National Institute for Health and Care Excellence

Guideline version (Draft)

Shared decision making

[C] Evidence review for decision aids for people facing health treatment or screening decisions

NICE guideline

Evidence review C

December 2020

Draft for Consultation

These evidence reviews were developed by the NICE Guideline Updates Team

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ISBN:

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Decision aids for people facing health treatment or screening decisions

Review question

What is the effectiveness of patient decision aids for helping people make health decisions?

This is a sub-question of the scope question:

What are the core components of effective shared decision making approaches and activities?

Introduction

Shared decision making is a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care., now or in the future (for example, through advance care planning). It involves healthcare professionals working together with people who use services and their families and carers to choose tests, treatments, management or support packages, based on evidence and informed personal preferences, health beliefs, and values. This involves making sure the person has a good understanding of the risks, benefits and possible consequences of different options through discussion and information sharing.

Although the benefits of shared decision making are increasingly being recognised it is not yet routinely practised in every setting, and definitions of what constitutes shared decision making can vary. National surveys have shown that many inpatients want to be more involved in decisions about their care (45% and over 30% of primary care patients [CQC inpatient survey 2019]. The GP survey 2020 suggests 93% of patients in primary care are as involved as they want to be in their care, but there are still opportunities for more evidence around the best ways to perform and implement SDM.

A landmark ruling was made in 2015 by the UK Supreme Court following the Montgomery v Lanarkshire case. A new legal standard set out that adults ‘of sound mind’ are entitled to make informed decisions when giving or withholding consent to treatment or diagnosis. Consent ‘must be obtained before treatment interfering with bodily integrity is undertaken’, and it should only be gained when patients have shared a decision informed by what is known about the risks, benefits and consequences of all reasonable NHS treatment options. It is the healthcare professional’s duty to ‘take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.’

The aim of this review is to contribute to the guideline by evaluating the effectiveness of patient decision aids (PDAs). This review is a summary of the Cochrane Review Stacey D, Légaré F, Lewis K, Barry MJ et al “Decision aids for people facing health treatment or screening decisions”. Cochrane Database of Systematic Reviews 2017, Issue 4. All data are extracted from that review.

PICO table

Table 1: PICO table for decision aids for people facing health treatment or screening decisions

Type of review	Effectiveness review
Population	Adults aged 18 years or older who were making decisions about screening or treatment options for themselves, a child, or an incapacitated significant other. Excluded: studies in which participants were making hypothetical choices.
Intervention	Use of a patient decision aid as part of the intervention (defined as interventions designed to help people make specific and deliberated choices among options (including the status quo), by making the decision explicit and by providing (at the minimum) information on the options and outcomes relevant to a person's health status as well as implicit methods to clarify values).
Comparators	Usual care, general information, clinical practice guideline, placebo intervention, or no intervention.
Outcomes	• 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, values-choice congruence)? • Attributes of the decision-making process: does the patient decision aid help patients to recognize that a decision needs to be made, feel informed about the options and their features, be clear about the option features that matter most, discuss values with their clinician, and become involved in decision making? •
Study types	• RCT's • SRs of RCTs

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A

For further details of the methods used see appendix B.

The search strategies used in this review are detailed in appendix C.

Declarations of interest were recorded according to NICE's 2018 conflicts of interest policy.

Clinical evidence

Included studies

A Cochrane review that matched that review protocol was identified (Stacey D, Légaré F, Lewis K, Barry MJ et al "Decision aids for people facing health treatment or screening decisions".). This review was judged to be of high quality according to the ROBIS systematic review quality checklist and was directly applicable. Consequently, it was used as a direct source of evidence for the review (see Appendix B for details of how published systematic reviews were incorporated).

No additional searches were undertaken since Cochrane are currently updating this review and NICE and Cochrane agreed that duplication was not desirable.

The Cochrane authors included 105 studies reported in 151 papers. References for papers included in the Cochrane Review can be found in appendix J.

Excluded studies

No additional searching was undertaken so no further studies were excluded.

Summary of studies included in the Cochrane systematic review

Study characteristics are presented in Table 2.

Table 2: Summary of characteristics of included studies

Study	Topic	Location	Study type
Allen 2010	Prostate cancer screening	Allen, Center for Community-Based Research, Dana-Farber Cancer Institute, Boston, MA, USA, 2010	Cluster RCT
Arterburn 2011	Bariatric surgery	Informed Medical Decisions Foundation, MA,USA, 2010	RCT
Auvinen 2004	Prostate cancer treatment	Auvinen, Helsinki, Finland, 1993	RCT
Barry 1997	Benign prostate disease treatment	Informed Medical Decisions Foundation, MA, USA, 2001	RCT
Bekker 2004	Prenatal screening	Bekker, Leeds, UK, 2003	RCT
Bernstein 1998	Ischaemic heart disease treatment	Informed Medical Decisions Foundation, MA,USA, 2002	RCT
Berry 2013	Prostate cancer treatment	Berry, Phyllis F. Cantor Center, MA, USA, 2011	RCT
Bjorklund 2012	Antenatal Down syndrome screening	Södersjukhuset, Department of Obstetrics and Gynecology, Stockholm, Sweden	RCT
Bozic 2013	Osteoarthritis of the knee or hip	Informed Medical Decisions Foundation and Health Dialog; USA	RCT

Study	Topic	Location	Study type
Brazell 2014	Pelvic Organ Prolapse	Healthwise, USA	RCT
Chabrera 2015	Prostate cancer treatment	C Chabrera. School of Health Sciences, Department of Nursing. Mataro, Spain	RCT
Chambers 2012	Healthcare personnel's influenza immunization	A McCarthy. Ottawa Influenza Decision Aid Planning Group, CA, 2008	RCT
Clancy 1988	Hepatitis B Vaccine	Clancy, Richmond VA, USA, 1983	RCT
Davison 1997	Prostate cancer treatment	Davison, Manitoba CA, 1992-1996	RCT
De Achaval 2012	Total knee arthroplasty treatment	Informed Medical Decisions Foundation, MA, USA	RCT
Dolan 2002	Colon cancer screening	Dolan, Rochester NY, USA, 1999	RCT
Evans 2010	Prostate cancer screening	Elwyn, Cardiff, UK	RCT
Fagerlin 2011	Breast cancer prevention	Fagerlin, Ann Arbor, MI, USA	RCT
Fraenkel 2007	Osteoarthritis knee treatment	Fraenkel, New Haven CT, USA	RCT
Fraenkel 2012	Atrial fibrillation	Veterans Affairs Connecticut Healthcare System, USA	RCT
Frosch 2008a	Prostate cancer screening	Frosch, Los Angeles, USA	RCT
Gattellari 2003	Prostate cancer screening	Gatellari, Sydney, AU, 2003	RCT
Gattellari 2005	Prostate cancer screening	Gatellari, Sydney, AU, 2003	RCT
Green 2001	Breast cancer genetic testing	Green, Hershey PA, USA, 2000	RCT
Hamann 2006	Schizophrenia treatment	Hamann, Munich, GER	RCT
Hanson 2011	Feeding options in advanced dementia	Mitchell, Tetroe, O'Connor; 2001 (updated 2008)	RCT
Heller 2008	Breast reconstruction	University of Texas MD Anderson Cancer Center, Houston TX, USA, 2003	RCT
Hess 2012	Stress testing for chest pain	Hess, Rochester, MN, USA, 2012	RCT
Jibaja-Weiss 2011	Breast cancer treatment	Jibaja-Weiss, Baylor College of Medicine, 2010	RCT
Johnson 2006	Endodontic treatment	Johnson, Chicago, USA, 2004	RCT

Study	Topic	Location	Study type
Kasper 2008	Multiple sclerosis	Jürgen Kasper	RCT
Kennedy 2002	Abnormal uterine bleeding treatment	Kennedy/Coulter, London UK, 1996	RCT
Knops 2014	Asymptomatic Abdominal Aortic Aneurysm treatment	Amsterdam, The Netherlands	RCT
Krist 2007	Prostate cancer screening	Krist, Fairfax VA, USA	RCT
Kupke 2013	Dental - posterior tooth decay	University of Cologne, Cologne, Germany	RCT
Kuppermann 2014	Prenatal screening	Kuppermann, San Francisco CA, USA	RCT
Lam 2013	Breast cancer treatment	Kwong Wah Hospital, Hong Kong, China	RCT
Langston 2010	Contraceptive method choice	World Health Organization, 2005	RCT
Laupacis 2006	Pre-operative autologous blood donation	Laupacis, Ottawa, CA, 2001	RCT
LeBlanc 2015	Treatment for osteoporosis	Mayo Clinic	RCT
Legare 2008a	Natural health products	Legare, Quebec City, CA, 2006	RCT
Legare 2011	Use of antibiotics for acute respiratory infections	Legare, Quebec City, CA, 2007	Cluster RCT
Legare 2012	Antibiotics for acute respiratory infections	Legare, Quebec City, CA	RCT
Leighl 2011	Advanced colorectal cancer chemotherapy	Princess Margaret Hospital, Toronto, 2011	Cluster RCT
Lepore 2012	Prostate cancer screening	Sally Weinrich University of Louisville, USA	RCT
Lerman 1997	Breast cancer genetic testing	Lerman/Schwartz, Washington DC, USA, 1997	RCT
Lewis 2010	Colorectal cancer screening	Lewis, University of North Carolina, Chapel Hill, NC, USA, 2010	RCT
Loh 2007	Depression treatment	Loh, Freiburg, GER	Cluster RCT
Man-Son-Hing 1999	Atrial fibrillation treatment	McAlister/Laupacis, Ottawa CA, 2000	RCT
Mann D 2010	Diabetes treatment - statins	Montori, Rochester MN, USA	RCT
Mann E 2010	Diabetes screening	Marteau, King's College London, London, England, 2010	RCT

Study	Topic	Location	Study type
Marteau 2010	Diabetes screening	Marteau, King's College London, London, England, 2010	RCT
Mathieu 2007	Mammography	Mathieu, Sydney, AU	RCT
Mathers 2012	Diabetes treatment	The University of Sheffield, Sheffield, UK, 2008	Cluster RCT
Mathieu 2010	Mammography	Mathieu, University of Sydney, AUS, 2010	RCT
McAlister 2005	Atrial fibrillation treatment	McAlister/ Laupacis, Ottawa CAN, 2000	RCT
McBride 2002	Hormone replacement therapy	Sigler/Bastien, Durham NC, USA, 1998	RCT
McCaffery 2010	Screening after mildly abnormal pap smear	Screening & test evaluation program, School of public health, University of Sydney 2007	RCT
Miller 2005	BRCA1/BRCA2 gene testing	Miller, Fox Chase PA, USA	RCT
Miller 2011	Colorectal cancer screening	University of North Carolina, Chapel Hill, NC, USA, 2007	RCT
Montgomery 2003	Hypertension treatment	Montgomery, UK, 2000	RCT
Montgomery 2007	Birthing options after caesarean	Montgomery, Bristol, UK, last update 2004	RCT
Montori 2011	Osteoporosis treatment	Montori, Mayo Foundation for Medical Education and Research, 2007	RCT
Morgan 2000	Ischaemic heart disease treatment	Informed Medical Decisions Foundation, MA, USA, 2002	RCT
Mott 2014	PTSD treatment	Michael E DeBakey Veterans Affairs Medical Center, Houston, USA	RCT
Mullan 2009	Diabetes treatment	Montori or Mayo Foundation(?) Rochester MN, USA,	Cluster RCT
Murray 2001a	Benign prostate disease treatment	Informed Medical Decisions Foundation, MA, USA, 2001	RCT
Murray 2001b	Hormone replacement therapy	Informed Medical Decisions Foundation, MA, USA	RCT
Nagle 2008	Prenatal screening	Nagle, Victoria, AU	Cluster RCT
Nassar 2007	Birth breech presentation	Nassar, West Perth WA, AU	RCT
Oakley 2006	Osteoporosis treatment	Cranney, Ottawa CA, 2002	RCT

Study	Topic	Location	Study type
Ozanne 2007	Breast cancer prevention	Ozanne, Boston MA, USA	RCT
Partin 2004	Prostate cancer screening	Informed Medical Decisions Foundation, MA, USA, 2001	RCT
Pignone 2000	Colon cancer screening	Pignone, Chapel Hill NC, USA, 1999	RCT
Protheroe 2007	Menorrhagia treatment	Protheroe, Manchester, UK	RCT
Rubel 2010	Prostate cancer screening	Centers for Disease Control and Prevention (CDC), USA, 2010	RCT
Ruffin 2007	Colorectal cancer screening	Regents of the University of Michigan (copyright info), Ann Arbor MI, USA, 2006	RCT
Sawka 2012	Adjuvant radioactive iodine treatment for patients with early-stage papillary thyroid cancer	University Health Network, Toronto, Canada, 2009	RCT
Schroy 2011	Colorectal cancer screening		RCT
Schwalm 2012	Coronary angiogram access site	Schwalm, Hamilton, ON, Canada, 2009	RCT
Schwartz 2001	Breast cancer genetic testing	Schwartz/Lerman, Washington DC, USA, 1997	RCT
Schwartz 2009a	BRCA mutation prophylactic surgery	Schwartz, Washington DC, USA	RCT
Sheridan 2006	Cardiovascular prevention	Sheridan, Chapel Hill, NC, USA	RCT
Sheridan 2011	Coronary heart disease prevention	Sheridan, University of North Carolina at Chapel Hill, Division of General Internal Medicine, North Carolina, USA, 2011	RCT
Shorten 2005	Birthing options after previous caesarean	Shorten, Wollongong, AU, 2000	RCT
Shourie 2013	Measles mumps and rubella vaccination	University of Leeds, UK & NSIRS Australia	Cluster RCT
Smith 2010	Bowel cancer screening	Smith, Sydney, AU 2008	RCT
Stacey 2014a	Osteoarthritis of the hip and knee	Informed Medical Decisions Foundation and Health Dialog; USA	RCT
Steckelberg 2011	Colorectal cancer screening	Steckelberg, Hamburg, Germany	RCT
Taylor 2006	Prostate cancer screening	Georgetown University Medical Center,	RCT

Study	Topic	Location	Study type
		Washington DC, USA, 2000	
Thomson 2007	Atrial fibrillation treatment	Thomson, Newcastle Upon Tyne, UK	RCT
Trevena 2008	Colorectal cancer screen	Trevena, Sydney, AU	RCT
Van Peperstraten 2010	Embryos transplant	Radboud University Nijmegen Medical Centre; 2006	RCT
Vandemheen 2009	Cystic Fibrosis referral transplant	Aaron, Ottawa ON, CA, 2009 (last update 2011)	RCT
Vodermaier 2009	Breast cancer surgery	Vodermaier, Vancouver BC, CA	RCT
Volk 1999	Prostate cancer screening	Informed Medical Decisions Foundation, MA, USA, 1999	RCT
Vuorma 2003	Menorrhagia treatment	Vuorma, Helsinki Finland, 1996	RCT
Watson 2006	Prostate cancer screening	Oxford, UK	RCT
Weymiller 2007	Diabetes mellitus type 2 treatment	Montori, Rochester MN, USA	Cluster RCT
Williams 2013	Prostate cancer screening	Georgetown University, Washington, DC, USA	RCT
Whelan 2003	Breast cancer chemotherapy	Whelan, Hamilton CA, 1995	RCT
Whelan 2004	Breast cancer surgery	Whelan, Hamilton CA, 1997	Cluster RCT
Wolf 1996	Prostate cancer screening	Wolf, Charlottesville VA, USA, 1996	RCT
Wolf 2000	Colon cancer screening	Wolf, Charlottesville VA, USA, 2000	RCT
Wong 2006	Pregnancy termination	Bekker, Leeds, UK, 2002	RCT

1 See appendix E for full evidence tables.

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1 Cochrane summary of findings table

2 **Table 3: Patient decision aids compared with usual care for adults considering**
3 **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)** **Assumed benefit** **Usual care**	 **Corresponding benefit** **Patient decision aid**	**Relative effect (95% CI)**	**No of participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
Knowledge - 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% across control groups, ranging from 27.0% to 85.2%	The mean knowledge score in the intervention groups was 13.27 higher (11.32 to 15.23 higher)	—	13,316 (52 studies)	⨁⨁⨁⨁ High[a,b]	Higher scores indicate better knowledge. 46 out of 52 studies showed a statistically significant improvement in knowledge
Accurate risk perceptions - all studies Assessed soon after exposure to the decision aid	269 per 1000c	565 per 1000 (447 to 716 per 1000)	RR 2.10 (1.66 to 2.66)	5096 (17 studies)	⨁⨁⨁⨀ Moderate[a,d]	—
Congruence between the chosen option and informed values - all studies Assessed soon after exposure to the decision aid	289 per 1000c	595 per 1000 (422 to 841 per 1000)	RR 2.06 (1.46 to 2.91)	4626 (10 studies)	⨁⨁⨀⨀ Low [a,d,e,f]	—
Decisional conflict: uninformed	The mean for outcome 'feeling	The mean feeling uninformed in the	—	5707 (27 studies)	⨁⨁⨁⨁ High[a,b]	Lower scores indicate feeling

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)** **Assumed benefit** **Usual care**	**Corresponding benefit** **Patient decision aid**	**Relative effect (95% CI)**	**No of participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
subscale - all studies Standardized on score from 0 (not uninformed) to 100 (uninformed) Assessed soon after exposure to the decision aid	uninformed' ranged across control groups from 11.1 to 61.1. Scores ≤ 25 associated with following through on decisions. Scores > 38 associated with delay in decision making	intervention groups was 9.28 lower (12.20 to 6.36 lower)				more informed
Decisional conflict: unclear about personal values subscale - all studies Standardized on score from 0 (not unclear) to 100 (unclear) Assessed soon after exposure to the decision aid	The mean for outcome 'feeling unclear about personal values' ranged across control groups from 15.5 to 53.2. Scores ≤ 25 associated with follow-through with decisions. Scores > 38 associated with delay	The mean feeling unclear values in the intervention groups was 8.81 lower (11.99 to 5.63 lower)	—	5068 (23 studies)	⨁⨁⨁⨁ High[a,b]	Lower scores indicate feeling clearer about values

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**				
	in decision making					
Participation in decision making: clinician-controlled decision making - all studies Assessed soon after consultation with clinician	228 per 1000c	155 per 1000 (125 to 189 per 1000)	RR 0.68 (0.55 to 0.83)	3180 (16 studies)	⨁⨁⨁⊖ Moderate [a,e]	Patient decision aids aim to increase patient involvement in making decisions; lower proportion of clinician-controlled decision making is better
Adverse events	There were no adverse effects on health outcomes or satisfaction, and no other adverse effects reported.					
*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						
[a]The vast majority of studies measuring this outcome were not at high risk of bias. [b]The GRADE ratings for these outcomes were not downgraded for heterogeneity given the generally consistent direction of effects across studies for the decision aid compared to usual care groups. [c]The data source for the assumed risk was the mean control event rate. [d]The GRADE rating was downgraded given the lack of precision. [e]The GRADE rating was downgraded given the lack of consistency. [f]The GRADE rating was downgraded given the lack of directness. As well, the outcome was measured using various approaches with no gold standard approach.						

Quality assessment of clinical studies included in the evidence review

The quality assessments for the included studies were conducted by the Cochrane review authors who used the Cochrane Risk of Bias tool. This is the same method as used by NICE for risk of bias assessment. Each individual study was classified into one of the following three groups:

- Low risk of bias – The true effect size for the study is likely to be close to the estimated effect size.
- Moderate risk of bias – There is a possibility the true effect size for the study is substantially different to the estimated effect size.
- High risk of bias – It is likely the true effect size for the study is substantially different to the estimated effect size.

See appendix E for appraisal of individual studies.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.3.1 to 1.3.5.

Committee discussion of the evidence

Outcomes that matter most

The committee agreed that outcomes based on the International Patient Decision Aid Standards (IPDAS) criteria (accurate risk perception, knowledge, values/choice congruence) were appropriate for this research question, and it was confident making recommendations based on these.

Quality of the evidence

Most of the outcomes were rated as high quality using GRADE. Two outcomes were of moderate quality and 1 of low quality. Outcomes were downgraded because of imprecision, inconsistency and indirectness.

Included studies were mostly at low or unclear risk of bias, with concerns predominantly about selective reporting and lack of blinding.

The committee agreed that the Cochrane review was robust enough to make strong recommendations. The committee noted that the review was published in 2017 and therefore not totally up to date, however the committee was also aware that the authors were in the process of updating the review.

The technical team had received communication from the Cochrane authors indicating that the update of the Cochrane review would not be available during the development period for this guideline, however the Cochrane authors were clear that there was no current evidence to indicate any change in the outcomes. They state that the addition of new studies will predominantly tighten the confidence intervals for some of the outcomes. Furthermore, there have been several updates and the main result of updates has been to strengthen the evidence base, rather than change conclusions. The committee agreed that on this basis it was content to use the 2017 data as the basis for recommendations.

Benefits and harms

The committee was supportive of the idea of a national library of PDAs. It agreed that a national library would make it much easier for clinicians to access and choose between high quality, appropriate PDAs.

Whilst a national library is the number one priority, in the interim, the committee agreed that NHS organisation (or departments, units or networks of organisations) should develop their own libraries, or secure access to libraries of PDAs that were accessible to healthcare professionals. These libraries should be kept up to date and ensure that all the PDAs they contain are of high quality (meeting the International Patient Decision Aid Standards [IPDAS] quality criteria) and based on high-quality data. This helps the healthcare professional to choose the appropriate PDA for the healthcare users preferences and current clinical context.

The committee made clear that PDAs are not the same as SDM, nor are they essential to it. They are simply a component within the toolbox for SDM approaches and options. They enable healthcare users to begin to shift from clinician-led decision-making situations

towards shared and informed decision making. It also made clear that PDAs are intrinsically linked with risk communication, and that therefore this review and the risk communication review were related - good quality decision aids will often provide a structured way of presenting and discussing risks around the options.

The committee reiterated that even with PDAs being based on high quality evidence, context appropriate and available the healthcare professional will still need to possess the communication skills to support the overall process of SDM.

The committee acknowledged that the onus is not just on the healthcare professional to deliver PDAs, but also organisations and institutions to ensure that PDAs are available to access in many different formats and that a database, should it exist, is accessible. Decision aids must be accessible to print out (if desired, or needed by the person) and provide healthcare users with different options for use, and the committee pointed out that “access” is not just limited to making something available online.. Quality assurance and accessibility are key for both healthcare users and professionals. The committee acknowledged that facilities to print decision aids may not be available, or be within the remit of every organisation.

The committee highlighted that if a PDA is not available, SDM should still be carried out in line with recommendations in other sections of this guideline, acknowledging there is not, and will never be, a PDA for every single decision.

The committee acknowledged there was no apparent difference in effectiveness between in consultation and pre-consultation/between consultation PDAs and thus left the decision about when in the decision process to use PDAs up to individual healthcare practitioners’ discretion and clinical situation

The committee stated that if new PDAs are created they should conform to IPDAS standards.

The committee was unaware of any harms that might be caused by using an appropriate, quality assured patient decision aid.

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Appendices

Appendix A: Review protocols

The full review protocol for this review is not available.

The review reports the following:

Criteria for considering studies for this review

Types of studies

We included all published studies that used a randomized controlled trial (RCT) design evaluating patient decision aids.

Types of participants

We included studies involving adults aged 18 years or older who were making decisions about screening or treatment options for themselves, a child, or 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 deliberated choices among options (including the status quo), by making the decision explicit and by providing (at the minimum) information on the options and outcomes relevant to a person's health status as well as 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 programmes not geared to a specific decision; and interventions designed to promote adherence or elicit informed consent regarding a recommended option. We also excluded studies when the relevant decision aid(s) were not available to us and not

adequately described in the article(s), because we could not determine the aids' characteristics and whether or not they met the minimum criteria to qualify as patient decision aids.

Types of comparisons

We included studies that compared patients exposed to a patient decision aid to patients in comparison groups that were exposed to usual care, general information, clinical practice guideline, placebo intervention, or no intervention. For the purposes of this review, we refer to all such control comparisons as 'usual care'.

We excluded studies that compared two different types of patient decision aids.

Types of outcome measures

To ascertain whether the decision aids achieved their objectives, we examined a broad range of outcomes. Although the decision aids focused on diverse clinical decisions, many had similar objectives such as improving knowledge scores, the accuracy of 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). The IPDAS criteria were attributes related to the choice (e.g. match between the chosen option and the features that matter most to the informed patient) and to the decision-making process (e.g. 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 features that matter most; discuss values with their clinician; and become involved in their preferred ways). A complete list of outcomes, specified in advance of the review, included primary and secondary outcomes.

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, values-choice congruence)?
- Attributes of the decision-making process: does the patient decision aid help patients to recognize that a decision needs to be made, feel informed about the options and their features, be clear about the option features that matter most, discuss values with their clinician, and become involved in decision making?

Other decision-making process variables

- Decisional conflict
- Patient-clinician communication
- Participation in decision making
- Proportion undecided
- Satisfaction with the choice, with the process of decision making, and with the preparation for decision making

Secondary outcomes

Behaviour

- Choice (the actual choice implemented; if not reported, the participants' 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 other resources.

Electronic searches

For this update, we used the same search strategy that was revised by the Trials Search Coordinator at the Cochrane Consumers and Communication Group in the last update (Stacey 2014b).

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

- Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 6) in the Cochrane Library (searched to 24 April 2015).
- MEDLINE Ovid (1966 to 24 April 2015).
- Embase Ovid (1980 to 24 April 2015).
- PsycINFO Ovid (1806 to 24 April 2015).
- CINAHL Ovid (1982 to September 2008), then in Ebsco (to 24 April 2015).

We present the search strategies in appendix C

Searching other resources

On 18 December 2015 we also searched trial registries (World Health Organization, ClinicalTrials.gov), the Internet using Google and Google Scholar, and the Decision Aid Library Inventory (decisionaid.ohri.ca). Finally, reference lists of all newly included trials were searched.

Data collection and analysis

For this current update, we focused only on new publications that had appeared since the previous publication (Stacey 2014b), and we limited the inclusion to patient decision aids versus usual care. As such, we removed studies from the previous reviews that compared detailed versus simple patient decision aids to provide a more focused review.

Selection of studies

Pairs of eight review authors screened all identified citations. We retrieved the full text of any papers identified as potentially relevant by at least one author, listing all papers excluded from the review at this stage, with reasons, in the 'Characteristics of excluded studies' table. We also

provided citation details and any available information about ongoing studies, and we collated and reported details of additional publications, so that each study (rather than each report) was the unit of interest. We report the screening and selection process in appendix D.

Appendix B: Methods

Incorporating published systematic reviews

Quality assessment

Individual systematic reviews were quality assessed using the ROBIS tool, with each classified into one of the following three groups:

- High quality – It is unlikely that additional relevant and important data would be identified from primary studies compared to that reported in the review, and unlikely that any relevant and important studies have been missed by the review.
- Moderate quality – It is possible that additional relevant and important data would be identified from primary studies compared to that reported in the review, but unlikely that any relevant and important studies have been missed by the review.
- Low quality – It is possible that relevant and important studies have been missed by the review.

Each individual systematic review was also classified into one of three groups for its applicability as a source of data, based on how closely the review matches the specified review protocol in the guideline. Studies were rated as follows:

- Fully applicable – The identified review fully covers the review protocol in the guideline.
- Partially applicable – The identified review fully covers a discrete subsection of the review protocol in the guideline (for example, some of the factors in the protocol only).
- Not applicable – The identified review, despite including studies relevant to the review question, does not fully cover any discrete subsection of the review protocol in the guideline.

Using systematic reviews as a source of data

If systematic reviews were identified as being sufficiently applicable and high quality, and were identified sufficiently early in the review process (for example, from the surveillance review or early in the database search), they were used as the primary source of data, rather than extracting information from primary studies. The extent to which this was done depended on the quality and applicability of the review, as defined in Table 4. When systematic reviews were used as a source of primary data, and unpublished or additional data included in the review which is not in the primary studies was also included. Data from these systematic reviews was then quality assessed and presented in GRADE tables as described below, in the same way as if data had been extracted from primary studies. In questions where data was extracted from both systematic reviews and primary studies, these were cross-referenced to ensure none of the data had been double counted through this process.

Table 4: Criteria for using systematic reviews as a source of data

Quality	Applicability	Use of systematic review
High	Fully applicable	Data from the published systematic review were used instead of undertaking a new literature search or data analysis. Searches were only done to cover the period of time since the search date of the review.
High	Partially applicable	Data from the published systematic review were used instead of undertaking a new literature search and data analysis for the relevant subsection of the protocol. For this section, searches were only done to cover the period of time since the search date

Quality	Applicability	Use of systematic review
		of the review. For other sections not covered by the systematic review, searches were undertaken as normal.
Moderate	Fully applicable	Details of included studies were used instead of undertaking a new literature search. Full-text papers of included studies were still retrieved for the purposes of data analysis. Searches were only done to cover the period of time since the search date of the review.
Moderate	Partially applicable	Details of included studies were used instead of undertaking a new literature search for the relevant subsection of the protocol. For this section, searches were only done to cover the period of time since the search date of the review. For other sections not covered by the systematic review, searches were undertaken as normal.

For this review, the Cochrane review was assessed as being of high quality and fully applicable, however additional searches were not done for this review because the Cochrane review is currently in the process of being updated and the duplication of effort would not have been useful. Communication with the Cochrane review team reassured the committee that the updated review would not show any meaningfully different effect sizes for any of the outcomes.

Appendix C: Literature search strategies

NICE did not undertake any literature searches for this review question. Below are details of the searches undertaken by the Cochrane review authors.

Cochrane Review Revised Search Strategies January 2009 to April 2015

CENTRAL via 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 2015

(Last line **restricted** to “Trials”, and to date range 2009 to 2015)

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"

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 20012:2015.(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
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 "randomi?ed 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 analys?s"	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	Search modes - Boolean/Phrase

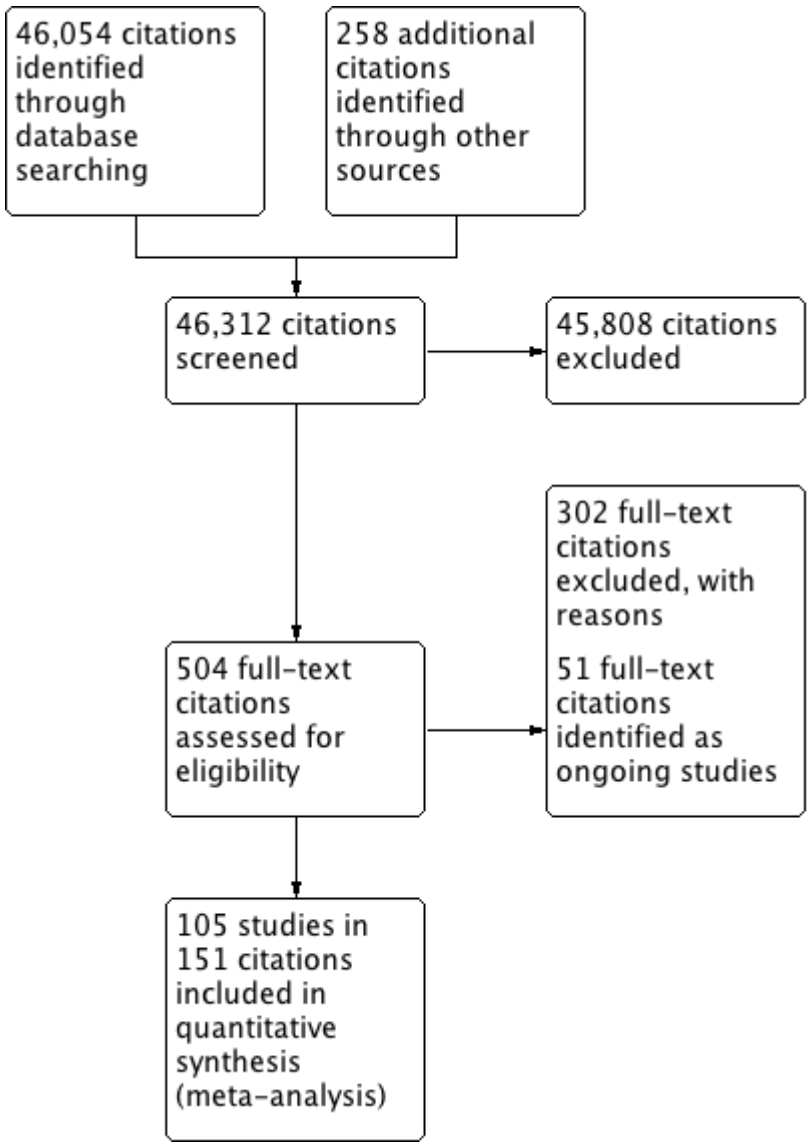
	(decision* N3 technolog*) or (decision* N3 technique*) or (decision* N3 system*) or (decision* N3 program*) or (decision* N3 algorithm*) or (decision* N3 process*) or (decision* N3 method*) or (decision* N3 intervention*) or (decision* N3 material*)	
S5	("decision making" or "choice behavior") and MH consent	Search modes - Boolean/Phrase
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

1

2

3

Appendix D: Cochrane clinical evidence study selection



Appendix E: Evidence tables

Systematic review

Cochrane review (Stacey et al, 2017)

Study type	Systematic review
Databases searched	• Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 6) in the Cochrane Library (searched to 24 April 2015). • MEDLINE Ovid (1966 to 24 April 2015). • Embase Ovid (1980 to 24 April 2015). • PsycINFO Ovid (1806 to 24 April 2015). • CINAHL Ovid (1982 to September 2008), then in Ebsco (to 24 April 2015).
Study inclusion criteria	Published studies that used a randomized controlled trial (RCT) design evaluating patient decision aids.
Study exclusion criteria	
Participant inclusion criteria	Adults aged 18 years or older who were making decisions about screening or treatment options for themselves, a child, or an incapacitated significant other
Participant exclusion criteria	Studies in which participants were making hypothetical choices.
Interventions	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 deliberated choices among options (including the status quo), by making the decision explicit and by providing (at the minimum) information on the options and outcomes relevant to a person's health status as well as implicit methods to clarify values. Studies were excluded if interventions focused on: decisions about lifestyle changes, clinical trial entry, or general advance directives (e.g. do not resuscitate); education programmes not geared to a specific decision; and interventions designed to promote adherence or elicit informed consent regarding a recommended option. Studies when the relevant decision aid(s) were not available and not adequately described in the article(s) were also excluded.
Outcome measures	***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*

Study type	Systematic review
	informed patient (demonstrated by outcomes such as knowledge, accurate risk perceptions, values-choice congruence)? • *Attributes of the decision-making process: does the patient decision aid help patients to recognize that a decision needs to be made, feel informed about the options and their features, be clear about the option features that matter most, discuss values with their clinician, and become involved in decision making?* ***Other decision-making process variables*** • *Decisional conflict* • *Patient-clinician communication* • *Participation in decision making* • *Proportion undecided* • *Satisfaction with the choice, with the process of decision making, and with the preparation for decision making*
Risk of bias	• Study eligibility and criteria: Low risk of bias *Review adhered to pre-defined objectives and eligibility criteria. Eligibility criteria were unambiguous, relevant to review question and there without inappropriate restrictions.* • Identification and selection of studies: Low risk of bias *Search strategy was appropriate.* • Data collection and study appraisal: Low risk of bias *Sufficient study characteristics were provided, all relevant study results were collected, and a formal risk of bias assessment was conducted.* • Synthesis and findings: Low risk of bias *All relevant identified studies were included in the evidence synthesis and all pre-defined analyses were reported.* • Overall risk of bias: Low • Applicability: Fully applicable

Studies contained within systematic review

The evidence tables below were based on information provided in the Cochrane review. Risk of bias and directness domains were decided by the Guideline Updates Team.

Allen 2010

Methods	Cluster-randomized to decision aid vs usual care
Participants	398 + 414 men considering prostate cancer screening in the USA
Interventions	DA: computer tailored programme on clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step-by-step process for making the decision; interactive computer programme: inherently guided the patient through the decision aid and decision making

	process), tailored printout given to patients to promote discussion with others (practitioner, significant others) Comparator: no intervention
Outcomes	Primary outcomes: decisional status, knowledge, decision self-efficacy, decisional consistency Secondary outcomes: desire for involvement in decision making, decisional conflict, preferred options Outcomes assessed pre- and postintervention
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Sites were blocked on size and percent of male employees and randomly assigned by computer-generated random numbers to condition within blocks" (p 2173, Setting)
Allocation concealment (selection bias)	Unclear risk	The study does not address this criterion.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The study does not address this criterion.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes measured were not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data and low rate of attrition that was consistent between groups
Selective reporting (reporting bias)	Unclear risk	No mention of protocol
Other bias	Low risk	Intervention delivery: mention of money incentive to complete paperwork, but was

	judged to have no effect on outcomes measured (p 2175)

1 **Arterburn 2011**

Methods	Randomized 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) Comparator: usual care (general information pamphlets on clinical problem)
Outcomes	Primary outcomes: knowledge, values, values concordance Secondary outcomes: treatment preference, decisional conflict, decisional self-efficacy, proportion undecided Primary outcomes assessed at baseline, postintervention and 3 months follow-up; secondary outcomes assessed at baseline and postintervention
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[U]sed computer-assisted, block randomisation process to ensure balanced allocation of participants" (p 1670, Participants and randomization)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment and no mention of impact on study
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[S]tudy was not blinded" (p 1670, Participants and randomization); 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

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Measures: mentioned 4 choices for treatment preference (surgery, drug therapy, diet and/or exercise programme and unsure) but only reported on surgery and unsure options (p 1671); minimal attrition that was consistent between groups
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

1 **Auvinen 2004**

Methods	Randomized 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 Comparator: usual care by clinical guideline
Outcomes	Primary outcome: uptake of options Secondary outcome: participation in decision making Other outcomes (from Huang 2014): death (5 years), disease-free survival (10-years), biochemical failure (serum PSA elevation) (5 years), biochemical failure-free survival (5 years), disease progression (5 years), disease progression-free survival (5 years) (data from 104 + 106 men)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Auvinen 2001, p 2: "randomized centrally, using software based on a random number generator"; no blocking used Auvinen 2004, (primary study), p 1: "randomized using a computer algorithm based on random numbers"

Allocation concealment (selection bias)	Unclear risk	Auvinen 2001,p 2, Patients and Methods: randomized centrally at the Finnish Cancer Registry Auvinen 2004, (primary study), p 1: randomized centrally Comment: central allocation confers low risk
Blinding of participants and personnel (performance bias) All outcomes	High risk	Auvinen 2001, p 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 (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.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Auvinen 2001, p 3: flow-chart "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, not seen by urologist" (p 4) Auvinen 2004 (primary study), p 2: flow diagram and results; low attrition and consistent between groups
Selective reporting (reporting bias)	Unclear risk	No indication that trial registered in central trials registry. Auvinen 2001, p 2: "The study protocol was approved by an ethical committee in each participating hospital" Auvinen 2004 (primary study), p 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

1 **Barry 1997**

Methods	Randomized 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 Comparator: usual care using general information on the clinical problem
Outcomes	Primary outcome: knowledge Secondary outcomes: uptake of option, satisfaction with DM process, satisfaction with decision, interest in DM, general health outcomes, condition specific health outcomes
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Stratified by study site in concealed blocks of 10" (p 2)
Allocation concealment (selection bias)	Low risk	Study coordinator opening serially numbered, opaque, sealed envelopes (p 2)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Patient accrual and follow-up reported; post-randomization withdrawals could have biased the results (more in intervention group) - however they reported no evidence of a differential effect of the study group (p 3)

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

1 **Bekker 2004**

Methods	Randomized 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 (in consult): decision analysis plus routine consultation on options' outcomes, clinical problem, outcome probability, values clarification, guidance/coaching Comparator: routine consultation on options' outcomes, outcome probability
Outcomes	Primary outcome: anxiety Secondary outcomes: uptake of option, knowledge, decisional conflict, informed decision making, satisfaction with consultation, consultation length
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Bekker 2003, p 2 - section 2.3 Sample and Procedure: "randomly allocated... using previously numbered... envelopes" Bekker 2004 (primary study), p 3: "Participants were randomly allocated by previously numbered envelopes"; does not mention how sequence was generated
Allocation concealment (selection bias)	Low risk	Bekker 2003, p 2 - section 2.3 Sample and Procedure: "Using previously numbered, sealed, opaque envelopes" Bekker 2004 (primary study), p 3: previously numbered, sealed, opaque envelopes
Blinding of participants and personnel	Low risk	Participants blinded, personnel not blinded. Same personnel did control & intervention. Tape recorded sessions to ensure no bias

(performance bias) All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Bekker 2003 flow diagram indicates postrandomization attrition with more attrition in decision aid group; no discussion on implications of attrition Bekker 2004 (primary study), p 4: results/flow diagram; baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	Bekker 2003: the coding frame was developed from literature. Does not mention protocol Bekker 2004 (primary study): no information provided about central trials registry
Other bias	Unclear risk	Bekker 2003: does not directly address baseline characteristics of participants Bekker 2004 (primary study): appears to be free of other potential biases

1 **Bernstein 1998**

Methods	Randomized 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 Comparator: usual care (no information provided)
Outcomes	Primary outcome: satisfaction with decision and decision making process Secondary outcomes: uptake of option, knowledge, satisfaction with care, general health outcomes, condition specific health outcomes
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was stratified by study site in blocks of 10" (p 3)
Allocation concealment (selection bias)	Low risk	"[R]andomization performed by a study coordinator opening opaque, sealed envelopes at study headquarters" (p 3)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3); low attrition of eligible participants randomized and consistent between group
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

1 **Berry 2013**

Methods	Randomized 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) Comparator: usual care
Outcomes	Primary outcome: decisional conflict Secondary outcome: preferred/actual treatment choice (pre- and post-DA), proportion undecided Other outcomes (Bosco 2012): choice concordance (6 months post-DA). (Data from 239 + 209 men)

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Methods section- second paragraph, p 3: "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	Methods section, p 3: "Participants were randomized automatically by the P3P application to study groups"
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis and low dropout (p 4)
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

1 **Bjorklund 2012**

Methods	Randomized 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) Comparator: usual care using pamphlet

Outcomes	Primary outcomes: knowledge (post-DA), attitude (post-DA), uptake of combined ultrasound and biochemical screening (post-DA) Secondary outcomes: values congruent with chosen option (post-DA)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"The midwife allocated the participants randomly by sealed envelopes" (p 391) but does not state the actual sequence generation method
Allocation concealment (selection bias)	Low risk	Used sealed envelopes, "prepared, sequentially coded and distributed to the maternity units by the research group" (p 391)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"It was not possible to blind neither [sic] the midwives nor the participants due to the characteristics of the intervention" (p 395). The study does not address the effects of this on the results
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but outcomes were objectively measured and not subjective to interpretation
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

1 **Bozic 2013**

Methods	Randomized to decision aid vs usual care
Participants	95 + 103 participants with hip and/or knee osteoarthritis considering hip/knee surgery

Interventions	DA: DVD and booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, and guidance/coaching with health coach Comparator: usual care using pamphlet
Outcomes	Primary outcomes: informed decision/knowledge (pre, immediately post, and 6 weeks follow-up) Secondary outcomes: preferred treatment choice (pre and immediately post), patient and provider satisfaction (immediately post), length of consultation time
Notes	Trial registration: NCT01492257

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomization was blocked with use of random permuted blocks in groups of four, six, or eight to help ensure that the groups were balanced" (p 1634)
Allocation concealment (selection bias)	Low risk	"Patients were randomized to either the intervention group or the control group with use of the sealed envelop method" (p 1634)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[S]urgeons were not blinded to the intervention" (p 1635). Knowing the allocation of participants, surgeons' favourable scoring could be due to greater investment in decision-making. Insufficient information to make a judgment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes are objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	62% (123/198) retention rate therefore high attrition rate - however the attrition was balanced between groups
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Low risk	Appears to be free of other sources of bias

1 **Brazell 2014**

Methods	Randomized to DA + standard counselling vs usual care + standard counselling
Participants	53 + 51 women presenting for the management and treatment of pelvic organ prolapse
Interventions	DA: paper-based or web-based DA on clinical problem, options' outcomes, outcome probabilities, patient stories and standard counselling Comparator: standard counselling alone
Outcomes	Primary outcomes: decisional conflict (immediately postconsultation) Secondary outcomes: choice (3 months after making decision), decisional regret (3 months after making decision)
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Patients were randomized 1:1 using a random numbers table in blocks of 6" (p 231)
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided to make judgment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High attrition but balanced between groups: "39 randomized subjects were either missed by the research assistant at their new patient visit and thus did not receive a DCS questionnaire

		to complete or they canceled their appointments and did not reschedule a new one" (p 233). There was a 48% (50/104) attrition rate for Decisional Regret measures.
Selective reporting (reporting bias)	Low risk	Trial registered
Other bias	High risk	Risk of contamination due to same physicians in both groups. Also, outcomes measured after the PtDA and physician consult

1 **Chabrera 2015**

Methods	Randomized to DA vs usual care
Participants	73 + 74 men recently diagnosed with prostate cancer considering treatment options
Interventions	DA: 2-part decision support booklet with clinical problem, options' outcomes, outcome probabilities, patient stories, explicit values clarification, and guidance Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict, satisfaction with decision-making process Secondary outcome: coping Outcomes assessed at 3 months postintervention
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[S]tudy participants were randomized into 1 of 2 arms using a computer-generated random list with unequal blocks" (p E44)
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided to make judgment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make judgment

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Balanced attrition in both groups
Selective reporting (reporting bias)	Unclear risk	No protocol provided; trial not registered
Other bias	Unclear risk	Prostate cancer in Catalonia is common; however, only 147 were recruited for this trial (p E44)

1 **Chambers 2012**

Methods	Randomized 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 Comparator: usual care using pamphlet
Outcomes	Primary outcomes: confidence in decision (post-DA) Secondary outcomes: impact on immunization intent (post-DA), proportion undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomization list was generated using the randomization function in Excel 2002 (version 10.6856.6856 SP3)" (p 199)
Allocation concealment (selection bias)	Low risk	"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." (p 199)
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
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

1 **Clancy 1988**

Methods	Randomized 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 Comparator: usual care (no information provided)
Outcomes	Uptake of option
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers table; all incoming residents were assigned to Group 2 (non-randomized residents identified as subgroup) (p 2)

Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding of participants or personnel. Did not report on how this may affect their findings
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but decisions for screening were retrieved from health records (objective data)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow chart not included. Insufficient information to make a judgment
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	High risk	Potential selection bias - non-randomized residents were added to group 2 and therefore potential unbalanced distribution (p 287) Low response rate among those offered decision analysis

1 **Davison 1997**

Methods	Randomized 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 Comparator: usual care (general information pamphlets on clinical problem)
Outcomes	Primary outcomes: role in decision making Secondary outcomes: anxiety, depression
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	"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." (p 5, Data collection)
Allocation concealment (selection bias)	Unclear risk	Not mentioned; group assignment predetermined by block randomization procedure (p 5)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; study does not report on how the results could be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding and whether outcomes could be affected by unblinded assessor
Incomplete outcome data (attrition bias) All outcomes	Low risk	No flow diagram; p 12 explains why certain men did not listen to audiotape. All men approached by study investigator agreed to participate; only 1 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

1 **De Achaval 2012**

Methods	Randomized to detailed vs simple vs usual care
Participants	70 + 70 + 71 patients diagnosed with knee osteoarthritis considering treatment in the USA
Interventions	Complex DA: video booklet + interactive joint analysis on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (list of questions) Comparator DA: video booklet on options' outcomes, clinical problem, outcome probabilities, others' opinion and guidance (list of questions) Comparator: usual care receiving generic booklet
Outcomes	Decisional conflict (baseline and postintervention)

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated list with uneven blocks (p 231)
Allocation concealment (selection bias)	Low risk	Numbered, sealed and opaque envelopes (p 231)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Likely not blinded, but low threat of bias in study (p 231)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Participants were not blinded but outcome was objectively measured (p 231)
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

1 **Dolan 2002**

Methods	Randomized 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 Comparator: usual care with information on options, clinical problem
Outcomes	Primary outcomes: uptake of option, decisional conflict Secondary outcomes: role in decision making

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomization schedules were created using a computer random number generator" (p 2, Study interventions)
Allocation concealment (selection bias)	Low risk	Computer-based (p 2, Study interventions)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram - low attrition
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

1 **Evans 2010**

Methods	Randomized 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 programme on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer programme; summary) Comparator: paper version of online DA on options' outcomes, clinical problem, outcome probabilities, explicit

	values clarification, others' opinion, guidance (interactive computer programme; summary) Comparator: received a questionnaire Comparator: received nothing
Outcomes	Primary outcomes: knowledge (post-DA) Secondary outcomes: attitude (post-DA), intention to undergo PSA testing (post-DA), anxiety (post-DA), uptake of PSA test (post-DA), total decisional conflict
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"[A] random sample of 100 men was selected from the list." "The process ensured individual level randomization" (p 4, Recruitment process)
Allocation concealment (selection bias)	Low risk	"[A]ffirmative 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" (p 4, Recruitment process)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram indicating high attrition consistently across groups
Selective reporting (reporting bias)	Low risk	Registered as a trial

Other bias	Low risk	The study appears free of other sources of bias

1 **Fagerlin 2011**

Methods	Decision aid vs delayed intervention vs control
Participants	382 + 159 + 100 women with an elevated 5-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 Comparator 1: given DA after 3-month follow-up Comparator 2: given DA after all outcome measures were taken
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) Other outcomes: • Banegas 2013: decisional conflict (post-DA) (data from 690 + 160 + 162 women), proportion undecided (3 months) • Korfage 2013: knowledge (immediately post and 3 months post-DA), attitudes (immediately post and 3 months post-DA), behavioural intent (post-DA), actual behaviour (3 months post-DA), informed decision defined as "participants with sufficient knowledge about chemoprevention behavior, whose attitudes were concordant with their intentions or decisions to engage in chemoprevention behavior" (data from 383 + 102 + 100 women).
Notes	Primary outcome was not specified

Risk of bias

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

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding - using an online decision aid would have avoided control participants accessing the decision aid
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Does not report exclusions; inadequate reporting on participant flow through the study to determine risk for attrition bias or incomplete outcome data
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	Low risk	Appears to be free of other sources of bias

1 **Fraenkel 2007**

Methods	Randomized 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 Comparator: usual care using the Arthritis Foundation information pamphlet
Outcomes	Decisional self-efficacy, preparation for decision making
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated randomization sequence (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided; computer generated

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding but study does not report if it had an 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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low risk of attrition bias - outcome data for all 40 controls and 44 of 47 intervention (p 3, Results)
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

1 **Fraenkel 2012**

Methods	Cluster-randomized control trial of clinics to decision aid versus usual care
Participants	69 + 66 patients with nonvalvular atrial fibrillation considering anticoagulation with aspirin or warfarin
Interventions	DA: computer-based tool on options' outcomes, clinical problem, options' probabilities, guidance, explicit values clarification Comparator: control arm (no further information provided)
Outcomes	Primary outcomes: feeling informed and having clear values (baseline, immediately post) Secondary outcomes: knowledge (baseline, immediately post), accuracy of risk (baseline, immediately post), anxiety (baseline, immediately post), worry (baseline, immediately post), rationale for preferred treatment (during the encounter - DA group only), discussion of related outcomes (during the encounter as captured on audiotape), change in treatment plan (post intervention), anxiety, accurate risk expectations (stroke, bleeding)
Notes	Trial registration NCT00829478

Risk of bias

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Unclear risk	Inadequate information on random sequence generation
Allocation concealment (selection bias)	Unclear risk	inadequate information on allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"To avoid contamination, participants were randomized at the level of the firm so that all participants in one firm received the intervention, and all participants in the second firm were included in the control arm" (p 1435)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"An interviewer blinded to the participant's group assignment reassessed the primary and secondary outcomes after participant's primary care visit" (p 1436)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Does not appear to be incomplete outcome data; flow diagram does not report participation beyond randomization
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Low risk	Does not appear to be any other potential sources of bias

1 **Frosch 2008a**

Methods	Randomized 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 Comparator 1: information on options' outcomes, clinical problem, outcome probabilities, others' opinions, explicit values clarification (utilities for outcomes associated with prostate cancer)

	Comparator 2: explicit values clarification (utilities for outcomes associated with prostate cancer) Comparator 3: usual care using public information on prostate cancer screening on American Cancer Society and Centers for Disease Control and Prevention websites 2005-2006
Outcomes	Primary outcomes: knowledge, actual option, decisional conflict Secondary outcomes: concern about prostate cancer, treatment preference if prostate cancer diagnosed
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
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
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
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; minimal attrition
Selective reporting (reporting bias)	Unclear risk	No indication of published protocol
Other bias	Low risk	Appears to be free of other potential biases

1 **Gattellari 2003**

Methods	Randomized 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 Comparator: 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	Pre-randomized code - no further information (p 1)
Allocation concealment (selection bias)	Low risk	Pre-randomized code unobtrusively marked on envelopes (p 1)
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Pre-test characteristics included. Flow chart not included and reasons for attrition not mentioned; some attrition but balanced between groups
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

1 **Gattellari 2005**

Methods	Randomized 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 Comparator 1: video on clinical problem, outcome probability, others' opinion Comparator 2: 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	Unique identification codes assigned to participants according to date and time enrolled into the interventional component of the study. Block randomization of identification codes then performed via computer software (p 2 - 2.3.1)
Allocation concealment (selection bias)	Low risk	"Allocation concealment was ensured as the interviewers, responsible for enrolling participants onto the trial, were blinded to the randomized 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." (p 2 - 2.3.1)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and 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

Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal attrition that is consistent across groups (figure 1)
Selective reporting (reporting bias)	Unclear risk	"[S]uccess 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 (p 13, paragraph 5)
Other bias	Low risk	"[H]igh follow-up rate and allocation concealment; study not subjected to selection bias" (p 13, paragraph 5). Appears to be free of other sources of bias

1 **Green 2001**

Methods	Randomized 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 Comparator: counselling Comparator: usual care
Outcomes	Primary outcome: preferred options Secondary outcome: knowledge
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[B]lock randomization schedule to one of three groups in a 2:2:1 ratio" (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel	Unclear risk	"[G]enetic counsellor blinded to randomization until just prior to the session" (p 2), unclear if participants were blinded

(performance bias) All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Values do not always add up to the number of participants due to missing data"; reasons not mentioned (p 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

1 **Hamann 2006**

Methods	Cluster-randomized trial of decision aid vs usual care
Participants	54 + 59 patients with schizophraenia considering treatment options (cluster-RCT with 12 wards paired and randomized) in Germany
Interventions	DA: 16-page booklet on options' outcomes, outcome probabilities, explicit values clarification, coaching/guidance Comparator: 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	"[O]ne member of each pair being randomly assigned to the control or to the interventional condition" (p 266). Sequence generation method was not stated

Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
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
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

1 **Hanson 2011**

Methods	Randomized 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) Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (3 months post-DA) Secondary outcomes: surrogate knowledge, risk perceptions, 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	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerized random number generation (p 2010, Randomization)
Allocation concealment (selection bias)	Unclear risk	No description of method used to conceal allocation (p 2010, Randomization)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Cluster randomization prevented double blinding and may have introduced bias due to site effects" (p 2014, Discussion); study authors unsure of effect on study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[B]ecause of cluster randomization, data collectors were not blinded to group assignment" (p 2010, Randomization); authors believe has little impact on study
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Intervention group missing data for 1 participant, reason for omission not reported (table 1) No explanation for number of participants in each group (n = 127) given numbers vary from those in 'recruitment and retention' figure (table 4)
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

1 **Heller 2008**

Methods	Randomized to decision aid vs usual care
Participants	66 + 67 breast cancer patients eligible for breast reconstruction in the USA
Interventions	DA: interactive software programme on options' outcomes, others' opinions Comparator: 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	"upon study entry, the participants were randomized (computer generated) to one of two groups" (p 2)
Allocation concealment (selection bias)	Unclear risk	Not enough information provided
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline anxiety and knowledge included in graphs. Participant numbers between study groups balanced (p 3). 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

1 **Hess 2012**

Methods	Randomized 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 (in consultation): 1-page printout on options' outcomes, clinical problem, and outcome probabilities Comparator: usual care

Outcomes	Primary outcomes: knowledge Secondary outcomes: risk perceptions, decisional conflict, actual choice, satisfaction with decision making process, patient-practitioner communication
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"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" (p 253)
Allocation concealment (selection bias)	Low risk	"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" (p 253)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel were blinded, but unclear if patients were blinded (p 253, Outcome measures). However, the primary outcome is unlikely to be biased.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Investigators assessing outcomes were blinded (p 253, Outcome measures).
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

1 **Jibaja-Weiss 2011**

Methods	Randomized to decision aid vs usual care
Participants	51 + 49 women diagnosed with breast cancer considering surgical treatment in the USA

Interventions	DA: computer programme on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step-by-step process for making the decision) Comparator: 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), proportion undecided
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients at each hospital were randomized using permuted blocks" (p 42, Methods section)
Allocation concealment (selection bias)	Unclear risk	Not addressed in the study
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There is no way to know if the plots include 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

1 **Johnson 2006**

Methods	Randomized to decision aid vs usual care
Participants	32 + 35 patients considering endodontic treatment options in the USA
Interventions	DA (in consultation): decision board on options' outcomes, clinical problem, outcome probability, guidance Comparator: usual care
Outcomes	Primary outcomes: knowledge, satisfaction with decision making process, anxiety
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[F]our computerized random generation lists to assign to one of two groups" (p 3)
Allocation concealment (selection bias)	Unclear risk	Not for residents: computer-generated randomization lists (1 for each resident) were prepared by the PI (p 3-4); therefore residents would have had pre-generated lists; Unclear for patients: "allocation was concealed from patients" (p 3) but does not explain how
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not mentioned. Allocation was concealed from patients only (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 6); 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 (p 5)

Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Unclear risk	"[B]aseline data obtained because possible that clinicians training in the EndoDB would alter usual care discussions" (p 5). Mentions taking baseline characteristics, but not included in article

1 **Kasper 2008**

Methods	Randomized 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) Comparator: information material on immunotherapy (80 pages)
Outcomes	Primary outcomes: role in decision making Secondary outcomes: choice, feeling undecided, helpfulness with making a decision, attitudes toward immunotherapy, expectations of side effects realized at 6 months
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[A]llocation using computer generated random numbers" (p 5)
Allocation concealment (selection bias)	Unclear risk	Randomization was carried out by concealed allocation, but method of concealment was not described (p 2, Assignment)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were not told whether the information they received was standard information or the newly developed DA (p 3, Masking)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were not told whether the information they received was standard information or the newly developed DA (p 3, Masking)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow of participants (p 2, Fig 1); baseline data/characteristics included
Selective reporting (reporting bias)	Low risk	"The protocol of this study has been published with the trial registration at http://controlled-trials.com/ ISRCTN25267500" (p 2)
Other bias	Unclear risk	Difference in preferred interaction style between groups at baseline (P value 0.04) (p 5)

1 **Kennedy 2002**

Methods	Randomized 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 seeing physician Comparator: usual care
Outcomes	Primary outcomes: general quality of life Secondary outcomes: uptake of option, satisfaction, menorrhagia severity, cost-effectiveness
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Allocation sequence was generated by computer and stratified by consultant and the age at which the woman left full-time education (p 3)

Allocation concealment (selection bias)	Low risk	"Secure randomization ensured by using a central telephone randomization system" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Possibility of contamination bias; clinicians could have applied the experience gained from consultations with the interventions groups in their consultations with the control group (p 6)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Table 1 and Figure 1 flow diagram (p 4-5)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free from other risks of bias

1 **Knops 2014**

Methods	Randomized to decision aid vs usual care
Participants	91 + 87 patients with asymptomatic abdominal aortic aneurysm considering elective surgery vs watchful waiting
Interventions	DA: interactive CD-ROM on options' outcomes, clinical problem, outcome probabilities, explicit values clarification Comparator: usual care with regular information
Outcomes	Primary outcomes: decisional conflict (baseline, 1, 4, and 10 months) Secondary outcomes: patient knowledge (baseline and 1 month), anxiety (baseline, 1, 4, and 10 months), satisfaction with conversation with the surgeon (baseline and 1 month), final treatment choice (10 months), aneurysm rupture (10 months), possible date of surgery (10 months), postoperative morbidity and mortality (10 months), physical quality of life (baseline, 1, 4, and 10 months)
Notes	Trial registration: NTR1524

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Computer-generated randomisation ALEA v.2.2, NKI-AVL, the Netherlands) was performed by the investigators" (p 2)
Allocation concealment (selection bias)	Low risk	"Computer-generated randomisation ALEA v.2.2, NKI-AVL, the Netherlands) was performed by the investigators" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients and investigators could not be blinded after group assignment, a factor which is inherent to the decision aid and the design of the study. Surgeons and nurses involved in the outpatient care of the participants were blinded to the patient's allocation group, although patients were not prohibited from sharing their allocation with them." (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome measurement is not likely to be influenced by lack of blinding as all outcomes were measured objectively using validated scales and data retrieved from medial records.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Appears to have similar attrition between groups. The proportion of values missing varied from 2% to 9% per outcome measure. Missing values were completed by multiple imputation analysis. If one of the outcome measures had more than 25% missing values, that outcome measure for that patient was excluded from analysis. Therefore, missing data have been handled appropriately (p 3).
Selective reporting (reporting bias)	Unclear risk	Insufficient information to make judgment
Other bias	High risk	"Considerable number of patients could not be included, were not asked to participation, or declined to participate. Selection bias may have occured in patients that were not included" (p 6) "Both patients and surgeons were aware of the aim and subject of the study and could not be blinded to the allocation. It is possible that

		surgeons in the contributing centres offered more than average information to their patients" (p 6). Performance bias may have been introduced in terms of altered communication style.

1 **Krist 2007**

Methods	Randomized 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 Comparator: web-site with same information as paper based DA Comparator: usual care
Outcomes	Primary outcomes: role in decision making Secondary outcomes: knowledge, decisional conflict, time spent discussing screening, choice (PSA test ordered)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]oordinator referred to pre-generated randomisation tables to inform the participant to which arm he was randomised" (p 2)
Allocation concealment (selection bias)	Low risk	At the time of enrolment, the allocation was concealed from the coordinator (p 2)
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	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

bias) All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	p 3, Results; p 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

1 **Kupke 2013**

Methods	Cluster-randomized trial of 2 groups of dental students to decision board group and non-decision board group. Patients randomized to students in either group.
Participants	57 + 36 patients with defect in posterior tooth (Class II defect) considering 6 treatment options, including no therapy
Interventions	DA (in consultation): options' outcomes, outcome probabilities Comparator: usual care with discussion of the treatment options
Outcomes	Knowledge (costs/self-payment, survival rate, characteristics and treatment time) (postintervention); overall satisfaction with consultation (postintervention)
Notes	Primary outcome not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomly assigned by a dice (selection of students and patient allocation) (p 20)
Allocation concealment (selection bias)	High risk	"The patients were assigned to the students according to common standards of the university independently and without knowing which group the student belonged to." (p 20)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients were assigned to the students independently and without knowing which group the students belonged to" (p 20)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge if blinding of outcome assessment occurred
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attribution in both groups; "missing answers were treated as incorrect answers, while illegible answers were treated as missing values" (p 22)
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol or trial registration. No way to ensure the outcomes they intended to measure are fully reported
Other bias	High risk	Did not adjust for clustering in analysis

1 **Kuppermann 2014**

Methods	Randomized to decision aid vs usual care
Participants	375 + 369 11-week pregnant women who had not yet undergone prenatal screening or diagnostic testing
Interventions	DA: describes clinical condition, options, outcome probabilities, values clarification Comparator: usual care
Outcomes	Primary outcomes: invasive prenatal diagnostic testing (3 to 6 months) Secondary outcomes: testing strategy undergone (3 to 6 months), knowledge (3 to 6 months), accurate risk perception (procedure related miscarriage, DS affected fetus) (3 to 6 months), decisional conflict (3 to 6 months), decisional regret (3 to 6 months)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	"A computer generated random allocation sequence assigned participants to experimental groups within permuted blocks of random size, with a 1:1 allocation ratio, stratified by age, clinical site, parity, and interviewer" (p 1211)
Allocation concealment (selection bias)	Low risk	"The randomization code was not available to any study-related personnel until data analysis was complete" (p 1211)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Different research associates facilitated baseline and follow-up interviews and medical record review to ensure blinding to the randomization assignment" (p 1211)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Different research associates facilitated baseline and follow-up interviews and medical record review to ensure blinding to the randomization assignment" (p 1211)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attrition in both groups. "[A]ll reported analyses were based on a modified intention-to-treat sample" (p 1211)
Selective reporting (reporting bias)	Low risk	Trial registered
Other bias	Low risk	Appears to be free of other sources of bias

1 **Lam 2013**

Methods	Randomized to decision aid or standard information booklet after initial consultation
Participants	138 + 138 women considering breast cancer surgery for early-stage breast cancer
Interventions	DA: take-home booklet on clinical problem, options' outcomes, outcome probabilities, guidance, explicit values clarification Comparator: standard information booklet
Outcomes	Primary outcomes: treatment decision making difficulties and decisional conflict scale at 1 week post consultation, knowledge at 1-week postconsultation, decision regret at 1 month after surgery Secondary outcomes: postoperative psychological distress (anxiety and depression) at 1, 4, and 10 months after surgery,

	decision regret at 4 and 10 months after surgery, treatment decision
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patient assignment to treatment and control arms was performed using a prior computer-generated random-number sequence" (p 2880)
Allocation concealment (selection bias)	Low risk	"A serially labeled, opaque, sealed-envelope method was used for block randomization" (p 2880)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Two research staff members - one responsible for preintervention assessment and block allocation and the other for postintervention assessments - ensured that the researcher performing follow-up assessments was blinded regarding women's allocation status." "Blinding surgeons to allocation status proved impractical." (p 2880)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	1 research staff member was responsible for postintervention assessments to ensure that the researcher performing follow-up assessments was blinded regarding women's allocation status (p 2880).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data; similar attrition in both groups
Selective reporting (reporting bias)	Low risk	Study protocol available online with published study
Other bias	Low risk	Does not appear to be subject to other sources of bias

1 **Langston 2010**

Methods	Randomized 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 Comparator: usual care
Outcomes	Primary outcomes: proportion of participants choosing very effective contraceptive method (post-DA and consult) Secondary outcomes: 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	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Using a random-number table, we determined the sequence for 1:1 allocation constrained by blocks of 10" (p 363, Methods-study procedures)
Allocation concealment (selection bias)	Low risk	"Randomization assignments were sealed inside numbered, opaque envelopes" (p 363, Methods-study procedures)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"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 asked not to change their counselling" (p 363, Methods-study procedures)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	For "method initiation on the day of the procedure" it is only said that the "[p]articipants 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

1 **Laupacis 2006**

Methods	Randomized 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) Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: uptake of option, satisfaction with decision making process, satisfaction with decision, accurate risk perceptions
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization envelopes were prepared centrally by a statistician" (p 2)
Allocation concealment (selection bias)	Low risk	"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." (p 2)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results, p 4; 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

1 **LeBlanc 2015**

Methods	Randomized to decision aid vs individualized score only vs usual care
Participants	32 + 33 + 14 women over 50 years diagnosed with osteopenia or osteoporosis not taking biphosphonates or other prescription medication
Interventions	DA (in consultation): clinical problem, individualized risk of condition, options' outcomes, guidance Comparator 1: individualized risk Comparator 2: usual care
Outcomes	Primary outcomes: knowledge (immediately post), decisional conflict (immediately post), participation in decision-making process (immediately post), decision to start (immediately post), adherence (6 months), acceptability (timing not specified), satisfaction with the decision-making process (not specified), quality of life (not specified), time (review of video consultation) Secondary outcome: decision quality (not reported)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were allocated using a computer-generated sequence that randomized them 1:1:1 in a concealed fashion" (p 5)

Allocation concealment (selection bias)	Low risk	"Patients were allocated using a computer-generated sequence that randomized them 1:1:1 in a concealed fashion" (p 5)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients and clinicians were aware of the overall objective, presented as improvement in communication between patients and clinicians during the clinical encounter, but remained blinded to the specific aims" (p 5)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"After randomization, only data analysts remained blind to allocation" (p 5)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis; similar attrition in both groups
Selective reporting (reporting bias)	Unclear risk	Trial registered; Checklists available for CONSORT and protocol. Sample size originally calculated based on adherence but re-calculated for decisional conflict given inability to reach original target
Other bias	High risk	"Possible contamination at the clinician level (i.e. clinician who, having used the decision aid with a prior patient, recreates elements of the decision aid with a subsequent patient allocated to receive FRAX alone or usual care) was monitored by a detailed review of the available video recorded encounters" (p 5)

1 **Legare 2008a**

Methods	Randomized 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) Comparator: general information brochure on the clinical problem (did not address risks and benefits)
Outcomes	Primary outcomes: decisional conflict

	Secondary outcomes: knowledge of natural health products in general (not specific option outcomes), preferred choice, values-choice agreement, proportion undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomization scheme was carried out by a biostatistician using computer-generated unequal blocks.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes containing 1 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.
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 to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	See Figure 1 for flow diagram, reason for loss to follow-up was described.
Selective reporting (reporting bias)	Low risk	Trial registration identifier is NCT00325923
Other bias	Low risk	No statistically significant difference in women's characteristics between groups (Table 1)

1 **Legare 2011**

Methods	Cluster-randomized to decision aid vs usual care
Participants	245 + 214 patients with non-emergent acute respiratory infections considering using antibiotics in Canada

Interventions	DA (in consultation): pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance and coaching Comparator: delayed intervention
Outcomes	Primary outcomes: • Patient outcomes: actual choice (pre and post-DA), perceived decision quality (pre and post-DA), decisional conflict (pre and post-DA), decision regret (pre and post-DA), general health outcomes • Practitioner outcomes: decision, perceived decision quality, decisional conflict Secondary outcomes: • Patient outcomes: intention to engage in future SDM (pre and post-DA), participation in decision making • Practitioner outcomes: intention to engage in future SDM and comply with clinical practice guidelines
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A biostatistician simultaneously randomised all FMGs and allocated them to groups using Internet-based software" (p 99)
Allocation concealment (selection bias)	Low risk	"Using Internet-based software" (p 99)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding of participants and personnel: only biostatistician was blinded (p 99)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biostatistician who assesses the outcomes is blinded, outcomes were objectively measured (p 99)
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appear 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

1 **Legare 2012**

Methods	Cluster-randomized controlled trial to decision aid vs usual care
Participants	239+210 adults and children with with a diagnosis of acute respiratory infection (e.g., bronchitis, otitis media, pharyngitis, rhinosinusitis)
Interventions	DA (in consultation): pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance and coaching (participating physicians also received training in the form of a 2-hour online tutorial and a 2-hour on-site interactive workshop). Comparator: usual care
Outcomes	Primary outcome: use of antibiotics (immediately post consultation) Secondary outcomes: decisional conflict (immediately post), control preference scale (immediately post), quality of decision (immediately post), adherence to the decision (2 weeks post), repeat consultation (2 weeks post), decisional regret (2 weeks post), quality of life (2 weeks post) and intention to engage in SDM in future consultations regarding antibiotics for acute respiratory infections (2 weeks post)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A biostatistician used internet-based software to simultaneously randomize all 12 family practice teaching units to either the intervention group or control group. The teaching units were stratified according to rural or urban location" (p E728)
Allocation concealment (selection bias)	Low risk	"A biostatistician used internet-based software to simultaneously randomize all 12 family practice teaching units to either the intervention group or control group. The

		teaching units were stratified according to rural or urban location" (p E728)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients with symptoms suggestive of an acute respiratory infection were initially recruited by a RA in the waiting room before consultation with a physician" (p E728)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The biostatistician was unaware of group allocation, the researchers and research assistants who recruited patients and collected data were not" and "Statistical analysis was performed by a statistician who was unaware of the teaching unit allocations" (p E729)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol registered and published
Other bias	Low risk	"To avoid contamination bias, access to the online tutorial was denied to providers in the control group during the trial" (p E728)

1 **Leighl 2011**

Methods	Randomized 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) Comparator: usual care
Outcomes	Primary outcomes: knowledge (post-DA), satisfaction with decision (post-DA) Secondary outcomes: anxiety (pre and 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), quality of life (post-DA)

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomized lists (p 2078, Study design)
Allocation concealment (selection bias)	Low risk	Code concealed in sealed envelopes until time of random assignment (p 2078, Study design)
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	31% dropout rate, 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

1 **Lepore 2012**

Methods	Randomized to decision support intervention (decision coaching by telephone + educational pamphlet) vs control
Participants	244 + 246 African American men aged 45-70 in the USA
Interventions	DA: condition-specific educational pamphlet on prostate cancer screening and tailored telephone education on options' outcomes, explicit values clarification, others' opinions, and guidance (decision coaching) Comparator: attention control (education on fruit and vegetable consumption)

Outcomes	Primary outcomes: knowledge (pretest and post-test at 8 months postrandomization), decisional conflict (posttest), physician visit to discuss testing (post-test), adherence as congruence between testing intentions and behaviors (post-test) Secondary outcomes: testing intention (post-test), benefit-to-risk ratio of testing (post-test), PSA screening (post-test), anxiety (pretest and post-test)
Notes	Trial registration NCT01415375

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The principal investigator used a computer-generated randomization schedule to randomize the participant." (p 322)
Allocation concealment (selection bias)	Unclear risk	"The principal investigator used a computer-generated randomization schedule to randomize the participant and emailed the randomization assignment to the interventionist." (p 322)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Interventionists were not blind to condition. We can assume that patients were blinded as the study design was a telephone call for both intervention and control groups (p 322)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Data collectors were blind to condition but the interventionists were not" (p 322).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data
Selective reporting (reporting bias)	Low risk	Appears to have reported on all pre-specified outcomes (protocol).
Other bias	Low risk	Appears to be free of other potential sources of bias

1 **Lerman 1997**

Methods	Randomized 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 Comparator: no intervention
Outcomes	Primary outcome: preferred option Secondary outcomes: knowledge, accurate risk perceptions, perceived personal risk/benefits/limitations, agreement between values and choice
Notes	—

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
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 440 women, 400 completed 1-month follow-up interviews; no reasons provided; baseline data/characteristics included (p 2)
Selective reporting (reporting bias)	Unclear risk	No information provided

Other bias	Low risk	Appears to be free of other potential biases

1 **Lewis 2010**

Methods	Cluster-randomized to decision aid vs usual care
Participants	211 + 232 patients considering colorectal cancer 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) Comparator: usual care using Aetna annual reminders to obtain CRC screening
Outcomes	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) **Practice level measures:** assess CRC screening practices (pre, post-DA), referrals (pre, post-DA), quality improvement initiatives
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomisation was done using matched pairs and a blocking procedure." (p 2, Practice recruitment and randomization section)

Allocation concealment (selection bias)	Unclear risk	"Thus, purposive assignment to treatment group was used, resulting in a hybrid randomisation" (p 3, Practice recruitment and randomization section). There is no mention of the effect of this purposive assignment on the study
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.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appear to be no missing outcome data
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	High risk	Unadjusted cluster analysis

1 **Loh 2007**

Methods	Cluster-randomized to decision aid vs usual care
Participants	263 + 142 patients with physician diagnosed depression (cluster RCT with 30 general practitioners randomized) in Germany
Interventions	DA (in consultation): options' outcomes, clinical problem, explicit values clarification, guidance/coaching Comparator: 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	"[T]wo-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" (p 3)
Allocation concealment (selection bias)	Low risk	Drawing blinded lots (p 3 - 2.1)
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 documented in minutes by the physicians following each consultation)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Further results resting on the baseline phase of this trial were already presented elsewhere" (p 5, fig); "unequal distribution of physicians was due to possibility of higher dropout rate in intervention group because of additional time and effort" (p 3).
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 (p 5-6, details pt and physician baseline characteristics). Statistically significant differences were controlled for in outcome analyses

1 **Man-Son-Hing 1999**

Methods	Randomized 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) Comparator: usual care

Outcomes	Primary outcomes: uptake of options, adherence Secondary outcomes: help with making a decision, knowledge, accurate risk perceptions, decisional conflict, satisfaction with decision making process, role in decision making
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated scheme (p 2)
Allocation concealment (selection bias)	Low risk	Administered from a central location (p 2)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear blinding however, "contamination, physicians may have provided DA information to patients receiving usual care" (p 7)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	P 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

1 **Mann D 2010**

Methods	Randomized to decision aid vs usual care
Participants	80 + 70 participants diagnosed with diabetes considering the use of statins to reduce coronary risk
Interventions	DA (in consultation): 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) Comparator: usual primary care visit + pamphlet
Outcomes	Knowledge (postconsult and post-DA), decisional conflict (postconsult and post-DA), risk estimation (postconsult and post-DA), beliefs (postconsult and post-DA), adherence (3 and 6 months postconsult 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	Participants were randomized but there is no mention of method used (p 138, Methods section)
Allocation concealment (selection bias)	Unclear risk	Not reported
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
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	"We did not adjust the clustering of effects given that few participants received care by the same clinicians" (p 139, Analysis

	section). No mention of magnitude in change of data due to this choice

1 **Mann E 2010**

Methods	Randomized 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 Comparator: usual care using screening invitation on clinical problem
Outcomes	Primary outcomes: preferred option (post-DA) Secondary outcomes: whether invitation type impacts on intention (post-DA), impact on knowledge (post-DA), impact on attitude (post-DA), risk perception
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"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" (p 2-3, Methods, Participants section). Unclear how invitation type was hidden
Allocation concealment (selection bias)	Low risk	"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" (p 2-3, Methods, Participants section).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	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 (p 3, Methods, Participants section).

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
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	"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" (p 6, Discussion section)

1 **Marteau 2010**

Methods	Randomized 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 Comparator: usual care using screening invitation on clinical problem
Outcomes	Primary outcome: attendance for screening (post-DA and consult) Secondary outcomes: intention to make changes to lifestyle (post-DA and consult), satisfaction with decisions made among attenders (post-DA and consult)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	"[G]enerated simultaneously in a batch by random numbers using Excel spreadsheet software, stratifying by number of participants in household" (p 2, Randomization section)
Allocation concealment (selection bias)	Low risk	"Randomisation … was undertaken by the study statistician from a central site" (p 2, Randomization section)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel were blinded and appears that patients were unaware which arm they were in (members of the same household received the same intervention) (p 2, Randomization section)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Clinical and trial staff taking measurements and entering data were unaware of the study arm to which participants had been assigned (p 2, Randomization section)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Published protocol (p 2, Methods)
Other bias	Low risk	Appears free of other potential biases

1 **Mathers 2012**

Methods	Cluster-randomized controlled trial of 49 general practices in the UK to decision aid, healthcare professional training workshop and use of PDA in consultation, or usual care.
Participants	95 + 80 participants with type 2 diabetes considering adding or changing to insulin therapy
Interventions	DA: booklet about clinical problem, treatment options, options' outcomes, outcome probabilities, explicit values clarification, structured guidance Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (immediately postintervention), glycaemic control (glycosolated haemoglobin, HbA1c) at 6 months Secondary outcomes: knowledge (immediately post), realistic expectations (immediately post), preference option (immediately post), proportion undecided (immediately post),

	participation in decision-making (immediately post), regret (6 months), adherence with chosen option (6 months)
Notes	Trial registration: ISRCTN14842077

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"All eligible and willing practices were randomly allocated by a computer" (p 3)
Allocation concealment (selection bias)	Low risk	"A statistician generated the random allocation sequence while a secretary who was not involved in the research study assigned participants to either the intervention or control groups" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied" (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied" (p 3)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data
Selective reporting (reporting bias)	Low risk	Trial registered
Other bias	Unclear risk	Cannot make a judgment with information provided regarding cessation of recruitment at 175 (yet 320 required to allow detection of 0.5% difference in HbA1c)

1 **Mathieu 2007**

Methods	Randomized 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) Comparator: BreastScreen NSW brochure - includes information for women 70 + but no numeric information about the outcomes of screening
Outcomes	Primary outcomes: actual decision, informed choice Secondary outcomes: knowledge (includes 5 questions about risk perceptions), anxiety, decisional conflict, breast cancer worry, preference/intension, attitudes about screening, relationship between objective and perceived risk of breast cancer
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer programme, which assigned allocations in accordance with a simple randomization schedule (p 2, Methods)
Allocation concealment (selection bias)	Low risk	Randomized by interview staff who accessed a previously concealed computer programme (p 2, Methods)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig 1 flow diagram (p 2)
Selective reporting (reporting bias)	Low risk	"The trial was registered with the Australian Clinical Trials Registry and the Clinical Trials Registration System" (p 5)

Other bias	Low risk	Appears to be free of other potential biases

1 **Mathieu 2010**

Methods	Randomized to decision aid vs usual care
Participants	189 + 223 women considering mammography screening
Interventions	DA: Internet programme + 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) Comparator: delayed intervention
Outcomes	Primary outcomes: knowledge (post-DA), risk perception Secondary outcomes: intention (post-DA), values (post-DA), informed choice (post-DA), proportion undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputer generated simple randomization schedule" (p 66, Randomization and baseline questions section)
Allocation concealment (selection bias)	Unclear risk	"[R]andomization was conducted in a concealed manner" (p 66). Method of allocation concealment not stated
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

Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcomes mentioned in Outcome measures section were reported in the results section (p 68, Table 2; information for intention as well as anxiety and acceptability can be found in text format in the secondary outcomes section on pg.67-68)
Selective reporting (reporting bias)	Unclear risk	No mention of protocol
Other bias	Low risk	Appears to be free of other potential sources of bias

1 **McAlister 2005**

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

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[C]luster randomization at level of primary care practice to minimize contamination; randomization was done centrally to preserve allocation concealment using a computer generated sequence" (p 2)
Allocation concealment (selection bias)	Low risk	Randomization was done centrally to preserve allocation concealment (p 2, Methods)
Blinding of participants and	Unclear risk	Not blinded, but not sure whether the lack of blinding would affect the outcomes

personnel (performance bias) All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results and Fig 1 - flow diagram (p 3)
Selective reporting (reporting bias)	Low risk	DAAFI trial protocol, including copies of the various questionnaires we employed, has been published (p 1, Methods)
Other bias	Low risk	Appears to be free of other potential biases

1 **McBride 2002**

Methods	Randomized to decision aid vs usual care
Participants	289 + 292 perimenopausal women considering hormone replacement therapy in the USA
Interventions	DA: options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching Comparator: delayed intervention
Outcomes	Primary outcome: accurate risk perceptions Secondary outcomes: satisfaction with decision, confidence with knowledge and making/discussing decision
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided; Bastian 2002, no information provided - Study design is described elsewhere (p 4)
Allocation concealment (selection bias)	Unclear risk	No information provided; Bastian 2002, no information provided - Study design is described elsewhere (p 4)
Blinding of participants and	Unclear risk	Unclear blinding

personnel (performance bias) All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Complete data are available for 520 (90%) of the women (p 2). Reasons why not mentioned (Bastian 2002, p 5, Results; p 6, Baseline characteristics/data 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; Bastian 2002, p 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

1 **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) Comparator 1: no decision support, received immediate HPV testing Comparator 2: no decision support, received a repeat cervical smear at 6 months
Outcomes	Primary outcomes: quality of life (post-DA) Secondary outcomes: waiting time anxiety (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	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomised centrally by the research team within each clinic in blocks of three" (p 2, Design)
Allocation concealment (selection bias)	Low risk	"Participants were randomised centrally by the research team within each clinic in blocks of three" (p 2, Design)
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
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

1 **Miller 2005**

Methods	Randomized 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 Comparator: 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	"[R]andomized by the CATI system" (p 4) after self-initiated telephone contact
Allocation concealment (selection bias)	Low risk	"[C]omputerized assisted telephone interview system (CATI)" (p 4)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons stated for initial drop-out of study participants (p 8). Patients contacted offered reasons for dropping out. Study protocol 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

1 **Miller 2011**

Methods	Decision aid vs attention placebo
Participants	132 + 132 participants considering colon cancer screening in the USA
Interventions	DA: computer-based web programme on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (encourages patient-practitioner communication, summary)

	Comparator: computer-based web programme on prescription drug refills and safety
Outcomes	Primary outcomes: receipt of CRC screening (post-DA) Secondary outcomes: ability to state a preference, change in readiness to receive screening (pre and post-DA), CRC test ordering (post-DA), proportion undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block-randomized, stratified by literacy level (p 609, Methods)
Allocation concealment (selection bias)	Unclear risk	Study does not address this domain
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Health care providers were not notified of patients' enrolment in the study at any time (p 609, Methods) RAs that administered post-DA questionnaire were not blinded but believed to be a low risk of bias (p 613, Discussion)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[C]linical outcome assessors were [blinded]" (p 613, Discussion)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol on ClinicalTrials.gov
Other bias	Unclear risk	USD 10 gift card for participation could affect participant pool

1 **Montgomery 2003**

Methods	Randomized 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 Comparator: decision analysis on options' outcomes, outcome probability, explicit values clarification Comparator: video and leaflet on options' outcomes, clinical problem Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: uptake of option, knowledge, anxiety
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation schedule was computer-generated by an individual not involved in the study (p 2)
Allocation concealment (selection bias)	Low risk	"[A]llocation was concealed to the author in advance by the nature of the minimization procedure" (p 2)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 5)
Selective reporting (reporting bias)	Unclear risk	No information provided

Other bias	Low risk	Appears to be free of other potential biases

1 **Montgomery 2007**

Methods	Randomized 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 Comparator: options' outcomes, clinical problem, outcome probability Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: choice, anxiety, knowledge, satisfaction with decision
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Blocked by using randomly permuted and selected blocks of sizes 6, 9, 12, and 15 generated by computer (p 2 Methods, Randomization)
Allocation concealment (selection bias)	Low risk	1 member of the study team generated the randomization sequence by computer, and another member of staff with no other involvement in the trial performed the allocation (p 2 Methods, Randomization)
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

Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow of women through the study
Selective reporting (reporting bias)	Low risk	Trials registry ISRCTN84367722
Other bias	Low risk	Recruited more than planned to account for lost data (p 4, Sample size); baseline characteristics were balanced

1 **Montori 2011**

Methods	Randomized 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 (in consultation): worksheet on options' outcomes, clinical problem, outcome probabilities, guidance (administered by physician) Comparator: 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	"computer generated allocation" (p 551, Randomization)
Allocation concealment (selection bias)	Low risk	Patients randomized "in a concealed fashion (using a secure study website)" (p 551, Randomization)
Blinding of participants and	Unclear risk	No mention of participants being blinded to their allocation; only mention of data

personnel (performance bias) All outcomes		collectors and analysts blinding (p 551, Randomization)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"After randomization, data collectors and data analysts were blind to allocation" (p 551, Randomization); Outcomes were not subject to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	"The protocol for this trial has been reported in full" (p 550, Design)
Other bias	Unclear risk	Appears to be free of other potential biases

1 **Morgan 2000**

Methods	Randomized to decision aid vs usual care
Participants	120 + 120 patients with ischaemic heart disease considering revascularization surgery in Canada
Interventions	DA: Health Dialog interactive videodisc on options' outcomes, clinical problem, outcome probability, others' opinions Comparator: usual care
Outcomes	Primary outcome: satisfaction with the decision making process Secondary outcomes: uptake of option, knowledge
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Morgan 1997, p 29: all randomization enrolment was performed by telephone at which time the participant was assigned Morgan 2000 (primary study), p 2, Methods, Patient Population: "Only the statistician was privy to the two randomisation schedules and blocking factor used"

Allocation concealment (selection bias)	Low risk	Morgan 1997, p 29: only the statistician was privy to the two randomization schedules and blocking factor; Morgan 2000, (primary study), p 2, Methods, Patient Population: "only the statistician was privy to the two randomisation schedules and blocking factor used. All randomization enrolment was performed by telephone"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[D]ue 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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Morgan 1997, p 39, Patient accrual and follow-up: baseline characteristics included Morgan 2000 (primary study): 78% completed follow-up (90 of 120 in the intervention; 97 of 120 in the control). reasons for attrition were provided
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Unclear risk	Morgan 1997, p 56: significant number of patients were lost to follow-up (25%); Morgan 2000 (primary study): baseline data imbalance (high school grad, income, no. of diseased arteries). Dropout group reported lower incomes, may have affected results. (discussion par. 6) "Selection bias was minimized by enrolling available consecutive patients"

1 **Mott 2014**

Methods	Randomized to shared decision-making process with DA versus usual care

Participants	13 +14 military veterans in USA diagnosed with PTSD and had served in Iraq or Afghanistan
Interventions	DA: booklet on clinical problem, options' outcomes, structured guidance Comparator: usual care
Outcomes	Satisfaction with SDM qualitatively (postintervention), perceived advantages and disadvantages of SDM qualitative (postintervention), treatment preferences (4 months), adherence using treatment engagement (4 months)
Notes	Not reported as registered in trials database; no primary outcome reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomized to SDM or UC using a computer-generated randomization sequence" (p 146)
Allocation concealment (selection bias)	Low risk	"[R]andomization envelopes were prepared by the study statistician to ensure that study staff remained masked to randomization sequence" (p 146)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study staff not blinded but because outcomes were taken from medical records. "At 4-month follow-up, study staff reviewed participants' medical records to extract information on treatment preferences and engagement. Medical-record reviews were conducted by a single rater trained in use of the dataextraction form. A second rater, masked to initial ratings, reextracted data from 20% of patients" (p 146).
Incomplete outcome data	High risk	27 participants were consented and enrolled , yet only 20 (UC = 11; SMD = 9) completed the study (p 146-147). Only 5 participants in the

(attrition bias) All outcomes		SDM arm completed the exit interview. No mention of missing data.
Selective reporting (reporting bias)	Low risk	No protocol available but all expected outcomes reported on
Other bias	Low risk	Does not appear to be any other sources of bias

1 **Mullan 2009**

Methods	Cluster-randomized to decision aid vs usual care
Participants	48 + 37 patients with type 2 diabetes considering treatment options (cluster RCT with 40 clinicians randomized) in the USA
Interventions	DA (in consultation): 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, HbA1C levels, trust in physician, OPTION to analyse audio-taped encounters
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Low risk	Central allocation
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reasons for attrition not included
Selective reporting (reporting bias)	Low risk	Trial registration no. at clinicaltrials.gov reported
Other bias	Low risk	Appears to be free of other sources of bias

1 **Murray 2001a**

Methods	Randomized 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 Comparator: usual care
Outcomes	Primary outcomes: uptake of option, prostate symptoms, costs, anxiety Secondary outcomes: decisional conflict, role in decision making, general health status, utility
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[R]andomisation schedule, stratified according to recruitment centre, was generated by computer" (p 4)
Allocation concealment (selection bias)	Low risk	"Allocation were sealed in opaque numbered envelopes, opened by the study nurse" (p 4)
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 to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 5); 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

1 **Murray 2001b**

Methods	Randomized 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 Comparator: usual care
Outcomes	Primary outcomes: preferred option Secondary outcomes: help with making a decision, decisional conflict, role in decision making anxiety, menopausal symptoms, costs, utility, general health status
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomisation schedule, stratified according to recruitment centre, was generated by computer" (p 3 Methods, Randomization)
Allocation concealment (selection bias)	Low risk	"Allocations were sealed in opaque numbered envelopes, opened by the study nurse after collection of the baseline data" (p 3 Methods, Randomization)
Blinding of participants and	Unclear risk	Unclear blinding

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

1 **Nagle 2008**

Methods	Cluster-randomized 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 randomized) 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) Comparator: standard pamphlet on prenatal testing
Outcomes	Primary outcomes: informed choice, decisional conflict Secondary outcomes: anxiety, depression, attitudes toward pregnancy, acceptability of the intervention, choice
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers (p 3)
Allocation concealment (selection bias)	Low risk	Computer-generated random numbers by an independent statistician; allocation concealment was achieved (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Due to the nature of the intervention, it was not possible to blind women, GP's or researchers" (p 3); 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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results, p 4; Fig 1 - flow diagram, p 5
Selective reporting (reporting bias)	Low risk	Trial Registration - The ADEPT trial was registered in the UK with Current Controlled Trials [ISRCTN22532458] and with the Australian Clinical Trials Registry (No: 012606000234516) (p 4)
Other bias	Low risk	Appears to be free of other potential biases (p 8); selection bias but was adjusted for in analysis

1 **Nassar 2007**

Methods	Randomized 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)

	Comparator: usual care counselling and information on the management of breech presentation
Outcomes	Primary outcomes: knowledge, decisional conflict, anxiety, satisfaction with the decision, Secondary outcomes: preferred role in decision making, preferred choice
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomly generated using computer and stratified by parity and center using random variable block sizes" (p 2)
Allocation concealment (selection bias)	Low risk	"[P]articipants were randomized by telephoning a remote, central location" (p 2)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up because of onset of labour or incomplete data forms (p 3). Baseline characteristics are included and equal. Minimum of 84 participants in each study group achieved; p 4 - flow diagram
Selective reporting (reporting bias)	Low risk	ISRCTN14570598
Other bias	Low risk	"Maternal characteristics and baseline measures of cognitive and affective outcomes were comparable between groups" (p 3 Results, Table 1)

		"Blinding clinicians and employment of a research midwife to interact with women" (p 6)

1 **Oakley 2006**

Methods	Randomized 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) Comparator: 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
Allocation concealment (selection bias)	Low risk	Group allocation was done by a third party, unconnected to the study and blinded to the identity of the patients (p 1)
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Sample characteristics not included; baseline satisfaction score included. "No evaluation was carried out to determine the reasons for non-participation" (p 2)

Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Unclear risk	No baseline characteristics (p 2). Only 16 patients in intervention group and 17 in control group; small sample size.

1 **Ozanne 2007**

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

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Patients were randomized evenly between groups; no information provided about generation (p 149)
Allocation concealment (selection bias)	Unclear risk	No information provided (p 149)
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

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)

1 **Partin 2004**

Methods	Randomized 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 Comparator 1: pamphlet on options' outcomes, clinical problem, outcome probability Comparator 2: usual care
Outcomes	Primary outcomes: knowledge Secondary outcomes: preferred option, help with making a decision, decisional conflict
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Using a computer-generated algorithm (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"[P]roviders were blinded to the fact that their patients were participating in a trial" "coordinator did not have direct contact with subjects" (p 5)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[F]ollow-up interviewers blinded, statisticians were not". Outcomes were objectively measured and not subjective to to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 2); reasons for attrition mentioned and participants balanced across study groups. Sample 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

1 **Pignone 2000**

Methods	Randomized 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 Comparator: video on car safety
Outcomes	Primary outcome: uptake of options
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputerized random number generator" (p 2, Methods, Group assignment)
Allocation concealment (selection bias)	Low risk	"[R]andomization 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" (p 2, Methods, Group assignment)
Blinding of participants and personnel (performance	Unclear risk	"The providers and staff were not blinded to intervention status" "3 to 6 months after,

bias) All outcomes		different RA blinded to participant intervention examined clinic records" (p 2) 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.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Because of an administrative error, 18 controls did not complete the second and third questionnaires (p 4).
Selective reporting (reporting bias)	Unclear risk	Protocol was not mentioned
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

1 **Protheroe 2007**

Methods	Randomized 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 Comparator: information leaflet
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge, anxiety, condition specific health outcomes, treatment preference, undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	Computer generated randomization, stratified by practice and minimized according to age (p 2, Methods)
Allocation concealment (selection bias)	Unclear risk	Random allocation was concealed from the individual who was making judgments of eligibility, but the method of concealment was not stated (p 2, Methods)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig 6 flow diagram (p 5); baseline data/characteristics included and balanced (p 4)
Selective reporting (reporting bias)	Low risk	ISRCTN72253427
Other bias	Low risk	Appears to be free of other potential biases

1 **Rubel 2010**

Methods	Randomized to pretest + decision aid + post-test vs decision aid + post-test 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 post-test Comparator : booklet on options' outcomes, clinical problem, outcome probabilities, others' opinions + post-test Comparator: pretest + post-test Comparator: post-test
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
Random sequence generation (selection bias)	Low risk	Electronically generated random number sequence (p 309, Study design section)
Allocation concealment (selection bias)	Low risk	They were given sealed, sequentially numbered packets (p 309, Study design section)
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.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol followed CONSORT checklist (p 310, Study design section)
Other bias	Low risk	Appears to be free of other potential biases

1 **Ruffin 2007**

Methods	Randomized to decision aid vs usual care
Participants	87 + 87 community dwelling adults not previously screened for CRC in the USA
Interventions	DA: interactive website with information on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinion, guidance Comparator: non-interactive website with information on clinical problem
Outcomes	Primary outcome: uptake of option

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A block randomisation process programmed by the study computer support staff and verified by a statistician was used including two strata, race and gender" (p 3)
Allocation concealment (selection bias)	Unclear risk	No information provided
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.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

1 **Sawka 2012**

Methods	Randomized to decision aid vs usual care
Participants	37 + 37 individuals with early-stage papillary thyroid cancer
Interventions	DA: web-based decision aid with clinical problem, options' outcomes, outcome probabilities, guidance, printout summary Comparator: usual care (consultation with a specialized head and neck surgeon, and with 1 or more medical specialist).

Outcomes	Primary outcomes: knowledge (baseline and immediately post intervention) Secondary outcomes: decisional conflict, undecided, treatment decision (baseline, immediately post intervention, 6 to12 months), individual primarily responsible for the treatment decision (6 to 12 months)
Notes	Trial registration: NCT01083550

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Central computerized randomization in a 1:1 ratio was performed at a patient level by using variable block sizes of 2 and 4 (allocation designed by a study statistician)" (p 2908)
Allocation concealment (selection bias)	Low risk	"Before the random assignment/testing visit, neither the participant, study staff, investigators, nor treating physicians were aware of the allocation, because it had not yet been assigned" (p 2908)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"There was no blinding of participants, study staff, or treating physicians after random assignment was completed" (p 2908), yet it is unlikely that the outcomes are affected by the lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"There was no blinding of participants, study staff, or treating physicians after random assignment was completed. However, the statistician was blinded to the allocation of groups at the time of data analysis." (p 2908)
Incomplete outcome data (attrition bias) All outcomes	Low risk	There does not appear to be any missing outcome data
Selective reporting (reporting bias)	Unclear risk	Authors state the trial is registered, but no link to trial number
Other bias	Low risk	Appears to be free of other potential sources of bias

1 **Schroy 2011**

Methods	Randomized 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 Comparator 1: web-based decision aid only Comparator 2: 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 randomization process
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
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 if participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors not blinded but outcome measures not believed to be influenced by it
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

1 **Schwalm 2012**

Methods	Randomized 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 Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge, risk perception, value congruent with chosen option
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerized random number generator (p 261, Study design)
Allocation concealment (selection bias)	Low risk	Sealed envelopes (p 261, Study design)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients and physicians were not blinded to the allocation (p 261, Study design)
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
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

1 **Schwartz 2001**

Methods	Randomized 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 Comparator: general information on breast cancer, *Understanding Breast Changes: A Health Guide for all Women,* published by the National Cancer Institute
Outcomes	Primary outcome: preferred option Secondary outcomes: knowledge, accurate risk perceptions
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated (p 3)
Allocation concealment (selection bias)	Unclear risk	No information provided
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	High retention rate, baseline data and reasons for lost to follow-up were provided (p 2, Participants section)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

1 **Schwartz 2009a**

Methods	Randomized 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) Comparator: genetic counselling on benefits and risks of testing, clinical problem (risk assessment, cancer risks associated with mutations, process of testing and interpretation of results) plus written letter outlining all guidelines and recommendations
Outcomes	Primary outcomes: decisional conflict, satisfaction with decision, actual choice (risk reduction mastectomy) Secondary outcomes: remaining undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomized via computer-generated random number in a 1:1 ratio (p 3, Procedure)
Allocation concealment (selection bias)	Unclear risk	No information provided
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig. 1 - flow diagram (p 3)

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)"

1 **Sheridan 2006**

Methods	Randomized 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 Comparator: 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)
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[C]omputerized random number generator" (p 2)
Allocation concealment (selection bias)	Low risk	"[S]ealed in security envelopes" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded but the doctors who saw both groups were not
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcome was patient reported

Incomplete outcome data (attrition bias) All outcomes	Low risk	Results (p 5); Flow diagram (p 10); Baseline characteristics/data included
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov NCT00315978
Other bias	Low risk	Appears to have no other potential risk of bias

1 **Sheridan 2011**

Methods	Randomized 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 Comparator: usual care using computer programme
Outcomes	Preferred choice (post-DA), adherence Other outcomes (Sheridan 2014): patient-provider communication (post-DA), patient participation (post-DA), patients perceptions of discussions and the health care visit (post-DA), preferred choice (baseline and post-DA) (data from 81 +79 patients).
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomised by study staff who accessed an online randomised schedule" (p 2). Sequence generation method not stated
Allocation concealment (selection bias)	Low risk	"Patients were randomised by study staff who accessed an online randomised schedule" (p 2).
Blinding of participants and personnel	Low risk	Patients blinded and physicians unblinded but objective outcomes are not likely affected by lack of blinding

(performance bias) All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes deemed objective therefore lack of blinding did not influence assessment
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

1 **Shorten 2005**

Methods	Randomized 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) Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: preferred option, help with making a decision
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-based randomized generation (p 3, Procedure)
Allocation concealment (selection bias)	Low risk	"[O]paque envelopes containing a random allocation for each participant code number" (p 3)

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 to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	16 women were lost to follow-up from the intervention group and 18 from the control group (no reasons listed) (p 4, Results)
Selective reporting (reporting bias)	Low risk	Reference to published protocol
Other bias	Low risk	Appears to be free of other potential biases

1 **Shourie 2013**

Methods	Cluster-randomized controlled trial of GP practices to web-based MMR DA + usual care, MMR leaflet + usual care, versus usual care
Participants	50 + 93 + 77 parents' of children facing their first dose MMR vaccination
Interventions	Web-based DA: clinical problem, options' outcomes, explicit values clarification, guidance MMR leaflet: Health Scotland leaflet, 'MMR: your questions answered' Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (baseline and 2 weeks postintervention) Secondary outcomes: choice uptake of first dose MMR (when child was 15 months), knowledge (baseline and 2 weeks; results not provided), MMR immunization cognitions (baseline and 2 weeks post; results not provided), immunization trade-off beliefs (baseline and 2 weeks post; results not provided),

	anxiety (baseline and 2 weeks post; results not provided), use of the intervention (baseline and 2 weeks post)
Notes	Trial registration: UK Clinical Research Network - UKCRN ID 4811

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Simple randomisation using a computer-generated random list allocated GP practices on a 1:1:1 basis" (p 3)
Allocation concealment (selection bias)	Low risk	"An independent researcher who had no contact with participants generated the allocation sequence and assigned the GP practices to their allocated arm" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"On receipt of the completed baseline questionnaire and consent form, the appropriate intervention was delivered. At this point the researchers and participants were no longer blind to allocation" (p 3). We don't know if receiving the intervention had an effect on the ultimate decision that was made.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome data assessment does not depend on the assessor. It is an objective questionnaire.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing primary outcome data.
Selective reporting (reporting bias)	Unclear risk	Protocol registered. Primary outcome reported as stated. Secondary outcomes are not reported (p 3).
Other bias	Unclear risk	Difference in allocation to groups (50 + 93 + 77). Unclear what effect this difference had on the results.

1 **Smith 2010**

Methods	Randomized to detailed vs simple decision aid vs usual care

Participants	196 + 188 + 188 socioeconomically 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) Comparator: 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) Comparator: usual care using standard information booklet
Outcomes	Primary outcomes: values congruent with chosen option (post-DA), participation in decision making (pre, post-DA) Secondary outcomes: knowledge (pre, post-DA), attitude, actual choice (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 Other outcomes (Smith 2014): screening participation (357 + 173 participants)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants who verbally consented to take part were then randomised to one of the three groups using random permutated blocks of size 6 and 9 for each sex stratum" (p 3, Participants and recruitment section)
Allocation concealment (selection bias)	Low risk	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" (p 3, Participants and recruitment section)

Blinding of participants and personnel (performance bias) All outcomes	Low risk	"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" (p 3, Outcome measures section)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[A]nalyses were by intention to treat and carried out blinded to intervention" (p 5, Statistical analysis section); outcomes measured were not subject to interpretation
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

1 **Stacey 2014a**

Methods	Randomized to decision aid vs usual care
Participants	71 + 71 adults diagnosed with knee osteoarthritis considering joint replacement in Canada
Interventions	DA: DVD + booklet + worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (1 page summary for the surgeon) Comparator: usual care
Outcomes	Primary outcomes: feasibility (including recruitment, data collection), preliminary effectiveness Secondary outcomes: knowledge (post-DA, pre-surgeon consult), informed values-congruent with chosen option (post-DA, pre-surgeon consult), uptake of chosen option at 1 year; decisional conflict (SURE test), preparation for decision making (4 items), wait times
Notes	Trial registration: NCT00743951

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The allocation schedule was computer-generated centrally by a statistician using a permuted block design with randomly varying block lengths of 4, 6, or 8." (p 3)
Allocation concealment (selection bias)	Low risk	"Allocations were concealed in numbered opaque sealed envelopes" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients were not informed of the intervention characteristics" (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Although the research assistant was not blinded to group allocation, study outcomes for effectiveness were objective and obtained from clinic data (e.g. date of surgery or wait list status)" (p 3).
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol registered on ClinicalTrials.gov
Other bias	Low risk	Appears to be free of other potential sources of bias

1 **Steckelberg 2011**

Methods	Randomized 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 Comparator: usual care using pamphlet
Outcomes	Primary outcomes: values congruent with chosen option (post-DA)

	Secondary outcomes: knowledge (post-DA), combination of actual and planned uptake (post-DA), risk perception
Notes	—

Risk of bias

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

1 **Taylor 2006**

Methods	Randomized to print DA versus video DA versus wait list control
Participants	98 + 95 + 92 African American men with no history of prostate cancer to consider prostate cancer screening
Interventions	Print DA: clinical problem; outcome probabilities; guidance (list of questions to ask at next appointment); others' opinions

	Video DA: clinical problem; others' opinions Wait list comparator: no information provided until 1 month postrandomization (baseline assessment for this group coincided with 1-month assessment of print and video arms)
Outcomes	Prostate cancer screening intention (baseline and 1 month; not reported), prostate screening uptake (1 year; not included because wait list received intervention before 1 year) process variables including use and perception of the intervention materials (1 month), prostate cancer knowledge (baseline and 1 month post), decisional conflict (baseline and 1 month post), satisfaction with screening decision (baseline and 1 month post)
Notes	No primary outcome reported; not found in trials registry

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information related to random sequence generation
Allocation concealment (selection bias)	Unclear risk	Insufficient information to judge allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to judge blinding; however, participants were requested to not share intervention materials with others to prevent contamination between groups (p 2180)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data
Selective reporting (reporting bias)	Unclear risk	No protocol registered or published

Other bias	Unclear risk	"All participants were mailed $25 for their participation following completion of the 1-month interview" (p 2181) "Men who reported that they had not yet had a chance to read/watch the materials were given an additional week to do so and called again to complete the follow-up assessment" (p 2181)

1 **Thomson 2007**

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

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[E]lectronically-generated random permuted blocks via a web-based randomisation service" (p 2, Recruitment and randomization)
Allocation concealment (selection bias)	Low risk	"[E]lectronically-generated random permuted blocks via a web-based randomisation service" (p 2, Recruitment and randomization)
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
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

1 **Trevena 2008**

Methods	Randomized 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) Comparator: consumer guidelines recommending faecal occult blood testing
Outcomes	Primary outcome: informed choice Secondary outcomes: knowledge, values, screening intention (choice); test uptake, anxiety, acceptability of the intervention, satisfaction with the decision
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Sequential ID numbers were randomly assigned by computer program to DA or Guidelines (G) in blocks of four" (p 3)
Allocation concealment (selection bias)	Low risk	"Allocation was concealed via the password-protected program" (p 3)

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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics included (p 3). Fig 2 flow chart (p 5). 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

1 **Van Peperstraten 2010**

Methods	Randomized to decision aid vs usual care
Participants	152 + 156 infertile women on wait list for in vitro fertilization 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; 1 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 fertilization care Comparator: standard in vitro fertilization care, including a session in which the number of embryos transferred was discussed
Outcomes	Primary outcomes: actual choice (postintervention and consult) Secondary outcomes: knowledge (pre, 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	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated list (p 2, Methods section)
Allocation concealment (selection bias)	Low risk	Central allocation (p 2, Methods section)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"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." (p 2, Methods section)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes assessed were not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There are categories in each column of table 1 (p 3) 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

1 **Vandemheen 2009**

Methods	Randomized to decision aid vs usual care
Participants	70 + 79 patients with cystic fibrosis considering referral for lung transplantation in Canada

Interventions	DA: self-administered booklet with clinical problem, outcome probability, explicit values clarification, guidance (Ottawa Decision Support Framework) Comparator: blank pages
Outcomes	Primary outcomes: knowledge, accurate risk perceptions, decisional conflict Secondary outcomes: preparation for decision making, choice, durability of decision, undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputer-generated random listing of two treatment allocations blocked in blocks of 2 or 4, stratified by site and infection status of Burkholderia cepacia" (p 2)
Allocation concealment (selection bias)	Low risk	Central allocation (p 2)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline characteristics included (Flow diagram, p 2)
Selective reporting (reporting bias)	Low risk	Clinical trial registered with www.clinicaltrials.gov (NCT00345449)
Other bias	Low risk	Appears to be free of other potential biases

1 **Vodermaier 2009**

Methods	Randomized to decision aid vs usual care
Participants	74 + 78 women with breast cancer considering treatment options in Germany
Interventions	DA: Decision board administered by research psychologists and booklet on options' outcomes, clinical problem, outcome probability Comparator: booklet on clinical problem
Outcomes	Primary outcome: decisional conflict Secondary outcomes: choice, length of consultation, satisfaction with decision making, participation in decision making
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomisation after the patient gave written informed consent" "Random assignment was performed by means of numbered cards in envelopes" "stratified by age group" (p 2)
Allocation concealment (selection bias)	Low risk	"[N]umbered cards in envelopes" (p 2)
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, p 5; baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	No information provided

Other bias	Low risk	Appears to be free of other potential biases

1 **Volk 1999**

Methods	Randomized 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 Comparator: usual care
Outcomes	Primary outcomes: knowledge, preferred/uptake of option
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Volk 1999 (primary study), p 3: "[r]andomization by permuted blocks" "Each block included the numbers 1 through 4"; Volk 2003, p 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 (primary study): no information provided Volk 2003, p 2: "[d]etails of the study procedures, subjects, and 2-week follow-up results can be found elsewhere"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were 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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Volk 1999 (primary study), p 2, Procedures: baseline values included.

		Volk 2003, p 4 Fig 1 - flow diagram; baseline data not included
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Volk 1999 (primary study): appears to be free of other potential biases Volk 2003: appears to be free of other sources of bias

1 **Vuorma 2003**

Methods	Randomized 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 Comparator: usual care
Outcomes	Primary outcomes: uptake of option Secondary outcomes: knowledge, proportion remaining undecided, anxiety, satisfaction, health outcomes, use and cost of healthcare services
Notes	—

Risk of bias

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

		Vuorma 2004, p 2 "sequentially numbered, opaque, sealed envelopes"
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Vuorma 2003 (primary study): flow chart balanced. Reasons for non-eligibility. "One women on HRT was randomized by mistake and included in analyses." Baseline characteristics included and balanced across groups (p 4-5) Vuorma 2004, flow diagram (p 3)
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), p 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

1 **Watson 2006**

Methods	Randomized 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 Comparator: usual care
Outcomes	Primary outcomes: knowledge, screening intention, attitudes Secondary outcomes: preferred role in decision making
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andom numbers generated centrally by Stata v8.2" (p 3)
Allocation concealment (selection bias)	Low risk	"[R]andom numbers generated centrally by Stata v8.2" (p 3)
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 2); reason for exclusion from analysis mentioned. Sample characteristics of risk included
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Unclear risk	"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" (p 3)

1 **Weymiller 2007**

Methods	Cluster-randomized to decision aid vs usual care

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

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated allocation sequence (p 2) Nannenga 2009: no information provided
Allocation concealment (selection bias)	Low risk	Computer-generated allocation sequence, unavailable to personnel enrolling patients. "[W]ith concealed allocation" (Abstract); "maintained allocation concealment" (p 5); randomized by concealed central allocation (Nannenga 2009, p 2)
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
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data analysts and statisticians blinded to allocation; intervention and outcomes; adequate blinding wherever possible
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3); reasons for attrition mentioned (p 4); baseline characteristics included; flow diagram Nannenga 2009, p 3: reasons for attrition mentioned and study groups balanced; baseline characteristics included

Selective reporting (reporting bias)	Low risk	ClinicalTrials.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 2009: appears to be free of other potential biases

1 **Whelan 2003**

Methods	Randomized 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 Comparator: booklet on clinical problem
Outcomes	Primary outcomes: knowledge, satisfaction of participant Secondary outcomes: preferred option, anxiety, accurate risk perceptions, participation in decision making
Notes	—

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	Randomization, which was performed at a central location (p 3)
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
Blinding of outcome assessment	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

(detection bias) All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram not included. "[O]ne patient excluded from analysis, determined by physician not to be candidate for chemotherapy" (p 4). 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

1 **Whelan 2004**

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

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Does not specify how the sequence was generated; a paired cluster randomization process was used (p 2, Study design and procedures).
Allocation concealment (selection bias)	Unclear risk	Randomly assigned in a concealed fashion, but method of concealment was not stated (p 2, Study design and procedures)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[C]hose cluster randomization method to avoid contamination that might have occurred if surgeons used decision board for some patients and not others" (p 6); unclear if 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
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

1 **Williams 2013**

Methods	Randomized to decision aid at home or in clinic versus usual care at home or in clinic
Participants	134 + 138 + 134 +137 men aged 40-70 years with no history of prostate cancer who had pre-registered for screening
Interventions	DA: content adapted from the Centers for Disease Control and Prevention's PCS educational tool. Includes clinical problem, treatment options, outcome probabilities, explicit values clarification, others' stories, summary worksheet Comparator: information booklet. A 3-page fact sheet requiring 5 minutes to read. Information presented in a Q&A format on who is recommended for testing, how to interpret results, and the limitations of testing
Outcomes	Knowledge, decisional conflict, screening outcomes, satisfaction with decision Outcomes assessed at baseline, 2 months, 13 months, except satisfaction with decision (2 months and 13 months)
Notes	No primary outcome reported; trial registration not provided

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to judge random sequence generation

Allocation concealment (selection bias)	Unclear risk	Insufficient information to judge allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to judge blinding of participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	There does not appear to be any outcome data missing
Selective reporting (reporting bias)	Unclear risk	No registered or published protocol
Other bias	Low risk	Appears to be free of other potential biases

1 **Wolf 1996**

Methods	Randomized 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 Comparator: usual care (single sentence)
Outcomes	Preferred option
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Wolf 1996 (primary study): no information provided Wolf 1998, p 2: "the methodology of the randomized trial has been reported previously"

Allocation concealment (selection bias)	Unclear risk	Wolf 1996 (primary study): no information provided Wolf 1998, p 2: "The methodology of the randomized trial has been reported previously"
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
Incomplete outcome data (attrition bias) All outcomes	Low risk	Wolf 1996 (primary study), p 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: no information provided except that methodology of the randomized trial and the content of the informational intervention reported previously (p 2). Baseline characteristics included; flow of participants not included
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Wolf 1996 (primary study): participant population had lower SES therefore external validity of the findings limited, but overall appears to be free of other potential biases Wolf 1998: appears to be free of other potential biases

Wolf 2000

Methods	Randomized to decision aid vs usual care
Participants	266 + 133 elderly (≥ 65 years) considering CRC screening in the USA
Interventions	DA: script of options' outcomes, clinical problem, outcome probabilities Comparator: usual care (5 sentences)

Outcomes	Primary outcome: preferred option Secondary outcomes: accurate risk perceptions
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"[P]atients were randomised" (p 2); does not indicate how
Allocation concealment (selection bias)	Unclear risk	No information provided
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline data not included (p 2, Results)
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other potential biases

1 **Wong 2006**

Methods	Randomized 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 Comparator: placebo leaflet on contraception use post pregnancy termination
Outcomes	Primary outcomes: uptake of option, knowledge, decisional conflict, anxiety

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"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" (p 2)
Allocation concealment (selection bias)	Low risk	Consecutive numbered, opaque trial envelope (p 2, Methods)
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
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics not included (p 3); reasons for attrition and incompletion mentioned.
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

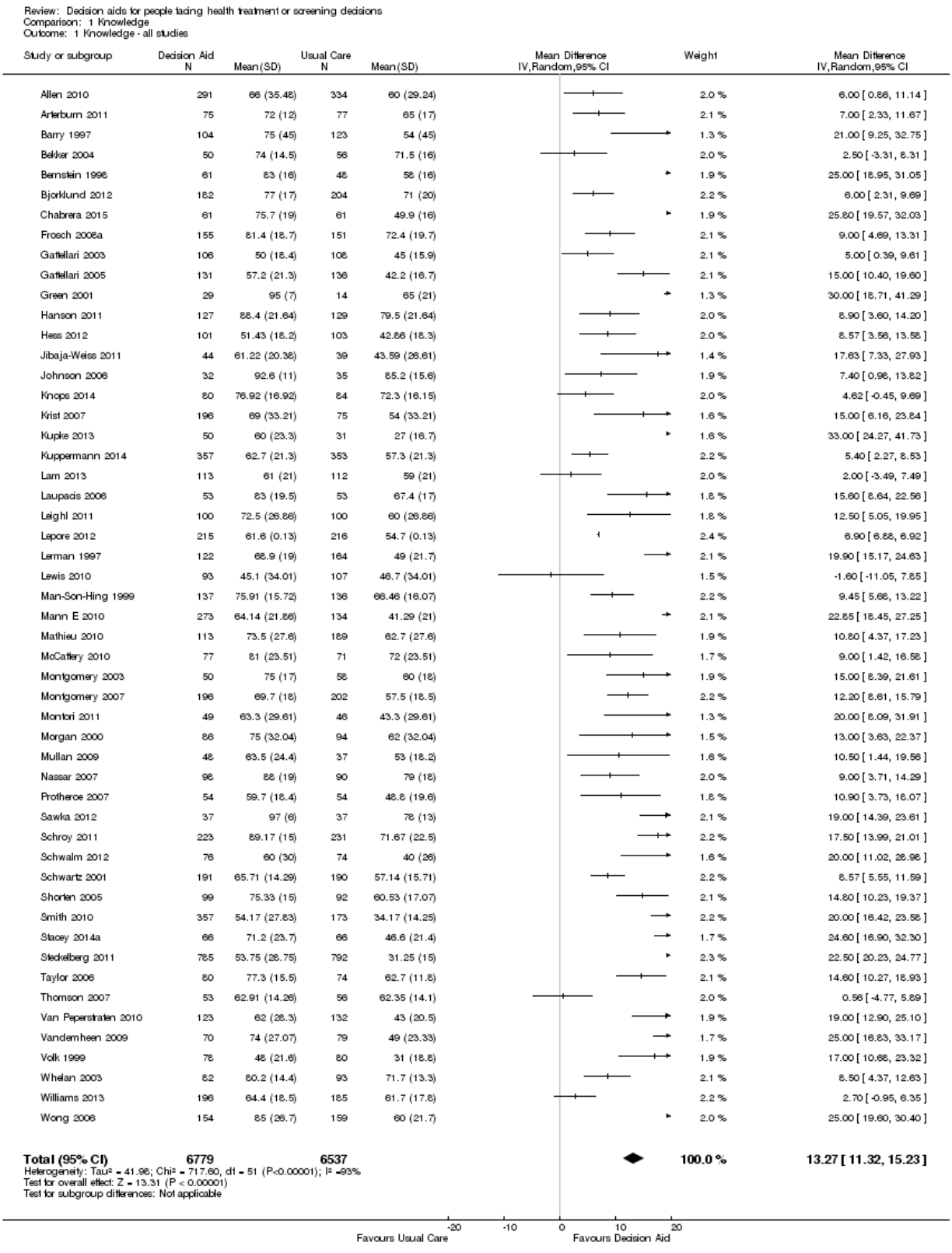
CHD: coronary heart disease; **CRC**: colorectal cancer; **DA**: decision aid; **HPV**: human papilloma virus; **HRT**: hormone replacement therapy; **NSW**: New South Wales; **OA**: osteoarthritis; **PSA**: prostate-specific antigen; **PTSD**: post-traumatic stress disorder; **RCT**: randomized controlled trial; **SES**: socioeconomic status.

Appendix F: Forest plots

The following plots are taken from the Cochrane review.

Analysis 1.1

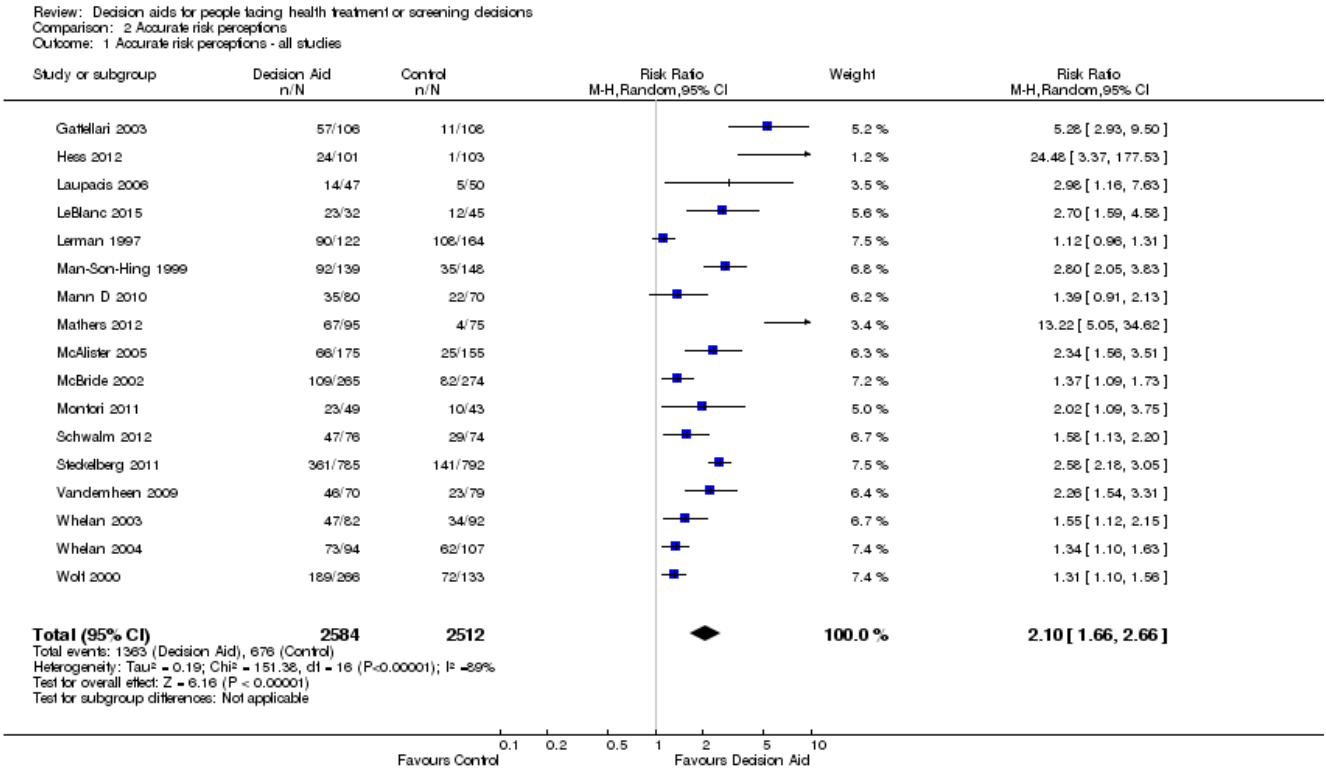
Comparison 1 Knowledge, Outcome 1 Knowledge - all studies.


Review: Decision aids for people facing health treatment or screening decisions
Comparison: 1 Knowledge
Outcome: 1 Knowledge - all studies
Study or subgroup
Decision Aid N
Mean(SD)
Usual Care N
Mean(SD)
Mean Difference IV,Random,95% CI
Weight
Mean Difference IV,Random,95% CI
Allen 2010 291 66 (35.48) 334 60 (29.24) 2.0 % 6.00 [0.86, 11.14]
Arterburn 2011 75 72 (12) 77 65 (17) 2.1 % 7.00 [2.33, 11.67]
Barry 1997 104 75 (45) 123 54 (45) 1.3 % 21.00 [9.25, 32.75]
Bekker 2004 50 74 (14.5) 56 71.5 (16) 2.0 % 2.50 [-3.31, 8.31]
Bernstein 1998 61 83 (16) 48 58 (16) 1.9 % 25.00 [18.95, 31.05]
Bjorklund 2012 182 77 (17) 204 71 (20) 2.2 % 6.00 [2.31, 9.69]
Chabrera 2015 61 75.7 (19) 61 49.9 (16) 1.9 % 25.80 [19.57, 32.03]
Frosch 2008a 155 81.4 (18.7) 151 72.4 (19.7) 2.1 % 9.00 [4.69, 13.31]
Gattellari 2003 106 50 (18.4) 108 45 (15.9) 2.1 % 5.00 [0.39, 9.61]
Gattellari 2005 131 57.2 (21.3) 136 42.2 (16.7) 2.1 % 15.00 [10.40, 19.60]
Green 2001 29 95 (7) 14 65 (21) 1.3 % 30.00 [18.71, 41.29]
Hanson 2011 127 88.4 (21.64) 129 79.5 (21.64) 2.0 % 8.90 [3.60, 14.20]
Hess 2012 101 51.43 (18.2) 103 42.86 (18.3) 2.0 % 8.57 [3.56, 13.58]
Jibaja-Weiss 2011 44 61.22 (20.38) 39 43.59 (26.61) 1.4 % 17.63 [7.33, 27.93]
Johnson 2006 32 92.6 (11) 35 85.2 (15.6) 1.9 % 7.40 [0.98, 13.82]
Knops 2014 80 76.92 (16.92) 84 72.3 (16.15) 2.0 % 4.62 [-0.45, 9.69]
Krist 2007 196 69 (33.21) 75 54 (33.21) 1.6 % 15.00 [6.16, 23.84]
Kupke 2013 50 60 (23.3) 31 27 (16.7) 1.6 % 33.00 [24.27, 41.73]
Kuppermann 2014 357 62.7 (21.3) 353 57.3 (21.3) 2.2 % 5.40 [2.27, 8.53]
Lam 2013 113 61 (21) 112 59 (21) 2.0 % 2.00 [-3.49, 7.49]
Laupacis 2006 53 83 (19.5) 53 67.4 (17) 1.8 % 15.60 [8.64, 22.56]
Leighl 2011 100 72.5 (26.86) 100 60 (26.86) 1.8 % 12.50 [5.05, 19.95]
Lepore 2012 215 61.6 (0.13) 216 54.7 (0.13) 2.4 % 6.90 [6.88, 6.92]
Lerman 1997 122 68.9 (19) 164 49 (21.7) 2.1 % 19.90 [15.17, 24.63]
Lewis 2010 93 45.1 (34.01) 107 46.7 (34.01) 1.5 % -1.60 [-11.05, 7.85]
Man-Son-Hing 1999 137 75.91 (15.72) 136 66.46 (16.07) 2.2 % 9.45 [5.68, 13.22]
Mann E 2010 273 64.14 (21.86) 134 41.29 (21) 2.1 % 22.85 [18.45, 27.25]
Mathieu 2010 113 73.5 (27.6) 189 62.7 (27.6) 1.9 % 10.80 [4.37, 17.23]
McCaffery 2010 77 81 (23.51) 71 72 (23.51) 1.7 % 9.00 [1.42, 16.58]
Montgomery 2003 50 75 (17) 58 60 (18) 1.9 % 15.00 [8.39, 21.61]
Montgomery 2007 196 69.7 (18) 202 57.5 (18.5) 2.2 % 12.20 [8.61, 15.79]
Montori 2011 49 63.3 (29.61) 46 43.3 (29.61) 1.3 % 20.00 [8.09, 31.91]
Morgan 2000 86 75 (32.04) 94 62 (32.04) 1.5 % 13.00 [3.63, 22.37]
Mullan 2009 48 63.5 (24.4) 37 53 (18.2) 1.6 % 10.50 [1.44, 19.56]
Nassar 2007 98 88 (19) 90 79 (18) 2.0 % 9.00 [3.71, 14.29]
Protheroe 2007 54 59.7 (18.4) 54 48.8 (19.6) 1.8 % 10.90 [3.73, 18.07]
Sawka 2012 37 97 (6) 37 78 (13) 2.1 % 19.00 [14.39, 23.61]
Schroy 2011 223 89.17 (15) 231 71.67 (22.5) 2.2 % 17.50 [13.99, 21.01]
Schwalm 2012 76 60 (30) 74 40 (26) 1.8 % 20.00 [11.02, 28.98]
Schwartz 2001 191 65.71 (14.29) 190 57.14 (15.71) 2.2 % 8.57 [5.55, 11.59]
Shorten 2005 99 75.33 (15) 92 60.53 (17.07) 2.1 % 14.80 [10.23, 19.37]
Smith 2010 357 54.17 (27.83) 173 34.17 (14.25) 2.2 % 20.00 [16.42, 23.58]
Stacey 2014a 66 71.2 (23.7) 66 46.6 (21.4) 1.7 % 24.60 [16.90, 32.30]
Steckelberg 2011 785 53.75 (28.75) 792 31.25 (15) 2.3 % 22.50 [20.23, 24.77]
Taylor 2006 80 77.3 (15.5) 74 62.7 (11.8) 2.1 % 14.60 [10.27, 18.93]
Thomson 2007 53 62.91 (14.26) 56 62.35 (14.1) 2.0 % 0.56 [-4.77, 5.89]
Van Peperstraten 2010 123 62 (28.3) 132 43 (20.5) 1.9 % 19.00 [12.90, 25.10]
Vandemheen 2009 70 74 (27.07) 79 49 (23.33) 1.7 % 25.00 [16.83, 33.17]
Volk 1999 78 48 (21.6) 80 31 (18.8) 1.9 % 17.00 [10.68, 23.32]
Whelan 2003 82 80.2 (14.4) 93 71.7 (13.3) 2.1 % 8.50 [4.37, 12.63]
Williams 2013 196 64.4 (18.5) 185 61.7 (17.8) 2.2 % 2.70 [-0.95, 6.35]
Wong 2006 154 85 (26.7) 159 60 (21.7) 2.0 % 25.00 [19.60, 30.40]
Total (95% CI) 6779 6537 100.0 % 13.27 [11.32, 15.23]
Heterogeneity: Tau² = 41.98; Chi² = 717.60, df = 51 (P<0.00001); I² =93%
Test for overall effect: Z = 13.31 (P < 0.00001)
Test for subgroup differences: Not applicable
-20
-10
0
10
20
Favours Usual Care
Favours Decision Aid

1

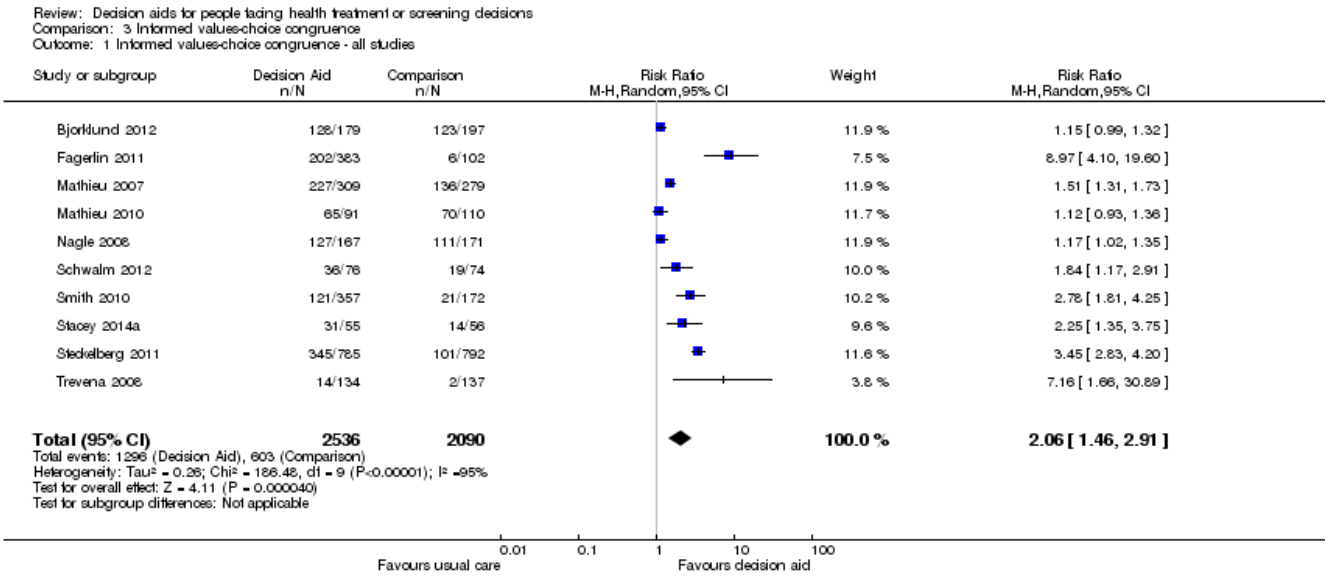
Analysis 2.1

Comparison 2 Accurate risk perceptions, Outcome 1 Accurate risk perceptions - all studies.



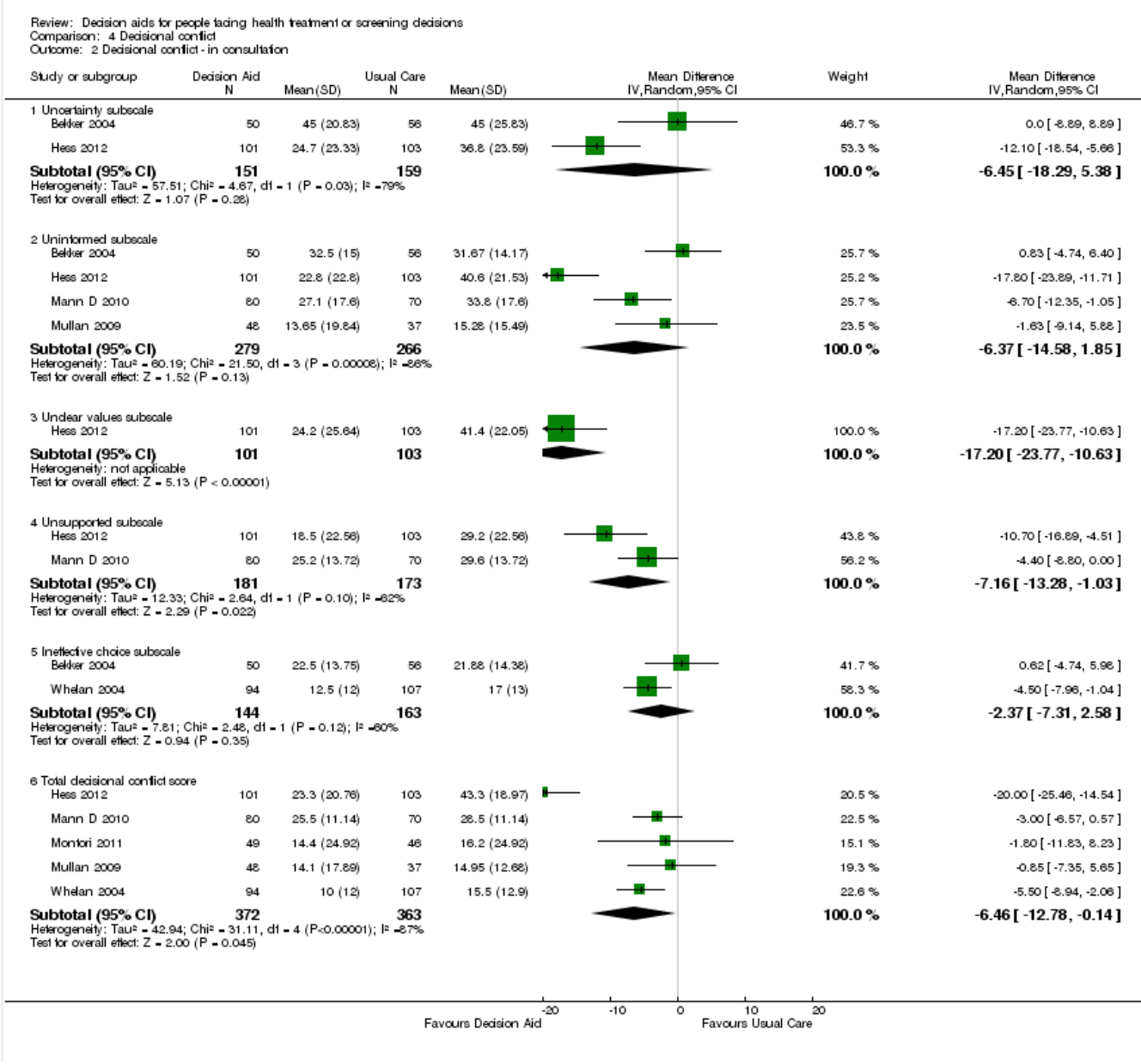
Analysis 3.1

Comparison 3 Informed values-choice congruence, Outcome 1 Informed values-choice congruence - all studies.



Analysis 4.1

1 Comparison 4 Decisional conflict, Outcome 1 Decisional conflict - all studies.



2

3

Appendix G: Grade tables

GRADE tables are not provided in the Cochrane review. Summary GRADE scores with reasons for downgrading are provided in the Summary of findings table.

Appendix H: Economic evidence

Economic evidence was not reviewed for this question

1

Appendix I: Excluded studies

There were no excluded studies because systematic searches were not undertaken.

Appendix J: References to included studies

Cochrane systematic review

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Appendix K: Research recommendations

The committee did not make any research recommendations about patient decision aids.