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Prostate Cancer Screening Patient Decision Aids: A Systematic Review and Meta-analysis

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Abstract

Context: Although screening recommendations for prostate cancer using prostate-specific antigen testing often include shared decision making, the effect of patient decision aids on patients' intention and uptake is unclear. This study aimed to review the effect of decision aids on men's screening intention, screening utilization, and the congruence between intentions and uptake.

Evidence acquisition: Data sources were searched until April 6, 2018, and included MEDLINE, Scopus, CENTRAL, [CT.gov](http://www.ct.gov), Cochrane report, PsycARTICLES, PsycINFO, and reference lists. This study included RCTs and observational studies of decision aids that measured prostate screening intention or behavior. The analysis was completed in April 2018.

Evidence synthesis: Eighteen studies (13 RCTs, four before–after studies, one non-RCT) reported data on screening intention for $\approx 8,400$ men and screening uptake for 2,385 men. Compared with usual care, the use of decision aids in any format results in fewer men (aged 40 years) planning to undergo prostate-specific antigen testing (risk ratio=0.88, 95% CI=0.81, 0.95, $p=0.006$, $I^2=66\%$, $p<0.001$, $n=8$). Many men did not follow their screening intentions during the first year after using a decision aid; however, most men who were planning to undergo screening did so (probability that men who wanted to be screened would receive screening was 95%).

Conclusions: Integration of decision aids in clinical practice may result in a decrease in the number of men who elect prostate-specific antigen testing, which may in turn reduce screening uptake. To ensure high congruence between intention and screening utilization, providers should not delay the shared decision-making discussion after patients use a decision aid.

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CONTEXT

Prostate cancer is the most commonly diagnosed cancer in men globally.¹ Its incidence and mortality rates are higher in more developed countries^{1,2} and increase with age. Estimates compiled by the Surveillance, Epidemiology, and End Results Program of the U.S. National Cancer Institute predicted^{3,4} that in 2017, prostate cancer would be the main cause of death from cancer in American men, with 161,360 men (9.6% of all cancer cases in the U.S.) diagnosed with prostate cancer and 26,730 men (4.4% of all cancer deaths in the U.S.) dying from it. Five-year survival rates depend on the stage at diagnosis: 100% for men with local disease, and only 29.8% (95% CI=28.8%, 30.9%) for men (all races, all ages) with distant disease.³ Approximately 12 of 100 American men will eventually be diagnosed with an invasive form of prostate cancer during their lifetime.³

The prostate-specific antigen (PSA) test can be used as a screening test in asymptomatic men to detect prostate cancer. However, research suggests that the potential harms of screening with the PSA test can outweigh its benefits. It is estimated that for every 1,000 men aged 55–69 years who are offered PSA-based screening over the next 13 years that 240 will have a positive test and require a biopsy, of whom 100 will be diagnosed with prostate cancer. Potential benefits include approximately one fewer patient dying of prostate cancer and three fewer patients experiencing metastasis, with no change in all-cause mortality.^{5,6} Potential harms include worry, a high false positive rate, overdiagnosis (treatment of many men whom the prostate cancer never would have harmed), and a high rate of surgical complications including erectile dysfunction and urinary incontinence.^{7,8}

The decision about PSA-based screening is confounded by current prostate cancer screening recommendations, which differ between countries and professional organizations. Although the majority of professional organizations (36 of 42) in developed countries do not recommend or recommend against national mass screening programs, they disagree about opportunistic and selective screening (Appendix Figure 1). Some professional North American organizations recommend against routine PSA-based screening (American College of Preventive Medicine 2016,⁹ American Academy of Family Physicians 2012,¹⁰ Canadian Task Force Preventive Health Care 2014¹¹), whereas others suggest shared decision making (SDM) to help patients decide (U.S. Preventive Services Task Force 2018,^{5,6} American Urological Association 2013 (confirmed in 2015),¹² American College of Physicians 2015,¹³ National Comprehensive Cancer Network 2018,¹⁴ American Cancer Society 2016¹⁵). The final recommendation statement⁵ from the U.S. Preventive Services Task Force includes new support for SDM among asymptomatic men in the general U.S. population who are aged 55 to 69 years. This change reflects a general shift, with recent and upcoming recommendations converging on the need for SDM (Appendix Figure 1).

Patient decision aids (DAs) are often used to ensure that patients make informed decisions that are congruent to their values and support SDM. None of the certification efforts around DAs focus on intention or uptake as an outcome; however, these outcomes are important because they demonstrate the effect that DAs and SDM have on patient behavior. The effects of DAs on men's intentions to undergo PSA-based screening, screening utilization, and their congruence remain unclear. Furthermore, the extent to which certain DA formats

(audiovisual materials, only visual, only audio, or interactive computer-based) influence these outcomes is unknown. Finally, previous studies have failed to determine whether men indeed follow through with their stated intention.

The purpose of this systematic review and meta-analysis is to determine how the use of DAs in clinical practice affects men's intention toward PSA screening, screening utilization rates, and the congruence between intention and screening uptake. This review addresses the following key questions (KQs; Appendix Figure 2): KQ1: In men from various racial and age groups, how do DAs, compared with the usual care, affect their intention to undergo PSA screening? KQ2: In men from various racial and age groups, does the use of DAs, compared with the usual care, decrease the number of men who are undecided about their screening plans? KQ3: In men from various racial and age groups, are computer-based interactive DAs, compared with other types of DAs, more influential in changing screening intention? KQ4: For men, are computer-based interactive prostate cancer screening patient DAs compared with other types of DAs more influential in changing utilization of PSA-based screening? KQ5: After using a DA, to what extent is men's screening intention associated with a change in the PSA-based screening utilization rate?

EVIDENCE ACQUISITION

The protocol for this review was registered in the PROSPERO database, #CRD42017060606.¹⁶ This manuscript followed two guidelines: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)¹⁷ for RCTs, and the Meta-analysis Of Observational Studies in Epidemiology (MOOSE)¹⁸ for observational studies.

Data Sources and Searches

The following databases were searched: MEDLINE Epub Ahead of Print, In-Process and Other Non-Indexed Citations, MEDLINE Daily, MEDLINE and Versions, SCOPUS, Cochrane Central Register of Controlled Trials (CENTRAL), PsycINFO, PsycARTICLES, and [ClinicalTrial.gov](https://www.clinicaltrials.gov) through April 6, 2018, without language restrictions (Appendix Tables 1–3). This search was supplemented by a hand search of reference lists from articles eligible for this review and the Cochrane reports.^{19–21}

Study Selection

Studies were eligible for this systematic review if they met the following predefined criteria: (1) used an intervention involving a DA in any format, (2) reported immediate or deferred intention or utilization data from men aged 40 years who were not diagnosed with prostate cancer prior to using a DA, and (3) were RCTs or observational studies (Appendix Table 4). Two reviewers independently screened each title and abstract, and then reviewed full-text articles by using Covidence®, Cochrane's online systematic review platform. All disagreements were solved through consensus adjudication and the authors confirmed exclusion or inclusion in Covidence®. The authors contacted corresponding authors of potentially eligible papers for further clarifications.

Data Extraction and Quality Assessment

Data extraction was performed with the use of the Covidence© platform. The data were extracted from each eligible study by two reviewers independently. The following data were extracted: study design, study period, patients' characteristics in each group, numbers of participants enrolled and number with outcome data, ages of participants, details of intervention and comparator, study settings, and other details. Two reviewers independently assessed each study's risk of bias by using the Cochrane Collaboration tool for assessing the risk of bias for RCTs,^{22,23} the Risk Of Bias In Non-randomized Studies of Interventions tool²⁴ for a non-RCT and controlled before–after study, and the NIH Quality Assessment Tool²⁵ for uncontrolled before–after studies. Discrepancies were resolved through consensus.

Data Synthesis and Analysis

The overall effect from studies with low or moderate risk of bias was pooled for all RCTs using data from control and intervention groups. Additionally, overall effect across RCTs (baseline data from all groups, after-intervention data in the DA group, and a control group) and before–after studies was pooled. The DerSimonian–Laird random effects model²⁶ with the recommended²⁷ Hartung–Knapp correction were used to calculate risk ratios (RRs) within the “meta” package²⁸ in R, version 3.4.4, accessed with RStudio, Version 1.1.422. The mean difference was used to compare change in patient knowledge. The presence of statistical heterogeneity was assessed with Cochran Q statistics via a chi-square test, and the magnitude of heterogeneity was evaluated with the I^2 statistic.²⁹ All studies were stratified based on study design and formats of DAs. Sensitivity analyses included examining the influence of (1) single studies, (2) the used effect model, (3) using before–after intention data in RCTs, and (4) the methodological quality of the studies and their design diversity. The number needed to treat was calculating by using the RR from the statistically significant results ($p < 0.05$) of a meta-analysis.³⁰ Egger's test³¹ was used to explore funnel plot asymmetry in meta-analyses with more than ten studies, as recommended.³² Cohen's κ and its 95% CI were used to evaluate the concordance between men's screening plans and actual screening behavior during the first year after using a DA. Evidence quality was assessed with the Grading of Recommendations Assessment, Development, and Evaluation (GRADE)³³ for RCTs. All conclusions are based on results of the RCTs.

EVIDENCE SYNTHESIS

Study Selection

Of the 1,042 identified records, 20 articles^{34–53} presenting 18 unique studies met inclusion criteria, 316 records were duplicates, and 706 did not meet the inclusion criteria and were therefore excluded (Figure 1 and Appendix Table 5). Of the 706 excluded articles, 53 were excluded after the full texts were assessed: 22 reported outcomes that were irrelevant to this review, 12 did not indicate a DA as an intervention, seven had an unsuitable study design, seven appeared in the wrong type of publication, and five included populations that did not fit the study protocol. Only one RCT⁵⁰ and a before–after study⁴⁰ focused on the effect of DAs on African American men who, compared with white men, are almost twice as likely to

be diagnosed with prostate cancer and more than twice as likely to die because of prostate cancer.^{5,6} For this reason DAs for African American men tend to adopt a tone intended to encourage screening, thus shifting the intention and screening uptake in this population. This RCT⁵⁰ was not used to pool the overall effect across RCTs that included all races, but was considered separately to evaluate the potential effect of DAs on outcomes in African American men. Both studies^{40,50} were included in the qualitative synthesis.

Study Characteristics

Of the 18 included English-language studies, 13^{34–38,43–45,47–53} were RCTs, one⁴⁶ was a non-RCT, and four^{39–42} were before–after studies. Of all the studies, 12^{34,36,37,39–43,45–47,50–52} were conducted in the U.S, three^{44,48,49} in Australia, two^{35,38} in the United Kingdom, and one⁵³ in France. Studies reported intention to undertake PSA-based screening among men aged 40 to 85 years who: (1) planned to undergo screening,^{34–42,44,46,48–53} (2) did not wish to be screened,^{34,38–42,44,48,49,53} (3) were unsure about their screening plans,^{34,38–42,48,53} or (4) underwent PSA-based screening after using a DA in 1 day,⁴⁵ 2^{43,51} or 3⁴⁷ weeks, 3 months,⁴⁰ 6 months,³⁵ 1 year,^{37,45,50,51} or 2 years.⁵⁰ The results from individual studies are presented in Table 1 and Appendix Table 6.

Risk of bias was assessed (Appendix Tables 7–9) in all studies. Eleven RCTs^{34–38,44,47–49,51–53} and two non-randomized studies^{41,46} were considered to have moderate risk of bias. Two RCTs^{43,45} had a high risk of bias. These two RCTs were omitted from quantitative and qualitative analyses due to high risk of bias; however, the effect of these studies was explored in the sensitivity analysis. Two uncontrolled before–after studies were assigned fair³⁹ and good⁴² quality rating, and one uncontrolled before–after⁴⁰ was assigned a poor quality rating.

Prostate cancer screening patient decision aids.—The 18 included studies evaluated 24 DAs (19 unique DAs). Of these 18 studies, 12 studies^{35,38,42–45,47–53} examined visual DAs (pamphlet or handout), six^{34,35,39,43,44,47} studies evaluated interactive DAs, and seven^{36,37,40,41,44,46,49,51,52} assessed audio-visual DAs. Five studies^{36,40,41,46,51} examined an audio-visual aid called *The PSA Decision: What You Need to Know*. Some DAs have been updated since the first publication, so the versions of the DA assessed in the studies may not be the same version currently available for patients. For inaccessible DAs evaluations were based solely on available descriptions. Thirteen DAs met all International Patient Decision Aids Standards Qualifying Criteria⁵⁴ for educational DAs, five lacked sufficient descriptive information to make a determination, and one failed to meet two of the criteria (Appendix Table 10).

Synthesis of the Results

Men's intention to undergo prostate-specific antigen–based screening.—The overall effect of DAs on men's willingness to undergo screening was derived from eight RCTs^{34–38,48,49,51–53} that studied 11 DAs. Compared with control interventions, the use of any format of DA resulted in fewer men planning to undergo PSA-based screening (RR=0.88, 95% CI=0.81, 0.95, $p=0.006$, $I^2=66\%$, $p<0.001$; Figure 2). This RR was used to calculate that 548 (95% CI=505, 595) of every 1,000 men in the DA group intended to be

screened, compared with 623 of 1,000 in the control group. This finding suggests that after using a DA, 75 (95% CI=118, 28) fewer men of 1,000 intended to undergo PSA test, in comparison with usual care (Table 2). With the use of a number needed-to-treat approach, 14 (95% CI=9, 35) men aged 40 to 85 years would need to use any format DA so that one man would reconsider his intention to be screened. Although the evidence was low in quality due to unknown risk of performance bias and considerable inconsistency (Table 2) for this outcome, the analysis of the difference in the number of men at the baseline and after the intervention show a similar significant change in intention for five RCTs^{34,36,37,48,49,53} (RR=0.82, 95% CI=0.72, 0.93, $p<0.01$, $I^2=81\%$, $p<0.01$), one non-RCT,⁴⁶ and one controlled before–after study.⁴¹ These findings are consistent.

When comparing the effects of various formats of DAs in RCTs on the change in the number of men aged 40 to 82 years planning to undergo the PSA test, the meta-analysis showed that only visual DAs statistically significantly affected men's intention (RR=0.87, 95% CI=0.78, 0.96, $p=0.018$, $n=6$, $I^2=51\%$, $p=0.068$; Figure 2). Using the above RR, 566 of 1,000 men planned to be screened in control groups, compared with 490 (95% CI=441, 545) of 1,000 after using a visual DA. Therefore, the use of visual DAs can result in 76 (95% CI=125, 21) fewer men of 1,000 intending to undergo PSA testing (Table 2). This effect is similar to the results after using a DA in any format.

The number of men who were reluctant to be screened did not appear to be affected in five RCTs^{34,38,48,49,53} that tested six DAs (RR=1.26, 95% CI=0.92, 1.73, $p=0.12$, $n=6$; Appendix Figure 3). Heterogeneity of this result was considerable ($I^2=70\%$, $p<0.01$) and its level was affected by one French trial⁵³ that showed a large, significant increase in the number of men who were reluctant to be screened after using a visual DA. Furthermore, one large uncontrolled before–after study³⁹ supported this change in intention (Appendix Figure 4). However, the overall effect from three before–after studies^{39,42,41} and before–after results from five RCTs^{34,44,48,49,53} that studied eight DAs, suggests a significant increase ($p=0.04$ and $p<0.01$, respectively) in the number of men who did not want to be screened after using a DA.

These analyses (Appendix Figure 5) did not identify a significant effect of DAs on the proportion of men who were undecided about their screening strategy. However, the before–after result from RCTs (eight DAs) indicates a lower number of men who were undecided about their screening plans after using a DA (Appendix Figure 6).

Effect on screening utilization.—Five RCTs^{35–37,45,50–52} evaluated the effect of seven DAs on screening behavior. Four of five RCTs studied men in general populations and provided screening behavior data during 2 weeks,^{51,52} 3 weeks,⁴⁷ 6 months,³⁵ or 1 year after using a DA^{36,37,51,52} (Appendix Figure 7). Compared with the control, the RCTs indicate that the use of DAs leads to a potential decrease in number of men who would undergo PSA testing during the first 3 weeks (RR=0.94, 95% CI=0.90, 0.97, $p=0.02$, $n=3$, $I^2=0\%$, $p=0.91$). However, this effect did not hold through the first 6 months (one RCT) or 1 year (two RCTs with three DAs). Only one^{36,37} of these four studies reported a statistically significant change in PSA test uptake at the 1-year follow-up and showed that 21% fewer (34% [24/70] vs 55% [37/67], $p=0.02$) men underwent screening after using an audio-visual DA. One

RCT⁵⁰ included African American men only, and this study showed nonsignificant effect of a visual DA (pamphlet) on changing the odds of men undertaking a PSA test during the first 2 years.

Congruence between screening intentions and screening utilization.—One RCT^{51,52} with audio-visual and visual DAs demonstrated that 61% (188/308) and 64% (189/295) of men planned to undergo PSA testing after using a DA, respectively. However, 67% (6% and 3% more than were intended initially) of the men in each group underwent screening by the end of the first year after using a DA.^{51,52}

Only one RCT^{36,37} provided patient-level data about men's primary intention toward PSA testing and screening utilization during the first year after using an audio-visual DA. The Cohen's κ coefficient 0.29 (95% CI=0.10, 0.48, $p=0.007$) demonstrates a slight to moderate strength of agreement between men's screening intentions and screening utilization by the end of the first year after using this DA. Nevertheless, the probability that men who wanted to be screened would receive screening was high (0.95, 95% CI=0.76, 0.99). This result indicates that it is very likely that men who intend to undergo screening will follow through with screening during the first year after using an audio-visual DA. However, many men will not realize their primary intentions.

Secondary Outcomes

Knowledge.—High-quality evidence was found that the use of DAs increased men's knowledge.^{34,36,37,47–49} Six RCTs,^{34,36–38,47–49} one non-RCT,⁴⁶ and one before–after study⁴¹ showed a significant increase in knowledge when compared with the control group. The overall effect in RCTs across (1) all types of DAs^{34,36,37,47,48,49} was mean difference of 8.45 (95% CI=3.44, 12.46, $p<0.01$, $I^2=78\%$, $p<0.01$), and (2) visual DAs^{36,37,47–49} was mean difference of 11.44 (95% CI=2.40, 20.47, $p<0.03$, $I^2=79\%$, $p<0.01$; Appendix Figure 8). Only one RCT⁴⁹ showed an insignificant increase in the number of correctly answered knowledge questions after using an audio-visual DA.

Decisional conflict.—Compared with the control group, men who used DAs in any format reported a reduction in decisional conflict $p<0.05$ (visual DAs^{47–49} or interactive DAs^{34,35}). Visual DAs were effective at improving men's feelings of being informed, feeling clear about values, feeling supported,⁴⁷ and feeling more certain.⁴⁸ No difference was found in the levels of decisional conflict in studies that compared various formats (visual DA with audio-visual DA,⁴⁹ and visual DA with interactive DA³⁵).

Attitude.—The use of either an interactive DAs³⁵ or visual DAs^{38,49} resulted in less favorable attitudes toward screening compared with the control group ($p=0.01$). After using a visual DA, men had a less positive attitude⁴⁹ than after using an audio-visual DA ($p=0.01$). Men using an interactive DA did not differ in attitude from men who used a visual DA ($p=0.39$).³⁵ Compared with the control group, men in the audio-visual DA group had a similar attitude toward PSA testing in two RCTs.^{48,49}

Anxiety.—There was no significant difference in men's anxiety level between the intervention and control groups in one RCT.³⁵

Outcomes for African American men.—The use of DAs by African American men resulted in: (1) reduced decisional conflict (visual DA, $p=0.014$),⁵⁰ (2) increased knowledge ($p<0.001$) for both RCT (visual DA⁵⁰) and before–after (audio-visual DA⁴⁰) study designs, and (3) no significant difference in men’s anxiety level between the intervention (visual DA) and control groups.⁵⁰

Publication Bias and Sensitivity Analyses

There was no identified publication bias as assessed by Egger test ($p=0.92$ for the proportion of men who were planning to undergo PSA testing after using various types of DAs).

Omitting single studies did not affect significance of the RR for number of men who wanted to undergo screening. Pooled effect of visual DAs became nonsignificant after removing either Watson et al.³⁸ or Partin and colleagues^{51,52} studies. The use of the DerSimonian–Laird random effects model without the Hartung–Knapp correction did not affect the significance of the change in men’s intention.

DISCUSSION

Low-quality evidence was found that the use of DAs in any format resulted in fewer men planning to undergo PSA-based screening. The inconsistent findings across studies limits the strength of these results. However, there is a moderate-quality evidence that the use of visual DAs (pamphlet, leaflet, or brochure) resulted in fewer men planning to undergo PSA testing. The use of DAs appeared not to affect the proportion of men who: (1) were reluctant about screening, (2) were unsure about their screening plans, and (3) underwent screening. The use of DAs in any format resulted in men making more informed screening decisions with less decisional conflict, and these men may develop a less favorable attitude toward screening. There is not enough evidence to conclude that the format of the DA affected secondary outcomes.

Compared with the previous reviews,^{20,55,56} this work identified additional evidence and provides more detailed analysis of the effect of DAs on the change in men’s screening intentions, actual screening uptake, and the congruence of these two. The data from one study⁵⁷ used in the Cochrane report was not included here because neither intention nor uptake data were found in the original articles. Another advantage of this research is the use of a more conservative approach for the meta-analysis—Hartung–Knapp small sample correction, in order to minimize the probability of type 1 error²⁷; this correction has not been done in previously published reviews.^{20,55} Also, additional studies not considered by earlier reviews were included, and outcomes for African American men were analyzed separately, which is unique to this review.

The generalizability of these results may be impacted by the fact that included studies enrolled men with a broader age range than is currently recommended by most of the professional organizations. The screening intentions of men from different age groups could not be explored because of a lack of age-stratified intention data in the identified studies. Only four RCTs reported screening utilization for men from the general population and one RCT for African American men—these data were insufficient to draw a strong conclusion

about the effect of DAs on men's actual screening behavior. More RCTs are needed to determine the generalizable effect of the use of DAs on PSA testing utilization.

CONCLUSIONS

Results of this review indicate that the use of visual DAs may decrease the number of men who choose PSA-based prostate cancer screening compared with men not using DAs, particularly in the short term. The findings suggest that engaging men in SDM shortly after using DAs can result in fewer men choosing to be screened, and more men feeling they have made a choice that aligns with their values. However, more high-quality RCTs are needed to validate the relationship between intentions and screening utilization.

Many modeling studies continue to show that PSA-based screening is not cost effective from a societal point of view. Future research should include decision models to explore the extent to which changes in men's screening behavior, as affected by their use of DAs, influences the cost effectiveness of PSA-based screening programs.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
PRISMA flow diagram of study selection.

Figure 2.

Forest plot of the proportion of men who were planning to undergo PSA-based screening after using various formats of DAs.

^aEvents – numbers of men who were intended to undergo screening.

PSA, prostate-specific antigen; DA, PSA-based prostate cancer screening patient decision aid.

Table 1.

Main Characteristics of the Included Studies

Study, design, country	Study period	N, Population, Age years (mean) or range	Settings	Intervention (I) and comparator (C)	Reported outcomes
Allen 2010, ³⁴ RCT, U.S.	September 2006–July 2007	625, with no prostate cancer, aged 45–70 years	Work (12 work sites with Standard Industrial Classification codes 20 to 39 that represent manufacturing industries were randomly assigned to an intervention or nonintervention comparison condition)	I: interactive DA C: No DA	Intention, knowledge, decisional conflict
Evans 2010, ³⁵ RCT, United Kingdom	NR	514, men were invited to participate by their general practitioners in South Wales, United Kingdom, mean age not reported, aged 50–75 years	Any Internet based and mailed interventions accessible from home or any setting	I: interactive DA, visual DA C: No DA	Intention, uptake, knowledge, anxiety, attitude, decisional conflict
Frosch 2001, ⁴⁶ Non-RCT, U.S.	NR	176, male patients at the Health Appraisal Clinic, in the department of preventive medicine, Kaiser Permanente, San Diego, California, aged >50 years	Outpatient clinic	I: audio-visual DA C: General information about PSA testing (presented orally)	Uptake, knowledge
Frosch 2008, ⁴⁷ RCT, U.S.	March 2005–May 2006	611, Participants were recruited from the Health Appraisal Clinic of Kaiser Permanente, San Diego, California. The clinic conducts preventive screening examinations, aged >50 years	Outpatient clinic	I: interactive DA, visual DA C: Not a DA (men were given links to public websites on prostate cancer screening)	Uptake, knowledge
Gattellari 2003, ⁴⁸ RCT, Australia	NR	248, men were recruited from the practices of 13 local general practitioners in Sydney, Australia, ~54, aged 40–70 years	Outpatient clinic (GP's office)	I: visual DA C: Not a DA (Pamphlet published by Australian Government)	Intention, knowledge, attitude, decisional conflict
Gattellari 2005, ⁴⁹ RCT, Australia	NR	421, men recruited by making telephone calls using randomly selected numbers from 29 contiguous postcodes in Sydney, Australia, from the white-page telephone directory, ~58, aged 50–70 years	Community	I: visual DA, audio-visual DA C: Not a DA (Leaflet "Testing for prostate cancer")	Intention, knowledge, attitude, decisional conflict
Lepore 2012, ⁵⁰ RCT, U.S.	June 2005–August 2006	490, African American men, a high immigrant percentage, 55.04, aged 45–70 years	Community	I: visual DA C: Not a DA (telephone conversation about fruit and vegetable consumption)	Intention, uptake, knowledge, anxiety, decisional conflict
Partin 2004, ^{51,52} RCT, U.S.	NR	893, male Veterans with primary care appointments at participating facilities aged 50 years	Outpatient clinic (mailed intervention)	I: visual DA, audio-visual DA C: Usual care	Intention, uptake, knowledge

Study, design, country	Study period	N, Population, Age years (mean) or range	Settings	Intervention (I) and comparator (C)	Reported outcomes
Tran 2015, ⁵³ RCT, France	October 2012–February 2013	1,170, men from 86 general practice clinics in France, in both urban and rural environments 61, aged 50–75 years	Outpatient clinic	I: visual DA C: Usual care (physicians answered patients' questions)	Intention
Volk 1999, ^{36,37} 2003, RCT, U.S.	NR	158, Male patients seen at primary care at the Family Medicine Center at The University of Texas Medical Branch in Galveston, Texas ~59 years, aged 45–70 years	Outpatient clinic	I: audio-visual DA C: No DA	Intention, uptake, knowledge
Watson 2006, ³⁸ RCT, United Kingdom	NR	977, men from 11 general practices in England (Oxfordshire and Hertfordshire) and Wales (Cwmbran and Aberystwyth) mean age not reported, aged 40–75 years	Any, (mailed DA)	I: visual DA C: Not a DA (questionnaire only)	Intention, knowledge, attitude
Barry 2015, ³⁹ Before after, U.S.	2009–2013 (data collection)	1,041, men recruited at primary care practices affiliated with two health systems –Dartmouth-Hitchcock Medical Center and Massachusetts General Hospital, mean age not reported, aged 50– 70 years	Any, (mailed DVD)	I: interactive DA C: NA	Intention, knowledge
Frencher 2016, ⁴⁰ Before after, U.S.	NR	120, African American men were recruited from 50 barbershops located in South Los Angeles, California, aged 40 years	Community (Black Barbershop Health Outreach Program [BBHOP])	I: audio-visual DA (culturally specific) C: audio-visual DA (not culturally specific)	Intention, knowledge
Ruthman 2004, ⁴¹ Controlled before-after, U.S.	NR	104, Subjects were men who attended a Veterans Administration clinic 66.32, aged 51–77 years	Outpatient clinic	I: audio-visual DA C: No DA	Intention, Knowledge
Sheridan 2004, ⁴² Before-after, U.S.	NR	188, men who were presenting to a university internal medicine clinic for routine care, 60, aged 45–85 years	Outpatient clinic	I: visual DA C: NA	Intention
Krist 2007, ⁴³ RCT, U.S.	June 2002–June 2004	497, men with no history of prostate cancer, aged 50–70 years	Any, (mailed DA)	I: interactive DA, visual DA C: Usual care	Uptake, knowledge, decisional conflict
Ilic 2008, ⁴⁴ RCT, Australia	NR	156, men who have never been screened for prostate cancer, aged >45 years	Any, (mailed DA)	I: audio-visual DA, interactive DA, visual DA C: DAs	Intention, knowledge, anxiety, decisional conflict
Siamm 2017, ⁴⁵ RCT, U.S.	NR	329, English speaking men with no history of prostate cancer, men who might have prostate screening more than 1 year ago, aged 50–75 years	Any, (mailed DA)	I: visual DA C: Usual care	Uptake, knowledge

NR, not reported; NA, not applicable; PSA, prostate-specific antigen; DA, PSA-based screening patient decision aid.

Table 2.

GRADE Summary of Findings and Certainty of the Evidence (Only RCTs)

Outcomes	Anticipated absolute effects ^a (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Numbers of men with control	Risk difference with DA				
Planning to undergo screening after using any format of DAs	623 per 1,000	75 fewer per 1,000 (118 to 28 fewer)	RR 0.88 (0.81, 0.95)	5,236 (8 RCTs)	⊕⊕○○ Low ^{b,c}	This effect is consistent with the before-after results from the RCTs
Planning to undergo screening after using visual format of DAs	566 per 1,000	76 fewer per 1,000 (125 to 21 fewer)	RR 0.87 (0.78, 0.96)	3,394 (6 RCTs)	⊕⊕⊕○ Moderate ^b	
Do not plan to undergo screening after using any format of DAs	202 per 1,000	53 more per 1,000 (17 fewer to 149 more)	RR 1.26 (0.92, 1.73)	3,514 (5 RCTs)	⊕⊕○○ Low ^{b,c}	
Unsure about undergoing screening after using any format of DAs	210 per 1,000	23 more per 1,000 (27 fewer to 86 more)	RR 1.11 (0.87, 1.41)	2,973 (4 RCTs)	⊕⊕○○ Low ^{b,c}	

^aThe risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

^bUnknown risk of performance bias: blinding of participants.

^cDowngraded due considerable inconsistency.

^dGrades of evidence — High certainty: High confidence that the true effect lies close to that of the estimate of the effect. Moderate certainty: Moderate confidence in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Low certainty: Limited confidence: the true effect may be substantially different from the estimate of the effect. Very low certainty: Very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

DA, decision aid