OREGON HEALTH & SCIENCE UNIVERSITY
SCHOOL OF MEDICINE – GRADUATE STUDIES

EFFECT OF PATIENT DECISION AIDS ON CHANGES IN MEN'S PROSTATE CANCER SCREENING BEHAVIOR: A SYSTEMATIC REVIEW AND META-ANALYSIS

By

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CERTIFICATE OF APPROVAL

This is to certify that the Master's Capstone Project of

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"Effect of Patient Decision Aids on Changes in Men's Prostate Cancer Screening Behavior: a Systematic Review and Meta-Analysis"

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ABSTRACT

Purpose: Prostate-specific antigen (PSA)-based prostate cancer screening recommendations are going through drastic changes. The U.S. Preventive Task Services 2017 (current draft recommendation), American Cancer Society 2016, and National Comprehensive Cancer Network 2016 have updated their recommendations to include a shared decision-making (SDM) process for men when they are considering PSA testing. To ensure that the recommendations are followed in clinical practice, patient decision aids (PSA-PtDAs) are one strategy to support SDM. However, the effect of the PSA-PtDAs on men's intention to undergo PSA testing remains unclear. The purpose of this systematic review and meta-analysis was to answer the following key questions: (1) how do PSA-PtDAs compared with usual care affect men's prostate cancer screening behavior and (2) are computer-based interactive PSA-PtDAs more influential in changing men's screening intention than other types of decision aids? **Methods**: We searched for evidence in the following databases: MEDLINE (OVID), Scopus, CENTRAL (OVID), PsycARTICLES (OVID), PsycINFO (OVID), and CT.gov. All potentially eligible papers were reviewed independently by two reviewers for inclusion, data abstraction, and risk of bias assessment. All disagreements between reviewers were resolved based on a consensus or an intermediary who was consulted for the final judgment. We used risk ratio (RR) and random effects to pool the overall effect of PSA-PtDAs on men's intention to undergo PSA-based screening. The protocol of this study was registered in the PROSPERO database, #CRD42017060606. **Results**: We ultimately included 18 studies (13 randomized controlled trials, 4 before-after studies, one non-randomized trial) with screening intention data for 6,490 men. Compared to usual care, the use of visual PSA-PtDAs resulted in significantly fewer men (aged 40–82) deciding to undergo PSA testing (RR 0.87; 95% CI 0.79–0.95; *P*=0.004;

[I^2=51%; P=0.07]; n=6 RCTs, moderate quality of evidence). Although the evidence was low in quality for men's intention after using any type of PSA-PtDAs, compared with usual care interventions, PSA-PtDAs resulted in fewer men planning not to undergo PSA-based prostate cancer screening (RR 0.88; 95% CI 0.81–0.95; P=0.002; [I^2=66%; P=0.001]; n=11 RCTs). The use of PSA-PtDAs had a non-significant effect on the proportion of men (aged 40–85) who were undecided or decided not to undergo PSA testing. The number of men who decided not to undertake PSA-based screening appeared not to be affected by the PSA-PtDAs used across RCTs (RR 1.26; 95% CI 0.96–1.65; P=0.09; [I^2=70%; P<0.006]; n=6). **Conclusions**: The implementation of new PSA-based screening recommendations and integration of PSA-PtDAs in clinical practice at the national level may result in a 7.6% decrease in the number of men (aged 40–85) who would plan to undergo PSA testing. The change in men's screening plans may reduce PSA-based screening utilization.

Registration: The protocol for this review was registered in PROSPERO database, #CRD42017060606.

Funding Source: This study was supported by United States National Library of Medicine Biomedical Informatics Training Grant #T15LM007088. The grantor had no role in the design, conduct, or reporting of the study. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

INTRODUCTION

Prostate cancer is the most common cancer in men worldwide;[1] its incidence and mortality rates are higher in more developed countries,[1,2] and increase with men's age. Estimates of the Surveillance, Epidemiology, and End Results program of the United States (US) National Cancer Institute predicted[3,4] that in 2016, prostate cancer would be the main cause of death from cancer in American men, with 180,890 (10.7% of all cancer cases in the US) men diagnosed with prostate cancer and 26,120 men dying from prostate cancer. Depending on the cancer stage at diagnosis, the percentage of men who survive after diagnosis rapidly decreases: 100% of men diagnosed at the local stage of prostate cancer will survive for five years, and only 29.6% (95% CI 29.0%–30.3%) of men diagnosed with a distant form of prostate cancer will survive for five years.[3] Thirteen out of 100 American men who are 40 years old today will eventually be diagnosed with an invasive form of prostate cancer during their lifetime, and 38 out of 100 diagnosed men will die from prostate cancer.[3]

The prostate-specific antigen (PSA) test can be used as a screening procedure in asymptomatic men to detect prostate cancer; however, evidence shows that the potential harms from using the PSA test can outweigh its benefits. The high number (10.4% American men aged 55–74 years)[5] of false-positive results obtained after undergoing the PSA test leads to more diagnostic tests, including biopsy, and further side effects, such as infection, distress in men, decreased quality of life, and other health-related problems.[5,6] Depending on the age at diagnosis men may not experience any prostate cancer-related symptoms throughout their remaining life[5,6] and would not also benefit from treatments.

The decision whether a patient should undergo PSA-based screening is confounded by current prostate cancer screening recommendations that are not unified. Some professional North American organizations recommend against routine PSA-based screening (US Preventive Services Task Force [USPSTF] 2012,[7] American College of Preventive Medicine 2016,[8] American Academy of Family Physicians 2012,[9] Canadian Task Force Preventive Health Care 2014[10]), whereas others suggest shared decision making to help patients decide whether they wish to undertake prostate cancer screening (American Urological Association,[11] American College of Physicians,[12] National Comprehensive Cancer Network, American Cancer Society[13]). The USPSTF will update prostate cancer recommendations and suggest implementing shared decision making for men aged 55–69 years.[14]

Patient decision aids (PtDAs) are being used to ensure a comprehensive shared decision-making, but the effects of these PtDAs on men's intention to undergo PSA-based screening and their actual screening behavior remain unclear. Furthermore, PtDAs have various types, such as audiovisual, visual, audio, and interactive, and the extent to which a certain type of PtDA can be more influential on men's behavioral outcomes is unknown.

The purpose of this systematic review was to answer the following Key Questions (KQs; Figure 1): KQ1: In men from various racial and age groups (40–49, 50–59, 60–69, 70–79, and ≥ 80), how do prostate cancer patient decision aids, compared with the usual care, affect intention to undergo prostate-specific antigen screening? KQ2: In men from various racial and age groups (40–49, 50–59, 60–69, 70–79, and ≥ 80), does the use of prostate cancer patient decision aids, 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 prostate cancer

patient decision aids, compared with other types of decision aids, more influential in changing screening intention?

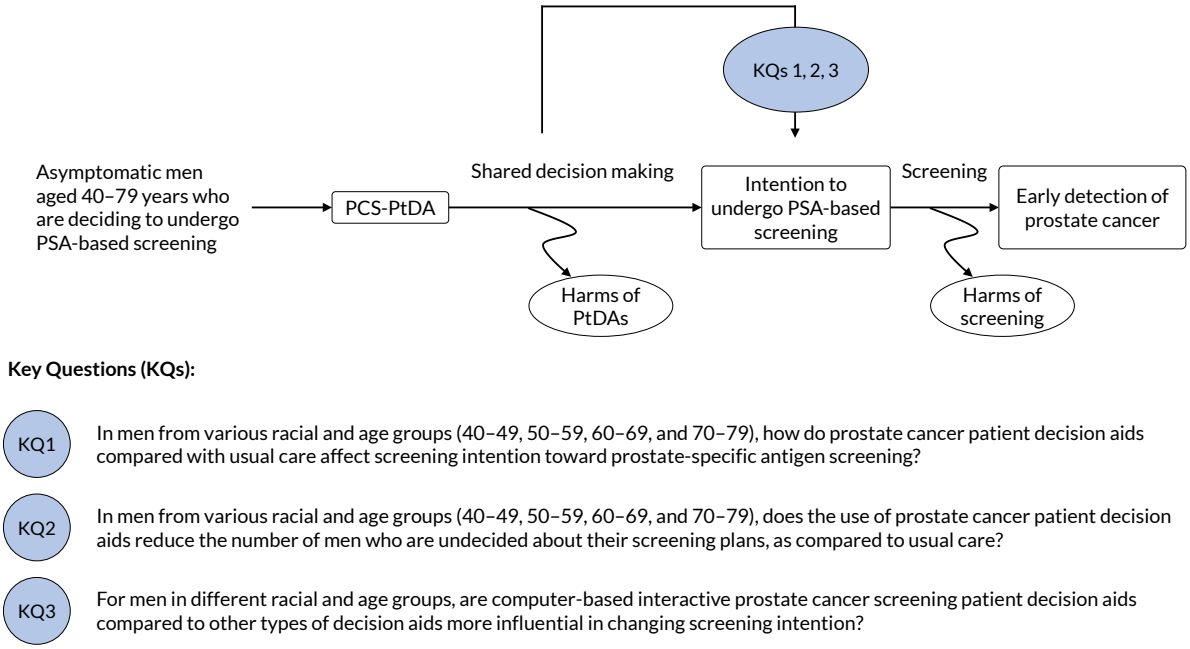

Figure 1. Analytic framework

METHODS

The protocol for this review was registered in the PROSPERO database, #CRD42017060606.[15] This study followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA).[16]

Eligibility Criteria, Data Sources, and Searches

Studies were eligible for this systematic review and meta-analysis if they met the following pre-defined criteria: (i) reported immediate or deferred intention data from men aged 40–79 years who

were not diagnosed with prostate cancer prior to using a PtDA; (ii) used an intervention involving any type of a PSA-PtDA; (iii) were randomized controlled trials (RCTs), non-randomized studies, cohort studies, case-control studies, or before–after studies (Appendix 1).

We searched Scopus (through January 17, 2017), MEDLINE Epub Ahead of Print (Ovid), MEDLINE Daily (Ovid; 1946 to January 17, 2017), Cochrane Central Register of Controlled Trials [(CENTRAL), Ovid; 1991 to November 2016), PsycINFO (Ovid; 1806 to January [week 4] 2017), PsycARTICLES Full Text (Ovid; through January 17, 2017), and ClinicalTrial.gov (through January 17, 2017) (Appendix 2). Additionally, we reviewed the cited references in the articles eligible for this review. We did not apply any language limitations.

Study Selection

Two reviewers (MM, SJ) independently screened titles and abstracts, and they reviewed full-text articles by using the Convidence©[17] online systematic review platform. All disagreements were solved through consensus, or an intermediary (II) was consulted for the final decision. A list of all included and excluded articles is presented in Appendix 3.

Data Collection and Quality Assessment

Data collection was performed with the use of the Convidence©[17] online systematic review platform. The data were extracted by two reviewers (MM, SJ) independently from each eligible study. Data from the same study reported in different papers were collapsed to avoid a larger effect of one study. All disagreements were resolved by consensus (II, KE, MM, SJ) and adjusted by II. We contacted study authors if the data were unclear. The results from individual studies are presented in (Appendix 4). Two reviewers independently assessed the risk of bias at the study level by using

the Cochrane Collaboration tool for assessing the risk of bias for RCTs, as recommended by the Cochrane Collaboration.[18,19] The Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I)[20] tool was used to evaluate the risk of bias in a non-randomized controlled trial. The National Institutes of Health Quality Assessment Tool was used to assess the risk of bias in uncontrolled before–after studies.[21] Discrepancies were resolved through consensus.

Synthesis of the Results

We omitted studies with an unacceptable risk of bias (i.e., studies that did not meet more than three criteria [Appendix 7]). The overall effect was pooled separately for all RCTs using data from control and intervention groups. Additionally, we pooled an overall effect across RCTs (baseline data from all groups, after-intervention data in the PSA-PtDA group, and a usual care group) and before–after studies. We used the Mantel-Haenszel random-effects model[22] to combine relative risks. 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.[23] Egger's test[24] was used to explore funnel plot asymmetry in meta-analyses with more than 10 studies, as recommended.[25] Sensitivity analyses included examining the influence of (i) major outliers, (ii) the used effect model, (iii) using before–after intention data in RCTs, and (iv) the methodological quality of the studies and their design diversity. Data for meta-analyses were stored and processed with Review Manager[26] software. The number that needed to be treated[27] was calculated from the statistically significant results ($p<0.01$) of a meta-analysis from risk ratio (RR). Evidence quality was assessed with the Grading of Recommendations Assessment, Development, and Evaluation.[28]

Role of the Funding Source

This study was supported by US National Library of Medicine Biomedical Informatics Training Grant #T15LM007088. The grantor had no role in the design, conduct, or reporting of the study. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

RESULTS

Study Selection

Of the 996 identified records, 20 articles[29–48] presenting 18 unique studies met the inclusion criteria (Appendix 1); 333 were duplicates, and 643 did not meet the inclusion criteria and were therefore excluded (Figure 2 and Appendix 3). Of the 643 excluded, 49 were excluded after the full texts were assessed: 25 reported outcomes that were irrelevant to our review; ten did not indicate a PSA-PtDA as an intervention; six had an unsuitable study design; six appeared in the wrong type of publication; and two included population that did not fit our protocol. Of the 18 studies included in the qualitative synthesis, 16 were included in a meta-analysis on men's intention to undertake PSA-based screening. One RCT[37] and a before–after[46] study that were focused on higher risk populations were excluded from the meta-analysis of men's intention to undergo PSA-based screening and screening uptake. The participants of these two studies consisted only of Black African-descent 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.[14] According to the USPSTF Draft Recommendation Statement, African American men might benefit more from PSA-based screening than men from the general population[14] and those PSA-PtDAs may have encouraging

effect on men, compared to the PtDAs based on the general population rates for prostate cancer. All selected studies had either low or moderate level of risk for bias (Appendix 7).

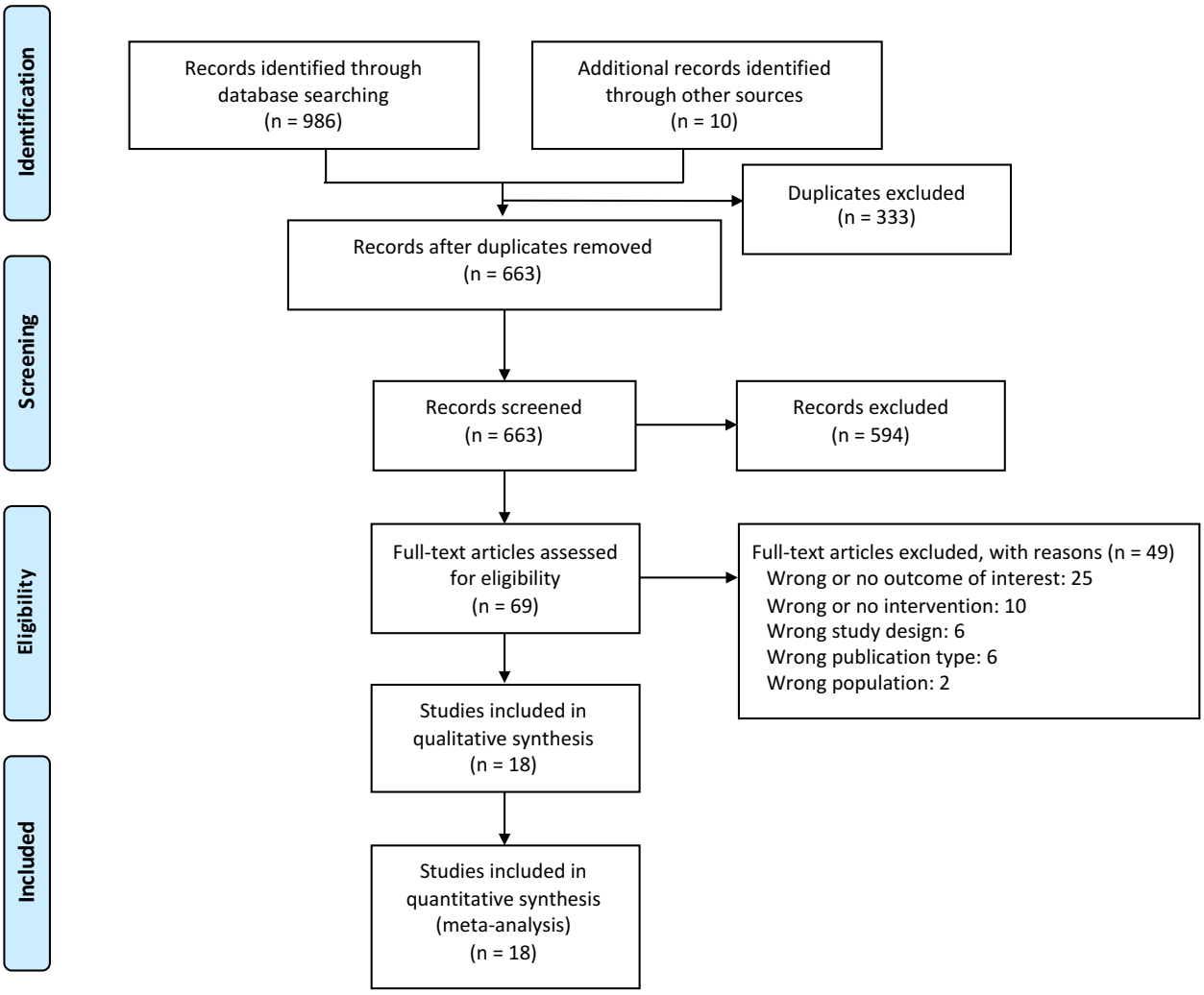

Figure 2. PRISMA flow diagram of study selection

Study Characteristics

Of the 18 included English-language studies, 13[29,30,32–44] studies were RCTs, one[31] was a non-randomized controlled trial, and four[45–48] were before–after studies. Of the 13 RCTs, four[32,33,36,44] used another PtDA as a control. Of all studies, four[34–36,44] were conducted in Australia, one[40] in

France, two[30,43] in the United Kingdom, and 11[29,31–33,37–39,41,42,45–48] in the US. All studies reported intention to undertake PSA-based prostate cancer screening for men (aged 40–85) who (i) planned to undergo PSA-based screening,[29–38,40–43,45–48] (ii) did not wish to be screened,[29,34–36,40,43,45–48] (iii) were unsure about their screening strategy,[29,30,34,36,40,43–48] or (iv) underwent PSA-based screening after using a PSA-PtDA in two weeks,[38] six months,[30] one year,[37,38,42] or two years.[37]

The included trials provided intention data for 6,490 men; four before–after studies provided intention data for 1,420 men. The meta-analysis of men's intention included a total of 6,842 men from 15 studies. One RCT[37] and a before–after[46] study included only Black men of African descent (aged 45–70) and reported no change in the proportion of men who planned to undergo PSA-based screening. One RCT[33] reported only a reduction in the intention to undergo PSA-based screening without providing the numbers of patients after the intervention.

Prostate Cancer Screening Patient Decision Aids

The included studies compared various PSA-PtDAs with usual care, a control group, or other PSA-PtDAs. The effects of the following types of PSA-PtDAs were studied:

a. Interactive PtDAs (I-PtDAs) – computer-biased decision aids the required some degree of interaction with the users.
b. Audio-video PtDAs (AV-PtDAs) – patients were exposed to the PtDAs that used video and audio to present information about benefits and harms of PSA-based prostate cancer screening
c. Visual PtDAs (V-PtDAs) – were pamphlets, leaflets or other kinds of decision aids that presented only visual information to the patients

d. Mixed PtDA (MX-PtDA) – this group contains only one PSA-PtDA (Volk, 1999). The authors provided patients with the interactive computer-based PSA-PtDA along with the paper-based PSA-PtDAs. The design of this study did not allow us to distinguish between the effects from the I-PtDA and V-PtDA.

Detailed information about particular PSA-PtDAs can be found in Appendix 4.

Synthesis of the Results

Key Questions 1 and 2: Men's intention to undergo PSA-based screening

We analyzed the overall effect of PSA-PtDAs on men's willingness to undertake PSA-based screening, which was pooled from eight RCTs[29,30,34,35,38–43] that studied 11 PSA-PtDAs. Compared with usual care interventions, PSA-PtDAs resulted in fewer men deciding to undergo PSA-based prostate cancer screening (RR 0.88; 95% CI 0.81–0.95; P=0.002; [I^2=66%; P=0.001]; Figure 3 – subgroup "1.1.1 RCTs"). Using the above risk ratio, we calculated that in the PSA-PtDA group, 548 (95% CI 506–594) out of 1,000 men intended be screened, compared with 623 of 1,000 in the usual care group. This finding suggests that after using a PSA-PtDA, 75 (95% CI 29–117) men out of 1,000 may change their primary screening plans and will not plan to undergo PSA-based screening, compared with usual care interventions (Table 1). With the use of a number needed-to-treat approach, 14 (95% CI 9–35) men aged 40–85 years would need to use a PSA-PtDA so that one man would reconsider his wish to be screened and decide not to undergo prostate cancer screening. Although the evidence was low in quality (Table 1) for this outcome, the analysis of the difference at the baseline for RCTs[29,32,34,36,40–42] (RR 0.82; 95% CI 0.74–0.92; P=0.0003; n=9; [I^2=82%; P<0.00001]; Figure 3 – subgroup 1.1.2), one non-randomized controlled trial[31] (Figure

3 – subgroup 1.1.3), and one controlled before–after study[47] (Figure 3, subgroup 1.1.4) shows a similar significant change in the outcomes and supports this conclusion (Figure 3).

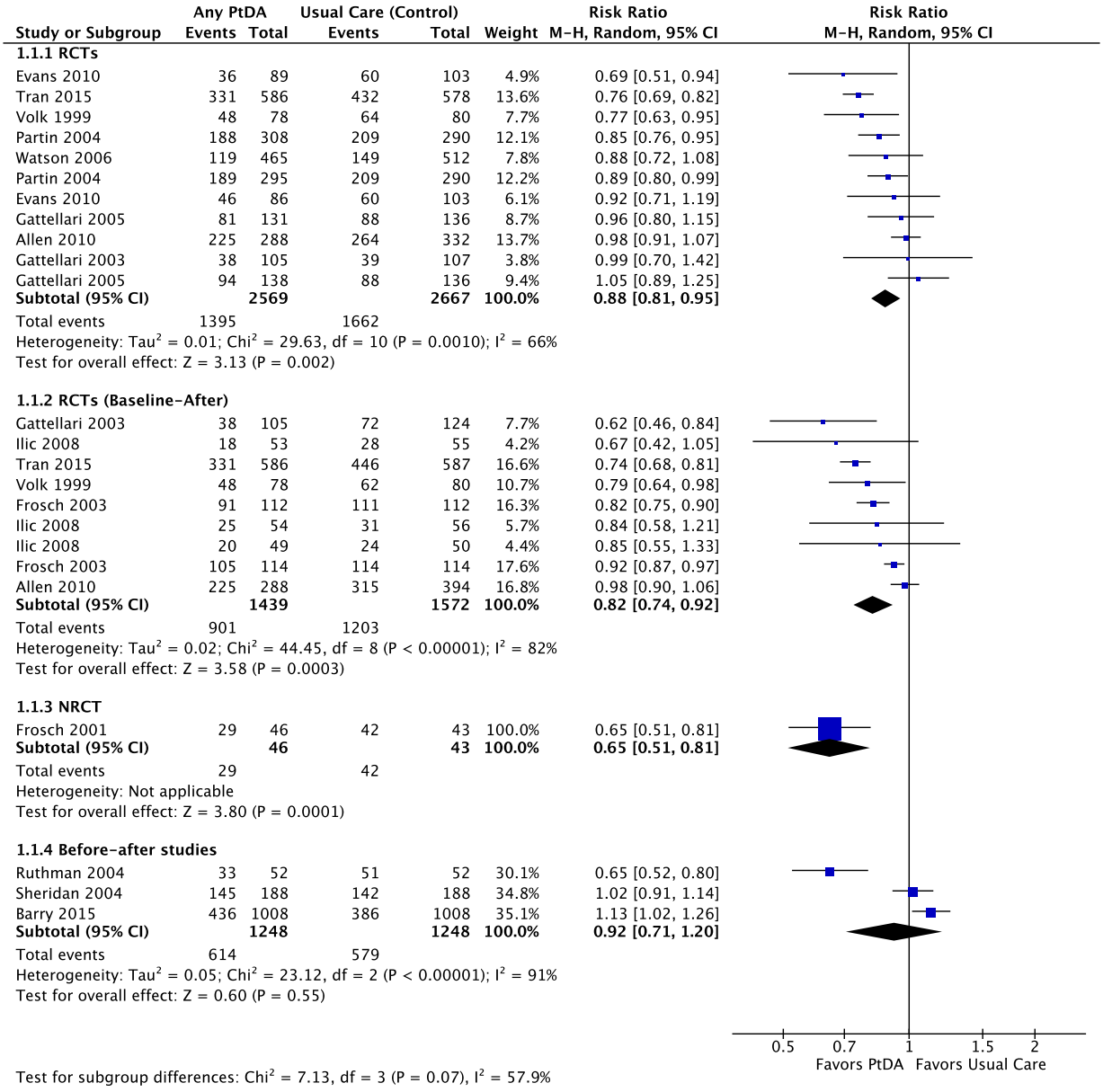

Figure 3. Forest plot of the proportion of men who were planning to undergo PSA-based screening after using any type of PSA-PtDAs, compared to usual care

In the comparison of the effects of various types of PSA-PtDAs on the change in the number of men (aged 40–82) who were planning to be screened across RCTs, the meta-analysis showed that only the overall effect of visual PSA-PtDAs is significant (RR 0.87; 95% CI 0.79–0.95; *P*=0.004; n=6; [I^2=51%; *P*=0.07]; Figure 4 – subgroup 2.1.2 "V-PtDAs vs. Usual Care"). Using the above risk ratio, we calculated that 566 of 1,000 men planned to be screened, compared with 490 (95% CI 445–541) of 1,000 for the PSA-PtDA group. Therefore, the use of visual PSA-PtDAs, compared with the usual care, can result in 76 (95% CI 25–121) fewer men who intend to be screened (Table 1).

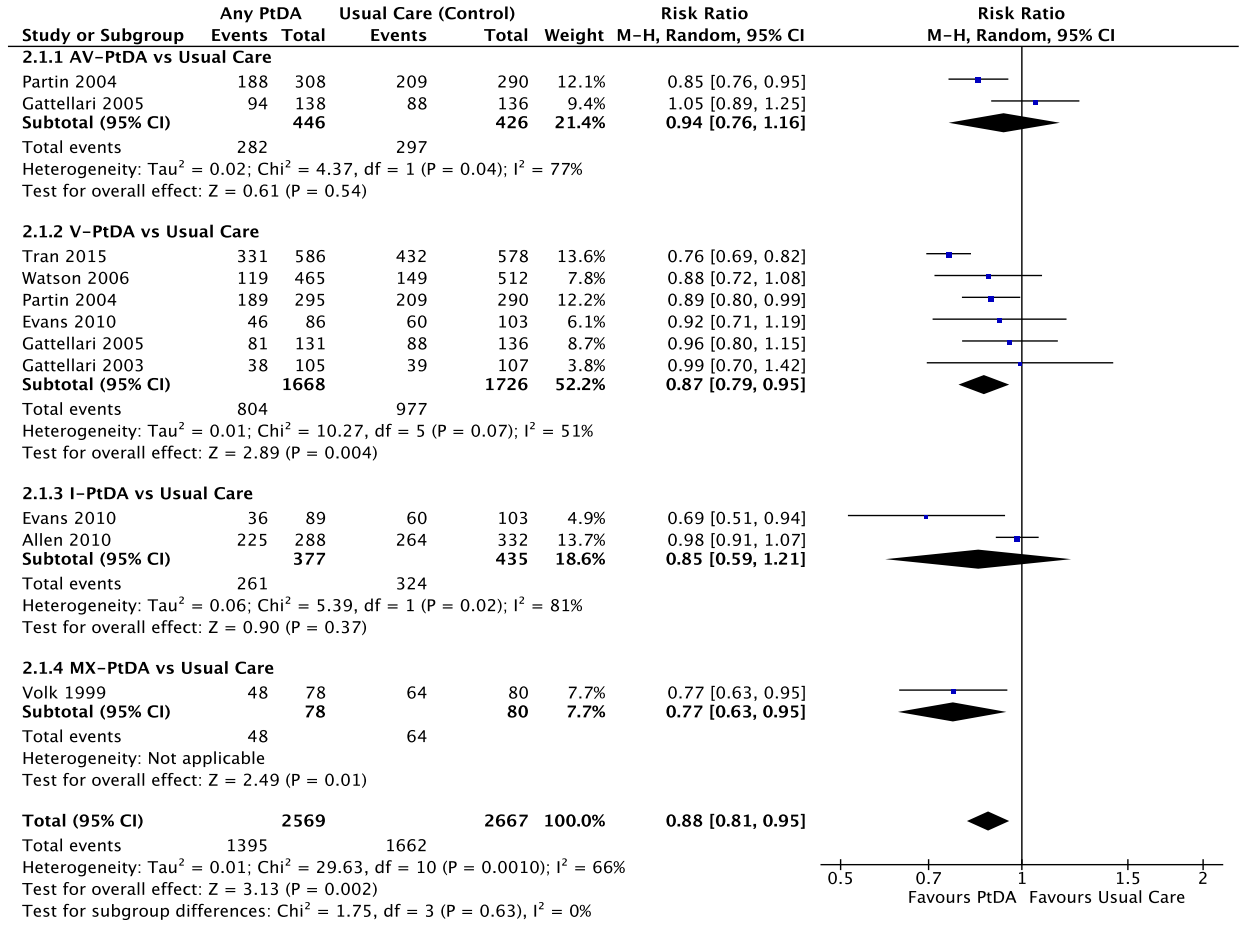

Figure 4. Forest plot of the proportion of men who were planning to undergo PSA-based screening after using various type of PSA-PtDAs, compared to usual care

The number of men who did not want to be screened appeared not to be affected by the PSA-PtDAs used across RCTs (RR 1.26; 95% CI 0.96–1.65; P=0.09; n=6 RCTs). A level of heterogeneity was significantly considerable (I^2=70%; P<0.006) and its level was affected by one French trial[40] that showed a large, significant increase in the number of men who were decided not to be screened after using a visual PSA-PtDA. This trial "In order to respect intention to treat, patients who answered 'I don't know' or for whom data concerning the main outcome measure were missing were classified as 'willing to perform PSA screening" that could be a main cause of increase heterogeneity. Furthermore, one uncontrolled before–after study[45] supported this change (Figure 4). Our analyses did not identify a significant effect of PSA-PtDAs on the proportion of men who were undecided about their PSA-based screening strategy (Appendix 5) or who were decided about any of the alternatives (Appendix 6).

Key Question 3: Actual Screening Bahavior

Four RCTs followed up with the men from the control and intervention groups to study the change in their screening behavior in two weeks,[38,39] 6 months,[30] and one year after using a PSA-PtDA[38,39,41,42] (Figure 5).

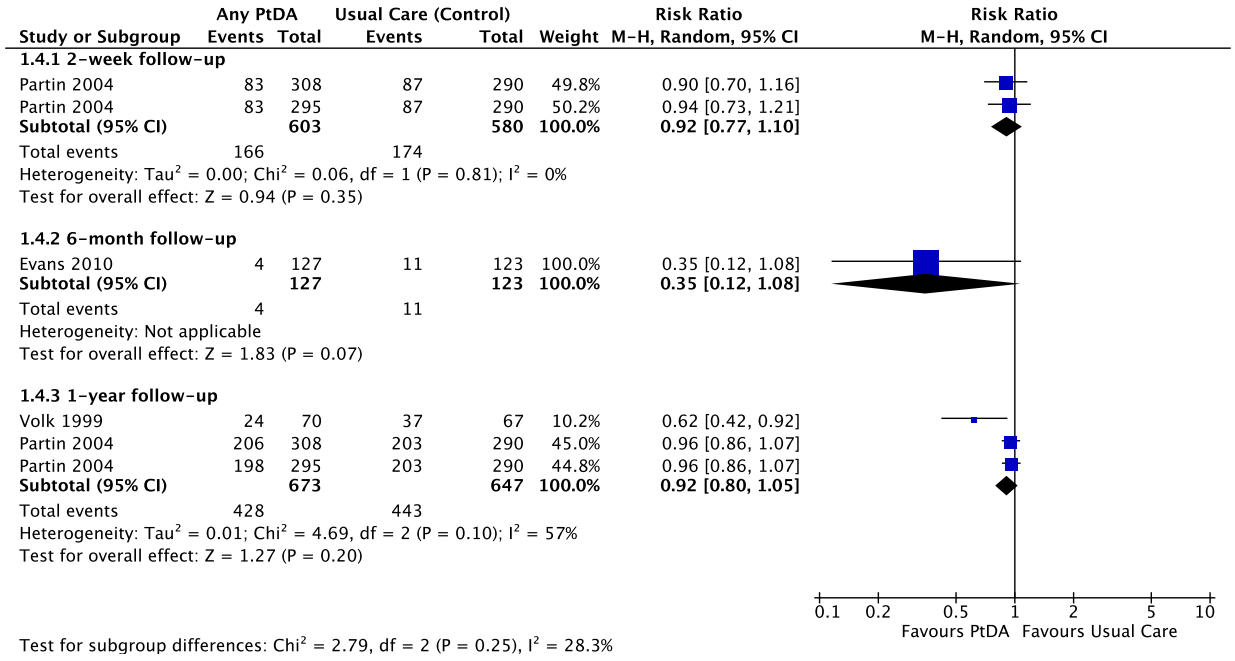

Figure 5. Proportions of men who underwent PSA-based screening in two weeks, 6 months, and one year after using a PSA-PtDA

Only one study[41,42] reported a significant change in screening behavior at one-year follow-up and suggested that 30% (34% vs. 55%, *P*=0.02) fewer men will undergo PSA-based prostate cancer screening after using a PSA-PtDA.

Table 1. GRADE Summary of Findings and Quality of Evidence

Patient decision aids compared to Usual Care for men's intention and actual screening behavior toward PSA-based prostate cancer screening

Patient or population: Men (aged 40–85) who were not diagnosed with prostate cancer before using a PSA-PtDA
Intervention: PSA-PtDAs
Comparison: Usual Care or Control

Outcomes	**Anticipated absolute effects*** (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with Usual Care	**Risk with a PtDA**				
Planning to undergo PSA-based screening after using *any PSA-PtDA*	623 per 1,000	**548 per 1,000** (505 to 592)	**RR 0.88** (0.81 to 0.95)	5,236 (8 RCTs)	⊕⊕◯◯ LOW	Considerable heterogeneity due Tran 2015
Planning to undergo PSA-based screening after using *visual PtDAs*	566 per 1,000	**492 per 1,000** (447 to 538)	**RR 0.87** (0.79 to 0.95)	3,394 (6 RCTs)	⊕⊕⊕◯ MODERATE	
Do not plan to undergo PSA-based screening after using *any PSA-PtDA*	202 per 1,000	**255 per 1,000** (194 to 333)	**RR 1.26** (0.96 to 1.65)	3,514 (5 RCTs)	⊕⊕⊕◯ MODERATE	Non-significant effect on changing intention

Patient decision aids compared to Usual Care for men's intention and actual screening behavior toward PSA-based prostate cancer screening

Patient or population: Men (aged 40–85) who were not diagnosed with prostate cancer before using a PSA-PtDA
Intervention: PSA-PtDAs
Comparison: Usual Care or Control

Outcomes	**Anticipated absolute effects*** (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with Usual Care	**Risk with a PtDA**				
Unsure about undergoing PSA-based screening after using *any PSA-PtDA*	210 per 1,000	**233 per 1,000** (183 to 296)	**RR 1.11** (0.87 to 1.41)	2,973 (4 RCTs)	⨁⨁⨁◯ MODERATE	Non-significant effect on changing intention

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident 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 quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

DISCUSSION

Summary of Evidence

The KQs reviewed in this systematic review and meta-analysis were as follows: (i) To what extent do PSA-PtDAs change men's plans to undergo PSA-based prostate cancer screening? (ii) To what extent are interactive computer-based PSA-PtDAs, compared with other types of decision aids, more influential in changing men's PSA-based screening plans? Overall, we found low-quality evidence that the use of PSA-PtDAs, compared with the usual care, by men aged 40–85 years can result in fewer men planning to undergo PSA-based screening (RR 0.88; 95% CI 0.81–0.95; P=0.002; [I^2=66%; P=0.001]). The inconsistent findings make the broad application of these results challenging. However, we found moderate-quality evidence that the use of visual PSA-PtDAs by men aged 40–82 years resulted in fewer men planning to undertake screening (RR 0.97; 95% CI 0.79–0.95; P=0.004; [I^2=51%; P=0.07]). The analysis did not identify a significant effect of PSA-PtDAs actual screening behavior (i) proportion who decieded not undergo PSA-based screening, (ii) were unsure or decided about their screening plans, and (iii) underwent PSA-based screening two weeks, six months, or one year after using a PSA-PtDA.

Limitations

We were not able to explore the intention in men from different age groups because of the lack of age-based reported intention data. The evidence was also insufficient to conclude the effect of PSA-PtDAs on men of Black African descent because only one RCT and one before–after study were identified. Only three RCTs reported men's screening behavior, and these data were insuffi-

cient to make a reliable conclusion about the effect of PSA-PtDAs on men's actual screening behavior. More RCTs are needed to determine the generalizable effect of PSA-PtDAs on men's intention and screening behavior.

CONCLUSIONS

In this review, we focused on men's intention to undergo PSA-based screening and men's actual screening behavior. In conclusion, our analysis shows that the use of visual PSA-PtDAs, compared with the usual care, may decrease the number of men who want to undertake PSA-based prostate cancer screening by 7.6%. The findings suggest that engaging men in shared decision making using PSA-PtDAs can result in fewer men who are willing to undertake PSA-based screening. However, more RCTs on actual screening behavior are needed to justify the relationship between intention and real action.

FUTURE WORK

We will update our search strategy to identify studies that include data on men's actual PSA-based screening behavior. Many modeling studies continue to show that PSA-based prostate cancer screening is not cost-effective from a social point of view. We plan to build a decision model so that we can explore the extent to which changes in men's screening behavior, as affected by their use of PSA-PtDAs, influence the cost-effectiveness of PSA-based prostate cancer screening. We assume that the new findings will demonstrate the economic impact of shared decision making and PSA-PtDA implementation on clinical practice in the US.

Disclaimer: The grantor had no role in the design or conduct of the study. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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Reproducible Research Statement: *Study protocol:* Registered in PROSPERO (CRD42017060606) at www.crd.york.ac.uk/PROSPERO/. *Statistical code:* Available from Dr. Ivlev (e-mail, ivlev@ohsu.edu). *Data set:* Supplementary data are available in the Supplement.

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instruments in barbershops." *J Cancer Educ*. 2016;31(3):506-513. doi:10.1007/s13187-015-0871-7.
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APPENDIX

Appendix 1

Search design: inclusion and exclusion criteria

Category	Include	Exclude
Populations	Men age ≥40 years old	Women, men age <30 years, men with prostate cancer; men who had prostate cancer; men with pre-existing prostate cancer.
Intervention	All kinds of PSA screening patient decision aids (i.e., paper-based, computer-based include mobile technology based [tablet, mobile phone], or audiotape)	Decision aids for providers
Comparators	Usual care or no care	Only another decision aid
Outcomes	Men who reconsider/not reconsider their decision to start or discontinue PSA screening after using a PCS-PtDA Change in men's attitude, knowledge, clarity of values, and anxiety Real screening behavior	Outcomes not listed as included.
Timing	Immediate outcomes Deferred outcomes	No follow-up after using an aid.
Setting	Settings and populations of men applicable to U.S.	
Study Design	randomized controlled trials, non-randomized studies, cohort studies, case-control studies, and before-after studies	Study designs not listed as included.
Language	No limitations	
Data Sources	MEDLINE Epub Ahead of Print, MEDLINE In-Process & Other Non-Indexed Citations, MEDLINE(R) Daily and MEDLINE (OvidSP), Scopus, Cochrane Central Register of Controlled Trials (CENTRAL) (OvidSP), PsycINFO (OvidSP), PsycARTICLES, ClinicalTrials.gov References in eligible studies	Sources not listed as included.
Search Dates	No limitations	

APPENDIX

Appendix 2

Search strategy

Databases: MEDLINE Epub Ahead of Print (Ovid), In-Process & Other Non-Indexed Citations (Ovid), MEDLINE Daily (Ovid), PsycINFO (Ovid), Cochrane Central Register of Controlled Trials (CENTRAL) (Ovid), PsycARTICLES (Ovid)

Step	Search Strategy
1	exp Health Behavior/
2	exp Attitude to Health/
3	1 or 2
4	exp decision support techniques/
5	exp Decision Making/
6	exp Clinical Decision-Making/
7	4 or 5 or 6
8	((aid* or assist* or help*) adj5 (decis* or decid* or choic* or choos* or option*)).mp.
9	(patient* adj5 (choic* or choos* or consent* or opt or opts or option* or intent* or view* or aid*)).mp.
10	((chang* or alter* or differ* or persua*) adj5 (decis* or decid* or choic* or choos* or consent* or option* or intent* or view* or mind or minds)).mp.
11	(inform* adj3 (choic* or choos*)).mp.
12	((willing or unwilling or intend* or intention* or plan or plans or planned or planning or consent*) adj5 (participa* or undergo or undertake)).mp.
13	8 or 9 or 10 or 11 or 12
14	7 and 13
15	3 and 14
16	4 and 13
17	3 and 16
18	exp Prostatic Neoplasms/
19	(prostat* adj3 (cancer* or tumor* or tumour* or malig* or carcino* or adenocarcin* or neoplas* or antigen)).mp.
20	18 or 19
21	exp Mass Screening/
22	20 and 21
23	exp Prostatic Neoplasms/di, pa, ra, ri, us
24	screen*.mp.

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25	23 and 24
26	(prostat* adj4 (cancer* or tumor* or tumour* or malig* or carcino* or adenocarcin* or neoplas* or antigen) adj7 (screen* or test*)).mp.
27	22 or 25 or 26
28	15 and 27
29	3 or 13
30	7 and 29
31	27 and 30
32	28 or 31

Databases: Scopus

Step	Search Strategy
1	TITLE-ABS-KEY((((aid* or assist* or help*) W/5 (decis* or decid* or choic* or choos* or option*))
2	OR (patient* W/5 (choic* or choos* or consent* or opt or opts or option* or intent* or view* or aid*))
3	OR ((chang* or alter* or differ* or persua*) W/5 (decis* or decid* or choic* or choos* or consent* or option* or intent* or view* or mind or minds))
4	OR (inform* W/3 (choic* or choos*))
5	OR ((willing or unwilling or intend* or intention* or plan or plans or planned or planning or consent*) W/5 (participa* or undergo or undertake)))
6	AND (prostat* W/4 (cancer* or tumor* or tumour* or malig* or carcino* or adenocarcin* or neoplas* or antigen*) W/7 (screen* or test*)
7	)
8	)

Databases: ClinicalTrial.gov

(prostate AND (screening OR antigen OR PSA OR specific) OR adenocarcinoma) AND (PtDA OR PtDAs OR “patient decision aid”)

APPENDIX

Appendix 3

List of included and excluded studies with the reasons

1. List of Included Studies

1. Allen JD, Othus MKD, Hart A, et al. A randomized trial of a computer-tailored decision aid to improve prostate cancer screening decisions: Results from the take the wheel trial. *Cancer Epidemiol Biomarkers Prev*. 2010;19(9):2172-2186. doi:10.1158/1055-9965.EPI-09-0410.
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the Uncertainty of Prostate Cancer for Black Men Using Decision Support Instruments in Barbershops." *J Cancer Educ*. 2016;31(3):506-513. doi:10.1007/s13187-015-0871-7.
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20. Sheridan SL, Felix K, Pignone MP, Lewis CL. Information needs of men regarding prostate cancer screening and the effect of a brief decision aid. *Patient Educ Couns*. 2004;54(3):345-351. doi:10.1016/j.pec.2003.12.003.

2. List of Excluded Studies

Wrong population

1. Barry MJ. Shared decision making supported by patient decision aids for prostate cancer screening and treatment. Psicooncologia. 2010;7(2–3):257–67.
2. Petrova D, Garcia-Retamero R, Cokely ET. Understanding the Harms and Benefits of Cancer Screening. Med Decis Mak. 2015;35(7):847–58.

Wrong intervention (not decision aid; not PSA test)

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3. Landrey, A. R., Matlock, D. D., Andrews, L., Bronsert, M., & Denberg, T. (2013). Shared decision making in prostate-specific antigen testing: the effect of a mailed patient flyer prior to an annual exam. *Journal of Primary Care & Community Health*, *4*(1), 67–74. https://doi.org/10.1177/2150131912447074
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9. Wolf, A. M. D. (1996). The Impact of Informed Consent on Patient Interest in Prostate-Specific Antigen Screening. *Archives of Internal Medicine*, *156*(12), 1333–6. https://doi.org/10.1001/archinte.1996.00440110105014
10. Wolf, A. M. D., Philbrick, J. T., & Schorling, J. B. (1997). Predictors of interest in prostate-specific antigen screening and the impact of informed consent: What should we tell our patients? *American Journal of Medicine*, *103*(4), 308–314. https://doi.org/10.1016/S0002-9343(97)00155-1

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Wrong outcome: does not have an included outcome (e.g., feasibility only, no outcome/just description)

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2. Gökce, M. I., Wang, X., Frost, J., Roberson, P., Volk, R. J., Brooks, D., … Pettaway, C. A. (2017). Informed decision making before prostate-specific antigen screening: Initial results using the American Cancer Society (ACS) Decision Aid (DA) among medically underserved men. Cancer, 123(4), 583–591.
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APPENDIX

Appendix 5
Proportions of men who were undecided about their screening strategy

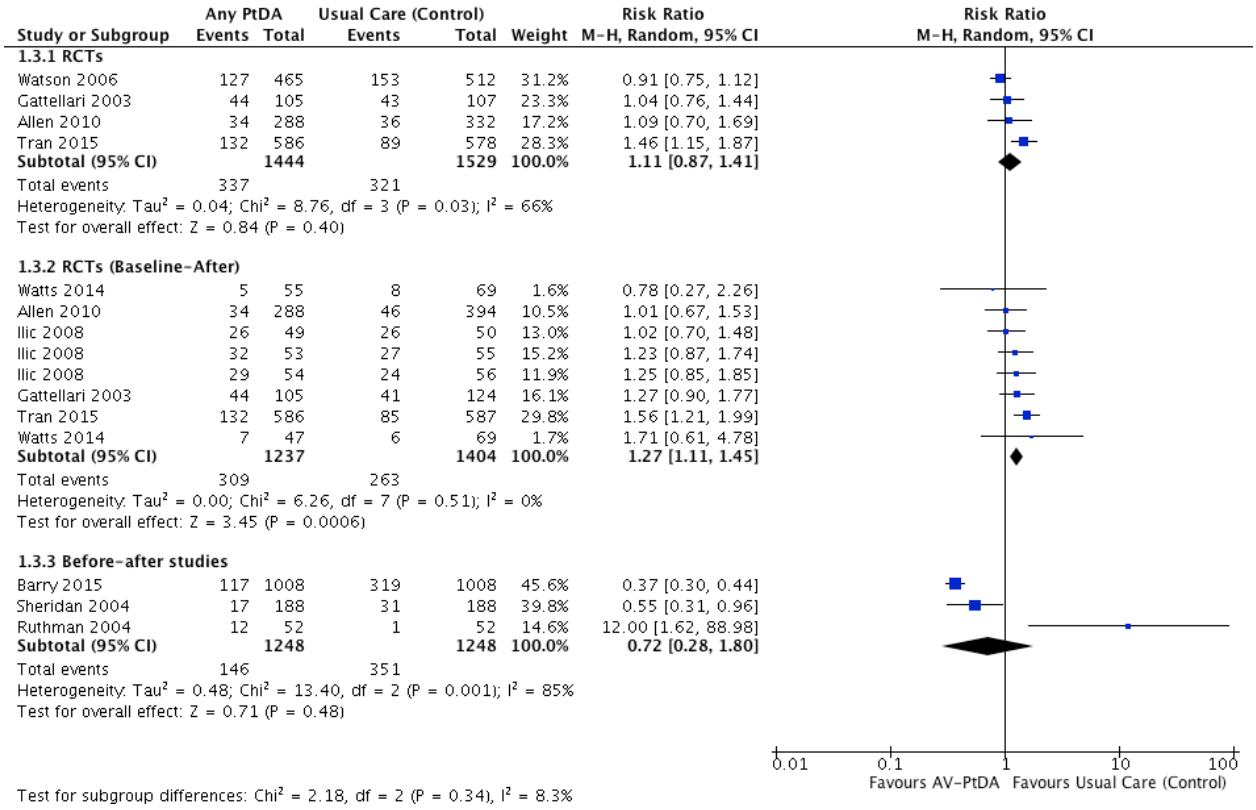

Figure 6. Proportion of men who were undecided about their PSA-based screening strategy after using any type of PSA-PtDAs, compared to usual care

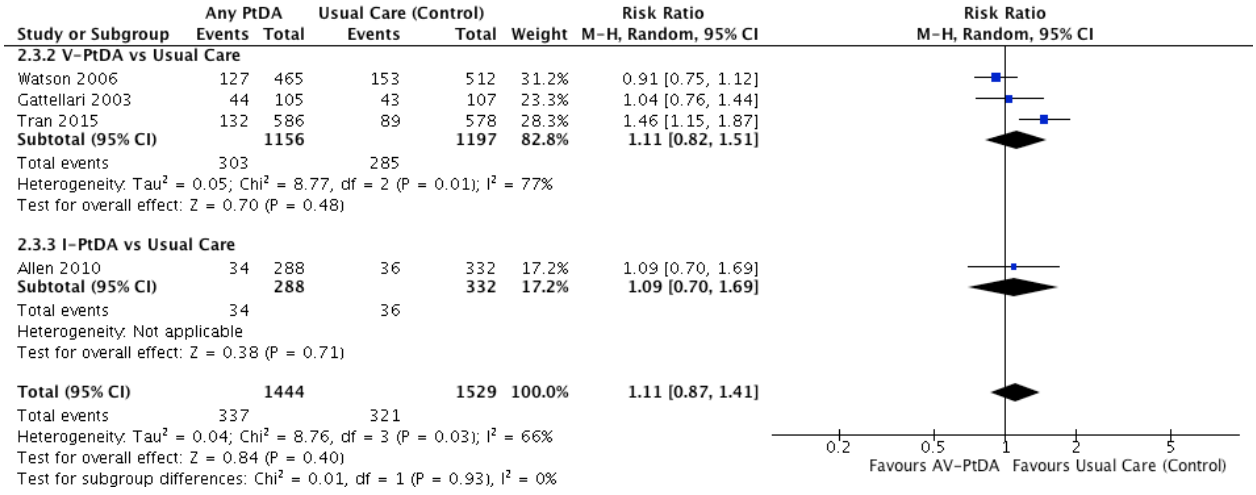

Figure 7. Proportion of men who were undecided about their PSA-based screening strategy after using visual and interactive PSA-PtDAs, compared to usual care

APPENDIX

Appendix 6
Proportions of men who were decided about their screening strategy

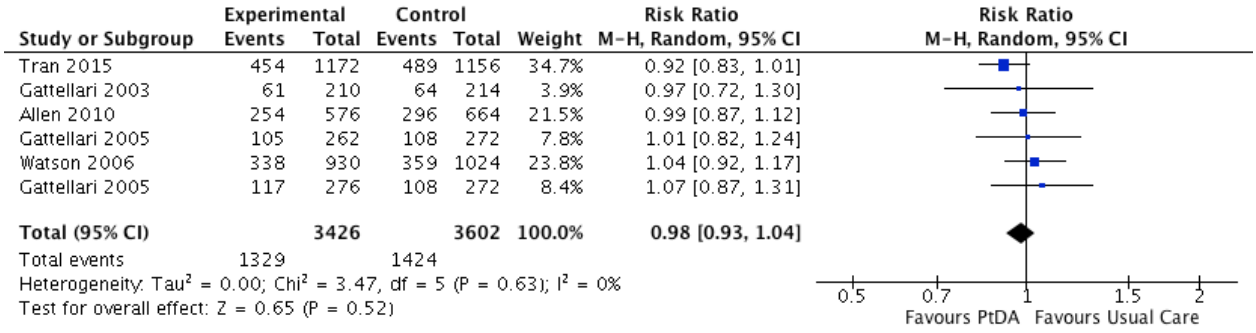

Figure 8. Proportions of men who were decided about their screening strategy after using any type of PtDAs, compared to usual care