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Assessing the effectiveness of decision aids for decision making in prostate cancer testing: a systematic review

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Abstract

***Background*: Prostate cancer is a leading disease affecting men worldwide. Conflicting evidence within the literature provides little guidance to men contemplating whether or not to be screened for prostate cancer. This systematic review aimed to determine whether decision aids about early detection of prostate cancer improve patient knowledge and decision making about whether to undergo prostate-specific antigen testing.**

***Methods*: Medline, EMBASE, CINAHL, PsychINFO, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects and Health Technology Assessment databases up until March 2014 were searched. All included randomised controlled trials were assessed for methodological quality. Clinical selection and assessment heterogeneity among studies prevented the pooling of data for meta-analyses. Descriptive analyses of all included studies and comparison were performed.**

***Results*: A total of 13 randomised controlled trials met the inclusion criteria. Significant heterogeneity was present for the design and implementation of decision aids including comparative interventions and outcomes. Eight studies were of a low methodological quality, with the remaining five of medium quality. Improvements in patient knowledge following use of a decision aid were demonstrated by 11 of the 13 included studies. Seven of 10 studies demonstrated a reduction in decisional conflict/distress. Three of four studies demonstrated no difference between a decision aid and information only in reducing decisional uncertainty. Three of five studies demonstrated an increase in decisional satisfaction with use of a decision aid.**

***Conclusions*: Decision aids increase patient knowledge and confidence in decision making about prostate cancer testing. Further research into effective methods of implementation is needed.**

Introduction

Prostate cancer is a leading cancer affecting men, with the incidence second only to lung cancer worldwide [1]. It is the most commonly diagnosed cancer in men living in developed countries and sixth commonest cancer in men living in developing countries [1]. Geographical variation in incidence rates has been attributed in part to different applications of screening and testing for prostate cancer [2]. Age, ethnicity and familial history are all accepted as non-modifiable risk factors for prostate cancer [3]. Both the prostate-specific antigen (PSA) test and the digital rectal examination are commonly used as primary diagnostic tests for prostate cancer. Yet testing for prostate cancer in individual patients is a controversial issue, as population screened randomised controlled trials (RCTs) have shown conflicting survival benefits [4].

Screening for prostate cancer aims to detect the disease at an early stage and provide the patient with a choice of treatment options including variations of surgery,

radiotherapy and delayed or non-intervention [4]. The effectiveness of the PSA test remains controversial, as there is no single cut-off for further investigation with biopsy, which provides both high sensitivity and specificity. The commonly used threshold of 4.1 ng/mL yields a low false-positive rate (6.2%), but has a low sensitivity, detecting cancer in one out of five men [5]. Decreasing the threshold for biopsy would increase the proportion of men diagnosed with prostate cancer, but would also increase the rate of false-positives. Furthermore, lowering the threshold is associated with diagnosing more men with clinically insignificant cancer than when a higher threshold is used. Consequently, implementation of PSA testing in the general asymptomatic population is associated with significant overdiagnosis and overtreatment [6]. This carries the risk of significant long lasting side effects including incontinence, erectile dysfunction and psychosocial implications on quality of life [7,8].

Given the relative benefits and harms of screening for prostate cancer, many peak medical bodies have recommended a shared approach to decision making on PSA testing between patient and clinician [9–12]. Central to this shared decision-making process is ensuring that the patient is properly informed about the benefits and limitations of the medical intervention on offer. Decision aids aim to provide people with an opportunity to make an informed decision about a screening or treatment intervention through the provision of information about the benefits, limitations and uncertainty associated with the choice. Decision aids differ from usual health education materials because the content of decision aids is focused to make explicit the decision being considered, with an emphasis on personalising the focus of the user to the options and subsequent outcomes [13]. Decision aids, or decision support interventions, may be implemented in a variety of formats including written hardcopy (e.g. pamphlet/booklet), multimedia (e.g. computer, DVD, internet-based) or in-person support (e.g. counselling via nurse or physician) [14]. The primary focus of decision aids is to ensure that the user is able to improve his/her decision-making process in order to reach a high-quality, well-informed decision [13].

The aim of this study was to systematically review the literature to identify whether a decision aid (or decision support intervention) about PSA testing for early detection of prostate cancer improves decision making and knowledge compared with usual care for men without evidence of prostate cancer.

Methods

Study selection

Randomised controlled trials that included men at average or high risk of developing prostate cancer, without evidence of prostate cancer and considering a PSA test were eligible for inclusion in this systematic review. A study was eligible if it assessed a decision support intervention, a decision aid or tailored information (including risk communication) about PSA testing for early detection of prostate cancer. Comparisons were made with usual care, no intervention, an attention control or provision of simple non-personalised information.

A decision support intervention/decision aid was defined as an intervention designed to help people make specific and deliberative choices among options (including the status quo) by providing (at the minimum) the following:

- information on the options and outcomes relevant to a person's health status; and
- implicit methods to clarify values.

The aid also may have included the following:

- 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 personalised recommendation on the basis of clinical characteristics and expressed preferences; and
- guidance or coaching in the steps of making and communicating decisions with others [14].

Tailored information was defined as an intervention through which information is given to patients or individuals at risk of developing cancer where

- the main objective of the information is to inform people about cancer risks, screening options, cancer genetic counselling and DNA testing;
- the information is delivered by computer (e.g. CD-ROM or internet) or as printed material (e.g. letter or leaflet);
- the information is tailored based on more than one variable using algorithms [15].

Non-tailored information was defined as the provision of information on risks and benefits of testing in a screening context or discussion of risks and benefits of different options in a treatment context but does not include tailoring for the individual and does not include specific decision-making advice about strategies such as, and in particular, weighing up pros and cons or consideration of personal values.

The primary outcome of the systematic review was differences in patient decision making; comprising decisional satisfaction, decision-related distress (including decisional conflict and anxiety) and decisional uncertainty. Secondary outcomes included changes in patient knowledge. Studies needed to be written in English and published after the 31st of December 1989. Conference proceedings

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identified by the literature searches were included if they met the inclusion criteria.

Data sources

Medline (1990 to current), Excerpta Medica dataBase (EMBASE) (1990 to current), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1990 to current), PsychINFO (1990 to current), Cochrane Database of Systematic Reviews (2005 to current), Database of Abstracts of Reviews of Effects and Health Technology Assessment databases up until March 2014 were searched using text terms and, where available, database specific subject headings. The search strategy employed for each of the databases is supplied in the supplementary materials. Relevant recent (2005 onwards) guidelines were identified by scanning the citations identified by the literature search and searching the National Guideline Clearinghouse (http://guideline.gov) and the Guidelines Resource Centre (www.cancerview.ca).

Two reviewers (S. H. and D. S.) screened the titles and abstracts of all articles returned from the search strategy. Full-text copies of articles were sourced in the event that a decision to include/exclude an article based on information presented in the title or abstract of the article was not sufficient. All articles that met the pre-specified study selection criteria were included in the review.

Data collection, extraction and assessment of quality

Data was extracted by two reviewers (S. H. and D. S.) from studies included in the review as per the Cochrane Collaboration's double-data collection and extraction methodology [16]. Data extracted included study design and setting, numbers and demographic details of study participants, methodological descriptions of the intervention and comparisons and results. The methodological quality of each study was assessed independently by two reviewers (S. H. and D. S.): each was assessed as to the adequacy of blinding, allocation concealment and intention-to-treat (ITT) analysis [17,18]. Methodological quality of studies was determined as follows:

- High quality: a review that received two for three main criteria (double-blinding, concealment of treatment allocation schedule, inclusion of all randomised participants in analysis (i.e. ITT))
- Medium quality: Received two and/or one for all three main criteria
- Low quality: Received 0 for all three criteria or 0 and one for all three criteria or received 0 for any of the three criteria.

Information about generation of allocation sequences was considered as additional information and not considered when calculating the overall quality score [17,18].

Data analysis

Because of the clinical heterogeneity between studies in terms of how outcomes were measured, pooling of published data for meta-analyses was not possible. Such outcomes may be pooled using a standardised mean difference; however, this method assumes that the differences in standard deviations among studies reflect differences in measurement scales and not real differences in variability among study populations [16]. This assumption is problematic in this review, given the heterogeneity between study participants. Additionally, comparisons differed, the design and implementation of the interventions were varied, and controls ranged from provision of generic information to no intervention. A descriptive analysis of all studies was performed, given the possible impact of this clinical heterogeneity in pooling such diverse data.

Results

Description of studies

A total of 737 citations were identified through the search of the literature, of which 13 articles met the inclusion criteria (Figure 1). The combined Medline and PsycINFO search identified 512 citations, the EMBASE search identified an additional 203 citations, the CINAHL search 16 citations and the search of the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects and Health Technology Assessment database identified an additional 6 citations. Titles and abstracts were examined and 67 articles were retrieved for a more detailed evaluation. An additional 12 potential citations were identified from the reference list of retrieved articles. A total of 66 articles were excluded, of which 11 were review articles, 14 were not an RCT, 4 had participants not meeting the inclusion criteria, 2 were not relevant to prostate cancer, 15 did not meet the criteria for the intervention, 5 did not meet the criteria for the control, 12 did not report relevant outcomes and 3 were duplicate or publications reporting pilot data.

Studies were only included if sufficient information was available to determine whether the intervention met the criteria of the aforementioned definitions. In particular, for decision aids, the method for clarifying men's values about undergoing the PSA test had to be described adequately. Studies examining the effect of a decision aid that did not meet these criteria or those that provided insufficient information to allow for assessment of adequacy of the decision aid were excluded. Study characteristics including methodology, participants, interventions and outcomes for included studies are detailed in Table 1. Reasons for the exclusion of studies are detailed in the supplementary document.

A total of 6909 men participated in the 13 included studies. Participants ranged in age from 40 to at least 80 years of age. Nine of the studies were based in the USA, with

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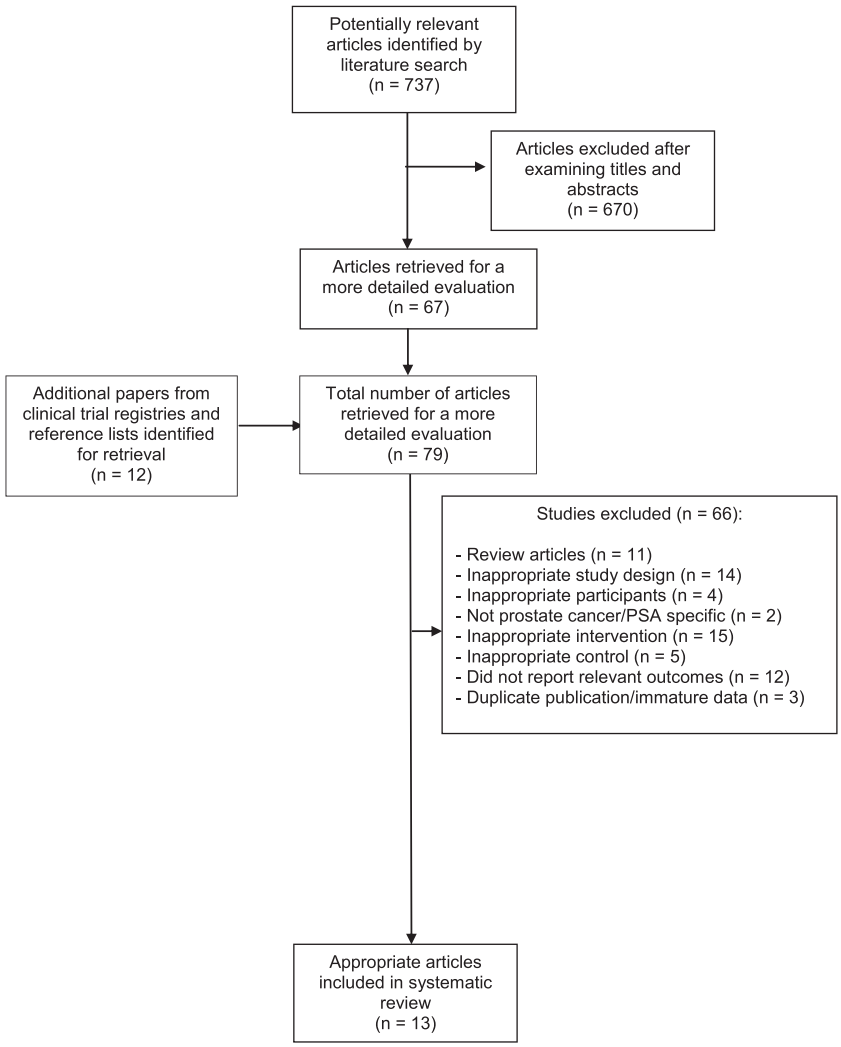

Figure 1. Flowchart for selection of inclusion of randomised controlled trials

three in Australia and one in the UK. Seven of the studies recruited men from a primary care setting, two from community settings and one each from a Department of Veteran's Affairs (DVA) outpatient clinic, pre-registered screening project, work sites and health insurance registries. Two studies were in populations at higher risk of prostate cancer [19,20]. Decision aids varied across studies, consisting of computer, paper or video-based materials, individual, group or professionally led discussions, tailored and general information. Decision making (including satisfaction) and knowledge were reported, but not on uniform outcome measures, for example, validated instruments versus pragmatic study-based outcomes.

Quality of studies

Eight of the 13 trials were assessed as being of a low methodological quality, with five trials assessed as being of a medium quality (Table 2). Only one study, Gattellari [21], was double-blinded. In this instance, blinding of participants and investigators may be difficult to achieve given the nature of the intervention under investigation. Despite this limitation, the majority of studies were limited in their attempt to control for allocation concealment, achieved by six studies, and intention-to-treat analysis, achieved only by three studies.

Effect of interventions

The primary outcome of differences in decision making was analysed across three sub-categories including decisional satisfaction, decision-related distress (including decisional conflict, anxiety) and decisional uncertainty.

Decisional satisfaction

Five studies assessed decisional satisfaction (Table 1) [19,21–24]. Four studies compared decision aids with information only, with two demonstrating a significant increase in decisional satisfaction with use of a decision aid [19,21]. One study compared the use of decision aids

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Table I. Summary of included studies

Study	Participants	Design	Intervention	Comparison	Results summary (*p*-value)	Size of effect
Allen 2010 (USA)	Male permanent employees, aged ≥45 years working ≥20 h per week recruited from work sites; 45.9% had undergone a previous PSA test.	Cluster RCT	Access to a computer-based decision aid with interactive video and audio components. The decision aid was available on computers at workplace for a minimum of 15 days during the 3-month intervention.	Non-intervention	≠ in decisional distress	NS
	N = 12 sites		*N* = 6 sites	*N* = 6 sites	(*p* = 0.09)	
	N = 2615 eligible		*N* = 398	*N* = 414	↑ in knowledge	Not reported
	N = 1195 selected				Change in mean score (scale: 0–100)	
	N = 812 consented to participate				D: 10 C: 4	
					(*p* = 0.03)	
					Follow-up = 77.0%	
					3 months after intervention	
Chan 2011 (USA)	Hispanic men aged ≥40 years (mean age 60.9 years) with no history of prostate cancer recruited from all senior social and housing centres in El Paso (Texas, USA).	Cluster RCT	Group discussions facilitated by 'promotores' using a script and slides with video clips of role models to trigger discussion.	Video about type 2 diabetes with discussion about the same topic.	↑ in decisional uncertainty	Not reported
	44% had undergone a previous PSA test.		*N* = 12 clusters	*N* = 13 clusters	% who found decision easy	
	N = 25 centres		*N* = 161 men	*N* = 160	D: 74 C: 87	Not reported
	N = 321 men				(*p* = 0.04)	
					↑ in knowledge	
					Mean score (scale: 0–12)	
					D: 8.7 C: 4.7	
					(*p* < 0.001)	
					Follow-up = 98.8% immediately after intervention	
Evans 2010 (UK)	Men aged 50–75 who could read English, use a computer, were not seriously ill, and whose records did not indicate that they had previously had prostate cancer or a PSA test, recruited at 25 GP practices in South Wales (UK).	RCT	Web-based Decision Aid ('Prosdex') providing information about prostate cancer and PSA testing.	No intervention	↓ in decisional distress	U/mn* = 0.32
	N = 382		*N* = 129	*N* = 127	Mean score (scale: 0–100)	U/mn* = 0.70
					D: 40.37 C: 47.73	
					(*p* < 0.001)	
					↑ in knowledge	
					Mean score (scale: −12 to 12)	
					D: 4.90 C: 2.17	
					(*p* < 0.001)	
					Follow-up = 72.8% immediately after intervention	
Gattellari 2003 (Australia)	Consecutive male patients aged 40–70 years (mean age 54.0 years) not diagnosed with prostate cancer, sufficiently fluent in English, recruited from 13 GP practices in Sydney.	RCT (multi-centre)	Booklet (published) containing information on prostate cancer including pros and cons of PSA testing and implicit methods to clarify values.	Government pamphlet advising men of Australian government policy on PSA screening.	↑ in decisional satisfaction	

(Continues)

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Table I. (Continued)

Study	Participants	Design	Intervention	Comparison	Results summary (*p*-value)	Size of effect
	N = 248		*N* = 126	*N* = 122	% who believe they can make an informed choice D: 90 C: 68 ($p = 0.008$)	Not reported
					↓ in decisional distress Mean score (scale: not reported) D: 21.6 C: 24.3 ($p < 0.001$)	Not reported
					≠ in decisional uncertainty ($p = 0.93$)	NS
					↑ in knowledge Mean score (Scale: 0–100) D: 50 C: 45 ($p = 0.049$) Follow-up = 86.3% at least 4 days after intervention	Not reported
Gattellari 2005 (Australia)	Community sample of men aged 50–70 years (mean age 58.1 years) without a history of prostate cancer, fluent in English, selected randomly from white-pages telephone directory (29 contiguous postcodes in Sydney), enrolled if interested in receiving information about PSA screening.	RCT	Booklet (published) containing information on prostate cancer including pros and cons of PSA testing and implicit methods to clarify values.	Leaflet brief information about the type of screening tests, chance of false positive result.	≠ in decisional satisfaction	
	N = 421		*N* = 140	*N* = 140 or	($p = 0.10$) ↓ in decisional distress compared with leaflet	Not reported
				Video with information about prostate cancer including the pros and cons of PSA 'screening' and a no values clarification exercise.	Mean score (scale: 3–15)	
				N = 141	D: 6.1 C: 6.6 ($p < 0.03$) ≠ in decisional distress compared with video ($p = 0.35$)	NS
					≠ in decisional uncertainty ($p = 0.56$)	NS
					↑ in knowledge Mean score (scale: 0–100) D: 57.2 Leaflet: 42.2 ($p < 0.001$) D: 57.2 Video: 45.8	Not reported

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					($p < 0.001$) Follow-up = 96.2% at least 8 days after intervention	
Lepore 2012 (USA)	Men of Black African descent aged 45–70 years (mean age 55.0 years) without a history of prostate cancer, who had not had a prostate cancer test in the 12 months before enrolment, were accessible by telephone and who had a primary care physician, selected from a list of health insurance beneficiaries of a healthcare workers' union in the New York City area; 45.9% had undergone a previous PSA test. *N* = 490	RCT	Print education material and discussions with a health educator. *N* = 244	Attention Control achieved via an educational pamphlet and tailored telephone education on a separate topic. *N* = 246	↓ in decisional distress Mean score (scale: 0–100) D: 34.15 C: 39.85 ($p < 0.05$) ↑ in knowledge Mean score (scale: 0–100) D: 61.6 C: 54.7 ($p < 0.001$) Follow-up = 88% at 8 months after randomisation	Not reported Not reported
Myers 2011 (USA)	Males aged 50–69 years with no history of prostate cancer or benign prostatic hyperplasia, who had not had a PSA test in the preceding 11 months, recruited from two primary care practice sites in Philadelphia. *N* = 313	RCT	Enhanced intervention consisting of a brochure on prostate cancer and screening and decision counselling sessions and discussion of prostate cancer screening with physician. *N* = 156	Standard intervention consisting of a brochure on prostate cancer and screening, and discussion of prostate cancer screening with physician. *N* = 157	≠ in decisional distress ($p = 0.62$) ↑ in knowledge Mean change in score (scale: 0–10) D: 1.5 C: 0.8 ($p = 0.001$) Follow-up = 91.4% at 7 days after intervention	NS Mean difference in change = 0.8
Partin 2004 (USA)	Male veterans aged 50+ years (mean age 68.4 years) without evidence of prostate cancer, who had scheduled primary care appointments at one of four Veterans Affairs medical facilities in the Midwest of the USA. Approximately 70% had undergone a previous PSA test.	RCT	Video presenting the risks and benefits of screening.	Usual Care.	↑ in knowledge	

(Continues)

Table I. (Continued)

Study	Participants	Design	Intervention	Comparison	Results summary (*p*-value)	Size of effect
	N = 768		*N* = 384	*N* = 384	Mean score (scale: 0–10) D: 7.44 C: 6.90 ($p < 0.001$) Follow-up = 77.9% up to 3 after intervention	Not reported
Sheridan 2012 (USA)	Men aged 40–80 years with no prior history of prostate cancer or evidence of a serious medical illness. *N* = 130	RCT × 2	Trial 1: Video-based decision aid + coaching session + brochure.	Attention control, video on highway safety.	↑ in knowledge	RR (95% CI) 4.28 (2.30–6.45)
			Trial 2: Trial 1 intervention with additional information on cardiovascular disease screening and colon cancer screening *N* = 60	*N* = 70	% with perfect score D: 47 C: 13 (*p*-value not reported) Follow-up = 98.5% immediately after intervention	
Taylor 2013 (USA)	Male primary care outpatients aged 45–70 years (mean age 56.9 years) with no history of prostate cancer who had had an outpatient appointment in the previous 24 months at one of three Washington DC medical facilities; 86% had been screened for prostate cancer, with 73% having previously discussed screening with physician. *N* = 1893	RCT	1. Web-based decision aid *N* = 631	Usual care *N* = 632	↑ in decisional satisfaction % with score above median Web: 52.2 C: 45.5 ($p = 0.04$) Print: 60.4 C: 45.5 ($p < 0.001$)	 OR = 1.29 OR = 1.79
			2. Print-based decision aid Same content as website *N* = 630		↓ in decisional distress Mean score (scale: 0–100) web: 12.7 C: 20.0 ($p < 0.001$) print: 12.2 C: 20.0 ($p < 0.001$) ↑ in knowledge Mean score (scale: 0–18) web: 13.5 C: 11.1 ($p < 0.001$) print: 13.5 C: 11.1 ($p < 0.001$) Follow-up = 88.8% at 1 month after intervention	Adjusted mean difference −6.7 −7.5 Adjusted mean difference 2.26 2.40
Volk 2008 (USA)	Patients aged 50–70 years if not African-American and 40–70 years if African-American, without a history of prostate cancer; 37.1% (low-literacy) and 74.5% (high literacy) had undergone a previous PSA test. *N* = 149 (low-literacy)	RCT	Entertainment-based multimedia decision aid. *N* = 76 (low-literacy)	Audiobooklet with same factual learner content. *N* = 73 (low-literacy)	≠ in decisional satisfaction ($p = 0.09$ (low-literacy) 0.96 (high-literacy))	NS

	N = 301 (high-literacy)		*N* = 148 (high-literacy)	*N* = 153 (high-literacy)	↓ in decisional distress Mean score (scale: 0–100) Low-literacy D: 12.0 C: 21.7 ($p < 0.04$)	Not reported
					≠ in decisional distress High-literacy ($p = 0.15$)	NS
					≠ in decisional uncertainty ($p = 0.80$ (low-literacy) 0.20 (high-literacy))	NS
					≠ in knowledge NS – no *p*-values reported Follow-up = 56.4–59.7% (low-literacy) 79.40% (high-literacy) 2 weeks after intervention	NS
Watts 2013 (Australia)	Men aged 40–79 years (mean age 55.9 years) with at least one first-degree or second-degree relative with a previous diagnosis of prostate cancer, who were proficient in English, able to give informed consent and who had not been diagnosed with prostate cancer.	RCT	Tailored online decision aid with information about (familial) prostate cancer, prevention, diagnosis and treatment.	Non-tailored online educational materials about prostate cancer screening.	↑ in decisional satisfaction	Not reported
	N = 138		*N* = 69	*N* = 69	Mean regret score (scale: 0–100) D: 11.7 C: 15.1 ($p < 0.01$)	
					≠ in decisional distress immediately after intervention ($p = 0.95$)	NS
					≠ in knowledge immediately after intervention ($p = 0.88$) Follow-up = 56.5% at 12 months after intervention	NS
Williams 2013 (USA)	English speaking men aged 40–70 years (mean age 54.9 years) with no history of prostate cancer, who had been pre-registered for prostate cancer screening; 73.8% previously tested for prostate cancer.	RCT	Decision aid booklet detailing pros and cons of PSA test and a values clarification section.	Usual care consisting of a booklet with a short fact sheet about PSA testing.	≠ in knowledge	NS
	N = 543		*N* = 272	*N* = 271	↑ in knowledge Mean score (Scale: 0-16) D: ~10.4 C: ~10.0 ($p < 0.05$)	Not reported
					↓ in decisional distress % with score above median D: 28 C: 39 ($p < 0.05$) Follow-up = 82.69% at 2 months	OR = 0.49

↑, increase in outcome; ↓, decrease in outcome; ≠, no statistically significant difference; U/mn*, effect size derived from the Mann–Whitney *U*-statistic divided by the product of the two samples sizes (<0.5 means intervention group scored lower than control, 0.5 = line of no effect); C, Control; D, decision aid; NS, not statistically significantly different; OR, odds ratio; RR, risk ratio; 95% CI, 95% confidence interval; RCT, randomised clinical trial.

Table 2. Methodological quality of included studies

	Blinding	Allocation concealment	Intention to treat analysis (ITT)	Generation of allocation sequence[a]	Overall rating
Allen 2010 [28]	1	0	0	1	Low
Chan 2011 [29]	1	2	2	1	Medium
Evans 2010 [26]	1	2	0	0	Low
Gattellari 2003 [21]	2	0	1	0	Low
Gattellari 2005 [22]	1	2	2	1	Medium
Lepore 2012 [20]	1	2	1	1	Medium
Myers 2011 [27]	1	1	1	0	Medium
Partin 2004 [30]	1	2	0	1	Low
Sheridan 2012 [31]	1	1	2	1	Medium
Taylor 2013 [23]	0	0	0	1	Low
Volk 2008 [24]	1	0	0	0	Low
Watts 2013 [19]	0	2	0	1	Low
Williams 2013 [25]	1	0	0	0	Low

[a]Not considered when calculating the overall evidence quality rating.

with usual care – concluding that a significant increase in decisional satisfaction was associated with the use of a decision aid [23].

Decision-related distress

Ten trials assessed decision-related distress, with seven trials demonstrating a significant reduction in decisional conflict/distress with use of a decision aid (Table 1) [20–26]. Six studies compared the effectiveness of decision aids with information only, of which two studies concluded no significant benefit [19,27]. One study compared men receiving a tailored decision aid with a non-tailored decision aid [19]. The second study provided the opportunity for men in both groups to discuss the issue of prostate cancer screening with their physicians. This may have provided participants in both study arms the opportunity to allay any concerns with their physicians. One study examining decision aids versus usual care demonstrated a significant reduction in decisional conflict/distress with a decision aid [23]. Two of the three studies comparing decision aids with no information reported a significant reduction in decisional conflict/distress with a decision aid [20,26]. Uptake of the decision aid in the study reporting no benefit was only 30% among participants randomised to it [28].

Decisional uncertainty

Four studies assessed decisional uncertainty, with three of the four demonstrating no difference between a decision aid and information only in reducing decisional uncertainty (Table 1) [21,22,24]. Only one study, which compared a decision aid with no information, demonstrated a significant increase in decisional uncertainty [29].

Knowledge

All 13 studies included in this review assessed patient knowledge (Table 1). Eleven of the 13 RCTs demonstrated a statistically significant improvement in knowledge with use of a decision aid [19–23,26–31]. Six studies compared the use of a decision aid with information only, of which four demonstrated that knowledge was significantly improved in patients using the decision aid, compared with information only [19,21,22,27]. Two studies concluded that use of decision aids significantly increased knowledge compared with usual care [23,30]. Five studies compared the use of decision aids to providing no information, all demonstrating a significant increase in knowledge in men receiving the decision aid [20,26,28,29,31].

Of the two studies that reported no significant changes in knowledge, one compared an entertainment approach with decision support and to an audio booklet [24]. In this study, the arms differed only in the decision aid arm having included a values exercise and so this result may be due to the similarity of the information in each arm. The other study reporting no significant difference compared a decision aid with tailored information versus non-tailored information [25].

Conclusions

This systematic review identified that the methodological quality of RCTs currently evaluating the effectiveness of decision support for PSA testing is low to moderate at best. Studies of a high methodological quality are urgently required to provide patients and clinicians with strong evidence on whether to utilise decision support tools for PSA testing. Furthermore, significant heterogeneity between the studies with respect to the design of the intervention and its implementation rule out the pooling of data and direct comparisons across studies. The studies included in this systematic review demonstrate an effect for knowledge and decision-related distress and so can be recommended with the previously stated caveats in mind.

Only one systematic review to date (published in 2007) has specifically investigated the impact of decision aids

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for prostate cancer screening [32]. Findings from that review concluded that decision aids increased patient knowledge and confidence in decision making. The results from our review support those findings. The 2007 review also identified that the use of decision aids significantly decreased men's interest in PSA testing and screening behaviour (relative risk [RR] = 0.88, 95% confidence intervals [CI] = 0.81–0.97). [32]. A 2014 update of a Cochrane systematic review on decision aids for people facing screening or treatment decisions (across a variety of health conditions) supported the findings that decision aids increase patient knowledge and decrease decisional conflict [13]. Furthermore, because of the long natural history of prostate cancer, a conclusive survival benefit is warranted before recommending testing for early disease.

Our systematic review differs from the Volk and Stacey reviews [13,32], as it deals specifically with decision aids and tailored information for PSA screening. Volk considers more general 'educational interventions' for PSA screening and Stacey focuses on screening behaviours in the context of PSA screening, but examines the other aspects of decision making and patient knowledge only in the context of screening in general not in the context of PSA screening. No meta-analysis was performed in our review because of the heterogeneity of the decision aids and comparisons. The presumption of homogeneity between studies, when it is not apparent, can alter statistical conclusion by up to 20% [33]. Despite the presence of such clinical heterogeneity, our results support (albeit descriptively) previous conclusions that decision aids support patient knowledge and confidence in decision making [13,32].

Given that the current evidence suggests that decision aids are effective at increasing patient knowledge and improving a patient's decision-making process, the next step is to ensure their successful implementation into clinical practice. For research to be successfully implemented, it must work its way through the 'evidence pipeline', which does not always ensure uptake into practice [34]. A four-step process has been suggested for the successful implementation of a decision aid, which includes (i) meeting the needs of the population, (ii) willingness of practitioners to utilise it in clinical practice, (iii) the presence of effective systems, and (iv) practitioners and consumers skilled in shared decision making [13]. Successful implementation of this modelled approach requires a tailored approach, accounting for other external factors aligned with a patient's level of health literacy and an ability to objectively assess other issues which, in prostate cancer includes a realistic estimation of life expectancy.

Clinicians are commonly supportive towards the use of decision aids in practice [35], particularly in a field such as prostate cancer in which the effectiveness of the intervention is questionable, the appropriateness of the advice uncertain and in which patient preferences play an important role [36]. However, intention to use does not align with actual use of decision aids in clinical practice [35]. Restrictions on practitioner time, awareness and access to decision aids and skill in utilising them with patients in a clinical environment have all been identified as barriers to successful implementation of decision aids in clinical practice [37–40].

Critical to successful implementation of decision aids in practice is the support of clinical staff (physicians and nursing staff) as well as administrative staff [41]. Yet, the main barrier to successful implementation still remains the first step in the 'evidence pipeline' – a lack of practitioner awareness about decision aids and their effectiveness [42]. Options for overcoming this barrier include automatic distribution of decision aids and the engagement of members other than physicians for their use [43]. Although still in its infancy, the use of practice-nurses to engage with patients in discussion about PSA testing with the assistance of decision aids has been effective in implementing the use of decision aids in clinical practice and promoting shared decision making between patients and practitioners [27].

This systematic review consisted of published data only, with outcomes limited to decision making and patient knowledge. Impact of decision aids upon uptake of PSA testing, or prostate cancer screening generally, was not assessed as the current evidence from systematic reviews of the literature conclude no significant reduction in prostate-specific, or all-cause, mortality [4]. Studies included in this systematic review were undertaken with populations from the US, UK and Australia with some US studies including Hispanic and African American populations. The evidence is generalizable to well men in Western countries who are considering PSA testing with some reservations in considering how effective these interventions may be for men with low levels of education and low literacy; from a non-English speaking background; or other minority or cultural groups.

Future research is required to further examine the effectiveness of decision aids across these populations, as well as various other ethnic groups including African and Asian populations. In addition to identifying successful models for implementing decision aids in clinical practice, further research is also required to determine equivalency between different modes of delivery, be it decision aid-related (i.e. written, audio-visual, web-based), or implementation-related (i.e. patient self-directed use or facilitated by practitioners) [44]. The continued long-term follow-up of patients from large prostate cancer screening and prevention trials has identified data that has been utilised in the development of prostate cancer risk calculators [45,46]. Further research into the effectiveness of such tailored risk identification is also required, along with the influence of patient health literacy, to truly underpin the benefit of these decision aids in providing information about PSA testing and prostate cancer to men.

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Author contributions

D. I. contributed to the development of the clinical question, search strategy, inclusion criteria, data interpretation and drafting of the manuscript. W. J. contributed to the development of the clinical question, search strategy, inclusion criteria, data interpretation and drafting of the manuscript. P. C. contributed to the development of the clinical question, search strategy, inclusion criteria, data interpretation and drafting of the manuscript. R. G. contributed to the development of the clinical question, search strategy, inclusion criteria, data interpretation and drafting of the manuscript. S. H. contributed to the development of the clinical question, search strategy, inclusion criteria, assessment of quality, data extraction and interpretation and drafting of the manuscript. D. S. contributed to the development of the clinical question, search strategy, inclusion criteria, assessment of quality, data extraction and interpretation and drafting of the manuscript. S. C. contributed to the development of the clinical question, search strategy, inclusion criteria, data interpretation and drafting of the manuscript.

Conflict of interest

The authors have declared no conflicts of interest.

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