Patient Preference and Adherence

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REVIEW

Shared decision making for men facing prostate cancer treatment: a systematic review of randomized controlled trials

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Aims: To synthesize the empirical evidence on the effectiveness of shared decision making (SDM) compared to usual care for prostate cancer (PC) treatment.

Methods and results: A systematic review of academic (MEDLINE, EMBASE, Cochrane Library, CINHAL, PsychINFO, and Scopus) and grey (clinicaltrials.gov, WHO trial search, meta-Register ISRCTN, Google Scholar, opengrey, and ohri.ca) literature, also identified from contacting authors and hand-searching bibliographies. We included randomized controlled trials (RCTs): 1) comparing SDM to usual care for decisions about PC treatment, 2) conducted in primary or specialized care, 3) fulfilling the key SDM features, and 4) reporting quantitative outcome data. Four RCTs from Canada (n=3) and the USA were included and comprised 1,065 randomized men, most (89.8%) of whom were in PC stage T1-T2. The studies reported 24 outcome measures. In 62.5% study estimates, SDM was similar to usual care at improving patient satisfaction and mood, and at reducing decisional conflict and decisional regret. In 37.5% study estimates, SDM significantly improved knowledge, perception of being informed and patient-perceived quality of life (QoL) at four weeks. There was a dearth of outcome data, particularly on the adherence to treatment and on patient-important and clinically relevant health outcomes such as symptoms and mortality.

Conclusion: SDM may positively influence men's knowledge and may have a positive but short-term effect on patient-perceived QoL. The (long-term) effects of SDM on patient-related outcomes for decisions about PC treatment are unclear. Future research needs consensus about the interventions and outcomes needed to evaluate SDM and should address the absence of evidence on health outcomes.

Keywords: systematic review, shared decision making, prostate cancer, treatment, controlled clinical trials, urology

Introduction

Prostate cancer (PC) is the second leading cancer in men and the fifth leading cause of death due to cancer in men worldwide.[1,2] Patients with PC often face more than one alternative to treatment eg, active treatment, active surveillance, or watchful waiting. These choices involve trade-offs between benefits and harms due to the limited evidence regarding the optimal treatment strategy for PC.[3–5] The survival benefit of treatment options including surveillance is associated with considerable morbidity due to potential adverse outcomes of treatment (eg, urinary and erectile dysfunction, loss of fertility, and chemotherapy and/or hormone therapy side

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effects), psychological distress, and impaired quality of life.[3–6] These factors make treatment decisions complex and highly preference-sensitive. Patients thus need to weigh carefully not only the diagnoses and prognoses but also their own fears, values, beliefs, ethics, hopes, and previous experience.

Shared decision making (SDM) is viewed as an approach to involve patients and their clinicians in a process of collaboration and deliberation to reach medical decisions, particularly for preference-sensitive conditions.[7–9] SDM helps inform patients about the options for, and the effectiveness of, treatment, taking into account the patient's needs, knowledge and their value of risks, benefits, and harms. Health authorities and policy makers strongly encourage SDM for decisions about PC treatment.[10–13] There is variation in the level of SDM implementation however, mainly due to the lack of consensus in SDM definition and goals.[14] We performed a systematic review to evaluate the evidence for the effectiveness of SDM compared to current clinical practice for the treatment of PC.

Methods

We followed a protocol based on the principles for systematic reviews[15,16] and report the methods according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (see Table S1).[17] We identified and selected studies following the methods published in detail elsewhere.[14]

Eligibility criteria

We included peer-reviewed and grey literature from RCTs published in English comparing the effects of SDM to usual care for decisions about PC treatment, which were conducted in primary and specialized care (general practice, community clinics, ambulatory care, hospital and private). We further limited the inclusion of studies to RCTs that, regardless of the intervention target (patients, HCP, surrogates, or family members): 1) met the criteria for SDM[9,18] supporting the principle of bi-directional deliberation,[8] as previously illustrated,[14] and 2) reported data in quantitative format for the outcomes of knowledge, patient satisfaction, perception of being informed, risk perception, decisional conflict, decisional regret, outcomes of emotional distress caused by the disease itself and/or treatment (eg, mood disturbance, anxiety, and depression), treatment behavior (eg, adherence to treatment), quality of life (QoL), symptoms, and mortality.

Study identification and search strategy

We searched for studies in: 1) academic databases: MEDLINE (Ovid), EMBASE (Elsevier), CINHAL (EBSCOHost), The Cochrane Library (Wiley), PsychINFO (EBSCOHost) and Scopus up to March 2015 (see Table S2); and 2) grey literature records (accessed: Feb–Aug, 2016) from clinicaltrials.gov and ISRCTN, the WHO search portal (http://apps.who.int/trialsearch), the Ottawa Hospital Research Institute website (http://www.ohri.ca), Google Scholar, and the system for Information on Grey Literature in Europe (http://opengrey.eu/). We additionally searched for the registration numbers of the trials using Medline and PubMed. We screened the reference lists of included studies, relevant reviews, and clinical guidelines, and contacted (Jun 2015–Jan 2017) the authors of abstracts for which the full-texts could not be located.

Selection of studies and data extraction

Two independent reviewers screened all titles and abstracts, and assessed the full-text of eligible publications. One reviewer extracted all data and a second reviewer independently verified data extractions. Differences in study selection and data extractions were resolved by consensus or by involving an arbitrator. We grouped outcomes into affective-cognitive, behavioral, and health outcomes following the system by Shay and Lafata (2015).[19]

Risk of bias

Two reviewers independently assessed in duplicate the quality features of the included studies following established guidelines and resolving differences by discussion.[16,20] We rated the adequacy of core items including generation of random sequence, concealment of allocation at randomization, blinding (patients, health care providers, and outcome assessors), intention-to-treat (ITT) (if participants were analyzed based on their original group allocation), follow-up (same length of time), and if there were attrition rates of significant concern (at least 20%). We also rated whether studies reported on the definition of inclusion and exclusion criteria, "a-priori" sample size calculation, primary and secondary outcomes, and funding sources.

Data synthesis

There was mostly one study per outcome precluding the ability to perform meta-analyses. We thus analyzed the data based on individual trial estimates. Where data were sufficiently reported, we calculated the unadjusted risk ratios (RR) or the standard mean differences (SMD) and the 95% confidence intervals (CI) assuming a random-effects model in RevMan 5.3.5 software.[21]

Results

We examined in detail the full-text of 270 articles. Four of these fulfilled the SDM criteria and investigated the comparative effectiveness of SDM with usual care (Figure 1).

Study and population characteristics

The studies were from Canada (n=3) and the USA (n=1), and comprised 1,065 patients individually randomized to the

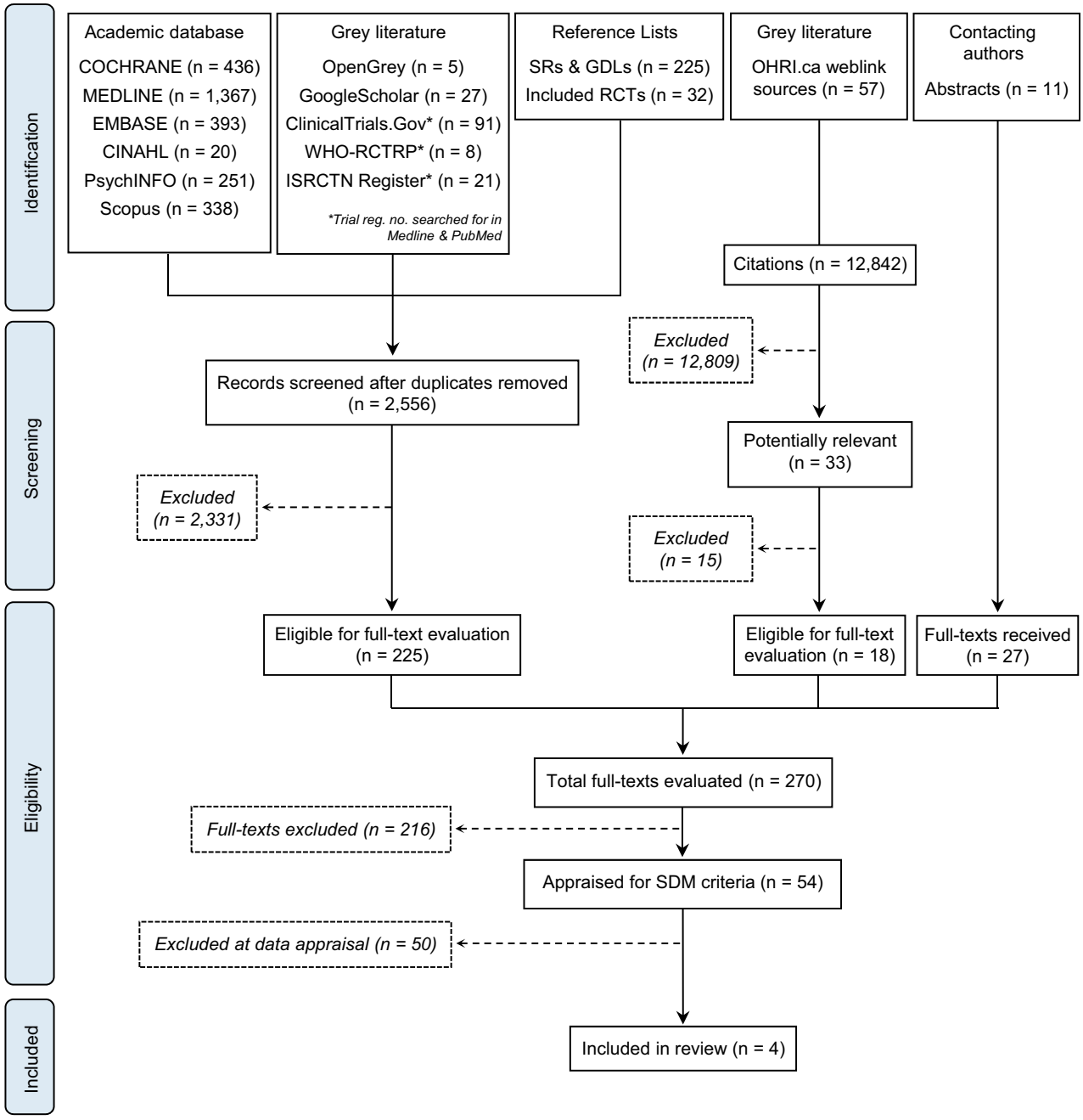

Figure 1 Process of identification and selection of studies.
Abbreviations: GDL, guidelines; SR, systematic reviews; SDM, shared decision-making.

intervention groups (Table 1). The patients were recruited from multidisciplinary or specialized care in hospital or general medicine. Three RCTs reported on cancer staging: 89.8% of the men had localized PC (clinical stage T1-T2),[22–24] 6.2% were in advanced stage (T3-T4),[23] and 4.1% were of "unknown" clinical stage.[22,23] Radical prostatectomy (36.7%) and watchful waiting (28.5%) were the most frequently selected treatments among 743 men from 2 RCTs, 1 in general (hospital) and 1 in specialized cancer care, respectively. "No treatment" accounted for 25.4% of all options offered in one study.[23] Men had a mean age of 64.6 (SD 7.8), 83.9% were married and at least 53.4% had a minimum of high school education. The only RCT reporting on ethnicity included White (71.5%) and Black (28.5%) men. In three RCTs reporting on employment status, 55.3% of the men were in full- or part-time employment. In two RCTs, 88.2% of the participating health care providers were radiation oncologists and 11.8% were urologists.

Interventions' characteristics

All interventions fulfilled the key features of SDM as illustrated in detail elsewhere.[14] All RCTs used patient-directed interventions; one included the patients' partners in the interventions sessions (Table 1).[25] The interventions were delivered before decision making, within the time of scheduled visits[23] or before consultations[22,24,25] in order to empower patient participation in decisions. Men were recommended to review the material before consultation or were specifically encouraged to participate in treatment decisions. Men were advised to bring their significant other(s) to the consultation in one RCT.[25] Three RCTs used multifaceted interventions on-site[22,25] or at home.[24] The interventions were self-administered or delivered by the research staff or by a nurse. The formats of the interventions included video, printed paper-based material, interviews, telephone calls, or audiotape recording. Only one RCT considered health care literacy for the development or pilot testing of the interventions.[24] One RCT evaluated two SDM interventions and usual care.[24] The content of the interventions included educational information, eg, about PC, treatment choices, advantages and disadvantages of treatment, side effects, and prognosis.

Risk of bias in the methods of included studies

All trials adequately randomized patients, but only two reported adequate concealment of allocation, leading to risk of selection bias in the other trials (Table 2). Only one RCT blinded patients and physicians, another blinded patients only, and no study performed or reported on the blinding of outcome assessors, resulting in high risk of performance and detection biases. Two RCTs with an attrition rate of less than 20% did not report on ITT analyses. Two RCTs had unclear reporting of attrition rates and ITT techniques. Men in all intervention arms were followed-up for the same length of time. All trials reported the participants' inclusion criteria but only one trial reported the exclusion criteria too. Two RCTs reported on the sample size calculation and power. All RCTs measured the success of interventions by definition of primary outcome(s). All RCTs were funded by non-profit organizations.

Effectiveness of interventions

There were twenty-four outcome measures reported in the four RCTs (Figure 2). Data were sparsely reported with one study per outcome, limiting the ability to conduct meta-analyses. Table 3 shows the effect estimates for each individual trial.

Affective-cognitive outcomes

Knowledge

One trial implemented two SDM interventions.[24] The different components between SDM groups consisted of nurse telephone calls to patients (treatment direct [TD]) or nurse telephone calls to patients and primary supporting persons (treatment supplement [TS]). Compared to usual care, TD significantly improved knowledge for PC and treatment at four weeks (SMD 0.33, 95% CI 0.03 to 0.64, p=0.03) and at three months (SMD 0.35, 95% CI 0.04 to 0.66, p=0.02). TS also showed a small but significant improvement in knowledge at four weeks (SMD 0.33, 95% CI 0.02 to 0.64, p=0.04), but not at three months. The combined effect of both SDM (TD and TS) interventions showed a significant improvement in knowledge at four weeks (SMD 0.35, 95% CI 0.08 to 0.62, p=0.01) and at three months (SMD 0.31, 95% CI 0.04 to 0.58, p=0.02).

Patient satisfaction

Individual trial effect estimates showed no significant difference between SDM and usual care in the number of patients who were satisfied with their treatment choice or who were satisfied with the levels of involvement in treatment decision making with the doctor.[22] Scores of patient

Table 1 Characteristics of included studies

Author, year, country	Health care context, setting and facilities, n	Target population	Patients with chosen treatment† (%)	Intervention(s) & randomized patients, N	Comparator(s) & randomized patients, N	Age: mean (SD) & target (range), years	Race or ethnicity, %			Married, %	Education	Employed, %	HCP
							White	Black	Hispanic				
Mishel et al, 2009[24] USA	Multidisciplinary (hospital and specialized) Cancer center, n=2 Community hospital, n=3 Veterans' medical center, n=1	Men with biopsy-confirmed localized PC, no major cognitive impairment, ability to read, access to telephone, no prior cancer history, and a patient-designated PSP willing to participate in the study	NR	1) Treatment supplemented: Communication strategy DVD + Information Booklet + 4 Telephone calls by same nurse to patients and PSP; N=89 2) Treatment direct: Communication strategy DVD + Information Booklet + 4 Telephone calls by nurse; N=93	Handout on staying healthy during treatment; N=74	62.5 (7.4)	71.5	28.5	0	80.8	15.1 (SD 3.4) years of education	56.6	NR
Hack et al, 2007[23] Canada	Specialized (Cancer) Tertiary oncology clinic treatment facilities, n=4 (in 3 cities)	Men with confirmed diagnosis of PC, presenting to a tertiary oncology clinic for their primary treatment consultation, without cognitive impairment disabling them from providing informed consent	• Radical prostatectomy (10.7) • Hormone therapy (18.0) • Watchful waiting (43.9) • No treatment (25.4) • Other (2.0)	Audiotape: Audio recording of primary treatment consultation: 1) Audiotape given to men, N=120; and 2) Given choice to receive audiotape or not, N=94	No audiotape: 1) Consultation not audiotaped: no audio recording of primary treatment consultation, N=113; and 2) Not given audiotape: audio recording without giving audiotape, N=98	67.0 (8.0) (>18)	NR	NR	NR	84	43.5% with more than HS	NR	Radiation oncologists, n=15

(*Continued*)

Table 1 (Continued).

Author, year, country	Health care context, setting and facilities, n	Target population	Patients with chosen treatment† (%)	Intervention(s) & randomized patients, N	Comparator(s) & randomized patients, N	Age: mean (SD) & target (range), years	Race or ethnicity, %			Married, %	Education	Employed, %	HCP
							White	Black	Hispanic				
Davison et al, 2007[22] Canada	Hospital care General hospital, n=1	Men with biopsy-confirmed localized PC, aware of their diagnosis, who had an initial urologic treatment consultation, but not scheduled for definitive treatment within the following 4 weeks, and able to read and write English Men's partners were included in the sessions if they accompanied the patient	• Radical prostatectomy (76.5) • External beam radiation (6.8) • Brachytherapy (10.5) • Watchful waiting (5.1) • Complementary (0.3) • Cryotherapy (0.3) • Unknown/NR (0.3)	Generic information 24-min videotape with section on the identification of men's preferences + Information printout individualized according to patient's disease characteristics + Written information package with list of relevant info and help sources + Telephone calls by RN approx. 4 weeks after visits; N=162 Men encouraged to bring PSP and were included in the sessions if present	Generic information 24-min videotape + Written information package with list of relevant info and help sources; N=162 Men encouraged to bring PSP and were included in the sessions if present	62.4 (6.9)	NR	NR	NR	85.4	68.8% with more than HS	59.3	NR

(*Continued*)

Table 1 (Continued).

Author, year, country	Health care context, setting and facilities, n	Target population	Patients with chosen treatment† (%)	Intervention(s) & randomized patients, N	Comparator(s) & randomized patients, N	Age: mean (SD) & target (range), years	Race or ethnicity, %			Married, %	Education	Employed, %	HCP
							White	Black	Hispanic				
Davison et al, 1997[25] Canada	General medicine Community clinic with practicing urologists, n=1	Men newly diagnosed with PC (stage not specified), aware of their diagnosis, who had not have an initial treatment consultation, with no evidence of mental confusion, able to read, speak and write English	• Pelvic lymph node dissection (NR) • Radical prostatectomy (NR) • Other (NR)	Written information package + Blank audiotape (optional) to record consultation + Interview with nurse with elements of patient empowerment to prepare men for consultation and to encourage participation in DM; N=30 Men encouraged to bring PSP to the treatment consultation	Written information package only; N=30	67.9 (7.1) (41–81)	NR	NR	NR	86.6	41.7% with at least HS Overall: 10.8 (SD 2.8) years of education	28.3	Urology physicians, n=2

Notes: †Hack, 2007: 449 patients received/selected treatment by the time of consultation; "Other" = transurethral resection of the prostate, orchiectomy. Davison, 2007: 294 patients. Davison, 1997: 75% of the men started/received treatment by the time of second interview.

Abbreviations: DM, Decision Making; HCP, Health care Professional(s); HS, High School; NR, Not Reported; PC, Prostate Cancer; PSP, Primary Support Person (eg, wife).

Table 2 Methodological features of included studies

Author, year	Country & funding	Outcome definition	Participants criteria	Study size	Sample size calculation and power	Groups comparable at baseline	Adequate sequence generation	Adequate allocation concealment	Adequate blinding	Attrition (outcome), % (range)	Adequate follow-up	ITT data
Mishel et al, 2009[24]	USA, non-profit	Primary & Secondary	Inclusion: yes Exclusion: yes	N>200	nr	partially†	Yes	Unclear	HCP: unclear Participants: unclear OA: unclear	Unclear	Yes	Unclear
Hack et al, 2007[23]	Canada, non-profit	Primary	Inclusion: yes Exclusion: nr	N>200	Yes	Yes	Yes	Yes	HCP: yes Participants: yes OA: nr	<20%	Yes	No
Davison et al, 2007[22]	Canada, non-profit	Primary	Inclusion: yes Exclusion: nr	N>200	Yes	Yes	Yes	Yes	HCP: unclear Participants: yes OA: no	<20% (9.26–9.57) or unclear	Yes	No
Davison et al, 1997[25]	Canada, non-profit	Primary	Inclusion: yes Exclusion: nr	N<200	nr	Yes	Yes	Unclear	HCP: no Participants: no OA: no	Unclear	Yes	Unclear

Notes: †Patients in the control group had higher level of education than patients in the treatment direct group.
Abbreviations: HCP, Health care Professionals; OA, Outcome Assessors; nr, not reported.

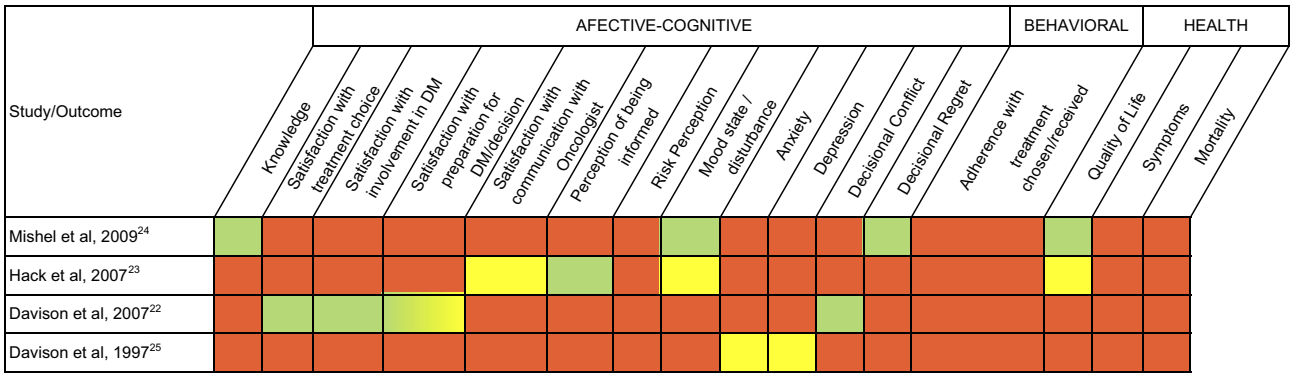

Figure 2 Outcomes reported in the included studies.
Notes: Green = quantitative data; Yellow = qualitative data; Red = no outcome data.
Abbreviation: DM, Decision-Making.

satisfaction with preparation for decision making were not significant between groups.

Perception of being informed and risk perception

Individual trial effect estimates showed a small but significant effect of SDM when compared to usual care on patients' perception of receiving information (SMD 0.20, 95% CI 0.01 to 0.39, p=0.04).[23] The same trial showed a marginal but statistically significant effect of SDM on positive perceptions of receiving information about treatment alternatives (SMD 0.19, 95% CI −0.00 to 0.38, p=0.05) and treatment side effects (SMD 0.25, 95% CI 0.06 to 0.44, p=0.010). No study reported on risk perception.

Mood state/disturbance, anxiety, and depression

Outcomes of emotional distress including mood/disturbance, anxiety, and depression caused by the personal situation, the disease itself, or treatment were scarcely reported. Individual trial effect estimates showed no significant differences between SDM (TD or TS) and usual care with respect to mood state or disturbance at four weeks or at three months.[24] No study reported quantitative data on anxiety and depression.

Decisional conflict

Individual trial effect estimates showed no significant differences between SDM and usual care in the scores of decisional conflict.[22]

Decisional regret

Individual trial effect estimates showed no significant differences between SDM (TD or TS) and usual care in the scores of decisional regret at three months.[24] The combined effect of both SDM (TD and TS) interventions compared to usual care was not significant at three months.

Behavioral outcomes

Adherence to treatment of choice

Radical prostatectomy and watchful waiting were the most frequent treatments received or chosen by men in two RCTs.[22,23] No trial reported on the adherence to a treatment initially chosen however.

Health outcomes

Quality of life, symptoms, and mortality

Individual trial effect estimates showed a significant effect of two SDM (TD or TS) interventions, compared to usual care, on men's positive feelings about their QoL at four weeks (TD: SMD 0.50, 95% CI 0.19 to 0.81, p=0.002; TS: SMD 0.50, 95% CI 0.18 to 0.81, p=0.002).[24] This effect did not sustain at three months for either of the SDM (TD or TS) interventions however. Health outcomes of symptoms and mortality were not reported.

Discussion

In this systematic review, we identified four RCTs that both fulfilled the criteria for SDM and evaluated the comparative effectiveness of SDM with usual care for men faced with decisions about PC treatment.

Despite the low volume of literature, 37.5% of the study estimates significantly favored SDM when compared to usual care. We found moderate effects of SDM on knowledge, perception of being informed, and QoL. The effects on knowledge and QoL did not sustain at long term (three months) however. The remaining 62.5% of the study

Table 3 Outcome effect estimates for SDM compared to usual care for decisions about prostate cancer treatment

Author, year	Outcome	Measurement method/tool	Measurement point	Intervention			Control			Effect estimate
BINARY DATA				**SDM**	**Patients, n**	**Total patients, N**	**Usual Care**	**Patients, n**	**Total patients, N**	**RR (95% CI)**
AFFECTIVE COGNITIVE OUTCOMES										
Patient Satisfaction										
Davison et al, 2007[22]	Satisfaction with treatment choice	10-item questionnaire based on 5-point Likert scale†	4–10 weeks after visit - after men had made a treatment decision with/out their urologist	Generic information 24-min videotape with section on the identification of men's preferences + Information printout individualized according to patient's disease characteristics + Written information package with list of relevant info and help sources + Telephone calls by RN approx. 4 weeks after visits	141	149	Generic information 24-min videotape + Written information package with list of relevant info and help sources	135	145	1.02 (0.96 to 1.08)
Davison et al, 2007[22]	Satisfaction with level of involvement in decision making	5-item questionnaire based on 5-point Likert scale‡	4–10 weeks after visit - after men had made a treatment decision with/out their urologist	Generic information 24-min videotape with section on the identification of men's preferences + Information printout individualized according to patient's disease characteristics + Written information package with list of relevant info and help sources + Telephone calls by RN approx. 4 weeks after visits	142	149	Generic information 24-min videotape + Written information package with list of relevant info and help sources	133	145	1.04 (0.98 to 1.10)

(*Continued*)

Table 3 (Continued).

Author, year	Outcome	Measurement method/tool	Measurement point	Intervention			Control			Effect estimate
CONTINUOUS DATA				**SDM**	**mean (SD)**	**Total patients, N**	**Usual Care**	**mean (SD)**	**Total patients, N**	**SMD (95% CI)**
AFFECTIVE COGNITIVE OUTCOMES										
Knowledge										
Mishel et al, 2009[24]	PC knowledge	20-item questionnaire (true/false/do not know)[‡]	4 weeks post-entry when treatment decision making meeting had occurred	1) Treatment supplemented: Communication strategy DVD + Information Booklet +4 Telephone calls by same nurse to patients and PSP	15.02 (3.00)	89	Handout on staying healthy during treatment	13.88 (3.83)	74	0.33 (0.02 to 0.64)
Mishel et al, 2009[24]	PC knowledge	20-item questionnaire (true/false/do not know)[§]	3 months post-entry after patients had started their treatment	1) Treatment supplemented: Communication strategy DVD + Information Booklet +4 Telephone calls by same nurse to patients and PSP	15.21 (2.48)	89	Handout on staying healthy during treatment	14.51 (3.32)	74	0.24 (−0.07 to 0.55)
Mishel et al, 2009[24]	PC knowledge	20-item questionnaire (true/false/do not know)[§]	4 weeks post-entry when treatment decision making meeting had occurred	2) Treatment direct: Communication strategy DVD + Information Booklet +4 Telephone calls by nurse	15.02 (3.00)	93	Handout on staying healthy during treatment	13.88 (3.83)	74	0.33 (0.03 to 0.64)
Mishel et al, 2009[24]	PC knowledge	20-item questionnaire (true/false/do not know)[§]	3 months post-entry after patients had started their treatment	2) Treatment direct: Communication strategy DVD + Information + 4 Telephone calls by nurse	15.51 (2.36)	93	Handout on staying healthy during treatment	14.51 (3.32)	74	0.35 (0.04 to 0.66)
Mishel et al, 2009[24]	PC knowledge	20-item questionnaire (true/false/do not know)[§]	4 weeks post-entry when treatment decision making meeting had occurred	1) +2)	15.02 (3.00)	182	Handout on staying healthy during treatment	13.88 (3.83)	74	0.35 (0.08 to 0.62)

(*Continued*)

Table 3 (Continued).

Author, year	Outcome	Measurement method/tool	Measurement point	Intervention			Control			Effect estimate
Mishel et al, 2009[24]	PC knowledge	20-item questionnaire (true/false/do not know)[§]	3 months post-entry after patients had started their treatment	1) +2)	15.36 (2.42)	182	Handout on staying healthy during treatment	14.51 (3.32)	74	0.31 (0.04 to 0.58)
Satisfaction with preparation for Decision Making										
Davison et al, 2007[22]	satisfaction with preparation for treatment decision making with respect to information received	10-item questionnaire based on 5-point Likert scale[a]	4–10 weeks after visit - after men had made a treatment decision with/out their Urologist	Generic information 24-min videotape with section on the identification of men's preferences + Information printout individualized according to patient's disease characteristics + Written information package with list of relevant info and help sources + Telephone calls by RN approx. 4 weeks after visits	2.8 (0.84)	149	Generic information 24-min videotape + Written information package with list of relevant info and help sources	2.67 (0.71)	145	0.17 (−0.06 to 0.4)
Perception of Being Informed										
Hack et al, 2007[23]	perception of having been informed (total score)	9-item measure of patient satisfaction with communication with oncologist[¶]	12 weeks post-consultation	Audiotape: audio recording of clinical encounter	21.83 (3.78)	214	Consultation not audiotaped	21.01 (4.31)	211	0.20 (0.01 to 0.39)
Hack et al, 2007[23]	perception of having been informed about treatment alternatives	9-item measure of patient satisfaction with communication with oncologist[¶]	12 weeks post-consultation	Audiotape: audio recording of clinical encounter	4.73 (0.74)	214	Consultation not audiotaped	4.56 (1.03)	211	0.19 (−0.00 to 0.38)

(*Continued*)

Table 3 (Continued).

Author, year	Outcome	Measurement method/tool	Measurement point	Intervention			Control			Effect estimate
Hack et al, 2007[23]	perception of having been informed about side effects of treatment	9-item measure of patient satisfaction with communication with oncologist[¶]	12 weeks post-consultation	Audiotape: audio recording of clinical encounter	4.63 (0.87)	214	Consultation not audiotaped	4.37 (1.17)	211	0.25 (0.06 to 0.44)
Mood State/Disturbance										
Mishel et al, 2009[24]	mood disturbance caused by the personal situation, the disease itself or treatment	35-item POMS-SF scale	4 weeks post-entry when treatment decision making meeting had occurred	1) Treatment supplemented: Communication strategy DVD + Information Booklet +4 Telephone calls by same nurse to patients and PSP	33.11 (23.29)	89	Handout on staying healthy during treatment	37.04 (24.64)	74	−0.17 (−0.48 to 0.14)
Mishel et al, 2009[24]	mood disturbance caused by the personal situation, the disease itself or treatment	35-item POMS-SF scale	3 months post-entry after patients had started their treatment	1) Treatment supplemented: Communication strategy DVD + Information Booklet +4 Telephone calls by same nurse to patients and PSP	30.00 (20.4)	89	Handout on staying healthy during treatment	32.85 (24.98)	74	−0.13 (−0.44 to 0.18)
Mishel et al, 2009[24]	mood disturbance caused by the personal situation, the disease itself or treatment	35-item POMS-SF scale	4 weeks post-entry when treatment decision making meeting had occurred	2) Treatment direct: Communication strategy DVD + Information Booklet +4 Telephone calls by nurse	33.11 (23.29)	93	Handout on staying healthy during treatment	37.04 (24.64)	74	−0.17 (−0.47 to 0.14)

(*Continued*)

Table 3 (Continued).

Author, year	Outcome	Measurement method/tool	Measurement point	Intervention			Control			Effect estimate
Mishel et al, 2009[24]	mood disturbance caused by the personal situation, the disease itself or treatment	35-item POMS-SF scale	3 months post-entry after patients had started their treatment	2) Treatment direct: Communication strategy DVD + Information Booklet +4 Telephone calls by nurse	30.44 (22.06)	93	Handout on staying healthy during treatment	32.85 (24.98)	74	−0.11 (−0.41 to 0.20)
Decisional Conflict										
Davison et al, 2007[22]	decisional conflict	10-item low-literacy scale††	4–10 weeks after visit - after men had made a treatment decision with/out their Urologist	Generic information 24-min videotape with section on the identification of men's preferences + Information printout individualized according to patient's disease characteristics + Written information package with list of relevant info and help sources + Telephone calls by RN approx. 4 weeks after visits	1.61 (0.33)	148	Generic information 24-min videotape + Written information package with list of relevant info and help sources	1.62 (0.23)	145	−0.04 (−0.26 to 0.19)
Decisional Regret										
Mishel et al, 2009[24]	decisional regret	3-item subscale of the QoL scale‡‡	3 months post-entry after patients had started their treatment	1) Treatment supplemented: Communication strategy DVD + Information Booklet +4 Telephone calls by same nurse to patients and PSP	3.93 (1.82)	89	Handout on staying healthy during treatment	4.17 (1.96)	74	−0.13 (−0.44 to 0.18)
Mishel et al, 2009[24]	decisional regret	3-item subscale of the QoL scale‡‡	3 months post-entry after patients had started their treatment	2) Treatment direct: Communication strategy DVD + Information Booklet +4 Telephone calls by nurse	3.83 (1.44)	93	Handout on staying healthy during treatment	4.17 (1.96)	74	−0.2 (−0.51 to 0.11)

(*Continued*)

Table 3 (Continued).

Author, year	Outcome	Measurement method/tool	Measurement point	Intervention			Control			Effect estimate
Mishel et al, 2009[24]	decisional regret	3-item subscale of the QoL scale[‡‡]	3 months post-entry after patients had started their treatment	1) +2)	3.88 (1.64)	182	Handout on staying healthy during treatment	4.17 (1.96)	74	−0.17 (−0.44 to 0.1)
HEALTH OUTCOMES										
Quality of Life										
Mishel et al, 2009[24]	men's perceptions of their overall QoL	10-item VAS[§§]	4 weeks post-entry when treatment decision making meeting had occurred	1) Treatment supplemented: Communication strategy DVD + Information Booklet +4 Telephone calls by same nurse to patients and PSP	7.61 (1.79)	89	Handout on staying healthy during treatment	7.33 (2.23)	74	0.50 (0.18 to 0.81)
Mishel et al, 2009[24]	men's perceptions of their overall QoL	10-item VAS[§§]	3 months post-entry after patients had started their treatment	1) Treatment supplemented: Communication strategy DVD + Information Booklet +4 Telephone calls by same nurse to patients and PSP	7.57 (1.73)	89	Handout on staying healthy during treatment	7.72 (1.72)	74	0.00 (−0.31 to 0.31)
Mishel et al, 2009[24]	men's perceptions of their overall QoL	10-item VAS[§§]	4 weeks post-entry when treatment decision making meeting had occurred	2) Treatment direct: Communication strategy DVD + Information Booklet +4 Telephone calls by nurse	7.61 (1.79)	93	Handout on staying healthy during treatment	7.33 (2.23)	74	0.50 (0.19 to 0.81)
Mishel et al, 2009[24]	men's perceptions of their overall QoL	10-item VAS[§§]	3 months post-entry after patients had started their treatment	2) Treatment direct: Communication strategy DVD + Information Booklet +4 Telephone calls by nurse	7.76 (1.56)	93	Handout on staying healthy during treatment	7.72 (1.72)	74	−0.15 (−0.45 to 0.16)

Notes: [†]Scale: 0= not at all, 5= a great deal; items scored and scores converted to 0–100; higher scores = higher levels of satisfaction. [‡]Scores: 1= strongly disagree, 5= strongly agree; higher scores = higher levels of satisfaction. [§]PC knowledge based on uncertainty management measures. Score based on the sum of the number of correct items. [¶]Highest possible satisfaction = score 9. [††]Scores: yes =1.5, no =4.5, unsure =3; range of scores: 15–45; higher scores = higher levels of decision conflict. [‡‡]Scores: higher = greater use of problem solving. [§§]Indexed subjects' perceptions of their overall QoL. Scores: 1–10 for how positive men felt about their QoL; higher scores = greater QoL.
Abbreviations: SDM, Shared Decision Making; QoL, Quality of Life; POMS-SF, Profile Of Mood States-Short Form; VAS, Visual Analogue Scale; PSP, Primary Supporting Person (eg, wife); RN, Research Nurse; n, number of patients with outcome; N, total number of patients in a group; RR, Relative Risk; SMD, Standard Mean Difference; CI, Confidence Intervals.

estimates showed no significant differences between SDM and usual care on patient satisfaction, decisional conflict, decisional regret, and mood.

This systematic review is based on published data. Surprisingly, six of the thirteen outcomes of interest were not reported. Of particular concern is the dearth of outcome data on the adherence to treatment and health outcomes including symptoms, mortality and QoL. The methodological quality of studies is low to moderate at best, mainly due to unclear allocation concealment, blinding and attrition. The interventions varied in characteristics and content, and were delivered before decision making mostly by trained nurses or research staff. The description of population characteristics was often incomplete too. The studies were carried out mostly in specialized and hospital care in high-income countries from North America, mainly Canada. The ethnicity of the populations was generally not described. Thus, the evidence is generalizable mostly to middle-aged men of at least fifty-five years of age, from Western countries, married, with low to moderate levels of education, who have an English-speaking background and face decision making for PC treatment.

SDM is highly recommended by major task force associations, policy makers, and clinical guidelines for medical decisions regarding PC treatment.[10,11,26–30] Our systematic review, however, reveals a lack and variable reporting of outcome measures in the included studies, particularly on health outcomes. This makes it difficult to relate patient involvement in decision making to the actual effects of SDM. The inconsistent reporting of outcomes across studies is most likely due to the lack of consensus in the definition and in the approach used to evaluate and implement SDM.[14] SDM is variably adopted in practice as suggested by the very few studies meeting the key SDM criteria. Perspectives of the health care team involved in SDM may play a role in this variability. In a multidisciplinary survey study, 63–71% of oncology nurses, urologists, and oncologists agreed that patients should be involved in decision making.[31] However, 52–55% of the urologists and oncologists felt inadequately trained to apply SDM in clinical practice. On the other hand, 20% of the oncology nurses felt inadequately trained to apply SDM. Although an assessment of economic outcomes was outside the focus of our review, we noted that no study reported on cost data.

Clinical implications

The variation in the definitions and goals of SDM[14] and the inconsistent reporting of outcomes across studies are the main barriers in generating an evidence base for the effectiveness of SDM in the care of PC patients. Before implementing SDM in clinical guidelines of PC care and applying these on a large scale in practice, more efforts in standardizing the definition, goals, and outcomes of SDM are needed. Our results may thus encourage researchers to engage in this area. The absence of evidence of SDM in PC care does not prove a lack of its beneficial effects. Thus, our results about the moderate effects of SDM on knowledge, perception of being informed and QoL may still motivate clinicians to activate their PC patients to participate in decision making.

Future research

Future research warrants further focus on the use of SDM interventions for decisions about PC treatment. Some guidance for SDM implementation based on a clear definition and objectives of SDM as previously reported[14] could be the leading step in building focused and solid evidence on SDM. Agreement on a standard set of outcomes that are best to assess SDM and that are most meaningful to patients is critical to guide appropriate outcome collection and evaluation of SDM. Future research then needs to address the absence of evidence, particularly on health outcomes. The link between patient involvement in decision making and the effect of SDM-chosen treatment on patient-important and health-related outcomes needs special consideration. Since treatment can have a significant impact on the patients' QoL and length of survival, studies of SDM for PC need to provide an appropriate description of the characteristics of the populations including comorbidities, status of cognitive function, literacy levels, sexual health, religious beliefs, side effects of treatment, and whether significant persons (eg, carer, partners) accompany the patients in the process of care. These factors influence not only the type of treatment of choice but also the patients' emotions, decisional regret, and the degree of involvement in decision making.[32] Patients with PC aged <40 years, for example, express significantly high positive and negative emotions, and partners of PC patients express more negative emotions than the patient himself. The physicians' specialty may also unintentionally influence the physicians' preference for treatment. Future studies should consider and address the perspectives of the health care team on SDM as a potential barrier for its implementation.[31] In particular, interventions and components should be described in detail so that results are interpreted appropriately, and

interventions can be replicated and evaluated. SDM should also be evaluated in relation to its costs and health gains so that SDM interventions can be reliably implemented. Therefore, future research needs to address the absence of evidence on cost data.

Strengths and limitations

To our knowledge, this is the first systematic review on SDM compared to usual care for men faced with decisions about PC treatment. It benefits from the inclusion of international literature without restrictions on countries or type of health care professionals. Including RCTs allows the estimation of causal effects with lower risk of bias. We only included studies meeting the key features of SDM[9,14,33] because of the continuing gaps in the conceptualization and implementation of SDM. We considered studies regardless of whether a specific decision was promoted. This was a rigorous and focused approach although we cannot exclude the possibility of underreported SDM characteristics in other studies. We only included literature published in English, but we made considerable efforts to identify all relevant studies. We searched several sources and contacted, between 2015 and 2017, the authors of relevant abstracts with no available full-text, thus increasing the likelihood of identifying more recent literature. The results from our systematic review are limited by the quantity and methodological quality of the available literature, in particular by a dearth of outcome data, and by lower quality reporting of outcome data. The studies focus primarily on SDM process-related outcomes and lack important data on health outcomes, affecting the ability to conduct meta-analyses.

Conclusion

There is little research currently available to appropriately evaluate the presumed benefits of SDM for decisions about PC treatment when compared to usual care. SDM may improve knowledge and perception of being informed and may have a positive but short-term effect on patient-perceived QoL. The (long-term) effects of SDM are unclear. Future rigorous research needs a consistent and relevant set of outcomes and interventions to assess the effects of SDM. In particular, it should address the absence of evidence and appropriately describe and test a reproducible form of SDM.

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Ethics

No ethical approval was required as this study is a systematic review.

Disclosure

The authors declare no conflicts of interest in this work.

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Supplementary materials

Table S1 PRISMA checklist for the reporting of the systematic review

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (eg, Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (eg, PICOS, length of follow-up) and report characteristics (eg, years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (eg, databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Table S2
Study selection	9	State the process for selecting studies (ie, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (eg, piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2
Data items	11	List and define all variables for which data were sought (eg, PICOS, funding sources) and any assumptions and simplifications made.	2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2
Summary measures	13	State the principal summary measures (eg, risk ratio, difference in means).	2
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (eg, I^2) for each meta-analysis.	2
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (eg, publication bias, selective reporting within studies).	2
Additional analyses	16	Describe methods of additional analyses (eg, sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	2

(*Continued*)

Table S1 (Continued).

Section/topic	#	Checklist item	Reported on page #
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3, Figure 1
Characteristics	18	For each study, present characteristics for which data were extracted (eg, study size, PICOS, follow-up period) and provide the citations.	3-4, Table 1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	4, Table 2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	4, 9, Figure 2, Table 3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Table 2
Additional analysis	23	Give results of additional analyses, if done (eg, sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (eg, health care providers, users, and policy makers).	9, 16
Limitations	25	Discuss limitations at study and outcome level (eg, risk of bias), and at review-level (eg, incomplete retrieval of identified research, reporting bias).	17
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (eg, supply of data); role of funders for the systematic review.	No external funding

Notes: Reproduced from: [1]For more information, visit: www.prisma-statement.org.

Table S2 Search strategy for OVID Medline

Item	Searches
1	exp Decision Making/or Decision Making, Organizational/or Decision Trees/or Decision Making/or Decision Support Techniques/or Decision Support Systems, Clinical/or Decision Making, Computer-Assisted/or exp Computer-Assisted Instruction/or exp Patient Participation/or exp Professional-Patient Relations/or exp "Attitude of Health Personnel"/or Counseling/or exp Health Communication/
2	exp Informed Consent/
3	(choice behavior or decision making or shared decision making).mp,tw.
4	(informed adj3 (consent or choice* or decision*)).mp,tw.
5	((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).mp,tw.

(*Continued*)

Table S2 (Continued).

Item	Searches
6	(decision adj3 (board* or guide* or counseling)).mp,tw.
7	(computer* adj4 decision making).mp.
8	(patient adj3 (participation or involvement or cent#d care)).mp,tw.
9	((risk communication or risk assessment or risk information) adj4 (tool* or method*)).mp,tw.
10	interact* health communication*.mp,tw.
11	(interact* adj (internet or online or graphic* or booklet*)).mp,tw.
12	(interact* adj4 tool*).mp,tw.
13	((interact* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).mp,tw.
14	adaptive conjoint analys#s.mp,tw.
15	or/1–14
16	(Prostat* adj3 (Neoplasm* or Cancer or tumo?r* or carcinoma)).mp,tw.
17	exp Prostatic Neoplasms/
18	16 or 17
19	15 and 18
20	(letter or letter$ or editorial or historical article or anecdote or commentary or note or case report$ or case study).pt,sh.
21	(animals not humans).sh.
22	20 or 21
23	19 not 22
24	exp Randomized Controlled Trial/or exp clinical trial/
25	randomized controlled trial.pt.
26	randomized controlled trial.sh.
27	controlled clinical trial.pt.
28	random allocation.sh.
29	double blind method.sh.
30	single blind method.sh.
31	or/24–30
32	31 not 22
33	exp clinical trial/or exp Clinical Trials as Topic/
34	clinical trial.pt.
35	((singl$ or doubl$ or trebl$ or trpl$) adj25 (blind$ or mask$)).ti,ab.
36	(clin$ adj25 trial$).ti,ab.
37	(random$ or placebo$).ti,ab.
38	(PLACEBO or RESEARCH DESIGN).sh.

(*Continued*)

Table S2 (Continued).

Item	Searches
39	or/33–38
40	39 not 22
41	40 not 32
42	exp EVALUATION STUDIES/
43	(comparative study or follow up studies or prospective studies).sh.
44	(control$ or prospectiv$ or volunteer$).ti,ab.
45	or/42–44
46	45 not 22
47	46 not (32 or 41)
48	23 and (32 or 41 or 47)

Notes: *Similar strategies were developed in EMBASE (Elsevier), CINHAL (EBSCOHost), The Cochrane Library (Wiley), PsychINFO (EBSCOHost), and Scopus.

Reference

1. Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009) Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097