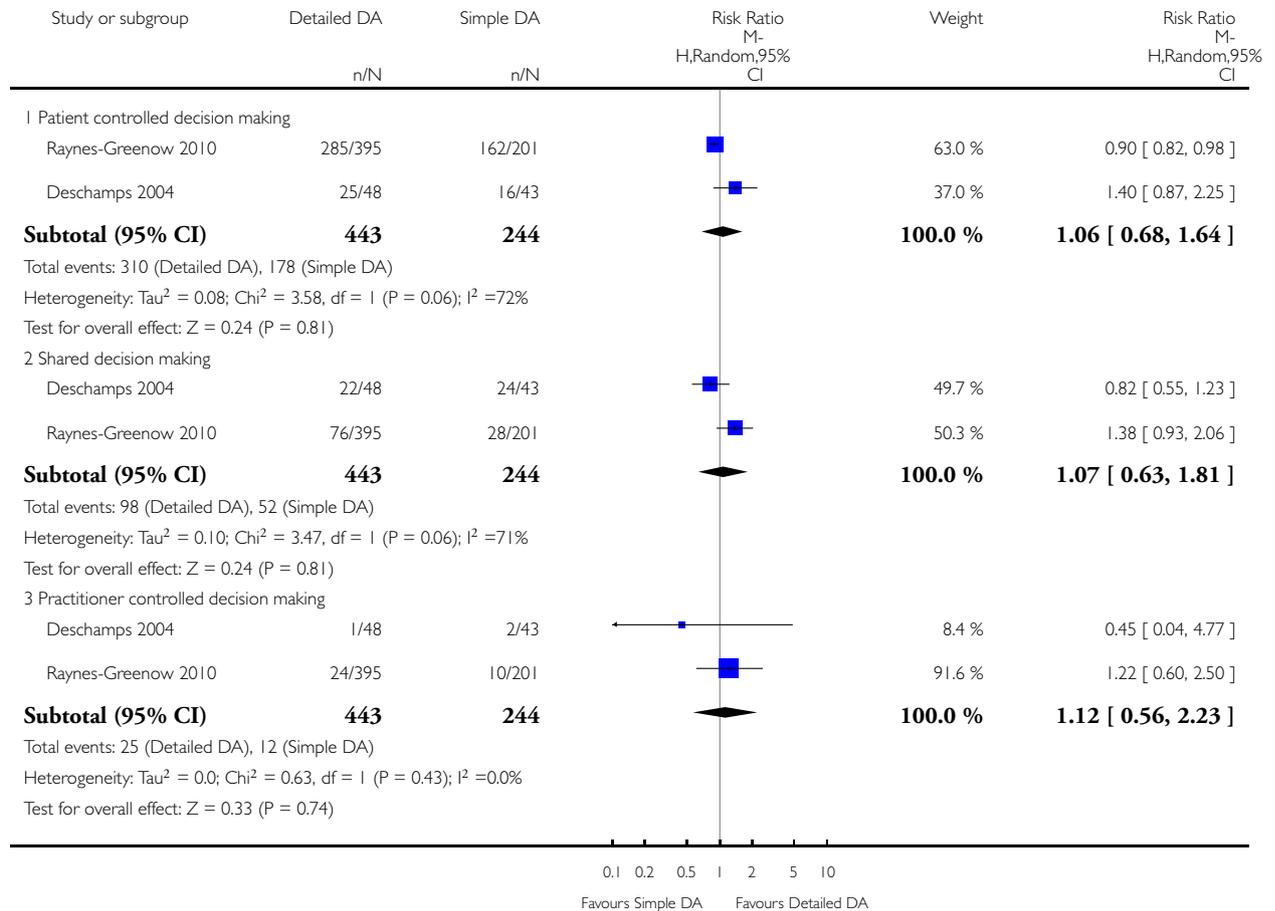


Analysis 5.5. Comparison 5 Participation in decision making, Outcome 5 Participation in decision making: Detailed vs simple decision aid - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 5 Participation in decision making

Outcome: 5 Participation in decision making: Detailed vs simple decision aid - treatment only

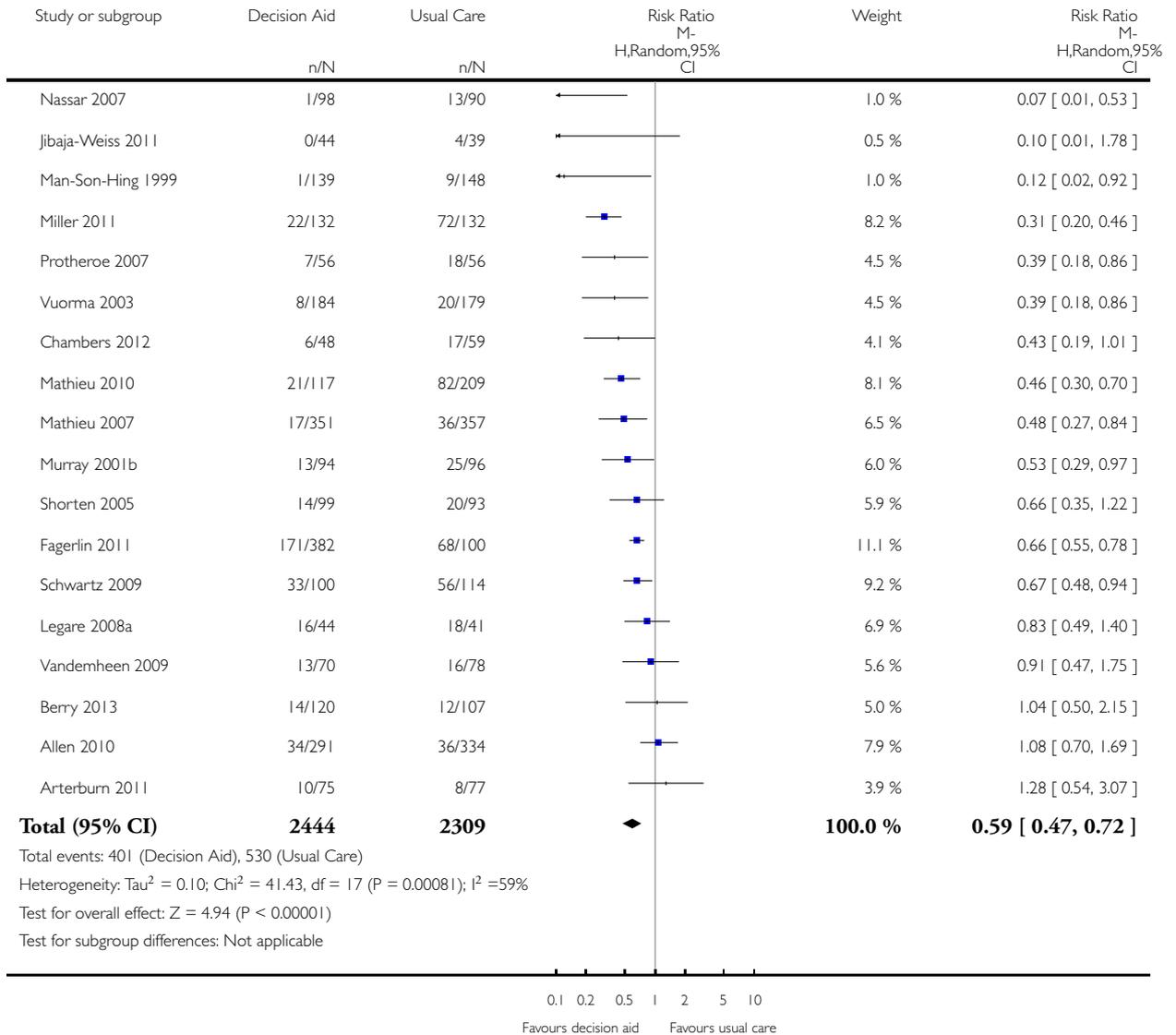


Analysis 6.1. Comparison 6 Proportion undecided, Outcome 1 Proportion undecided: DA vs usual care - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 6 Proportion undecided

Outcome: 1 Proportion undecided: DA vs usual care - all studies

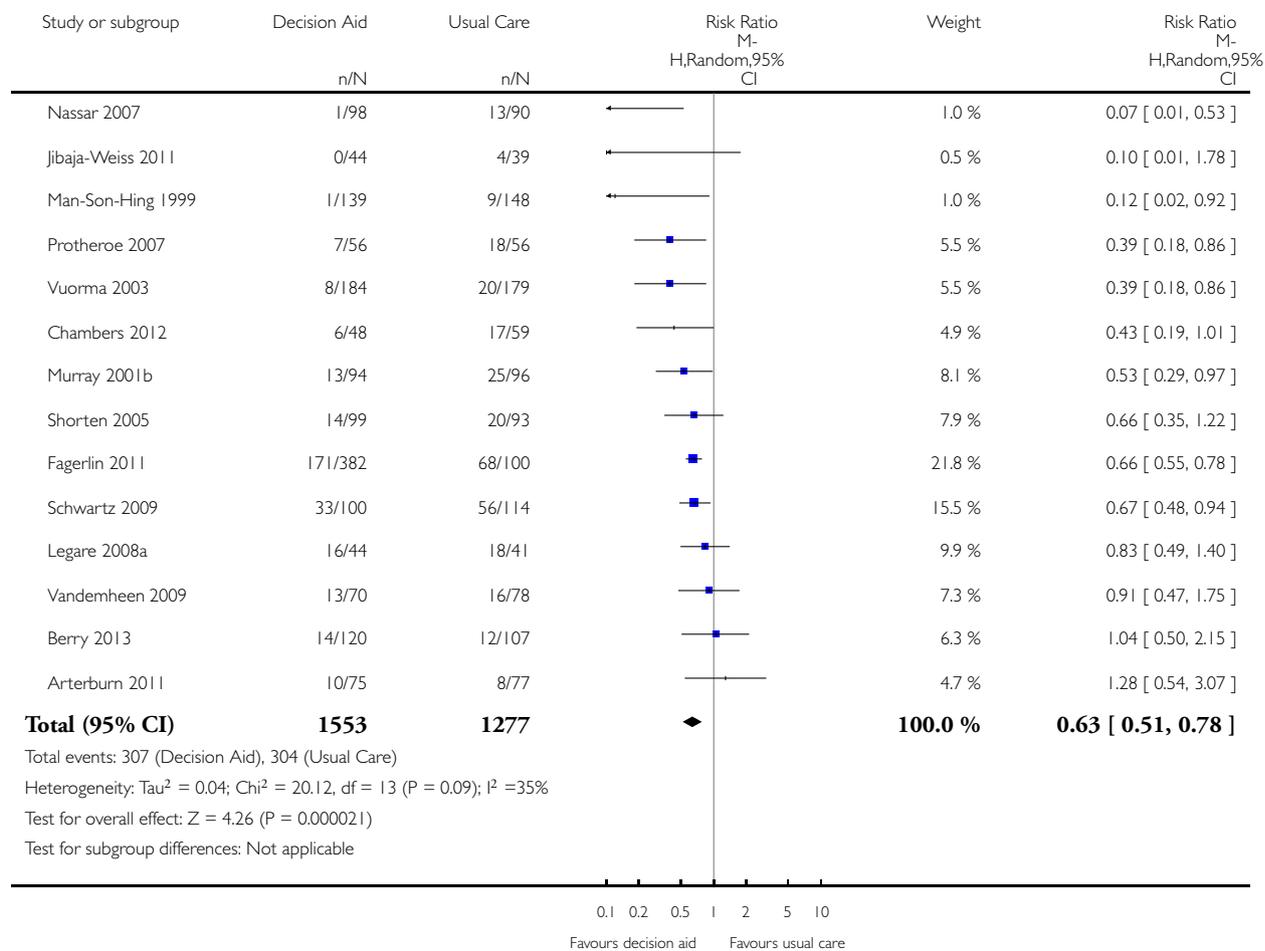


Analysis 6.2. Comparison 6 Proportion undecided, Outcome 2 Proportion undecided: DA vs usual care - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 6 Proportion undecided

Outcome: 2 Proportion undecided: DA vs usual care - treatment only

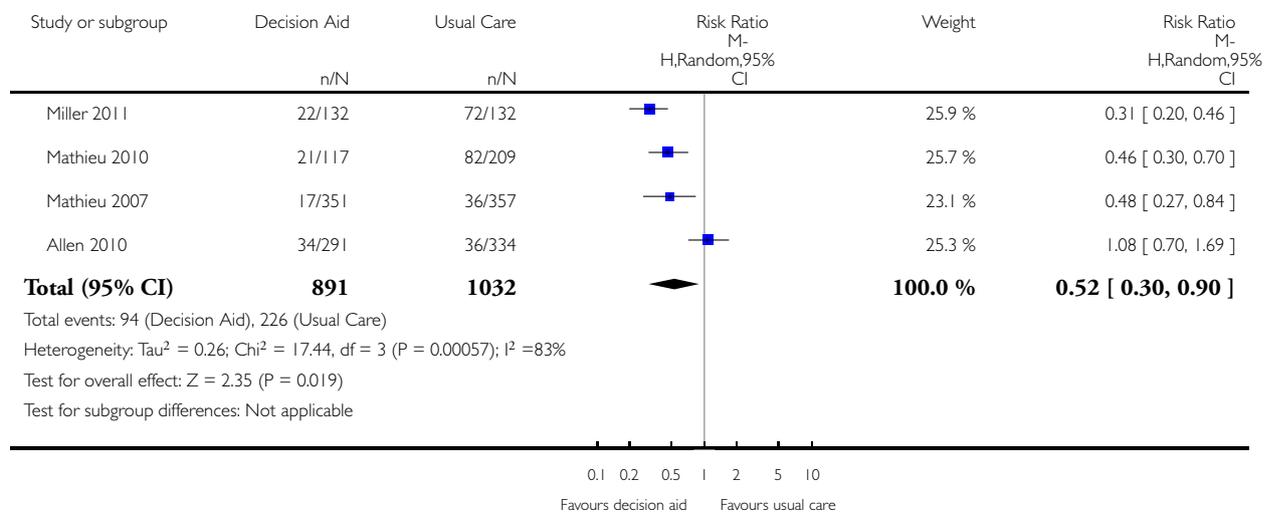


Analysis 6.3. Comparison 6 Proportion undecided, Outcome 3 Proportion undecided: DA vs usual care - screening only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 6 Proportion undecided

Outcome: 3 Proportion undecided: DA vs usual care - screening only

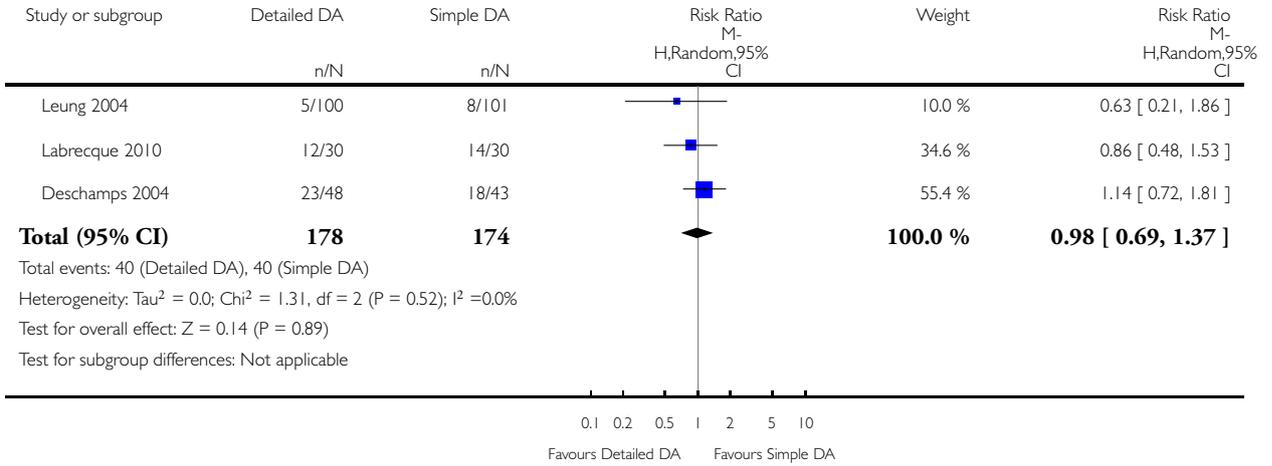


Analysis 6.4. Comparison 6 Proportion undecided, Outcome 4 Proportion undecided: Detailed vs simple decision aids - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 6 Proportion undecided

Outcome: 4 Proportion undecided: Detailed vs simple decision aids - all studies

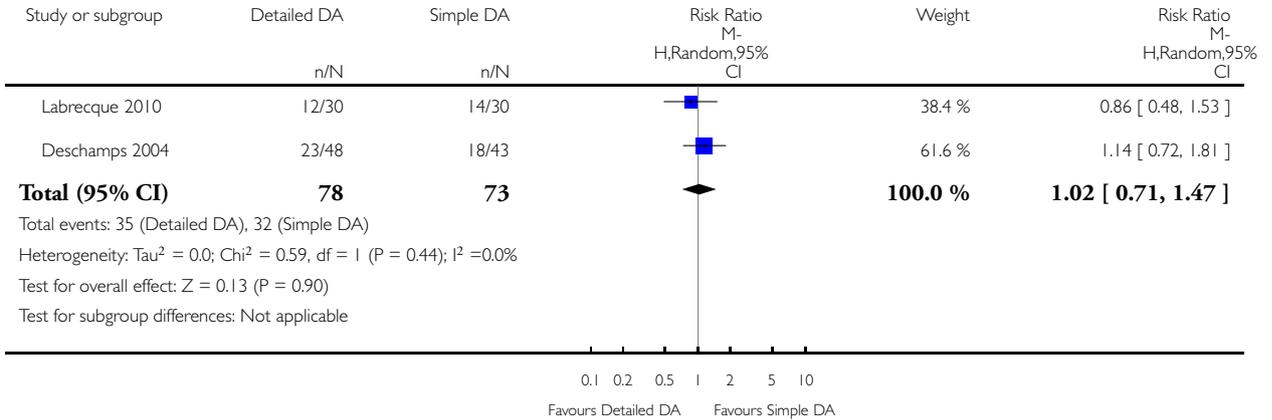


Analysis 6.5. Comparison 6 Proportion undecided, Outcome 5 Proportion undecided: Detailed vs simple decision aids - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 6 Proportion undecided

Outcome: 5 Proportion undecided: Detailed vs simple decision aids - treatment only

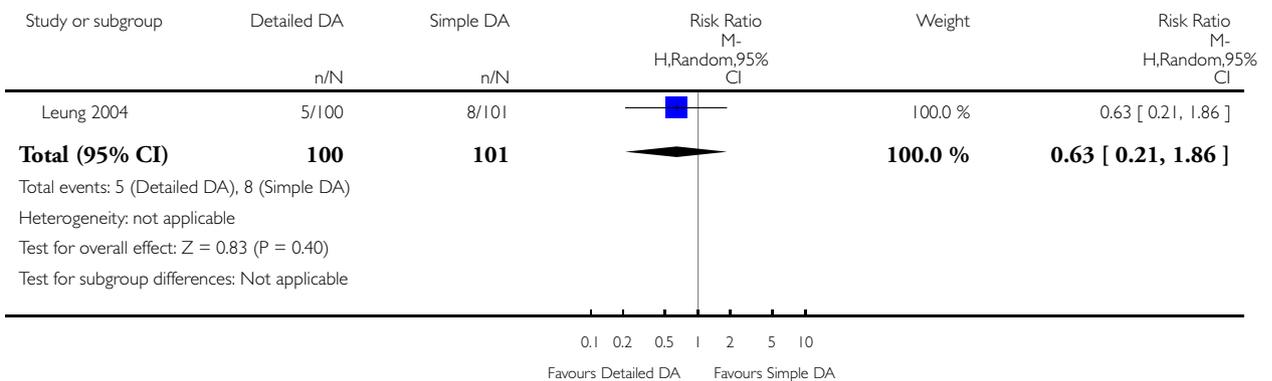


Analysis 6.6. Comparison 6 Proportion undecided, Outcome 6 Proportion undecided: Detailed vs simple decision aids - screening only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 6 Proportion undecided

Outcome: 6 Proportion undecided: Detailed vs simple decision aids - screening only

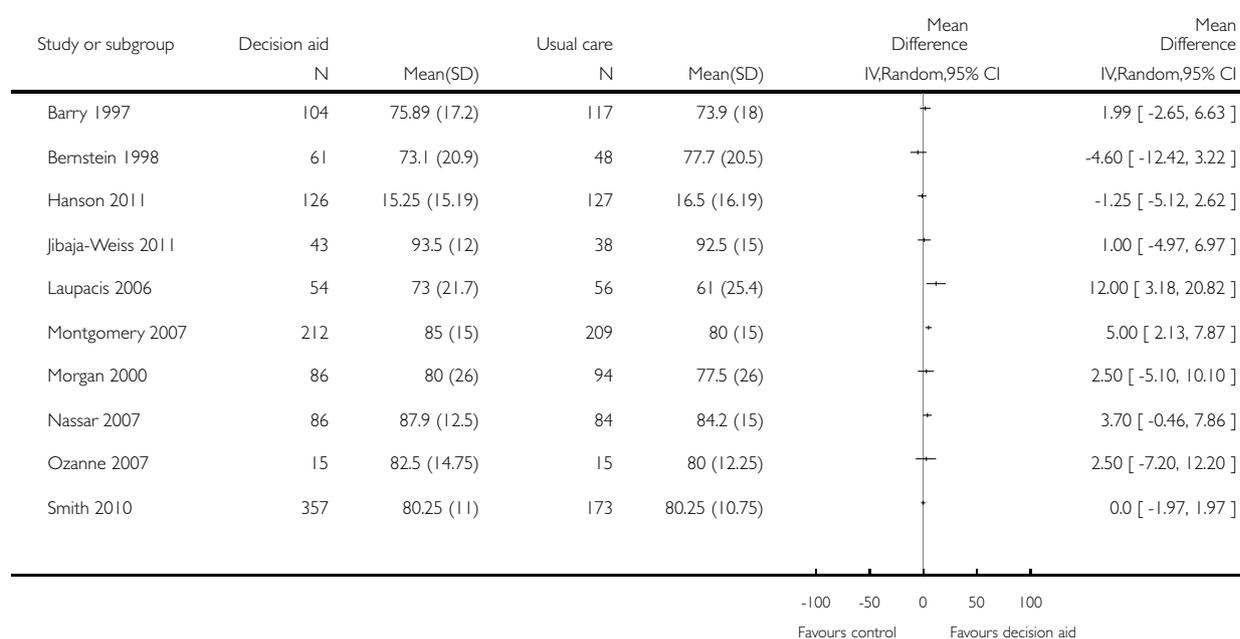


Analysis 7.1. Comparison 7 Satisfaction, Outcome 1 Satisfaction with the choice: DA vs usual care - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 7 Satisfaction

Outcome: 1 Satisfaction with the choice: DA vs usual care - all studies

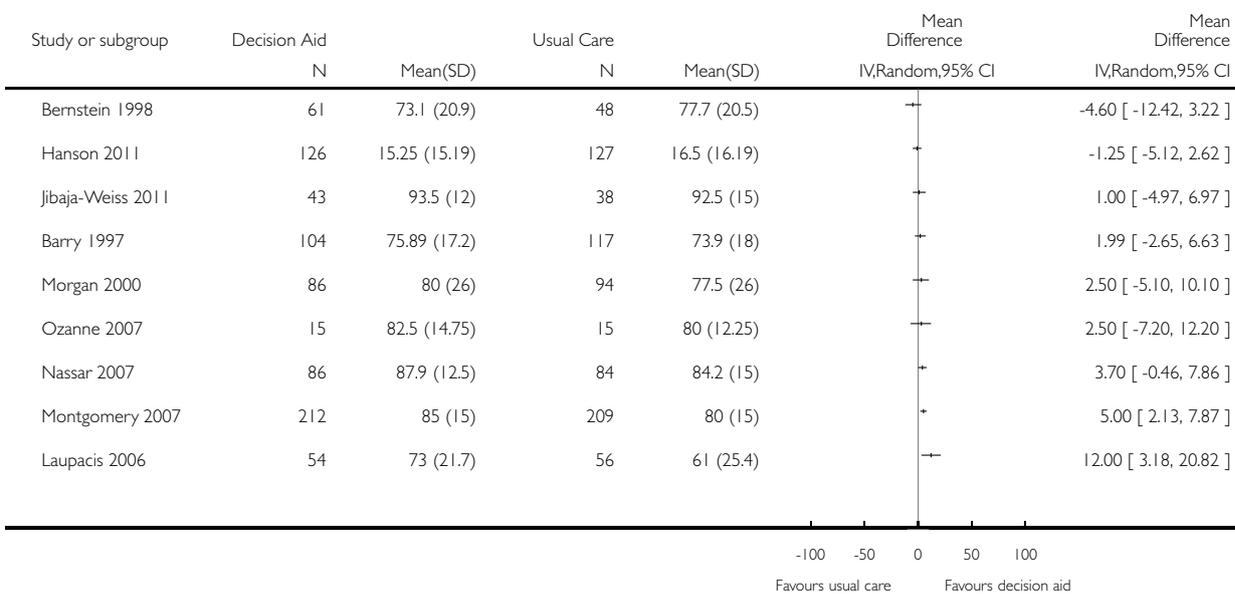


Analysis 7.2. Comparison 7 Satisfaction, Outcome 2 Satisfaction with the choice: DA vs usual care - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 7 Satisfaction

Outcome: 2 Satisfaction with the choice: DA vs usual care - treatment only

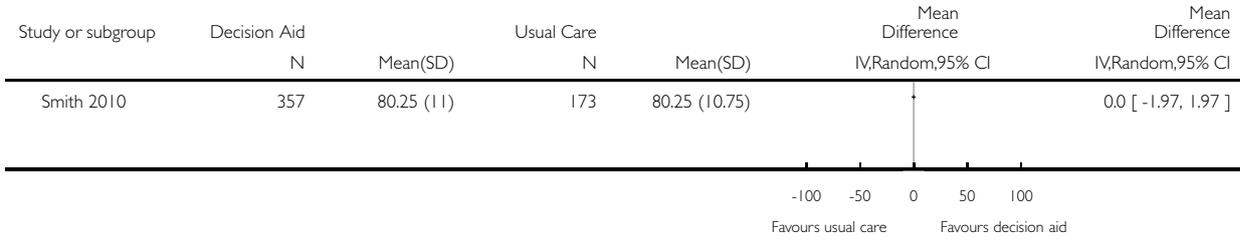


Analysis 7.3. Comparison 7 Satisfaction, Outcome 3 Satisfaction with the choice: DA vs usual care - screening only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 7 Satisfaction

Outcome: 3 Satisfaction with the choice: DA vs usual care - screening only

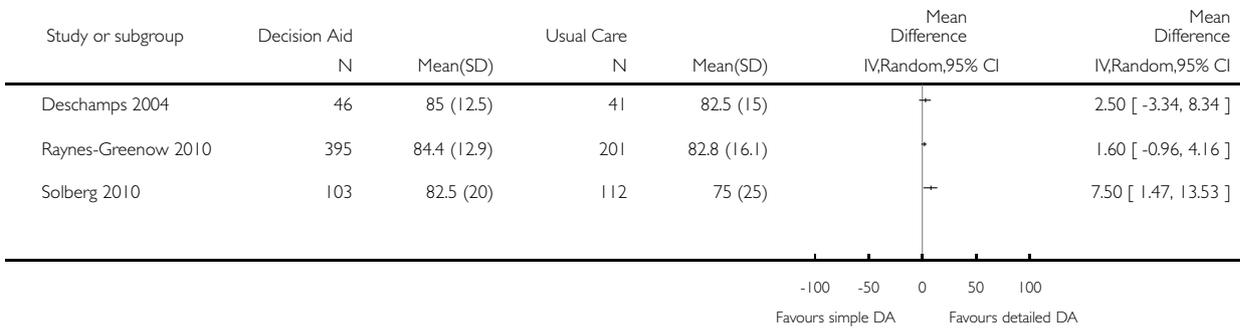


Analysis 7.4. Comparison 7 Satisfaction, Outcome 4 Satisfaction with the choice: Detailed vs simple DA - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 7 Satisfaction

Outcome: 4 Satisfaction with the choice: Detailed vs simple DA - all studies

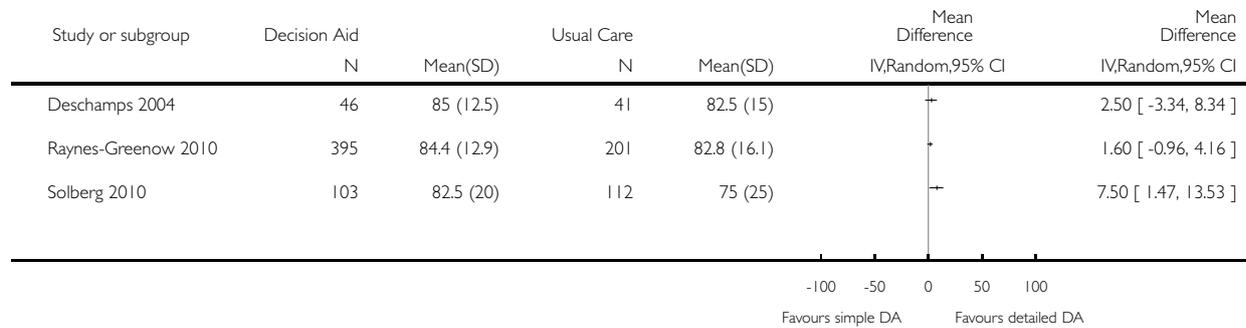


Analysis 7.5. Comparison 7 Satisfaction, Outcome 5 Satisfaction with the choice: Detailed vs simple DA - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 7 Satisfaction

Outcome: 5 Satisfaction with the choice: Detailed vs simple DA - treatment only

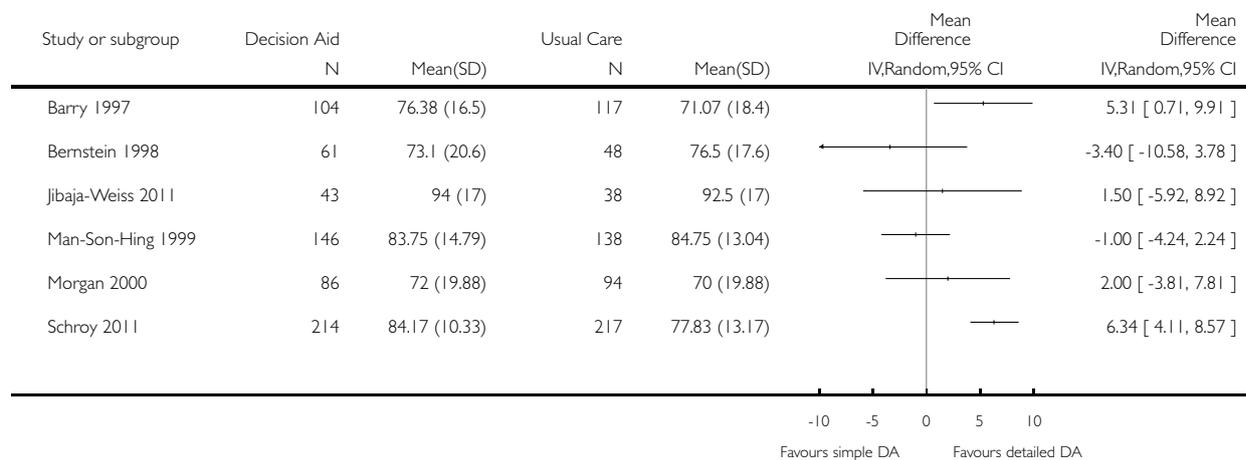


Analysis 7.6. Comparison 7 Satisfaction, Outcome 6 Satisfaction with the decision making process: DA vs usual care - all studies.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 7 Satisfaction

Outcome: 6 Satisfaction with the decision making process: DA vs usual care - all studies

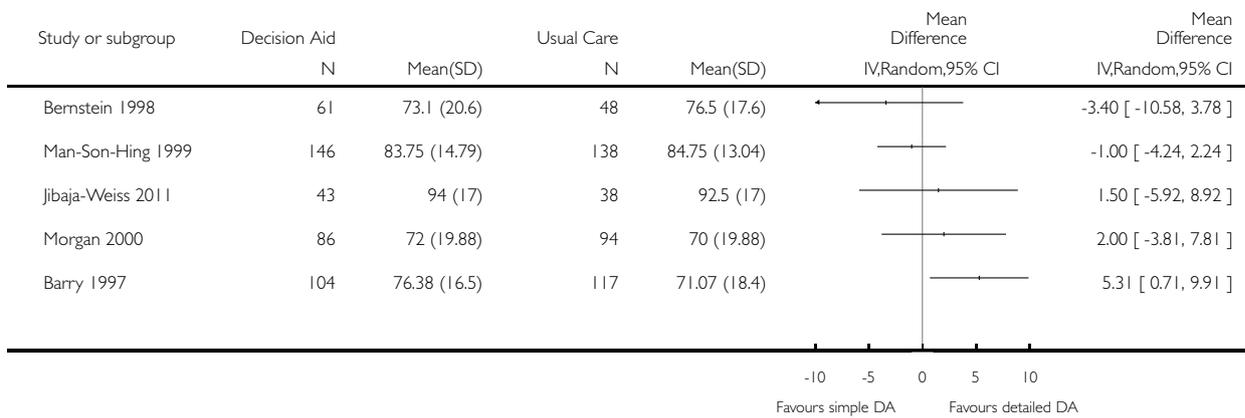


Analysis 7.7. Comparison 7 Satisfaction, Outcome 7 Satisfaction with the decision making process: DA vs usual care - treatment only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 7 Satisfaction

Outcome: 7 Satisfaction with the decision making process: DA vs usual care - treatment only

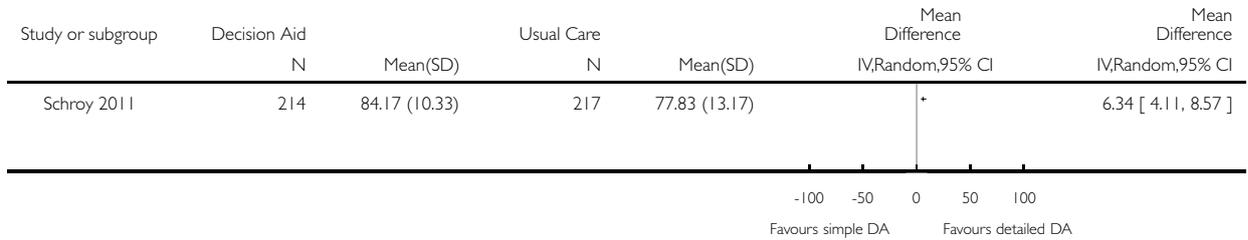


Analysis 7.8. Comparison 7 Satisfaction, Outcome 8 Satisfaction with the decision making process: DA vs usual care - screening only.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 7 Satisfaction

Outcome: 8 Satisfaction with the decision making process: DA vs usual care - screening only

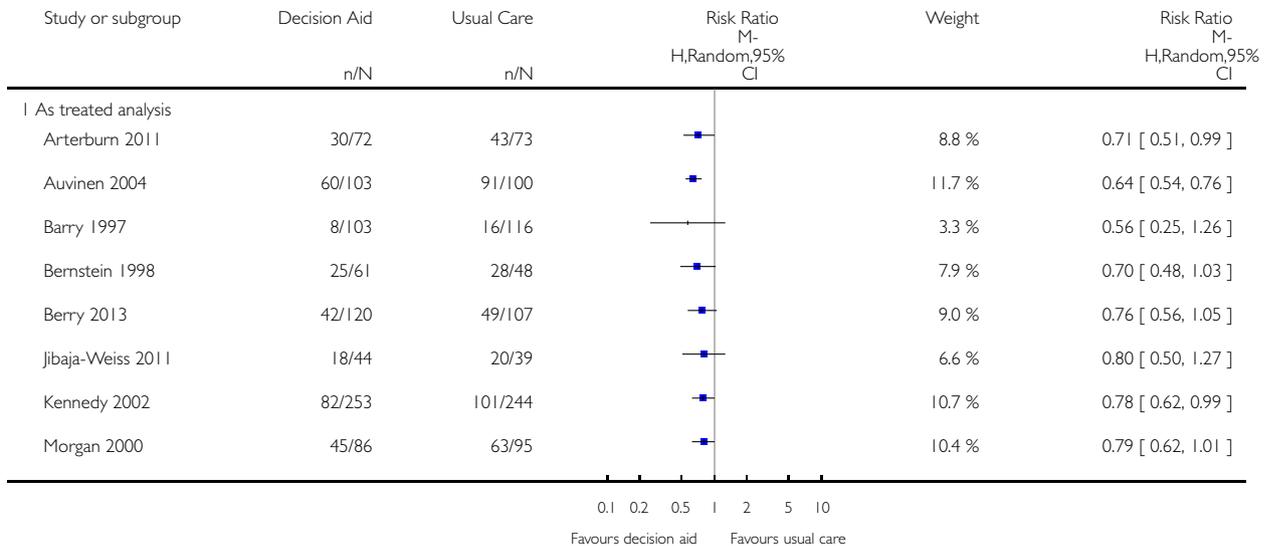


Analysis 8.1. Comparison 8 Choice, Outcome 1 Choice: Surgery over conservative option: DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

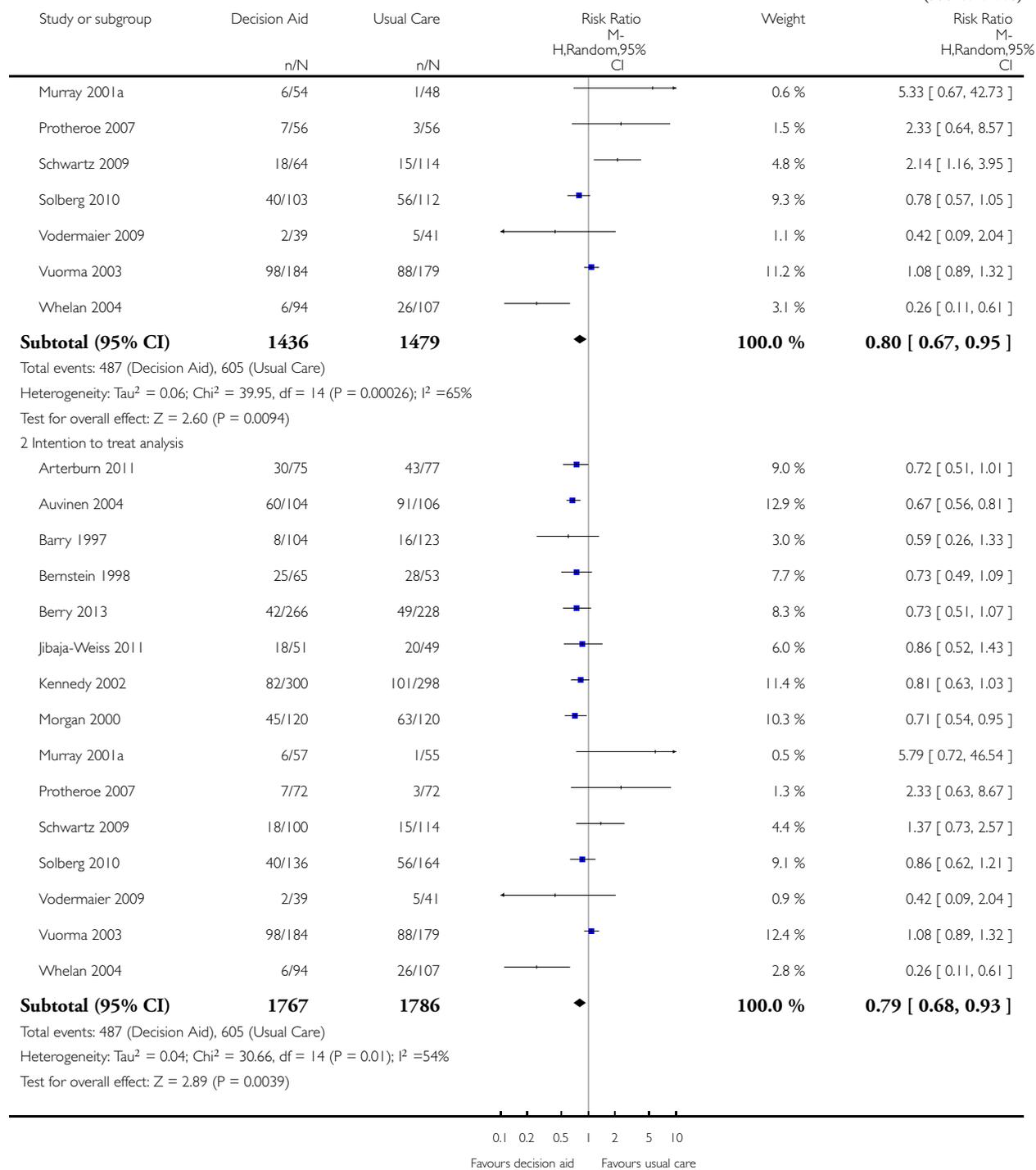
Comparison: 8 Choice

Outcome: 1 Choice: Surgery over conservative option: DA vs usual care



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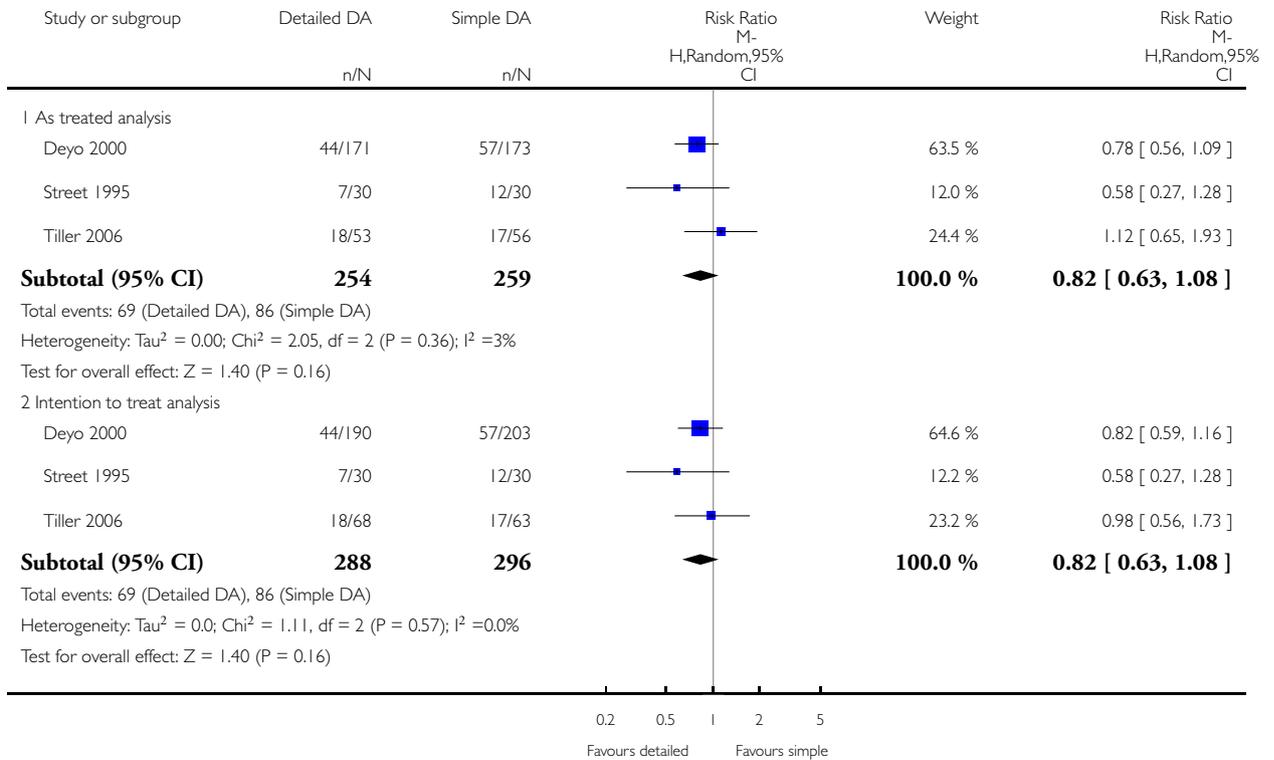


Analysis 8.2. Comparison 8 Choice, Outcome 2 Choice: Surgery over conservative option: Detailed vs simple decision aid.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 8 Choice

Outcome: 2 Choice: Surgery over conservative option: Detailed vs simple decision aid

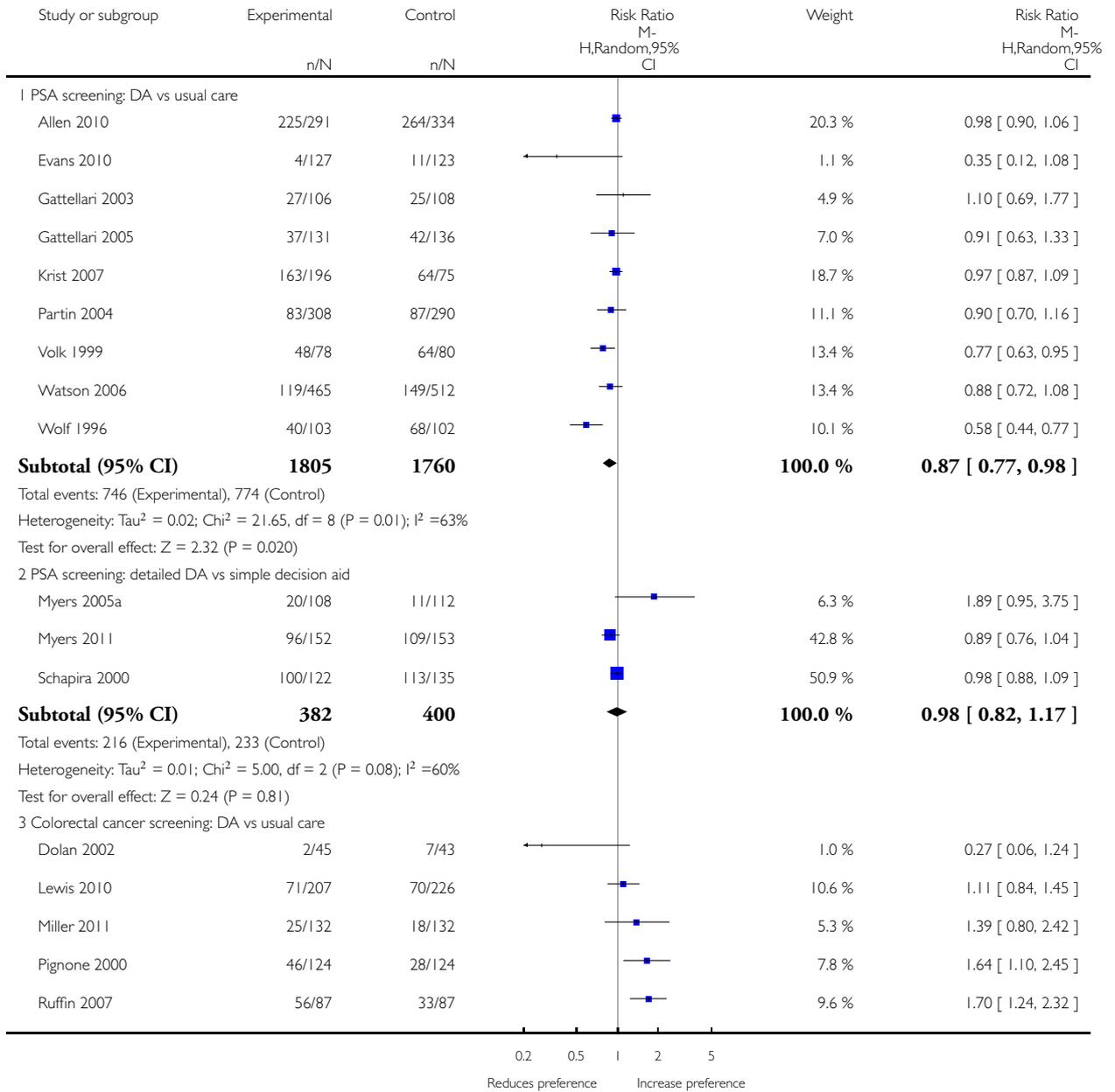


Analysis 8.3. Comparison 8 Choice, Outcome 3 Choice for screening.

Review: Decision aids for people facing health treatment or screening decisions

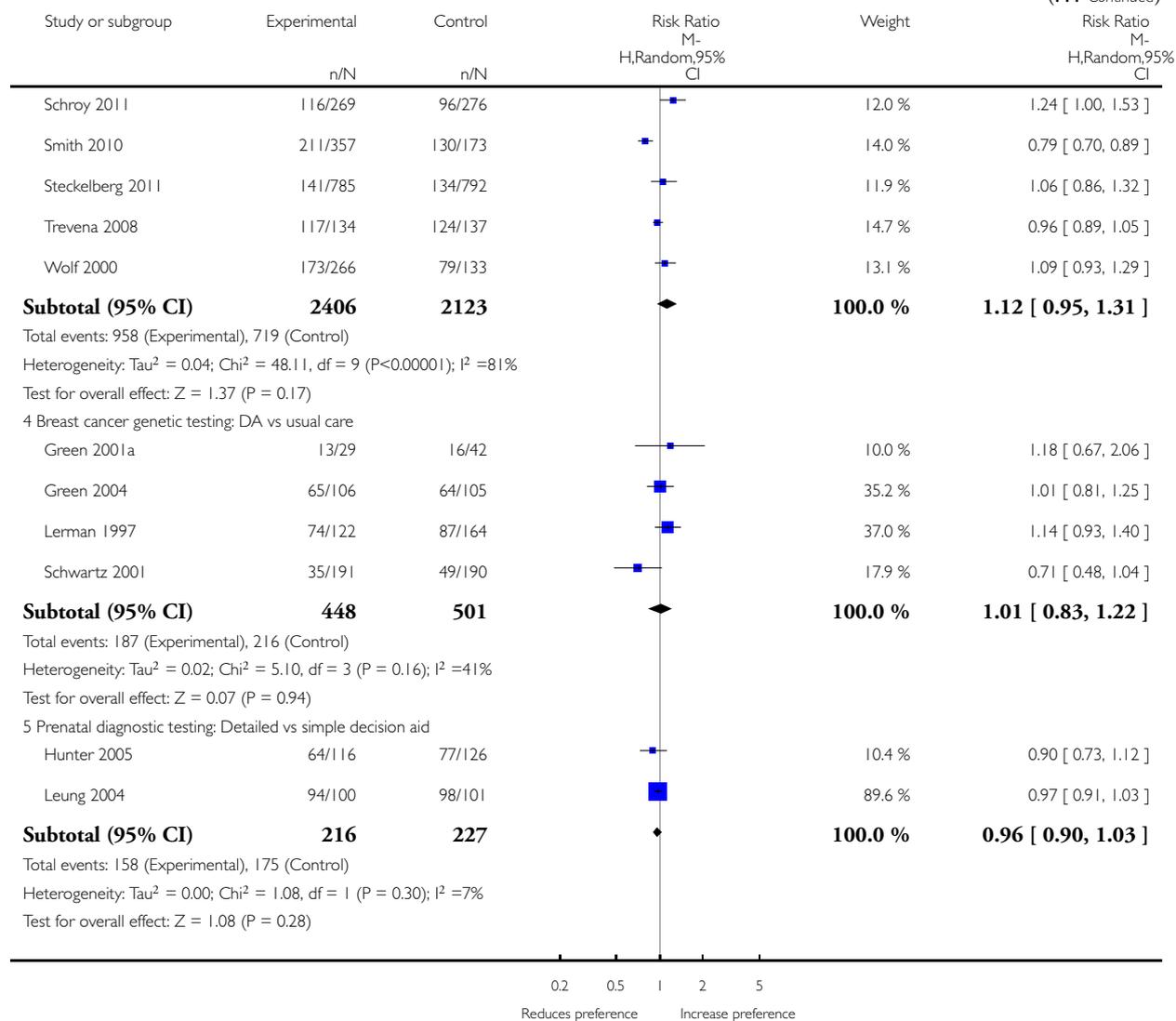
Comparison: 8 Choice

Outcome: 3 Choice for screening



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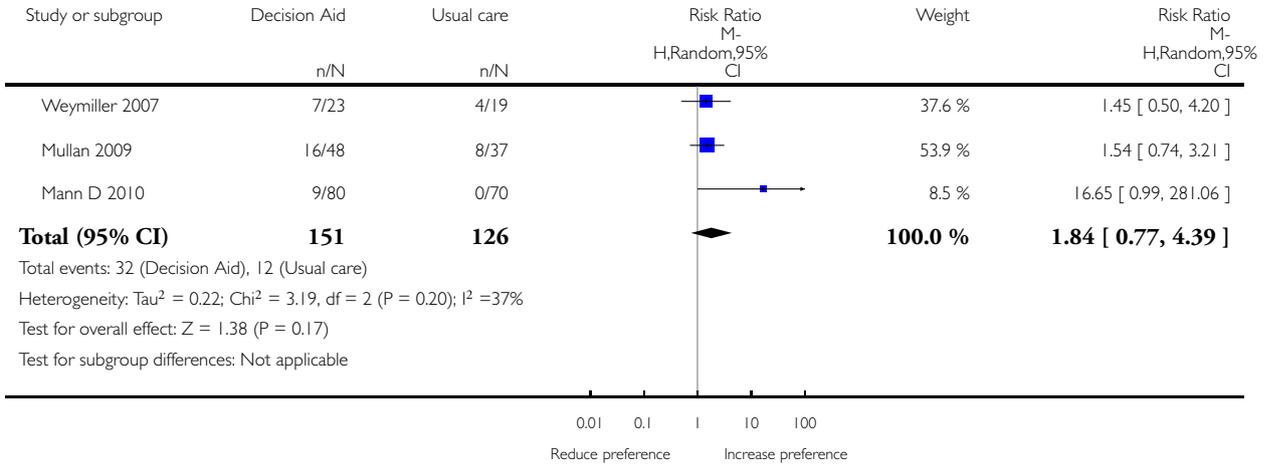


Analysis 8.4. Comparison 8 Choice, Outcome 4 Choice: Diabetes medication (uptake new medication): DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 8 Choice

Outcome: 4 Choice: Diabetes medication (uptake new medication): DA vs usual care

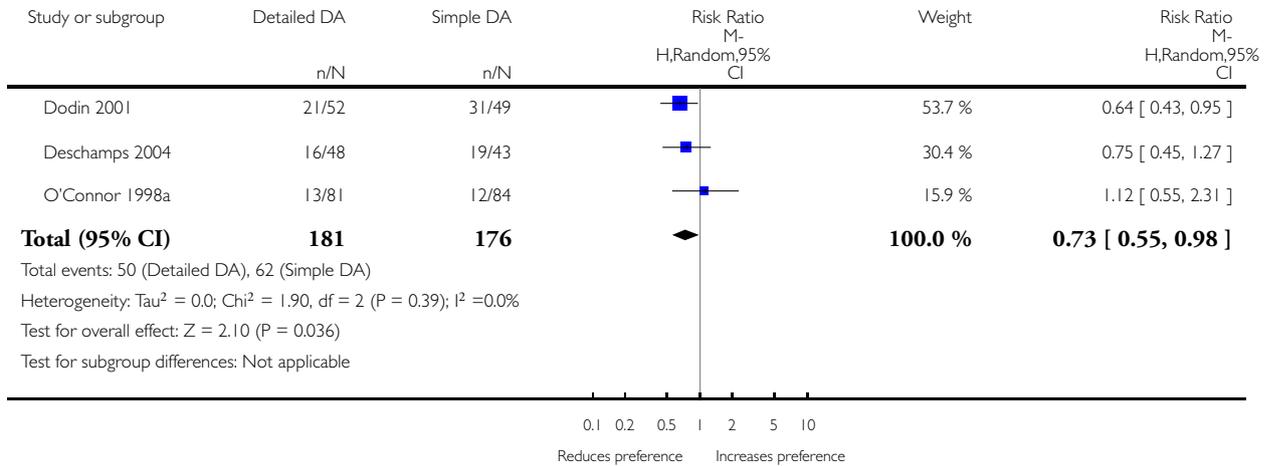


Analysis 8.5. Comparison 8 Choice, Outcome 5 Choice: Menopausal hormone therapy: Detailed vs simple decision aid.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 8 Choice

Outcome: 5 Choice: Menopausal hormone therapy: Detailed vs simple decision aid



ADDITIONAL TABLES

Table 1. Decision aids evaluated in the trials

Study	Topic	Availability	Source	Contact Information
Allen 2010	Prostate cancer screening	No	Allen, Center for Community-Based Research, Dana-Farber Cancer Institute, Boston, MA, US, 2010	requested access
Arterburn 2011	Bariatric surgery	Yes	Informed Medical Decisions Foundation, MA, US, 2010	informedmedicaldecisions.org/imdf_decision_aid/making-decisions-about-weight-loss-surgery/
Auvinen 2004	Prostate cancer treatment	Yes	Auvinen, Helsinki, Finland, 1993	included in publication

Table 1. Decision aids evaluated in the trials (Continued)

Barry 1997	Benign prostate disease treatment	Yes	Informed Medical Decisions Foundation, MA, US, 2001	informedmedicaldecisions.org/imdf_decision_aid/treatment-options-for-benign-prostatic-hyperplasia/
Bekker 2004	Prenatal screening	Yes	Bekker, Leeds, UK, 2003	included in publication
Bernstein 1998	Ischaemic heart disease treatment	Yes	Informed Medical Decisions Foundation, MA, US, 2002	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-carotid-artery-disease/
Berry 2013	Prostate cancer treatment	No	Berry, Phyllis F. Cantor Center, MA, USA, 2011	donna_berry@dfci.harvard.edu
Bjorklund 2012	Antenatal Down syndrome screening	Yes	Södersjukhuset, Department of Obstetrics and Gynecology, Stockholm, Sweden	vimeo.com/34600615/
Chambers 2012	Healthcare personnel's influenza immunization	Yes	A McCarthy. Ottawa Influenza Decision Aid Planning Group, CA, 2008	decisionaid.ohri.ca/decaids.html#oida
Clancy 1988	Hepatitis B Vaccine	No	Clancy, Richmond VA, US, 1983	
Davison 1997	Prostate cancer treatment	No	Davison, Manitoba CA, 1992-1996	
de Achaval 2012	Total knee arthroplasty treatment	Yes	Informed Medical Decisions Foundation, MA, US	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-knee-osteoarthritis/
Deschamps 2004	Hormone replacement therapy	No	O'Connor, Ottawa, CA, 1996	decisionaid.ohri.ca/decaids-archive.html
Deyo 2000	Back surgery	Yes	Informed Medical Decisions Foundation, MA, US, 2001	informedmedicaldecisions.org/imdf_decision_aid/managing-chronic-low-back-pain/
Dodin 2001	Hormone replacement therapy	No	O'Connor, Ottawa, CA, 1996	decisionaid.ohri.ca/decaids-archive.html

Table 1. Decision aids evaluated in the trials (Continued)

Dolan 2002	Colon cancer screening	No	Dolan, Rochester NY, US, 1999	
Evans 2010	Prostate cancer screening	Yes	Elwyn, Cardiff, UK	www.prosdex.com
Fagerlin 2011	Breast cancer prevention	Yes	Fagerlin, Ann Arbor, MI, US	
Fraenkel 2007	Osteoarthritis knee treatment	No	Fraenkel, New Haven CT, US	author said DA never fully developed, all info in paper
Frosch 2008	Prostate cancer screening	No	Frosch, Los Angeles, US	Screenshots from author
Gattellari 2003	Prostate cancer screening	Yes	Gatellari, Sydney, AU, 2003	included in publication 2003
Gattellari 2005	Prostate cancer screening	Yes	Gatellari, Sydney, AU, 2003	included in publication 2003
Goel 2001	Breast cancer surgery	No	Goel/Sawka, Toronto CAN, 2001	
Green 2001a	Breast cancer genetic testing	Yes	Green, Hershey PA, US, 2000	1-800-757-4868 dwc@mavc.com
Green 2004	Breast cancer genetic testing	Yes	Green, Hershey PA, US, 2000	1-800-757-4868 dwc@mavc.com
Hamann 2006	Schizophrenia treatment	Yes	Hamann, Munich, GER	emailed by author (in German)
Hanson 2011	Feeding options in advanced dementia	Yes	Mitchell, Tetroe, O'Connor; 2001 (updated 2008)	decisionaid.ohri.ca/decaids.html#feedingtube
Heller 2008	Breast reconstruction	Yes	University of Texas M.D. Anderson Cancer Center, Houston TX, US, 2003	Disc mailed
Hess 2012	Stress testing for chest pain	Yes	Hess, Rochester, MN, US, 2012	Included in publication
Hunter 2005	Prenatal screening	No	Hunter, Ottawa, CA, 2000	decisionaid.ohri.ca/decaids-archive.html
Jibaja-Weiss 2011	Breast cancer treatment	Yes	Jibaja-Weiss, Baylor College of Medicine, 2010	www.bcm.edu/patchworkoffife

Table 1. Decision aids evaluated in the trials (Continued)

Johnson 2006	Endodontic treatment	Yes	Johnson, Chicago, US, 2004	Included in publication
Kasper 2008	Multiple Sclerosis	No	Jürgen Kasper	
Kennedy 2002	Abnormal uterine bleeding treatment	No	Kennedy/Coulter, London UK, 1996	
Krist 2007	Prostate cancer screening	Yes	Krist, Fairfax VA, US	www.familymedicine.vcu.edu/research/misc/psa/index.html
Kuppermann 2009	Prenatal screening	No	Kuppermann, San Francisco CA, US	Computerized tool
Labrecque 2010	Vasectomy	Yes	Labrecque, Quebec City, CA, 2010	www.vasectomie.net (in French)
Lalonde 2006	Cardiovascular health treatment	No	Lalonde, Ottawa, CA, 2002	decisionaid.ohri.ca/dec aids-archive.html
Langston 2010	Contraceptive method choice	Yes	World Health Organization, 2005	www.who.int/reproductivehealth/publications/family_planning/9241593229index/en/index.html
Laupacis 2006	Pre-operative autologous blood donation	No	Laupacis, Ottawa, CA, 2001	decisionaid.ohri.ca/dec aids-archive.html
Legare 2003	Hormone replacement therapy	No	O'Connor, Ottawa, CA, 1996	decisionaid.ohri.ca/dec aids-archive.html
Legare 2008a	Natural health products	No	Legare, Quebec City, CA, 2006	
Legare 2011	Use of antibiotics for acute respiratory infections	Yes	Legare, Quebec City, CA, 2007	www.decision.chaire.fmed.ulaval.ca/index.php?id=192&L=2
Leighl 2011	Advanced colorectal cancer chemotherapy	Yes	Princess Margaret Hospital, Toronto, 2011	Natasha.Leighl@uhn.on.ca.
Lerman 1997	Breast cancer genetic testing	No	Lerman/Schwartz, Washington DC, US, 1997	
Leung 2004	Prenatal screening	No	Leung, Hong Kong, China, 2001	

Table 1. Decision aids evaluated in the trials (Continued)

Lewis 2010	Colorectal cancer screening	Yes	Lewis, University of North Carolina, Chapel Hill, NC, USA, 2010	decisionsupport.unc.edu/CHOICE6/
Loh 2007	Depression treatment	Yes	Loh, Freiburg, GER	(emailed to us by author - in German)
Man-Son-Hing 1999	Atrial fibrillation treatment	No	McAlister/Laupacis, Ottawa CA, 2000	decisionaid.ohri.ca/decids-archive.html
Mann D 2010	Diabetes treatment - statins	Yes	Montori, Rochester MN, US	mayoresearch.mayo.edu/mayo/research/ker_unit/form.cfm
Mann E 2010	Diabetes screening	Yes	Marteau, King's College London, London, England, 2010	Additional file 2 of publication
Marteau 2010	Diabetes screening	Yes	Marteau, King's College London, London, England, 2010	Provided by author, same DA as Mann E 2010
Mathieu 2007	Mammography	Yes	Mathieu, Sydney, AU,	DA emailed by author
Mathieu 2010	Mammography	Yes	Mathieu, University of Sydney, AUS, 2010	http://www.psych.usyd.edu.au/cemped/com_decision_aids.shtml
McAlister 2005	Atrial fibrillation treatment	No	McAlister/Laupacis, Ottawa CAN, 2000	decisionaid.ohri.ca/decids-archive.html
McBride 2002	Hormone replacement therapy	Yes, update in progress	Sigler/Bastien, Durham NC, US, 1998	basti001@mc.duke.edu
McCaffery 2010	Screening after mildly abnormal pap smear	Yes	Screening & test evaluation program, School of public health, University of Sydney 2007	kirstenm@health.usyd.edu.au
Miller 2005	BRCA1/BRCA2 gene testing	No	Miller, Fox Chase PA, US	
Miller 2011	Colorectal cancer screening	Yes	University of North Carolina, Chapel Hill, NC, USA, 2007	intmedweb.wakehealth.edu/choice/choice.html (no longer available)
Montgomery 2003	Hypertension treatment	No	Montgomery, UK, 2000	

Table 1. Decision aids evaluated in the trials (Continued)

Montgomery 2007	Birth options after caesarean	Yes	Montgomery, Bristol, UK, last update 2004	www.computing.dundee.ac.uk/acstaff/cjones/diamond/Information.html
Montori 2011	Osteoporosis treatment	Yes	Montori, Mayo Foundation for Medical Education and Research, 2007	shareddecisions.mayoclinic.org/decision-aids-for-diabetes/other-decision-aids/
Morgan 2000	Ischaemic heart disease treatment	Yes	Informed Medical Decisions Foundation, MA, US, 2002	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-carotid-artery-disease/
Mullan 2009	Diabetes treatment	Yes	Montori or Mayo Foundation?, Rochester MN, US,	included in publication
Murray 2001a	Benign prostate disease treatment	Yes	Informed Medical Decisions Foundation, MA, US, 2001	informedmedicaldecisions.org/imdf_decision_aid/treatment-options-for-benign-prostatic-hyperplasia/
Murray 2001b	Hormone replacement therapy	No, update in progress	Informed Medical Decisions Foundation, MA, US	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-managing-menopause/
Myers 2005a	Prostate cancer screening	No	Myers, Philadelphia PA, US, 1999	
Myers 2011	Prostate cancer screening	Yes	Myers, Philadelphia PA, 1999	
Nagle 2008	Prenatal screening	Yes	Nagle, Victoria, AU	www.mcri.edu.au/Downloads/PrenatalTestingDecisionAid.pdf
Nassar 2007	Birth breech presentation	Yes	Nassar, West Perth WA, AU	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php
O'Connor 1998a	Hormone replacement therapy	No	O'Connor, Ottawa CA, 1996	decisionaid.ohri.ca/decids-archive.html

Table 1. Decision aids evaluated in the trials (Continued)

O'Connor 1999a	Hormone replacement therapy	No	O'Connor, Ottawa CA, 1996	decisionaid.ohri.ca/dec aids-archive.html
Oakley 2006	Osteoporosis treatment	No	Cranney, Ottawa CA, 2002	decisionaid.ohri.ca/dec aids-archive.html
Ozanne 2007	Breast cancer prevention	No	Ozanne, Boston MA, US,	
Partin 2004	Prostate cancer screening	Yes	Informed Medical Decisions Foundation, MA, US, 2001	informedmedicaldecisions.org/imdf_decision_aid/deciding-if-the-psa-test-is-right-for-you/
Pignone 2000	Colon cancer screening	Yes	Pignone, Chapel Hill NC, US, 1999	www.med.unc.edu/medicine/edusr/colon.htm
Protheroe 2007	Menorrhagia treatment	No	Protheroe, Manchester, UK	computerized decision aid, Clinical Guidance Tree - no longer in existence, author sent chapter in thesis
Raynes-Greenow 2010	Labour analgesia	Yes	Raynes-Greenow, Sydney, Australia, 2004	http://www.psych.usyd.edu.au/cemped/com_decision_aids.shtml
Rostom 2002	Hormone replacement therapy	No	O'Connor, Ottawa CA, 1996	decisionaid.ohri.ca/dec aids-archive.html
Rothert 1997	Hormone replacement therapy	No, update in progress	Rothert, East Lansing MI, US, 1999	
Rubel 2010	Prostate cancer screening	No	Centers for Disease Control and Prevention (CDC), US, 2010	[No longer available]
Ruffin 2007	Colorectal cancer screening	Yes	Regents of the University of Michigan (copyright info), Ann Arbor MI, US, 2006	colorectalweb.org
Schapira 2000	Prostate cancer screening	Yes	Schapira, Milwaukee WI, US, 1995	mschap@mcw.edu
Schapira 2007	Hormone replacement therapy	Yes	Schapira, Milwaukee WI, US	computer-based DA

Table 1. Decision aids evaluated in the trials (Continued)

Schroy 2011	Colorectal cancer screening	Yes	Schroy III, Boston, USA	Paul.schroy@bmc.org
Schwalm 2012	Coronary angiogram access site	Yes	Schwalm, Hamilton, ON, Canada, 2009	http://www.phri.ca/workfiles/studies/presentations/PtDA%20Vascular%20Access%202023-May-2012.pdf
Schwartz 2001	Breast cancer genetic testing	No	Schwartz/Lerman, Washington DC, US, 1997	
Schwartz 2009	BRCA mutation prophylactic surgery	No	Schwartz, Washington DC, US	
Sheridan 2006	Cardiovascular prevention	Yes	Sheridan, Chapel Hill, NC, US	http://www.med-decisions.com/cvtool/
Sheridan 2011	Coronary heart disease prevention	Yes	Sheridan, University of North Carolina at Chapel Hill, Division of General Internal Medicine, North Carolina, US, 2011	http://www.med-decisions.com/h2hv3/
Shorten 2005	Birthing options after previous caesarean	Yes (updated 2006)	Shorten, Wollongong, AU, 2000	ashorten@uow.edu.au or www.capersbookstore.com.au/product.asp?id=301
Smith 2010	Bowel cancer screening	Yes	Smith, Sydney, AU 2008	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php
Solberg 2010	Uterine fibroid treatment	Yes	Informed Medical Decisions Foundation, MA, US, 2006	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-uterine-fibroids/
Steckelberg 2011	Colorectal cancer screening	Yes	Steckelberg, Hamburg, Germany	
Street 1995	Breast cancer surgery	No	Street, College Station TX, US, 1995	
Thomson 2007	Atrial fibrillation treatment	Yes	Thomson, Newcastle Upon Thyne, UK	disc sent by mail

Table 1. Decision aids evaluated in the trials (Continued)

Tiller 2006	Ovarian cancer risk management	No	Tiller, Randwick NSW, AU	
Trevena 2008	Colorectal cancer screen	Yes	Trevena, Sydney, AU	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php
van Peperstraten 2010	Embryos transplant	Yes	Radboud University Nijmegen Medical Centre; 2006	www.umcn.nl/ivfda-en
Vandemheen 2009	Cystic Fibrosis referral transplant	Yes	Aaron, Ottawa ON, CA, 2009 (last update 2011)	decisionaid.ohri.ca/decaids.html#cfda
van Roosmalen 2004	BRCA1/2 mutation: prophylactic surgery	Yes	vanRoosmalen, Netherlands, 1999	see publication
Vodermaier 2009	Breast cancer surgery	Yes	Vodermaier, Vancouver BC, CA	received by email (in German)
Volk 1999	Prostate cancer screening	Yes	Informed Medical Decisions Foundation, MA, US, 1999	informedmedicaldecisions.org/imdf_decision_aid/deciding-if-the-psa-test-is-right-for-you/
Volk 2008	Prostate cancer screening	No	Volk, Houston TX, US	
Vuorma 2003	Menorrhagia treatment	No	Vuorma, Helsinki Finland, 1996	
Wakefield 2008	Colorectal cancer screening	Yes	Wakefield, Sydney, AU,	www.genetics.edu.au/Information/PublicationsBrochuresandPamphlets/Understanding%20Genetic%20Tests%20for%20Lync
Wakefield 2008a	Breast cancer genetic testing	Yes	Wakefield, Sydney, AU,	
Wakefield 2008b	Breast cancer genetic testing	Yes	Wakefield, Sydney, AU,	
Watson 2006	Prostate cancer screening	Yes	Oxford, UK	included in publication
Weymiller 2007	Diabetes mellitus type 2 treatment	Yes	Montori, Rochester MN, US	mayoresearch.mayo.edu/mayo/research/ker_unit/form.cfm

Table 1. Decision aids evaluated in the trials (Continued)

Whelan 2003	Breast cancer chemotherapy	Yes	Whelan, Hamilton CA, 1995	included in publication
Whelan 2004	Breast cancer surgery	Yes	Whelan, Hamilton CA, 1997	included in publication
Wolf 1996	Prostate cancer screening	Yes	Wolf, Charlottesville VA, US, 1996	Script in publication
Wolf 2000	Colon cancer screening	Yes	Wolf, Charlottesville VA, US, 2000	Script in publication
Wong 2006	Pregnancy termination	No	Bekker, Leeds, UK, 2002	

Table 2. Risk of bias by primary outcome

Outcome		Knowledge	Accurate risk perception	Value-choice agreement	Uninformed	Unclear values	Participation - practitioner controlled
Total studies		n = 42	n = 19	n = 13	n = 22	n = 18	n = 14
Random sequence generation	low	35 (83.3%)	8 (42.1%)	7 (53.8%)	19 (86.4%)	17 (94.4%)	12 (87.7%)
	unclear	7 (16.7%)	11 (57.9%)	6 (46.2%)	3 (13.6%)	1 (5.6%)	2 (14.3%)
	high	0	0	0	0	0	0
Allocation concealment	low	30 (71.4%)	12 (63.2%)	11 (84.6%)	20 (90.9%)	17 (94.4%)	10 (71.4%)
	unclear	12 (28.6%)	7 (36.8%)	2 (15.4%)	2 (9.1%)	1 (5.6%)	4 (28.6%)
	high	0	0	0	0	0	0
Incomplete outcome data	low	26 (61.9%)	11 (57.9%)	11 (84.6%)	15 (68.2%)	13 (72.2%)	10 (71.4%)
	unclear	16 (38.1%)	8 (42.1%)	2 (15.4%)	7 (31.8%)	5 (27.8%)	4 (28.6%)
	high	0	0	0	0	0	0
Selective reporting	low	15 (35.7%)	7 (36.8%)	6 (46.2%)	9 (40.9%)	8 (44.4%)	4 (28.6%)
	unclear	27 (64.3%)	12 (63.2%)	7 (53.8%)	13 (59.1%)	10 (55.6%)	10 (71.4%)
	high	0	0	0	0	0	0
Other bias	low	34 (81.0%)	14 (73.7%)	11 (84.6%)	19 (86.4%)	17 (94.4%)	11 (78.6%)

Table 2. Risk of bias by primary outcome (Continued)

	unclear	7 (16.7%)	5 (26.3%)	2 (15.4%)	3 (13.6%)	1 (5.6%)	3 (21.4%)
	high	1 (2.4%)	0	0	0	0	0
Blinding of participants and personnel	low	9 (21.4%)	1 (5.3%)	2 (15.4%)	3 (13.6%)	2 (11.1%)	2 (14.3%)
	unclear	31 (73.8%)	17 (89.5%)	11 (84.6%)	18 (81.8%)	15 (83.3%)	9 (64.3%)
	high	2 (4.8%)	1 (5.3%)	0	1 (4.5%)	1 (5.6%)	3 (21.4%)
Blinding of outcome assessment	low	41 (97.6%)	19 (100%)	13 (100%)	22 (100%)	18 (100%)	13 (92.9%)
	unclear	1 (2.4%)	0	0	0	0	1 (7.1%)
	high	0	0	0	0	0	0

Table 3. Knowledge

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Evans 2010	12 true or false questions; scores ranging from -12 to +12	immediately post	89	4.9	103	2.17	P < 0.001
Hamann 2006	7-item multiple choice knowledge test (unable to standardize results)	on discharge (- 1 month)	49	15 (4.4 SD)	58	10.9 (5.4 SD)	P = 0.01
Heller 2008	12-item multiple choice	pre-operatively	66	14%*	67	8%*	*mean increase from baseline P = 0.02
Legare 2008a	10-item yes/no/unsure general knowledge test about natural health	change scores from baseline to 2 weeks	43	0.86 ± 1.77 P = 0.002	41	0.51 ± 1.47 P = 0.031	No difference between groups (P = 0.162)

Table 3. Knowledge (Continued)

	products (not specific to outcomes of options)						
Mann D 2010	14 items survey	immediately post					No difference in level of knowledge between groups
Mathieu 2007	9 item - 4 concept questions and 5 numeric questions		351		357		Significantly higher mean increase for the intervention group (2.62) compared to control group (0.68) from baseline, $P < 0.001$
Miller 2005	8 items survey	2-week, 2-month, and 6-month follow-ups					Intervention type had no impact on general or specific knowledge
Nagle 2008	Good level knowledge was scored higher than the midpoint of the knowledge scale (greater than 4)						88% (147/167) in DA group compared to 72% (123/171) pamphlet group. Odds ratio (3.43 95%CI 1.79 to 6.58)
Ozanne 2007	Change in knowledge from baseline	post-test	15	48% to 64%	15	45% to 57%	change in knowledge score was significant for decision aid ($P = 0.01$) but not control ($P = 0.13$)

Table 3. Knowledge (Continued)

Partin 2004	10-item knowledge index score	2 weeks	308	7.44	290	6.9	P = 0.001
Rubel 2010	24-items adapted from existing prostate cancer knowledge measures	immediately post	100		100		the total mean standardized knowledge score was 84.38 (SD 12.38)
Trevena 2008	Adequate knowledge (positive score: understanding benefits/harms)	1 month	134	28/134	137	8/137	P = 0.0001
Watson 2006	12-item true/false/don't know	post-test	468	75% (range 0 to 100)	522	25% (range 0 to 100)	P < 0.0001
Weymiller 2007	14-item - 9 addressed by decision aid; 5 were not	immediately post	52		46		Mean difference between groups 2.4 (95% CI 1.5 to 3.3) P < 0.05 (when decision aid administered during the consultation only - not if prior to the consultation)
<i>Detailed versus simple DA</i>							
Volk 2008		2 weeks	233		223		Significant improvement in knowledge with no difference between groups (entertainment decision aid or audio-booklet)

CI: confidence interval; DA: decision aid; SD: standard deviation

Table 4. Accurate risk perceptions

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Compari-son	Comparison - mean	Notes
<i>DA versus usual care</i>							
Hanson 2011	Expectation of benefit index 11 items score from 1 to 4 with lower score indicating better knowledge	post (after re-viewing DA)	127	2.3	129	2.6	P = 0.001
Mann E 2010	3 of 8 multiple choice items in the knowl- edge test (question 4, 5, 7)	2 weeks post					total knowledge re-ported only
Mathieu 2010	5 item numer- ical questions (max = 5)	post	113	3.02	189	2.45	P < 0.001
Miller 2005		2-week, 2- month, and 6- month follow- ups					Interven- tion type had no impact on risk perceptions
Smith 2010	8 numer- ical questions (max = 8)		357	2.93 (SD 2. 91)	173	0.58 (SD1.28)	P < 0.001
Weymiller 2007		immediately	52		46		Difference be- tween group OR 22.4 (95% CI 5.9 to 85.8) when decision aid admin- istered during the consulta- tion only (not if prior to) OR 6.7 (95% CI 2.2 to 19.

Table 4. Accurate risk perceptions (Continued)

								7) when the decision aid administered prior to or during the consultation
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CI: confidence interval; DA: decision aid; OR: odds ratio; SD: standard deviation

Table 5. Values congruent with chosen option

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Arterburn 2011	Percent match procedures described by Sepucha et al (2007; 2008). For values items were most predictive and used to specify logistic models to estimate predicted probability of selecting surgery > 0.5	post intervention	75		77		The intervention group experienced a more rapid early improvement in value concordance immediately after the intervention compared to control, see Figure 2 .
Frosch 2008	Concordance between patient's preferences and values for potential outcomes related to the decision and the choice made	within weeks	155		151		Men assigned to the decision aid who chose not to have a PSA test rated their concern about prostate cancer lower than did men who requested a PSA test. Men as-

Table 5. Values congruent with chosen option (Continued)

							signed to usual care provided similar ratings of concern about prostate cancer regardless of their PSA decision. There was no statistically significant difference between groups
Legare 2008a							Women valuing of non chemical aspect of nature health products was positively associated with their choice of nature health products, P = 0.006
Lerman 1997	Association between values and choice	-----	-----	-----	-----	-----	No difference; between group differences were not reported
Vandemheen 2009	Congruence between personal values and decision	3 weeks	70			70	Patient choices were consistent with their values across both randomised groups
<i>Detailed versus simple DA</i>							
Rothert 1997	Correlation between expected utilities and their like-	-----	-----	-----	-----	-----	Simple DA showed lower correlations between

Table 5. Values congruent with chosen option (Continued)

	likelihood of taking hormones						expected value of hormones and likelihood of taking hormones than did more detailed DA
Solberg 2010	My decision was consistent with my personal values. (Likert Scale, ranged from 1-5)	4-5 weeks after intervention	103	87.5 (SD 20)	112	80 (SD 22.5)	P < 0.01
	multi-nomial logistic regression analysis						No significant difference between groups

DA: decision aid; SD: standard deviation

Table 6. Decisional Conflict Score

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Arterburn 2011	Total Decisional Conflict- change from baseline (standardised values)	immediately post	75	mean (-20) SD (19.44)	77	mean (-11.8) SD (22.83)	P = 0.03
Berry 2013	Decisional conflict scale	uncertainty		-3.61 units			P = 0.04
		uninformed					No significant difference
		unclear values		-3.57 units			P = 0.002
		unsupported					No significant difference
		Ineffective decision					No significant difference

Table 6. Decisional Conflict Score (Continued)

		total		-1.75 units			P = 0.07
Fagerlin 2011	Decisional conflict scale	immediately post					DCS was higher in the intervention group compared to control, P < 0.001
Frosch 2008	Decisional conflict - subscales only	Feeling uninformed	155	23.37	151	29.68	P < 0.05
		Feeling unclear values	155	32.25	151	37.93	P < 0.05
		Feeling supported	155	30.51	151	35.21	P < 0.05
		Feeling uncertain	155		151		No difference
		Effective decisions	155		151		No difference
Krist 2007	Decisional conflict	immediately after office visit	196	1.54	75	1.58	No difference
Leighl 2011	Decisional conflict scale median (range)	1-2 weeks post intervention	107	26 (range 0-79)	100	26 (range 0-67)	No difference
Mathieu 2010	Based on approaches suggested by Marteau et al. (informed choice)	immediately after intervention	91	71%	110	64%	P = 0.24
Ozanne 2007	Decisional conflict	post consultation	15		15		Both groups showed lower decisional conflict post-consultation (P < 0.001) but no difference be-

Table 6. Decisional Conflict Score (Continued)

							tween groups
Rubel 2010	Decisional conflict	immediately post					The total mean score was 24.5 with a SD of 15.25 (n=200)
Schwartz 2009a	Decisional conflict	12 of 16 items of the original scale					Significant longitudinal impact of the decision aid was moderated by baseline decision status; decision aid led to significant decreases in decisional conflict for those who were undecided at the time of randomisation
Thomson 2007	Decisional conflict	post consultation	53		56		Difference between decision aid and control group were -0.18 (95% CI -0.34 to -0.01) . P = 0.036
		3-months post	51		55		Difference between decision aid and control group were -0.15 (95% CI -0.37 to 0.06) , no significant difference
van Peperstraten 2010	15 item questionnaire (1-5) - satisfaction-	post intervention, pre IVF	124	72.5	128	75	P = 0.76

Table 6. Decisional Conflict Score (Continued)

	uncertainty						
	15 item questionnaire (1-5) - informed (includes some items from DCS)	post intervention, pre IVF	124	77.5	128	87.5	P = 0.001
Weymiller 2007	Decisional conflict	immediately post	52		46		Mean difference indicates statistically significantly lower decisional conflict for decision aid compared to usual care Total DCS - 10.6 (-15.4 to -5.9) Uncertain - 12.8 (-18.4 to -7.3) Informed -17.3 (-22.6 to -12.0) if administered during consult -6.6 (-14.3 to -1.1) if administered prior to consult Values clarity - 8.5 (-15.7 to -1.3) Support -9.4 (-14.8 to -3.9) Effective decision -10.0 (-15.0 to -5.0)

CI: confidence interval; DA: decision aid; DCS: decisional conflict scale; IVF: in vitro fertilisation; SD: standard deviation

Table 7. Decisional Conflict Score - low literacy version

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Smith 2010	Total DCS	2 week follow-up	357	13.63 (SD 20.55)	173	14.91(SD 18.34)	P = 0.02
<i>Detailed versus simple DA</i>							
Volk 2008	Uncertainty	2 weeks	39	5.8 (SD 18.0)	48	6.8 (SD 18.0)	P = 0.80
	Informed	2 weeks	39	9.1 (SD 26.0)	46	18.8 (SD 26.1)	P = 0.09
	Values	2 weeks	40	17.4 (SD 36.8)	48	34.9 (SD 36.6)	P = 0.03
	Social Support	2 weeks	39	17.8 (SD 29.6)	48	27.6 (SD 29.5)	P = 0.12
	Total DCS	2 weeks	38	12.0 (SD 21.9)	46	21.7 (SD 21.8)	P = 0.04

DA: decision aid; DCS: decisional conflict scale; SD: standard deviation

Table 8. Patient-practitioner communication

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Hanson 2011	Dis-cussed feeding with physician, nurse practitioner, or physician's assistant	3 months	126	46%	127	33%	P = 0.04
	Dis-cussed feeding with other nursing home staff	3 months	126	64%	127	71%	P = 0.42

Table 8. Patient-practitioner communication (Continued)

Hess 2012	OPTION scale	analysis of the consultation using video-recorded consultations	101	Mean of 26.6 (95% CI 24.9 to 8.2)	103	Mean of 7% (95%CI 5.9 to 8.1)	Significantly greater in the intervention arm
Legare 2011	DCS / Dolan's Provider DCS	immediately post					Difference 0.26 (95%CI -0.06 to 0.53, P = 0.06)
Montori 2011	OPTION 100 point Scale	analysis of the consultation using video-recorded consultations	38	49.8	32	27.3	P < 0.001
Mullan 2009	OPTION Scale	analysis of the consultation using video-recorded consultations	48 used decision aid within consultation	49.7% (SD 17.74)	37 usual care	27.7% (SD 11.75)	MD 21.8 (95% CI 13.0, 30.5) for decision aid vs usual care. All but 2 of the 12 items significantly favoured the decision aid
Sheridan 2006	Discussed CHD with doctor	patient reported immediately post	16/41 decision aid preconsult with summary report to bring to consult		8/34 usual care		absolute difference 16%; 95% CI -4% to 37%
	Plan to reduce CHD risk & discussed with doctor	patient reported immediately post	15/41 decision aid preconsult with summary report to bring to consult		8/34 usual care		absolute difference 13%; 95% CI -7% to 34%).
	Plan to reduce CHD risk & not discussed with doctor	patient reported immediately post	37/41 decision aid preconsult with summary report to bring to consult		25/34 usual care		absolute difference 16%; 95% CI -1% to 33%

Table 8. Patient-practitioner communication (Continued)

Weymiller 2007	OPTION Scale	analysis of the consultation using video-recorded consultations	1/2 used decision aid prior to consult and 1/2 used it during consult		usual care		Greater patient participation (MD 4.4; 95% CI 2.9 to 6.0) in decision aid compared to usual care
<i>Detailed versus simple DA</i>							
Legare 2003	Agreement between women's and physicians' decisional conflict scores	immediately post	87	ICC = 0.44 (95% CI 0.25 to 0.59)	80	ICC = 0.28 (95% CI 0.06 to 0.47)	Agreement measure was higher for the DA group.
	DCS / Dolan's Provider Decision Process Assessment Instrument	immediately post	97 detailed decision aid pre consult	ICC 0.44 (0.9 SD)	87 simple decision aid pre consult	ICC 0.28 (1.0 SD)	Agreement measure was higher for the DA group (ICC 0.44; 95% CI 0.25 to 0.59) than for the pamphlet group (ICC 0.28; 95% CI 0.06 to 0.47)
Myers 2011	Informed decision making	analysis of the physician-patient encounter using audio-recordings		3.0 items		2.4 items	RR 1.30 (CI 1.03 to 1.64) P = 0.029

CHD: coronary heart disease; CI: confidence interval; DA: decision aid; DCS: decisional conflict scale; ICC: intraclass correlation coefficient; OPTION scale: observing patient involvement scale; RR: risk ratio; SD: standard deviation

Table 9. Participation in decision making

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Allen 2010	control preferences - patients choosing active/ collaborative decision making	post intervention	291	95%	334	92%	No difference
	control preferences did not change	post intervention	291	92%	334	87%	No difference
	control preferences changed to passive	post intervention	291	3%	334	5%	No difference
	control preferences changed to active/ collaborative	post intervention	291	3%	334	7%	No difference
Hamann 2006	COMRADE used to measure patients' perceived involvement in decisions	post-consultation	49	79.5 (SD 18.6) 76.8 (SD 20.9)	58	69.7 (SD 20.0) 73.5 (SD 19.3)	increased patient involvement in decision aid group post intervention compared to usual care at baseline. At discharge there was no difference between groups
Hanson 2011	surrogates feeling somewhat or very involved in decision making	post intervention		83%		77%	P = 0.18
Leighl 2011	achieved decision involvement	post intervention		32%		35%	No difference

Table 9. Participation in decision making (Continued)

Loh 2007	patients' perceived involvement in decision making	post-consultation	191	26.3 pre 28.0 post	96	24.5 pre 25.5 post	Improved patient participation from baseline to post exposure to the decision aid (P = 0.010) and in comparison to the usual care group (P = 0.003) but there was no change in the control group for the pre-post comparison
Rubel 2010	adapted from the Control Preferences Scale	post-intervention					the total mean scores were: 2.74±1.25 (n=99) pre and 2.83±1.16 (n=199) post, no statistically significant difference
van Peperstraten 2010	Decision Evaluation scale (15 item questionnaire) Decision control subscale	post-consultation	124	85	128	87.5	P = 0.33

DA: decision aid; SD: standard deviation

Table 10. Proportion undecided

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Kasper 2008	single item - ranging from '0 = completely unde-						No difference

Table 10. Proportion undecided (Continued)

	cided' to '100 = made my decision'						
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DA: decision aid

Table 11. Satisfaction with the choice

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Heller 2008	1-item; pleased with treatment choice	1 month post-surgery	62/66		55/67		P = 0.03
Leighl 2011	satisfaction with decision scale: median (range)	1 month post-intervention	107	22(13-25)	100	21(15-25)	No difference
Marteau 2010	7-point scale: ranging from 1-7	4 weeks		91.17 (14)		91.33(14.50)	No difference
Schwartz 2009a	6-item	1, 6, 12 months	100		114		Overall, no difference between groups; decision aid led to significantly increased satisfaction compared to US among those who were undecided at randomisation but not among those who had made a decision before randomisation;

Table 11. Satisfaction with the choice (Continued)

							(only graph in paper with no raw data)	
Trevena 2008	satisfaction with the decision	immediately post	134			137	No difference (P = 0.56)	
Detailed versus simple DA								
Rothert 1997	6-item scale (measured on 1 to 5)	1 day	83	4.0 (0.56)		89	3.8 (0.66)	No difference
		6 months	63	3.8 (0.63)		75	3.8 (0.67)	No difference
		12 months	62	3.9 (0.62)		74	3.9 (0.67)	No difference
Schapira 2007	6-item scale	3 months					No difference	

DA: decision aid

Table 12. Satisfaction with the decision-making process

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
DA versus usual care							
Green 2004	Effectiveness of consultation - patient assessment. Single item 1 (not at all effective) to 7 (extremely effective)		106	6.6	105	6.6	No difference
	Effectiveness of consultation - counsellor assessment. Single item 1 to 7			5.9		5.8	No difference
Hess 2012	Satisfaction with decision process		101		103		Patients in DA group reported greater

Table 12. Satisfaction with the decision-making process (Continued)

	(0 for strongly agree to 5 for strongly disagree)								sat- isfaction with the DM pro- cess (strongly agree, 61% DA vs 40% usual care)
Kennedy 2002	Measured sat- isfaction with opportu- nities to par- ticipate in de- cision making using a single item								Com- pared to usual care, women who re- ceived the de- cision aid fol- lowed by nurse coach- ing were statisti- cally signifi- cantly more satisfied with the op- portunities to participate in decision mak- ing (OR 1.5; 95% CI 1.1 to 2.0)
Laupacis 2006	Satisfac- tion with in- formation re- ceived sub- scale 4-item (0 to 100; low to high)	average days	10	54	76 (15.5 SD)	56	59 (23.3 SD)	P = 0.001	
	Satisfac- tion with prac- titioner treat- ment during decision pro- cess sub-scale 4-item (0 to 100; low to high)	average days	10	54	69 (25.3 SD)	56	54 (26.7 SD)	P = 0.004	
Miller 2005	Sat- isfaction with cancer infor-	2 weeks			4.37 (0.84 SD)		4.38 (0.86 SD)	No difference	

Table 12. Satisfaction with the decision-making process (Continued)

	mation service 1-item (1 to 5; low to high)							
		6 months		4.51 (0.75 SD)		4.51 (0.64 SD)		No difference
Montori 2011	(7 point scales) <i>Participants' satisfaction with knowledge transfer</i> -amount of information -clarity of information -helpfulness of the information -would want other decisions -recommend to others	post intervention	49	6.6 6 6 6.1 6.4	46	6.3 6 5.8 5.8 6.2		P = 0.798 P = 0.296 P = 0.624 P = 0.248 P = 0.435
	<i>Clinicians' satisfaction with knowledge transfer</i> -helpfulness of the information -would want other decisions -recommend to others	post intervention	39	5.8 6.1 5.9	33	5.2 4.9 4.8		P = 0.006 P < 0.001 P < 0.001
Oakley 2006	Satisfaction with information about medicines	4 months post	16	10.4 (SD 2.9)	17	10.1 (SD 2.2)		No difference
Vodermaier 2009	- physician helped me understand - physician understood im-	1 week follow-up	53	49 (92.5%) 47 47 44 36	56	53 (94.6%) 50 51 45 36		High satisfaction with no difference by group

Table 12. Satisfaction with the decision-making process (Continued)

	<ul style="list-style-type: none"> - important to me - physician answered questions - satisfied with involvement - satisfied with physician's involvement - satisfied with process 			42		50		
Detailed versus simple DA								
Deyo 2000	Satisfaction with decision making process 7-item scale (5-point response)	3 months	171	separate responses provided with no total	172	separate responses provided with no total	No difference except DA more likely to report they had as much information as they wanted and less likely to report having relied too much on physician's opinion	
Hunter 2005	Satisfaction with genetic counselling 11-item short form (range 4 to 44; low to high)	immediately post	116	37.27 (5.74 SD)	126	40.48 (4.26 SD)	P < 0.001 higher satisfaction with individual counselling compared to decision aid	
Kuppermann 2009	Satisfaction with involvement in decision making (3 questions)	26 to 30 weeks gestation	244	44.8 44.3 72.6	252	49.2 48.1 79.9	P = 0.40 P = 0.45 P = 0.10	

DA: decision aid; SD: standard deviation

Table 13. Preparation for decision making

Study	Scale used	Timing	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>DA versus usual care</i>							
Fraenkel 2007	Preparation for Decision Making Scale	Pre-consultation	43	35 (median)	40	20.5 (median)	P = 0.0001
Vandemheen 2009	Preparation for Decision Making Scale	3 weeks	70	65.1 (24.9 SD)	79	53.9 (27.1 SD)	P = 0.009
<i>Detailed versus simple DA</i>							
Deschamps 2004	Preparation for Decision Making Scale	Post-physician consultation	48	28 (6.1 SD)	42	27(5.5 SD)	No difference

DA: decision aid; SD: standard deviation

Table 14. Choice

Study	Type of comparison	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Notes
<i>Other elective surgery - uptake</i>						
Hanson 2011	DA versus usual care	127	1	129	3	No difference
Wong 2006	DA versus usual care					No difference
<i>Other elective surgery - preference</i>						
Labrecque 2010	Detailed versus simple DA	32	13	31	14	No difference
<i>Screening - Breast cancer genetic testing - uptake</i>						
Wakefield 2008a	Detailed versus simple DA					No difference

Table 14. Choice (Continued)

Wakefield 2008b	Detailed versus simple DA						No difference
Screening - Breast cancer genetic testing - preference							
Miller 2005	DA versus usual care						The intervention decreased intention to obtain genetic testing among women at average risk, but increased in women at high risk
Screening - Cardiac stress testing - uptake							
Hess 2012	DA versus usual care	101	58%	100	77%		P < 0.0001
Screening - Colorectal cancer genetic testing - uptake							
Wakefield 2008	Detailed versus simple DA						No difference
Screening - Breast screening - uptake							
Mathieu 2007	DA versus usual care						No difference
Mathieu 2010	DA versus usual care	117	82%	209	61%		P < 0.001
Screening - Diabetes - uptake							
Marteau 2010	DA versus usual care	633	353	639	368		P = 0.51
Screening - Diabetes - preference							
Mann E 2010	DA versus usual care	273		134			No difference
Screening - Prenatal - uptake							
Bekker 2004	DA versus usual care						No difference

Table 14. Choice (Continued)

Bjorklund 2012	DA versus usual care	184	50%	206	53.8%	No difference
Nagle 2008	DA versus usual care					No difference
Screening - PSA - uptake						
Frosch 2008	DA versus usual care					The experimental interventions led to significant reductions in requests for prostate-specific antigen tests (-2 times greater decline)
Medication - Antibiotics for upper respiratory infections - uptake						
Legare 2011	DA versus usual care	81	33	70	49	P = 0.08
Medication - Cardiovascular disease - preference						
Sheridan 2011	DA versus usual care	79	63%	78	42%	P < 0.01
Medication - Breast cancer prevention - uptake						
Fagerlin 2011	DA versus usual care	382	0.5%	100	0%	No difference
Medication - Chemotherapy for advanced cancer						
Leighl 2011	DA versus usual care	107	77%	100	71%	No difference
Medication - Hormone replacement therapy - uptake						
Murray 2001b	DA versus usual care					8% decrease in DA group, not statistically significant
Schapira 2007	Detailed versus simple DA					No difference

Table 14. Choice (Continued)

<i>Medication - Natural health products - preference</i>						
Legare 2008a	DA versus usual care		41%		41%	No difference
<i>Medication - Anti-thrombosis - uptake</i>						
Man-Son-Hing 1999	DA versus usual care					25% decrease in DA group, not statistically significant
McAlister 2005	DA versus usual care					No difference
Thomson 2007	DA versus usual care		93.8%		25%	risk ratio 0.27 (95% CI 0.11 to 0.63)
<i>Medication - Hypertension - uptake</i>						
Montgomery 2003	DA versus usual care					No difference
<i>Medication - Chemotherapy for breast cancer - preference</i>						
Whelan 2003	DA versus usual care					No difference
<i>Medication - Osteoporosis - uptake</i>						
Montori 2011	DA versus usual care	52	44%	48	40%	No difference
<i>Medication - Immunotherapy - uptake</i>						
Kasper 2008	DA versus usual care					No difference
<i>Medication - Schizophrenia treatment - uptake</i>						
Hamann 2006 - prescriptions	DA versus usual care					No difference
Hamann 2006 - psycho-education	DA versus usual care					Higher uptake in DA group (P = 0.003)

Table 14. Choice (Continued)

<i>Obstetrics - Birth control method - preference</i>						
Langston 2010	DA versus usual care	114			108	No difference in the methods chosen between groups, participants in the intervention group were not more likely to initiate the requested method immediately compared to those in the usual care group (OR 0.65, 95% CI 0.31 to 1.34)
<i>Obstetric - Childbirth procedure - uptake</i>						
Montgomery 2007	DA versus usual care					No difference
Nassar 2007	DA versus usual care					No difference
<i>Obstetric - Childbirth procedure - preference</i>						
Shorten 2005	DA versus usual care					No difference
<i>Obstetric - Embryo transplant - uptake</i>						
van Peperstraten 2010 - single embryo transfer	DA versus usual care	152	43%		156	32% P = 0.05
<i>Obstetric - Pain relief in labour - uptake</i>						
Raynes-Greenow 2010	Detailed versus simple DA	308			146	No difference
<i>Other- Lung transplant referral</i>						
Vandemheen 2009	DA versus usual care					No difference

Table 14. Choice (Continued)

<i>Other - Pre-operative blood transfusion - uptake</i>						
Laupacis 2006	DA versus usual care					No difference
<i>Vaccine - Flu shot - uptake</i>						
Chambers 2012	DA versus usual care	48	46%	59	27%	No difference
<i>Vaccine - Hepatitis B - uptake</i>						
Clancy 1988	DA versus usual care					Significant increase of 76% in the DA group

DA: decision aid; OR: odds ratio

Table 15. Adherence with chosen option

Reference	Scale used	N Decision aid	Mean (SD) Decision aid	N Comparison	Mean (SD) Comparison	Notes
<i>DA versus usual care</i>						
Langston 2010	3 months - Using a contraceptive method that was in the same effectiveness group as the method requested at enrolment, 'very effective', as chosen option - eg. if chose sterilization and ended up using an IUD counted as adhering	48	85%	52	77%	P = 0.28
	3 months - Using a contraceptive method that was in the same effectiveness group, 'ef-	41	68%	31	68%	P = 0.96

Table 15. Adherence with chosen option (Continued)

	fective', as chosen option					
Loh 2007	6 to 8 weeks - Patient reported - 5-point Likert scale on steadiness of following the treatment plan: 1-very bad to 5-very good	191	4.3 (0.9)	96	3.9 (1.0)	P = 0.073
	6 to 8 weeks - Physician reported - 5-point Likert scale steadiness of following the treatment plan: 1-very bad to 5-very good	191	4.8 (0.6)	96	4.3 (1.1)	P = 0.56
Mann D 2010	3 months - telephone administration of the 8-item Morisky adherence (7 yes/no items and 1 item with 5 point Likert scale to elicit behaviours such as skipping medicines when they have no symptoms)					70% of participants reported good adherence to statins with no difference between groups
	6 months - telephone administration of the 8-item Morisky adherence (7 yes/no items and 1 item with 5 point Likert scale to elicit behaviours such as skipping medicines)					80% of participants reported good adherence to statins with no difference between groups

Table 15. Adherence with chosen option (Continued)

	when they have no symptoms)					
Man-Son-Hing 1999	6 months - Self reported - Measured % of patients taking therapy initially chosen	129	95.35%	134	93.28%	P = 0.44
Montgomery 2003	~ 3 years - Self reported - 6 item Adherence Questionnaire: from "I take all my tablets at the same time of day" to "I take hardly any of my tablets"					No difference
Montori 2011	6 months - Percentage of participants that self-reported currently taking medication who have not missed one dose within last week	17	65%	19	63%	P = 0.92
	6 months - Percentage of participants who opted to take biophosphonates who took their medication on more than 80% of the days for which it was prescribed, based on pharmacy records	23	100%	19	74%	P = 0.009
Mullan 2009	6 months - Pharmacy records - days covered (range)	48	97.5% (range 0 to 100)	37	100 (range 73.9 to 100)	AMD -8.88 (-13.6% to -4.14%) Positive AMD

Table 15. Adherence with chosen option (Continued)

						favours decision aid arm. This finding is statistically significant
	6 months - Self reported by telephone call - did not miss a dose in last week	41	76%	31	81%	OR 0.74 (95% CI 0.24-2.32)
Oakley 2006	4 months - Extent to which the patients' be-	16	10.4% (32) [improvement from baseline]	17	2% (26) [improvement from baseline]	Not significant
	Any therapy promoted in decision aid	76	45 (59%)	73	25 (34%)	P < 0.01
	any therapy promoted in decision aid + others (eg. diet or physical activity)	77	64 (83%)	77	52 (68%)	P = 0.02
	aspirin	32	30 (94%)	19	11 (58%)	P < 0.01
	cholesterol medicine	14	12 (86%)	6	5 (83%)	The intervention had little effect blood pressure or cholesterol medication, however, the sample sizes for these estimates were small and underpowered
	blood pressure medicine	9	9 (100%)	12	11 (92%)	
	stop smoking	8	25%	5	20%	No effect on smoking, although subgroups were small and underpowered

Table 15. Adherence with chosen option (Continued)

Weymiller 2007	3 months - Self reported - mailed surveys & telephone call to non-respondents on adherence to statin use: missed 1 dose or more within the last week	33	93.94%	29	79.31%	No difference in adherence when analysis adjusted by sex, cardiovascular disease, and number of medications
<i>Detailed versus simple DA</i>						
Deschamps 2004	12 months - Self reported - Telephone call to patients to ask estimated days missed per week and reasons Response categories: 1) taking medication as prescribed (omitting no more than one day/week) , 2) missing doses occasionally and randomly, 3) systematically deviating from the prescribed directions	16	-72%	20	-72%	No difference
Rothert 1997	12 months - Self reported - daily adherence recorded on a calendar	62	-89%	74	-89%	No difference
Trevena 2008	1 month - faecal occult blood test uptake	134	5.2%	137	6.6%	P = 0.64

DA: decision aid; OR: odds ratio

Table 16. General health outcomes

Reference	Timing	N Decision aid	Mean Decision aid (SD)	Change from baseline	N Comparison	Mean Comparison (SD)	Change from Baseline	Notes
<i>General health - DA versus usual care</i>								
Barry 1997 (SF-36)	Baseline	104	67.2 (19.0)		123	71.1 (17.6)		P = 0.02
	3 months			-0.96 (1.41)			-3.59 (1.57)	
	6 months			-1.46 (1.41)			-4.93 (1.45)	
	12 months			0.61 (1.58)			-4.99 (1.44)	
Legare 2011 (percentage of people who felt they had a stable and better health, (SF-12))	2 weeks post	not reported	94	+7	not reported	85	-6	P = 0.08
Morgan 2000 (SF-36)	6 months post	72	62 (23)	+4.0	88	65 (20)	+7.0	No difference
Kennedy 2002 (SF-36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		2.2	159		2.8	No difference
<i>Physical function - DA versus usual care</i>								
Barry 1997 (SF-36)	Baseline	104	81.9 (20.0)		123	83.0 (18.9)		P = 0.02
	3 months			-0.34 (1.61)			-1.81 (1.07)	
	6 months			0.10 (1.28)			-3.26 (1.37)	
	12 months			0.15 (1.40)			-3.74 (1.18)	
Morgan 2000 (SF-36)	6 months post	72	67 (29)	+7.0	88	71 (24)	+10.0	No difference

Table 16. General health outcomes (Continued)

Kennedy 2002 (SF-36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		2.4	159		2.2	No difference
Physical function - Detailed versus simple DA								
Bernstein 1998 (SF-12)	3 months post	61	38 (12.1)	+0.6	48	37.6 (10.6)	+3.8	No difference
Social function - DA versus usual care								
Barry 1997 (SF-36)	Baseline	104	90.6 (15.5)		123	91.7 (15.7)		P = 0.17
	3 months			0.34 (1.58)			-2.26 (1.36)	
	6 months			-0.05 (1.92)			-2.46 (1.45)	
	12 months			-1.46 (1.85)			-3.52 (1.71)	
Kennedy 2002 (SF-36)	2 years	176			157			No difference
McCaffery 2010 (SF-36)	2 weeks	77	84.7		71	82.1		P = 0.39
Vuorma 2003 (RAND-36)	1 year	156		5.2	159		7.1	No difference
Mental function - DA versus usual care								
McCaffery 2010 (SF-36)	2 weeks	77	71.3		71	71.6		P = 0.46
Kennedy 2002 (SF-36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		4.7	159		5.3	No difference

Table 16. General health outcomes (Continued)

<i>Mental function - Detailed versus simple DA</i>									
Bernstein 1998 (SF-12)	3 months post	61	49.1 (11.4)	0.0	48	48.9 (10.8)	+0.9	No difference	
<i>Role function - DA versus usual care</i>									
Morgan 2000 (SF-36)	6 months post	72	62 (44)	+20.0	88	58 (43)	+15.0	No difference	
Kennedy 2002 (SF-36)	2 years	176			157			P = 0.04	
Vuorma 2003 (RAND-36)	1 year			9.2			6.3	No difference	
<i>Bodily pain - DA versus usual care</i>									
Morgan 2000 (SF-36)	6 months post	72	81 (22)	+6.0	88	77 (24)	+5.0	No difference	
Kennedy 2002 (SF-36)	2 years	176			157			No difference	
Vuorma 2003 (RAND-36)	1 year	156		6.5	159		6.2	No difference	
<i>Role emotional - DA versus usual care</i>									
Kennedy 2002 (SF-36)	2 years	176			157			No difference	
McCaffery 2010 (SF-36)	2 weeks	77	80.3		71	77.4		P = 0.61	
Vuorma 2003 (RAND-36)	1 year	156		12.6	159		1.9	P = 0.01	

Table 16. General health outcomes (Continued)

<i>Energy/vitality - DA versus usual care</i>								
Kennedy 2002 (SF-36)	2 years	176			157			No difference
McCaffery 2010 (SF-36)	2 weeks	77	55.2		71	54.1		P = 0.09
Vuorma 2003 (RAND-36)	1 year	156		8.9	159		8.8	No difference
<i>SF-36 all dimensions - DA versus usual care</i>								
McCaffery 2010 (SF-36)	2 weeks	77	47		71	46.3		P = 0.35
Murray 2001b (SF-36)	9 months	93			94			No difference
Murray 2001a (SP-36)	9 months	54			48			No difference
<i>Functional status - DA versus usual care</i>								
Deyo 2000 (Roland Disability Questionnaire)	1 year	171	20.4	+5.4	173	20.9	+5.7	No difference
Leighl 2011 (FACT-G) median (range)	1 month post	74	17 (6-28)		68	17.5 (7-28)		P = 0.02
<i>Health utilities - DA versus usual care</i>								
Murray 2001a (Euroqol EQ-5D)								No difference

Table 16. General health outcomes (Continued)

Murray 2001b (Euroqol EQ-5D)									No difference
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DA: decision aid; SF-36: Medical Outcomes Study 36-item Short-Form Health Survey; SF-12: 12-item Short-Form Health Survey; RAND-36: the 36-item short form survey from the RAND Medical Outcomes Study
 FACT-G: Functional Assessment of Cancer Therapy-General

Table 17. Condition-specific health outcomes

Study	Outcome	Scale used	Timing	N Decision aid	Decision aid mean change	N Comparison	Comparison mean change	Notes
<i>DA versus usual care</i>								
Barry 1997	Urinary symptoms	AUA Symptom Index (0 to 100)	3 months	104	-4.80% (1.74)	117	-1.40% (1.37)	No difference; trend toward DA
	Urinary symptoms	AUA	6 months	104	-3.66% (2.06)	117	-3.17% (1.77)	No difference
	Urinary symptoms	AUA	12 months	104	-2.51% (2.11)	117	-4.14% (1.66)	No difference; trend toward control
	Impact of symptoms	BPH Impact Index (0 to 100)	3 months	104	-6.58% (1.10)	117	-3.00% (1.05)	No difference; trend toward DA
	Impact of symptoms	BPH	6 months	104	-4.37% (1.32)	117	-3.89% (1.16)	No difference; trend toward DA
	Impact of symptoms	BPH	12 months	104	-5.53% (1.32)	117	-2.63% (1.32)	No difference; trend toward DA
Bernstein 1998	Satisfaction	SAQ (0 to 100)	3 months	61	+6.2%	48	+10.5%	Control significantly more satisfied
	Angina stability	SAQ	3 months	61	+17.2%	48	+28.3%	No difference

Table 17. Condition-specific health outcomes (Continued)

	Angina frequency	SAQ	3 months	61	+5.5%	48	+15.3%	No difference
	Disease Perception	SAQ	3 months	61	+14.1%	48	+18.8%	No difference
	Physical Capacity	SAQ	3 months	61	-0.5%	48	+7.1%	No difference
Leighl 2011 (FACT-G) median (range)	Physical function at 1 month post	74	21 (0-28)		68	20 (4-28)		No difference
	Role emotional at 1 month post	74	17 (0-20)		68	17(7-20)		No difference
Morgan 2000	No Angina	CCVA	6 months	72	+49%	88	+48%	No difference
	Class I Angina	CCVA	6 months	72	-1%	88	+6%	No difference
	Class II Angina	CCVA	6 months	72	-23%	88	-26%	No difference
	Class III Angina	CCVA	6 months	72	-26%	88	-28%	No difference
	Class IV Angina	CCVA	6 months	72	0%	88	0%	No difference
Murray 2001a	Urinary symptoms	AUA symptom Index (0 to100)						No difference
Murray 2001b	Menopausal symptoms	MenQol						No difference
Protheroe 2007	Menorrhagia specific utility scale	(0 to 100)	6 months	60	59.3 (30.0)	56	50.9 (25.1)	P = 0.03 higher menorrhagia quality of life favouring DA group

Table 17. Condition-specific health outcomes (Continued)

Thomson 2007	Strokes or bleeds requiring admission		3 months	51		55		No strokes and no bleeds requiring admission. 1 bleed and 1 transient stroke both in control group that required GP consultation
van Peperstraten 2010	Ongoing pregnancies (> 12 weeks gestation)		after 1st IVF cycle	152		156		32% of participants in the intervention group and 38% of participants in the control group had ongoing pregnancies, P = 0.25
	Twin pregnancies (> 12 weeks gestation)		after 1st IVF cycle	152		156		4% of participants in intervention group and 6% of participants in control group had twin pregnancies, P = 0.33
Vuorma 2003	Inconvenience due to menstrual bleeding	(5 to 25)	1 year	156	10.4	159	10.5	No difference
	Menstrual pain	(0 to 12)	1 year	156	4.7	159	4.6	No difference
<i>Detailed versus simple DA</i>								

Table 17. Condition-specific health outcomes (Continued)

Deyo 2000	% working		1 year	171	+17.3%	173	+18.3%	No difference
	% missed 1+ day work within past month		1 year	171	-38.4%	173	-35.2%	No difference
	Back pain severity		1 year	171	-22.4%	173	-22%	1 year scores: DA 27.6% significantly better than control 37.2%
	Leg pain severity		1 year	171	-42.1%	173	-43.9%	No difference
	Seeking compensation		1 year	171	-2.9%	173	-5.9%	No difference
	Satisfied with symptoms		1 year	171	+32.1%	173	+32.4%	No difference
Raynes-Greenow 2010	Apgar score	scores > 7	1 minute after birth	395	221 (82%)	201	149 (75%)	P = 0.12
		scores > 7	5 minutes after birth	395	235 (90%)	201	167 (84%)	P = 0.68
	Birth weight	in grams	mean (SD)	395	3445 (451)	201	3412 (450)	P = 0.11

AUA: American Urological Association; CCVA: Canadian Cardiovascular Angina; BPH: benign prostatic hyperplasia; DA: decision aid; SAQ: Seattle Angina Questionnaire;

Table 18. Anxiety

Study	Timing	N Decision aid	Mean Decision aid (SD)	Change from base-line	N Comparison	Mean Comparison (SD)	Change from Base-line	Notes
<i>State Anxiety Inventory: < 30 days post-intervention - DA versus usual care</i>								

Table 18. Anxiety (Continued)

Bekker 2004 ; pre-natal screening	Immediately post	50	58.9 (16.6)		56	61.2 (13.7)		No difference
Evans 2010 ; PSA screening	Immediately post DA	89	4.98		103	4.88		P = 0.98
Green 2004 ; breast cancer screening (low risk group)	Immediately post	56	29	-4	61	30	-3	P = 0.04 (for difference in change score)
Green 2004 ; breast cancer screening (high risk group)	Immediately post	50	30	-3	44	33	-5	P = 0.04 (for difference in change score)
Leighl 2011	post consult, 1-2 weeks and 4 weeks post							No difference; see Figure 3
Mathieu 2007 ; mammography screening	Immediately after	321	29.61		315	29.34		No difference
McCaffery 2010 ; HPV screening (state trait anxiety inventory)	2 weeks	77	10.5		71	10.6		P = 0.25
Montgomery 2003 ; hypertension	Immediately post DA	44	35.45 (10.52)		50	37.67 (13.92)		No difference
Montgomery 2007 ; previous cesarean section	37 weeks gestation	196	38.7 (12.2)		195	42.1 (12.2)		P = 0.016

Table 18. Anxiety (Continued)

Nassar 2007; breech presentation	1 week	98	41.4 (12.5)		90	44.4 (13.9)		No difference
Protheroe 2007; menorrhagia	2 weeks	59	11.6 (3.7)		61	12.2 (3.7)		P = 0.016
Rubel 2010; PSA screening	immediately after							20 items adapted from state portion of State-Trait Anxiety Inventory Scale STAI - Form Y; total mean score = 1.66 ± 0.59 (n = 200) for patients in both groups
Smith 2010; bowel cancer screening	2 week follow-up	357	13.67		173	14.05		P = 0.80
Thomson 2007; anti-thrombotic treatment for atrial fibrillation	immediately after	53			56			Significant fall in anxiety (-4.57) but no difference between groups (P = 0.98)
Trevena 2008 colorectal cancer screening	immediately after	134			137			No difference (P = 0.59)
van Peperstraten 2010; number of em-	immediately after	152	27.33%		156	24.5%		P = 0.14

Table 18. Anxiety (Continued)

bryos transferred								
Whelan 2004; breast cancer surgery	7 days post DA	94	42.3 (1.3)		107	41.9 (1.3)		No difference
Whelan 2003; breast chemotherapy	7 days post DA	82	45.6	+2.2	93	47.4	+0.8	No difference
Wong 2006; pregnancy termination	Immediately post	154	54 (15.8)		159	54 (16.1)		No difference
State Anxiety Inventory: < 30 days post-intervention - Detailed versus simple DA								
Goel 2001; breast cancer surgery	1 to 3 days post DA	74	51.2 (14.2)	-0.7	43	50.7 (14.8)	-0.1	No difference
Hunter 2005; pre-natal screening	Immediately post	116	45.50 (9.69)	-1.17	126	47.98 (10.14)	-0.37	No difference
Raynes-Greenow 2010; labour analgesia	37 weeks gestation	395	33.3 (9.3)	-0.6	201	34.3 (11.0)	0	P = 0.32
Tiller 2006; prophylactic ovarian cancer treatment	2 weeks	58	38.2 (13.4)		60	38.0 (15.2)		No difference
State Anxiety Inventory: 1 month post-intervention - DA versus usual care								
Bekker 2004; pre-natal screening	1 month post DA	29	35.3 (12.5)		39	34.7(14.8)		No difference

Table 18. Anxiety (Continued)

Davison 1997; prostate cancer treatment	5 to 6 weeks post DA	30	35.5	-9.0	30	34.5	-2.5	No difference	
<i>State Anxiety Inventory: 1 month post-intervention - Detailed versus simple DA</i>									
van Roosmalen 2004	1 month post DA	43	35.4 (11.7)		43	37.4 (10.7)		No difference	
<i>State Anxiety Inventory: 3 months post-intervention - DA vs usual care</i>									
Murray 2001a; benign prostatic hypertrophy	3 months post DA	55	36.36 (14.99)	+2.4	48	32.08 (9.836)	+0.7	No difference	
Murray 2001b; hormone replacement therapy	3 months post DA	93	38.42 (10.83)	-0.5	95	40.53 (12.96)	+1.8	No difference	
Nagle 2008; prenatal screening	-1 to 12 weeks post DA	167	37.2 (12.1)		171	37.36 (12.6)		No difference	
Nassar 2007; breech presentation	3 months post DA	86	29.2 (9.9)		84	30.8 (10.5)		No difference	
Vuorma 2003; menorrhagia treatment	3 months post DA	184	37.1	+1.0	179	35.9	-1.0	No difference	
Whelan 2003; breast chemotherapy	3 months post DA	82	36.0		93	37.8		No difference	
<i>State Anxiety Inventory: 6 months post-intervention - DA versus usual care</i>									

Table 18. Anxiety (Continued)

Protheroe 2007; menorrhagia	6 months post DA	47	11.2 (4.2)		52	13.3 (4.9)		P = 0.067
Whelan 2004; breast cancer surgery	6 months post DA	94	39.3 (1.3)		107	38.9 (1.6)		No difference
Whelan 2003; breast chemotherapy	6 months post DA	82	38.2		93	38.2		No difference
State Anxiety Inventory: 6 months post-intervention - Detailed versus simple DA								
Goel 2001; breast cancer surgery	6 months post DA	59	36.6 (12.9)	-15.3	39	34.3 (11.6)	-16.5	No difference
Tiller 2006; prophylactic ovarian cancer treatment	6 months post DA	53	35.7 (9.0)		55	36.2 (13.6)		No difference
State Anxiety Inventory: 12 months post-intervention - DA versus usual care								
Whelan 2004; breast cancer surgery	12 months post DA	94	37.5 (1.4)		107	36.6 (1.5)		No difference
Whelan 2003; breast chemotherapy	12 months post DA	82	39.2		93	40.2		No difference
Other - DA versus usual care								
Johnson 2006; endodontic treatment	Immediately post - single question 7-point Likert scale.	32	3.2 (1.7)		35	3.8 (2.1)		P = 0.27
Lewis 2010; colorectal	intrusive thoughts - 3	139	66.2%		157	68.0%		P = 0.92

Table 18. Anxiety (Continued)

cancer screening	items; 4 point scale - not at all							
	intrusive thoughts - 3 items; 4 point scale - sometimes	66	31.4%		69	29.9%		
	intrusive thoughts - 3 items; 4 point scale - often	5	2.4%		5	2.2%		
McCaffery 2010	intrusive thoughts - measured using 1 item from the impact of events scale	77	43%		71	32%		No difference
Smith 2010	Worry about developing bowel cancer - quite or very	357	6%		173	8%		P = 0.78
	Worry about developing bowel cancer - none or a bit	357	94%		173	92%		

DA: decision aid; HPV: human papilloma virus; PSA: prostate-specific antigen

Table 19. Depression

Study	Timing	N Decision aid	Mean Decision aid (SD)	Change from Base-line	N Comparison	Mean Comparison (SD)	Change from Base-line	Notes
<i>DA versus usual care</i>								

Table 19. Depression (Continued)

Davison 1997 (20-item CES-D)	5 to 6 weeks	30	29.8	-0.6	30	29.5	+1.3	No difference
Loh 2007 (Brief Patient Health Questionnaire-D)	6 to 8 weeks	191	29.8 (2.7)		96	27.0 (3.6)		P = 0.236
Nagle 2008 (Edinburgh Postnatal Depression Scale)	~1 to 12 weeks post DA	167	19 (11.6)		171	19 (11.2)		No difference
Tiller 2006 (Hospital Anxiety and Depression Scale)	2 weeks post DA	58	10.9 (5.6)		61	10.7 (6.4)		P = 0.03
	6 mos post DA	50	10.1(4.7)		56	10.8 (6.4)		P = 0.12
van Peperstraten 2010 (Beck Depression Inventory)	after multifaceted intervention/ before IVF	126	16 (13%)		136	5 (4%)		P = 0.01
	at uptake of IVF	147	16 (11%)		151	113 (9%)		No difference
Whelan 2004 (20-item CES-D)	1 week post DA	94	13.8 (1.0)		107	13.4 (1.1)		No difference
	6 months post DA	94	15.1 (1.1)		107	14.2 (1.2)		No difference
	12 months post DA	94	13.2 (1.3)		107	12.8 (1.2)		No difference
<i>Detailed versus simple DA</i>								
Wakefield 2008 (Hospital Anxiety and Depression Scale)	1 week post	48			61			No difference

Table 19. Depression (Continued)

Wakefield 2008a (Hospital Anxiety and Depression Scale)	1 week post	56			63			No difference
Wakefield 2008b (Hospital Anxiety and Depression Scale)	immediately	55			55			No difference

CES-D: Centre for Epidemiology Studies Depression Scale; DA: decision aid; IVF: in vitro fertilisation

Table 20. Decisional regret

Author	Item	N Decision aid	Proportion or Mean (SD)	N Control	Proportion or Mean (SD)	Notes
<i>DA vs usual care</i>						
Hanson 2011	5-item Decisional Regret Index	126	11.9	127	14.3	P = 0.14
Legare 2011	Proportion of patients with decisional regret		7%		9%	P=0.91
<i>Detailed vs simple DA</i>						
Goel 2001	Right decision	63	58 (92.06%)	44	42 (95.45%)	No difference
	Regret choice	63	8 (12.70%)	44	5 (11.36%)	No difference
	Would make same choice	63	54 (85.71%)	44	40 (90.91%)	No difference
	Choice did me harm	63	7 (11.11%)	44	3 (6.82%)	No difference
	Decision was wise	63	54 (85.71%)	44	41 (93.18%)	No difference
Kuppermann 2009	Decisional Regret - 3 items	244	9.6	252	12.8	P = 0.28

Table 20. Decisional regret (Continued)

	at 26 to 30 weeks gestation					
Wakefield 2008	Decision Regret Scale at 6 months	41		54		No difference
Wakefield 2008a	Decision Regret Scale	-57	7.04 (12.12)	-63	6.39 (13.68)	No difference
Wakefield 2008b	Decision Regret Scale	-56	9.78 (14.49)	-49	5.13 (10.16)	No difference

DA: decision aid

Table 21. Confidence

Study	Scale used	Timing	N Decision aid	Decision mean	N Comparison	Comparison - mean	Notes
<i>DA vs usual care</i>							
Allen 2010	11-item self-efficacy scale	post intervention	291	83% (40.26% SD)	334	79% (33.08% SD)	No difference
Arterburn 2011	Decisional self efficacy	changes from baseline	75	+ 3.0 (95% CI 0.6 to 5.4)	77	+ 2.8 (95%CI 0.9 to 4.8)	P = 0.78
Chambers 2012	Mean confidence with decision: scale from 1 (low confidence) to 5 (high confidence)	post intervention	48	4	59	3.6	P = 0.02
Fraenkel 2007	Decisional self-efficacy scale	pre-consultation	43	32 (median)	40	27 (median)	P = 0.001
Gattellari 2003	Perceived ability to make an informed choice 1-item; 5-point Likert scale	3 days post	106		108		P = 0.008; DA group more likely to agree that they could make an informed choice about PSA screening

Table 21. Confidence (Continued)

Gattellari 2005	Perceived ability to make an informed choice 1-item; 5-point Likert scale	Immediately post	131			136			No difference
McBride 2002	Confidence with ability to understand outcomes of hormone replacement therapy, make a decision, engage in discussion with practitioner 3-items (0 to 10; low to high confidence)	1 month post	273	78% (18% SD)		284	70% (19% SD)		P < 0.0001
		9 months post	261	80% (17%SD)		278	75% (20% SD)		P = 0.0004
Smith 2010	3 items adapted from the Decisional self-efficacy scale	2 week follow-up	357	4.67 (0.54 SD)		173	4.61(0.62 SD)		P = 0.26
Detailed versus simple DA									
Rothert 1997	8-items (1 to 10; low to high confidence)	post DA	83	78% (16% SD)		89	80% (19% SD)		No difference
		12 months post	63	78% (15% SD)		74	80% (19% SD)		No difference

CI: confidence interval; DA: decision aid; SD: standard deviation

Table 22. Healthcare system effects

Study	Scale used	N Decision aid	Decision aid - mean	N Comparison	Comparison - mean	Difference between groups	Notes
Consultation length - DA versus usual care							

Table 22. Healthcare system effects (Continued)

Bekker 2004	Consultation length using DA in consult (minutes)	50	32.2 (13.0 SD)	56	26.3 (11.5 SD)	+5.9 minutes	P = 0.01 (longer with decision aid)
Green 2004	Consultation length with practitioner post DA (minutes)	106	82	105	90	-8 minutes	P = 0.03 (shorter with decision aid)
Krist 2007	Time spent discussing prostate cancer with practitioner post DA (minutes) -patient reported	196	5.3	75	5.2	+0.1 minutes	No difference between groups
	Time spent discussing prostate cancer with practitioner post DA (minutes) - physician reported	196	3.8	75	4.2	-0.4 minutes	No difference between groups but physicians thought they spent less time than patients (P < 0.001)
Loh 2007	Consultation length using DA in consult (minutes)	191	29.2 (10.7)	96	26.7 (12.5)	+2.5 minutes	P = 0.681
Ozanne 2007	Consultation length using DA in consult (minutes)	15	24	15	21	+3 minutes	P = 0.42
Thomson 2007	Consultation length using DA in consult (minutes)	8	44 (39 to 55)	10	21 (19 to 26)	+23 minutes	P = 0.001 Compared computerized decision aid with standard gam-

Table 22. Healthcare system effects (Continued)

							ble within the consultation to guideline driven consultation
Vodermaier 2009	Consultation length with practitioner post DA						
	5 to 10 min	53	6 (11.3%)	54	5 (9.3%)		P = 0.91
	10 to 15 min		17 (32.1%)		19 (35.2%)		
	15 to 25 min		15 (28.3%)		14 (25.9%)		
	25 to 35 min		7 (13.2%)		5 (9.3%)		
	Above 35 min		8 (15.1%)		11 (20.4%)		
Whelan 2003	Consultation length using DA in consult (minutes)	50	68.3	50	65.7	+2.6 minutes	P = 0.53
Weymiller 2007	Consultation length using DA in consult (minutes)	52		46		+3.8 minutes	Not statistically significant 3.8 min longer in DA group (95%CI -2.9 to 10.5)
Consultation length - Detailed versus simple DA							
Myers 2011	Encounter length with practitioner post DA (minutes)						Median 16 minutes for both groups (range 6 to 44)
Cost and resource use - DA versus usual care							
Hollinghurst 2010; Montgomery 2007	Cost-consequences analysis	235	£2019 (SD £741)	238	£2033 (SD £677)		no difference

Table 22. Healthcare system effects (Continued)

Kennedy 2002	Cost effectiveness	204	\$1556 USD	215	\$2751 USD		Mean difference \$1184 (95%CI \$684 to \$2110)
Murray 2001a	Total costs excluding intervention	57	£310.3 (SD £602.0)	48	£188.8 (SD £300.4)		Mean difference £121.5 (95% CI £ -58.9 to £302.0)
	Total costs including intervention	57	£594.10 (SD £602)	48	£188.8 (SD £300.4)		Mean difference £405.4 (95% CI £224.9 to £585.8) P < 0.001
Murray 2001b	Total costs excluding intervention	85	£90.5	84	£90.9 (SD £39.2)		No difference
	Total costs including intervention	85	£306.5 (SD £42.8)	84	£90.9 (SD £39.2)		Mean difference £215.5 (95% CI £203.1 to £228.0) P < 0.001
Thomson 2007	GP consultations post intervention	39/51		32/54			P = 0.35
	Hospital appointments post intervention	29/51		10/54			P = 0.06
van Peperstraten 2010	Mean total savings per couple						Mean total saving per couple in the intervention group were EURO169.75 (\$219.12 USD)
Vuorma 2003	Cost and productivity losses	184	EURO2760 Euro	179	EURO3094 Euro		P = 0.1 No difference

Table 22. Healthcare system effects (Continued)

							between intervention and control when treatment cost and productivity losses were analysed
Cost and resource use - Detailed versus simple DA							
Deyo 2000	Healthcare use at 1 year	171			172		No difference in most services; DA less surgery for herniated disk

CI: confidence interval; DA: decision aid; SD: standard deviation

Table 23. Sub-analysis using higher quality trials

Outcome	Overall mean effect (95% CI)	Without trials having high risk of bias on at least 1 of 7 criteria	Without trials having high or unclear risk of bias for at least 3 of 7 criteria
Knowledge - decision aid versus usual care	13.29 (11.32 to 15.25) n = 42	13.67 (11.60 to 15.74) n = 39	14.97 (11.84 to 18.10) n = 21
Knowledge - detailed versus simple decision aid	5.52 (3.9 to 7.15) n = 19	5.48 (3.78 to 7.18) n = 18	6.97 (2.39 to 11.55) n = 3
Accurate risk perceptions - with probabilities versus no probabilities	1.82 (1.52 to 2.16) n = 19	1.76 (1.48 to 2.10) n = 18	2.28 (1.78 to 2.92) n = 7
Values congruent with chosen option	1.51 (1.17 to 1.96) n = 13	1.52 (1.17 to 1.97) n = 13	2.15 (1.35 to 3.44) n = 6
Uninformed sub-scale of Decisional Conflict Scale - decision aid versus usual care	-7.26 (-9.73 to -4.78) n = 22	-7.40 (-10.06 to -4.74) n = 21	-8.26 (-11.74 to -4.78) n = 15
Uninformed sub-scale of Decisional Conflict Scale - detailed versus simple decision aid	-2.39 (-4.39 to -0.39) n = 10	-2.39 (-4.39 to -0.39) n = 10	too few to assess, n = 1
Unclear values sub-scale of Decisional Conflict Scale - decision aid versus usual care	-6.09 (-8.5 to -3.67) n = 18	-6.40 (-9.02 to -3.79) n = 17	-7.02 (-10.00 to -4.04) n = 14

Table 23. Sub-analysis using higher quality trials (Continued)

Unclear values sub-scale of Decisional Conflict Scale - detailed versus simple decision aid	-2.31 (-4.67 to 0.05) n = 10	-2.31 (-4.67 to 0.05) n = 10	too few to assess, n = 1
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CI: confidence interval

Table 24. Heterogeneity (based on 55 trials in search to 2006)

Outcome	Overall effect	Treatment decision	Screening decision	Video/ computer Decision aid	Audio/ pamphlet Decision aid	Base risk control	Removal of Outliers*
Knowledge - decision aid versus usual care	15.2 (11.7 to 18.7)	16.5 (11.9 to 21.2)	13.1 (7.7 to 18.5)	21.3 (16.3 to 26.2)	11.9 (8.3 to 15.6)	15.5 (11.3 to 19.8)	17.3 (13.6 to 20.9) (* Bekker 2004, Gattellari 2003, Johnson 2006)
Accurate risk perceptions - probabilities versus no probabilities	1.6 (1.4 to 1.9)	1.6 (1.4 to 1.9)	1.6 (1.1 to 2.3)	No data	1.6 (1.4 to 1.9)	1.3 (1.2 to 1.5) (P = 0.3)	1.5 (1.3 to 1.7) (*Gattellari 2003)
Uninformed sub-scale of the Decisional Conflict Scale - decision aid versus usual care	-8.4 (-11.9 to -4.8)	-9.4 (-13.3 to -5.5)	-3.5 (-12.9 to 5.8)	-12.6 (-19.5 to -5.8)	-4.9 (-7.6 to -2.3) (P = 0.06)	-5.4 (-7.7 to -3.2) (P = 0.11)	-6.2 (-8.4 to -4.1) (P = 0.06) (* Montgomery 2003)
Unclear values sub-scale of the Decisional Conflict Scale - decision aid versus usual care	-6.3 (-10.0 to -2.7)	-6.0 (-9.8 to -2.3)	Insufficient data	-8.0 (-15.1 to -1.0)	-4.5 (-8.4 to -0.6)	-3.6 (-6.8 to -0.5)	-4.0 (-6.7 to -1.3) (* Montgomery 2003)

APPENDICES

Appendix I. Revised Search Strategies January 2009 to June 2012

MEDLINE (Ovid)

1. decision support techniques/
2. decision support systems clinical/
3. decision trees/
4. (decision making or choice behavior).mp. and informed consent.sh.
5. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).tw.
6. (decision adj (board* or guide* or counseling)).tw.
7. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).tw.
8. decision-making computer assisted/
9. (computer* adj2 decision making).tw.
10. interactive health communication*.tw.
11. (interactive adj (internet or online or graphic* or booklet*)).tw.
12. (interacti* adj4 tool*).tw.
13. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw.
14. shared decision making.tw.
15. (informed adj (choice* or decision*)).tw.
16. adaptive conjoint analys#s.tw.
17. or/1-16
18. randomized controlled trial.pt.
19. controlled clinical trial.pt.
20. randomized.ab.
21. placebo.ab.
22. clinical trials as topic.sh.
23. randomly.ab.
24. trial.ti.
25. or/18-24
26. exp animals/ not humans.sh.
27. 25 not 26
28. 17 and 27
29. limit 28 to yr="2009 -Current"

CENTRAL (*The Cochrane Library*)

1. (decision-support or decision-aid):kw in Trials
2. decision-tree:kw in Trials
3. patient-decision-making:kw
4. (decision-making or choice-behavior):ti,ab,kw and (informed-consent:kw,ti or (patient or parent* or carer or caregiver or care-giver):ti,ab,kw) in Trials
5. ((decision or decid*) near/4 (support* or aid* or tool or instrument or technolog* or technique or system or program* or algorithm or process or method or intervention or material)):ti,ab,kw
6. (decision next (board or guide or counseling)):ti,ab,kw
7. ((risk-communication or risk-assessment or risk-information) near/4 (tool or method)):ti,ab,kw
8. (computer* near/2 decision-making):ti,ab,kw
9. (interactive-health-communication or (interacti* near/4 tool)):ti,ab,kw
10. (interactive next (internet or online or graphic* or booklet)):ti,ab,kw
11. ((interactiv* or evidence-based) near/3 (risk-information or risk-communication or risk-presentation or risk-graphic*)):ti,ab,kw

12. shared-decision-making:ti,ab,kw
13. (informed next (choice or decision)):ti,ab,kw
14. adaptive-conjoint-analysis:ti,ab,kw
15. (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14), from 2009 to 2012
(Last line **restricted** to “Trials”, and to date range 2009 to 2012)

EMBASE (Ovid)

1. decision support system/
2. patient decision making/
3. decision aid/
4. “decision tree”/
5. decision making.hw,kw,tw. and informed consent.hw,kw.
6. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).tw,kw.
7. (decision adj (board* or guide* or counseling)).tw,kw.
8. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).tw,kw.
9. (computer* adj2 decision making).tw,kw.
10. interactive health communication*.tw,kw.
11. (interactive adj (internet or online or graphic* or booklet*)).tw,kw.
12. (interacti* adj4 tool*).tw,kw.
13. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw,kw.
14. shared decision making.tw,kw.
15. (informed adj (choice* or decision*)).tw,kw.
16. adaptive conjoint analys#s.tw,kw.
17. or/1-16
18. randomized controlled trial/
19. controlled clinical trial/
20. single blind procedure/ or double blind procedure/
21. crossover procedure/
22. random*.tw.
23. placebo*.tw.
24. ((singl* or doubl*) adj (blind* or mask*)).tw.
25. (crossover or cross over or factorial* or latin square).tw.
26. (assign* or allocat* or volunteer*).tw.
27. or/18-26
28. nonhuman/ not (human/ and nonhuman/)
29. 27 not 28
30. 17 and 29
31. 30 and 2009:2012.(sa`year).
32. limit 31 to exclude medline journals

PsycINFO (Ovid)

1. decision support systems/
2. (decision making or choice behavior).mp. and (informed consent.sh. or (patient* or parent* or carer* or caregiver* or care giver*).mp.)
3. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).ti,ab,id.
4. (decision adj (board* or guide* or counseling)).ti,ab,id.
5. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).ti,ab,id.
6. computer assisted therapy/
7. (computer* adj2 decision making).ti,ab,id.

8. interactive health communication*.ti,ab,id.
9. (interactive adj (internet or online or graphic* or booklet*)).ti,ab,id.
10. (interacti* adj4 tool*).ti,ab,id.
11. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).ti,ab,id.
12. shared decision making.ti,ab,id.
13. (informed adj (choice* or decision*)).ti,ab,id.
14. adaptive conjoint analys#s.ti,ab,id.
15. or/1-14
16. random*.ti,ab,hw,id.
17. intervention.ti,ab,hw,id.
18. trial.ti,ab,hw,id.
19. placebo*.ti,ab,hw,id.
20. ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.
21. (cross over or crossover).ti,ab,hw,id.
22. latin square.ti,ab,hw,id.
23. (assign* or allocat* or volunteer*).ti,ab,hw,id.
24. treatment effectiveness evaluation/
25. mental health program evaluation/
26. exp experimental design/
27. or/16-26
28. 15 and 27
29. limit 28 to yr="2009 -Current"

CINAHL (EBSCO)

#	Query	Limiters/Expanders
S31	S30	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase
S30	S28 and S29	Search modes - Boolean/Phrase
S29	EM 2009-	Search modes - Boolean/Phrase
S28	S17 and S27	Search modes - Boolean/Phrase
S27	S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26	Search modes - Boolean/Phrase
S26	TI (singl* or doubl* or tripl* or trebl*) and TI (blind* or mask*)	Search modes - Boolean/Phrase
S25	AB (singl* or doubl* or tripl* or trebl*) and AB (blind* or mask*)	Search modes - Boolean/Phrase
S24	AB (random* or trial or placebo*) or TI (random* or trial or placebo*)	Search modes - Boolean/Phrase
S23	MH Quantitative Studies	Search modes - Boolean/Phrase

(Continued)

S22	MH Placebos	Search modes - Boolean/Phrase
S21	MH Random Assignment	Search modes - Boolean/Phrase
S20	MH Clinical Trials+	Search modes - Boolean/Phrase
S19	PT Clinical Trial	Search modes - Boolean/Phrase
S18	PT “randomized controlled trial”	Search modes - Boolean/Phrase
S17	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16	Search modes - Boolean/Phrase
S16	“informed choice*” or “informed decision*”	Search modes - Boolean/Phrase
S15	“shared decision making”	Search modes - Boolean/Phrase
S14	“adaptive conjoint analysis”	Search modes - Boolean/Phrase
S13	(interactive N2 “risk information”) or (interactive N2 “risk communication”) or (interactive N2 “risk presentation”) or (interactive N2 “risk graphic”)	Search modes - Boolean/Phrase
S12	“interactive internet” or “interactive online” or “interactive graphic*” or “interactive booklet*” or (interacti* N3 tool*)	Search modes - Boolean/Phrase
S11	“interactive health communication*”	Search modes - Boolean/Phrase
S10	computer* N1 “decision making”	Search modes - Boolean/Phrase
S9	(“risk communication” N3 tool*) or (“risk communication” N3 method*) or (“risk information” N3 tool*) or (“risk information” N3 method*) or (“risk assessment” N3 tool*) or (“risk assessment” N3 method*)	Search modes - Boolean/Phrase
S8	“evidence based risk communication” or “evidence based risk information”	Search modes - Boolean/Phrase
S7	“decision board*” or “decision guide*” or “decision counseling”	Search modes - Boolean/Phrase
S6	(decision* N3 support*) or (decision* N3 aid*) or (decision* N3 tool*) or (decision* N3 instrument*) or (decision* N3 technolog*) or (decision* N3 technique*) or (decision* N3 system*) or (decision* N3 program*) or (decision* N3 algorithm*) or (decision* N3 process*) or (decision* N3 method*) or (decision* N3 intervention*) or (decision* N3 material*)	Search modes - Boolean/Phrase
S5	(“decision making” or “choice behavior”) and MH consent	Search modes - Boolean/Phrase

(Continued)

S4	MH decision making, computer assisted	Search modes - Boolean/Phrase
S3	MH decision making, patient	Search modes - Boolean/Phrase
S2	MH decision support systems, clinical	Search modes - Boolean/Phrase
S1	MH decision support techniques+	Search modes - Boolean/Phrase

Appendix 2. Search strategies to 2009

MEDLINE, 1966 to December 2009 (Ovid)

1. choice behavior/
2. decision making/
3. exp decision support techniques/
4. Educational Technology/
5. decision\$.tw.
6. (choic\$ or preference\$).tw.
7. communication package.tw.
8. or/1-7
9. exp health education/
10. Health Knowledge, Attitudes, Practice/
11. informed consent.tw,hw.
12. patient.tw,hw.
13. consumer.tw,hw.
14. or/9-13
15. 8 and 14
16. ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.
17. ((women or men) adj1 (decision\$ or choice or preference or participation)).tw.
18. (parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw.
19. ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.
20. shared decision making.tw.
21. decision aid\$.tw.
22. informed choice.tw.
23. or/16-22
24. 15 or 23
25. clinical trial.pt.
26. randomized controlled trial.pt.
27. random\$.tw.
28. (double adj blind\$).tw.
29. double-blind method/
30. or/25-29
31. 24 and 30

CENTRAL

CENTRAL, *The Cochrane Library* was searched using the MEDLINE search above in Ovid to the end of 2006; for the 2011 update, the CENTRAL search was conducted at www.thecochranelibrary.com to the end of 2009 using the following search strategy:

1. decision.tw,hw.
2. patient.tw,hw.
3. consumer.tw,sh.
4. 1 and (2 or 3)
5. shared decision making.tw.
6. decision aid\$.tw.
7. informed choice.tw.
8. or/4-7
9. clinical trial.pt.
10. randomized controlled trial.pt.
11. random\$.tw.
12. or/9-11
13. 8 and 12

CINAHL, 1982 to September 2008 (Ovid)

1. exp Decision Making/
2. information seeking behavior/
3. Help Seeking Behavior/
4. (choic\$ or preference\$).tw.
5. decision\$.tw.
6. Educational Technology/
7. or/1-6
8. exp Health Behavior/
9. consumer participation/
10. exp Health Education/
11. health knowledge/ or exp professional knowledge/
12. exp Consent/
13. informed consent.tw.
14. patient.tw,hw.
15. consumer.tw,sh.
16. or/8-15
17. 7 and 16
18. ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.
19. ((women or men) adj1 (decision\$ or choice or preference or participation)).tw.
20. (parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw.
21. ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.
22. shared decision making.tw.
23. decision aid\$.tw.
24. informed choice.tw.
25. or/18-24
26. 17 or 25
27. exp clinical trials/
28. Clinical trial.pt.
29. (clinic\$ adj trial\$1).tw.
30. random\$.tw.
31. Random assignment/
32. placebo\$.tw,sh.
33. Quantitative studies/
34. Allocat\$ random\$.tw.

35. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$3 or mask\$3)).tw.
36. or/27-35
37. 26 and 36

EMBASE, 1980 to December 2009 (Ovid)

1. decision making/
2. decision theory/
3. decision\$.tw.
4. Educational Technology/
5. or/1-4
6. exp health behavior/
7. exp Patient Attitude/
8. exp health education/
9. informed consent.tw,sh.
10. patient.tw,sh.
11. consumer.tw,sh.
12. or/6-11
13. 5 and 12
14. ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.
15. ((women or men) adj1 (decision\$ or choice or preference or participation)).tw.
16. (parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw.
17. ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.
18. shared decision making.tw.
19. decision aid\$.tw.
20. informed choice.tw.
21. or/14-20
22. 13 or 21
23. Controlled Study/
24. Randomized Controlled Trial/
25. Clinical Study/
26. Clinical Trial/
27. Major Clinical Study/
28. Prospective Study/
29. Multicenter Study/
30. Randomization/
31. Double Blind Procedure/
32. Single Blind Procedure/
33. Crossover Procedure/
34. Placebo.tw,sh.
35. random\$.tw.
36. (double adj blind\$).tw.
37. or/23-36
38. 22 and 37

PsycINFO, 1806 to December 2009 (Ovid)

1. decision\$.tw.
2. (choic\$ or preference\$).tw.
3. exp decision making/
4. computer assisted instruction/
5. or/1-4
6. exp health education/

7. exp health personnel attitudes/
8. informed consent.tw,sh.
9. patient.tw,hw.
10. consumer.tw,hw.
11. exp health behavior/
12. or/6-11
13. 5 and 12
14. ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.
15. ((women or men) adj1 (decision\$ or choice or preference or participation)).tw.
16. (parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw.
17. ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.
18. shared decision making.tw.
19. decision aid\$.tw.
20. informed choice.tw.
21. or/14-20
22. 13 or 21
23. random\$.tw.
24. (double adj blind\$).tw.
25. placebo\$.tw,hw.
26. or/23-25
27. 22 and 26

WHAT'S NEW

Last assessed as up-to-date: 30 June 2012.

Date	Event	Description
29 January 2014	Amended	Minor typographical corrections.

HISTORY

Protocol first published: Issue 1, 1999

Review first published: Issue 3, 2001

Date	Event	Description
5 December 2013	New citation required and conclusions have changed	This update added 33 new studies for a total of 115 studies involving 34,444 participants. GRADE was used to summarize the quality of the evidence, and findings were reported using a 'Summary of findings' table. We excluded three previously-included trials on the basis of their quasi-randomized controlled trial (q-RCT) design identified using the more rigorous 'Risk of bias' assessment tool, as well as one other study that

(Continued)

		<p>used the same decision aid content for both groups but varied the format used</p> <p>Overall, the results are similar to the previous update, but this update indicates the quality of the evidence to support the reported outcomes (high-quality evidence that decision aids compared to usual care improve people's knowledge and reduce their decisional conflict related to feeling uninformed and unclear about their personal values; moderate-quality evidence that decision aids compared to usual care stimulate people to take a more active role in decision making and improve accurate risk perceptions when probabilities are included; and low-quality evidence that decision aids improve the congruence between the chosen option and their values)</p> <p>We added two new authors to the review, LT in Sydney and JW in Ottawa who helped coordinate this update</p>
30 June 2012	New search has been performed	Search strategies were updated and new searches run in June 2012
18 January 2012	Amended	Minor change to wording, Plain Language Summary.
5 September 2011	New search has been performed	An update of this review was conducted in 2010 and published on issue 10 2011 of <i>The Cochrane Library</i> . Citations were searched from 2006 to December 2009.
5 September 2011	New citation required but conclusions have not changed	<p>This update added 31 new studies, and all 86 included studies were assessed for risk of bias. Overall the results were consistent with the previous update</p> <p>New in this update is the meta-analysis of informed values-based choices for decision aids including explicit values-clarification compared to those with no explicit values-clarification. We have also conducted a post-hoc analysis to evaluate the effect of risk of bias assessment ratings on outcomes</p>
29 April 2009	New search has been performed	See the 'History' items dated 29 April 2009 and 28 July 2006
29 April 2009	New citation required and conclusions have changed	<p>A substantially updated version of this review was published on issue 1 2009 of <i>The Cochrane Library</i>. The changes are outlined in the 'History' (date 28 July 2006). The updated review ought to have had a new citation to reflect the new authorship and substantial changes to the review and its conclusions; however because of a technical error this new citation was not given to the updated review</p> <p>The new citation for this review for issue 3 2009 (</p>

(Continued)

		O'Connor 2009) reflects the updated review contents as actually published from issue 1 2009 onwards
28 April 2009	Amended	Corrected mislabelled table 'Summary of pooled outcomes'.
17 July 2008	Amended	Converted to new review format.
28 July 2006	New search has been performed	<p>Changes for the 2006 update (first published on issue 1 2009 of <i>The Cochrane Library</i>):</p> <ul style="list-style-type: none">• Outcomes focus on the new effectiveness criteria of the International Patient Decision Aids Standards (IPDAS) Collaboration.• There are now 55 randomized controlled trials evaluating decision aids in the review. Twenty-five new randomized controlled trials have been added for this update. Four trials that were previously included were excluded from this review as the decision support intervention was not available to determine whether it met the inclusion criteria - a requirement for this update in light of the new IPDAS standards. There are an additional 15 trials in progress.• The number of included countries has doubled from the last update. We now have results from 7 countries (AU, CA, China, Finland, Netherlands, US, UK). <p>Findings from the 2006 update (*new to this update):</p> <ul style="list-style-type: none">• * Thirty-eight trials used at least one measure that mapped onto an IPDAS effectiveness criterion. No trials evaluated the extent to which patient decision aids achieve the IPDAS decision process criteria: helped patients to recognize that a decision needs to be made, understand that values affect the decision, or discuss values with their practitioner.• * Exposure to a decision aid with probabilities resulted in a higher proportion of people with accurate risk perceptions; the effect was stronger when probabilities were measure quantitatively rather than qualitatively.• Compared to usual care, exposure to decision aids improved knowledge, decreased decisional conflict, reduced the proportion of people who were passive in decision making, reduced the proportion who remained undecided, and reduced rates of elective invasive surgery.• Detailed decision aids (compared to simpler decision aids) improved knowledge and reduced the uptake of hormone replacement therapy.

(Continued)

		<ul style="list-style-type: none">• * Compared to usual care, exposure to decision aids reduced prostate-specific antigen (PSA) screening.• There are too few studies to comment on the effects of decision aids on length of the consult, patient-practitioner communication, persistence with chosen option, costs, and resource use.
21 February 2003	New search has been performed	<p>For the 2002 update (O'Connor 2003b), the following changes were made:</p> <ul style="list-style-type: none">• There are now 221 decision aids (increased from 87) that have been identified for the inventory with 131 available and up-to-date: many of which are available on the Internet. However few have undergone any form of evaluation for impact on decision making.• There are now 35 randomized controlled trials evaluating decision aids in the review. Eleven new randomized controlled trials have been added for this update including 1 large scale trial that evaluated a suite of 8 decision aids in a number of health services.• There are an additional 6 trials pending publication and 24 trials in progress.• In conjunction with the benefits reported in the earlier reports, there is now evidence that decision aids compared to usual care also help with making actual choices and there is a statistically-significant reduction in major elective surgery by a quarter. Detailed compared to simple decision aids also show an improved agreement between values and actual choice.• There continues to be too few studies to comment on the effects of decision aids on persistence with chosen therapy, costs, resource use, or efficacy of dissemination.

CONTRIBUTIONS OF AUTHORS

1999 Review (O'Connor 1999b):

AO, AR, VF, JT, VE, HLT, MHR, VF, MB, JJ contributed to the design of the protocol, the interpretation of results, and the revision and final approval of the final paper.

AO led the team, JT coordinated the project.

AO, MH-R, AR, VF, and JT pilot tested the data extraction forms.

AR, VF, JT screened studies and extracted data.

AR, JT, and AO analyzed the results.

2001 Review (O'Connor 2001b):

AO, DS, DR, MHR, HLT, VE, MB, JT, VF, AR contributed to the interpretation of results, and the revision and final approval of the final paper.

AO lead the team and DS coordinated the update.

AO, DR, MHR, HLT, JT, DS, JP screened studies and extracted data.

DS, JP evaluated decision aids using the CREDIBLE criteria.

AO and DS analyzed the results.

2002 Review (O'Connor 2003b):

AO, DS, DR, MHR, HLT, VE, MB, JT, VF contributed to the interpretation of results, and the revision and final approval of the paper.

AO lead the team and DS coordinated the update.

DS, JP, VT, JT screened studies and extracted data.

DS, JP, VT, SK evaluated decision aids using the CREDIBLE criteria.

AO and DS analyzed the results.

2006 Review (O'Connor 2009):

AO, CB, DS, MB, NC, KE, VE, VF, MHR, SK, HLT, DR, contributed to the interpretation of results, and the revision and final approval of the paper.

AO led the team and CB coordinated the update.

CB, SK, DS, AO, VF screened studies and extracted data.

AO and CB analyzed the results.

2009 Review (Stacey 2011):

DS, CB, MB, NC, KE, FL, AL, MHR, HLT, RT contributed to the interpretation of results, and the revision and final approval of the paper.

DS led the team and CB coordinated the update.

CB, DS screened studies; SM, AD extracted data; CB entered the data; DS verified the data entered.

DS and CB analyzed the results.

2013 (current) Review

DS, CB, MB, NC, KE, FL, AL, MHR, HLT, RT, and LT contributed to the interpretation of results, and the revision and final approval of the paper.

DS led the team with help coordinating the update from SB and JW.

CB, DS, RT, MB, MHR, NC, KE, BV, DR, AS screened studies; SB, RW, JW, and CC extracted data; SB and JW entered the data; DS verified the data entered.

DS and JW analyzed the results.

DECLARATIONS OF INTEREST

Several of the investigators have developed patient decision aids (DS, FL, HL, MHR, MB, NC, KE, RT, LT), but none reviewed their own studies.

Within the last five years, two investigators (HL, MB) have received financial support from the not-for-profit Informed Medical Decisions Foundation (IMDF). MB serves on the Board of and receives salary support as President of the Foundation. Several investigators (DS, FL, HL, MHR, MB, KE, RT, LT), who were involved in a special issue in BMC Medical Informatics and Decision Making that included a series of 14 papers focused on the theoretical and empirical evidence underlying the International Patient Decision Aid Standards (IPDAS), received partial funding from the Foundation to cover publishing costs. The Foundation has a licensing agreement with Health Dialog (a commercial firm) that distributes and promotes patient decision aids.

NC is the founder of Shared Decision Making Resources, an organization devoted to the development and dissemination of interactive patient decision aids; served as an adviser to Emmi Solutions LLC, Janssen Scientific Affairs, LLC, Expert Medical Navigation Inc, University of Chicago, Miami University and BlueCross/Blue Shield; and has received travel and/or speakers fees/honoraria from various organizations that have sponsored conferences addressing Shared Decision Making (including the World Congress Leadership Summit on Shared Decision Making).

SOURCES OF SUPPORT

Internal sources

- University of Ottawa, Canada.

University Research Chair in Knowledge Translation to Patients

- Ottawa Hospital Research Institute, Canada.

Director, Patient Decision Aids Research Group

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are three main differences between the original protocol and the review. The 2009 update (O'Connor 2009) was re-structured to organize the long list of outcomes into primary and secondary outcomes based on the new effectiveness criteria of the International Patient Decision Aid (IPDAS) Collaboration (Elwyn 2006). For the 2011 update (Stacey 2011), study quality assessment was changed to the 'Risk of bias' assessment (Higgins 2011). For the 2013 (current) update, GRADE was used to summarize the quality of the evidence and findings were reported using a 'Summary of findings' table.

INDEX TERMS

Medical Subject Headings (MeSH)

*Decision Support Techniques; *Patient Participation; Elective Surgical Procedures; Patient Education as Topic [*methods]; Randomized Controlled Trials as Topic

MeSH check words

Humans