

Appendix

Supplementary Tables

Table S1. PRISMA checklist.

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 (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., 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 of this appendix

Study selection	9	State the process for selecting studies (i.e., 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 (e.g., 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 (e.g., 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.	na
Summary measures	13	State the principal summary measures (e.g., 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 (e.g., I^2) for each meta-analysis.	2-3
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	na
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	na
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
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3
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).	na
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.	3-5
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).	na
Additional analysis	23	Give results of additional analyses, if done (e.g., 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 (e.g., healthcare providers, users, and policy makers).	5
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	11
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11-12

FUNDING

Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	No external funding
---------	----	--	---------------------

From: 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

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.
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.mptw.
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.
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)

Table S3. Models of shared decision-making.

MODEL	Paternalistic (traditional)	Shared decision-making	Informed decision	Physician as perfect agent
Role				
Healthcare provider (HCP)	Active: transfers selected information to patient; makes decisions about the therapy s/he considers best for the patient without obtaining personal information or involving the patient in decision-making process.	Active: shares information and therapy options, their benefits and harms with patient; discusses preferences and values with patient; recommends therapy alternatives; decides on the choice of therapy in consensus with the patient.	Passive: transfers information and treatment options with benefits and harms to patient; withholds recommendations; makes no decisions.	Active: patient's preferences are transferred to HCP who has the knowledge to identify the treatment options most desirable from patient' perspective and recommends such to the patient.
Patient	Passive: accepts professional authority and agrees to therapy proposed by professional.	Active: shares information and knowledge; receives information; makes own judgement about options, harms and benefits; discusses values and preferences with HCP; decides on the choice of therapy in consensus with HCP.	Active: receives information; makes own judgement on options, based on harms, benefits, values and preferences; chooses freely between options without HCP intervention; decides on therapy alone.	Active: receives all information about the treatment and accepts or rejects it according to his/her expectations.
		Requires the sharing of treatment preferences and decisions by both HCP and patients	Preferences of the HCP are excluded	Relies on the HCP determining patient preferences and including these in the decision. HCP may not accurately gauge patients' preferences and thus patients' perspective may not be involved in the decision
Process flow				
Interaction	Uni-directional:	Bi-directional:	Uni-directional:	Uni-directional:
Information-exchange	HCP → patient	HCP ↔ patient	HCP → patient	HCP → patient
type of information	medical, legal requirement	medical and personal, anything relevant for decision making	medical, anything relevant and enough to enable patient to make a treatment decision	
Deliberation	at least one HCP	HCP and patient +/- patient care-related parties (significant others, legal guardian, relatives and/or caregivers or other clinicians)	patient (+/- patient care-related parties: significant others, legal guardian, relatives and/or caregivers or other clinicians)	HCP
Decision implementation	HCP	HCP and patient	patient	HCP
Adapted from Charles <i>et. al.</i> [24, 35].				

Table S4. Method for assessing the key features of SDM implementation.

Extent of SDM	a. information exchange (physician ↔ patients)	b. deliberation (physician ↔ patients)	c. implementation (physician ↔ patients)	Classification
1. SDM	1	1	1	[1-1-1]
2. Partial SDM	0	1	1	[0-1-1]
	1	1	0	[1-1-0]
	?	1	1	[?-1-1]
	1	1	?	[1-1-?]
3. Unclear deliberation	?	?	?	[?-?-?]
	?	?	1	[?-?-1]
	1	?	?	[1-?-?]
	1	?	1	[1-?-1]
4. No-SDM: no deliberation				
No-SDM: unidirectional	0	0	0	[0-0-0]
No-SDM: isolated information	1	0	0	[1-0-0]
No-SDM: no deliberation	1	0	1	[1-0-1]
No-SDM: isolated decision	0	0	1	[0-0-1]
Key features based on Charles <i>et al</i> [24, 35]. 1 = criteria met, 0 = criteria not met, unclear (?) = judgement could not be made due to unclear or lack of reporting.				

Table S5. Characteristics of study, population and interventions of 36 RCTs in review.

First author, publication year	Country, study design & period of conduct	Setting and facilities, n	Inclusion criteria	Exclusion criteria	Intervention arm	Control arm	Operational framework
					Intervention & randomised patients, N	Comparator & randomised patients, N	
SCREENING							
Lewis, 2015 [37]	USA RCT, parallel Feb 2011 to Dec 2012 (intervention) Funding: non-profit	Primary care practices, 7 Primary care academic general internal medicine practice, 1	Men 50 to 75 years old, selected from the pool of eligible patients in the electronic medical records, without diagnosis of prostate cancer who had not had a PSA test in the past 10 months and who had not seen their primary care physician in the last 3 months	n.r.	1) DESI group: 31 min PSA DVD DESI (decision Support Interventions) (developed by the Informed Medical Decisions Foundation); N=831	1) SMA group: invitation to participate in a shared (group) medical appointment (SMA) to watch and discuss the PSA DVD DESI with a mid-level healthcare provider and other patients; N=840 2) DESI + SMA group: 31 min PSA DVD DESI + invitation to participate in a SMA; N=828 3) No additional intervention material; N=828	Unclear/n.r.
Tomko, 2015 [38-41] (Starosta, 2015; Tomko, 2015; Taylor, 2013)	USA RCT, parallel Oct 2007 to Jan 2010 (recruitment) Funding: non-profit	University hospital, 1 Hospital centre, 1 Medstar physician partners, 1	Men 45 to 70 years old, no prior history of prostate cancer, English speaking, with ability to provide informed consent, independent living, having had an outpatient visit in the last 24 months	Men with history of prostate cancer, nursing home residents	1) 8th grade reading level web-based DA with six informational sections, six video testimonials, and a values clarification tool; N=631	1) 8th grade reading level print-based DA with six informational sections, six video testimonials, and a values clarification tool; N=630 2) Usual care; N=632	Ottawa Decision Support Framework (ODSF)
Wilkes, 2013 [42]	USA RCT, cluster May 2007 to Dec 2008 Funding: non-profit	Primary care networks academic-medical-centre affiliated, 2 Staff model health maintenance organisations, 2 Medical group practice network, 1	Men 55 to 65 years old, patients with no serious comorbidity (including any known cancer) and English speakers; physicians consented to participate in educational activities and to help recruit patients	n.r.	1) MD-Ed+A: 30-min interactive web-based educational program + 30-min web-based patient activation + access to CDC brochure in waiting area; 19 waiting areas, 113 patients, 36 physicians	1) MD-Ed: 30-min interactive web-based educational program + access to CDC brochure in waiting area (19 waiting areas; 41 physicians with 246 patients); 19 waiting areas, 246 patients, 41 physicians 2) Usual care practice: CDC educational brochures on prostate cancer in waiting areas (17 waiting areas; 43 physicians with 353 patients); 17 waiting areas, 353 patients, 43 physicians	Unclear/n.r.

Williams, 2013 [43]	USA RCT, parallel Period, n.r. Funding: non-profit	University medical centre, 1 University cancer centre, 1	Men 40 to 70 years old, who had pre-registered for screening at least 5 days in advance, had no history of prostate cancer and English-speakers	Walk-in patients	1) 20-min 8th-grade reading level DA-Home booklet CDC-adapted (mailed 5–10 days before the scheduled screening date), 24-page colour, titled "prostate cancer Screening: Making an Informed Decision"; N=138	1) 5-min, 3-page fact sheet DA-Clinic booklet NCI (National Cancer Institute) (distributed at the screening appointment), titled "Questions and Answers About the Prostate Specific Antigen Test"; N=134 2) Usual care at home (information mailed to participants' homes 5–10 days before screening date; contained little information about the prostate, treatment options, and had no values clarification tool); N=137 3) Usual care at clinic (information was distributed at the screening appointment; contained little information about the prostate, treatment options, and had no values clarification tool); N=134	Unclear/n.r.
Landrey, 2013 [44]	USA RCT, parallel Oct 2009 to Aug 2010 Funding: non-profit	General internal medicine practices - University-Hospital affiliated, 2	Men 50 to 74 years old, patients scheduled to have an annual health maintenance exam between October 2009 and August 2010	Men with PSA test within the past 12 months, had a history of prostate cancer, or any other diagnosis of cancer, terminal illness or dementia	1) Flyer (mailed), 4th grade level (about the PSA test, prostate cancer, risks and benefits of screening) with patient encouragement to talk with their providers (about whether a PSA test was appropriate for them); N=145	1) Usual care with no flyer; N=158	Patient-Centred Approach
Sheridan, 2012 [45]	USA RCT, parallel Mar 2005 to Apr 2006 Funding: non-profit	Academic practice, 2 Community practice, 2	Men 40 to 80 years old, with no prior history of prostate cancer, seen in the practice for at least 1 year; physicians also were invited and agreed to participate	Men presenting for an acute medical visit, evidence of serious medical illness (e.g. Intensive care hospitalization within the last 6 months, more than 2 hospitalizations in the last 6 months)	1) 12-min video-based DA + 8-min coaching session + supplemental brochure; N=60	1) Educational video on highway safety; N=70	Shared Participation Approach to Decision-Making
Lepore, 2012 [46]	USA RCT, parallel Period, n.r. Funding: non-profit	Insurance company for beneficiaries healthcare workers' union, 1	Men 45 to 70 years old, of Black African descent, accessible by telephone, have a primary care physician	Men with prostate cancer test in the past 12 months before enrollment and who had a history of prostate cancer	1) 2(max.)-telephone tailored education sessions (initial call: 20-min; follow-up call: 5-min) within 1 month (median: 1 week) about prostate cancer testing with key elements (rapport building, values clarification and importance of talking with a physician) + low	1) Attention control: 2(max.)-telephone tailored education sessions (initial call: 20-min; follow-up call: 5-min) within 1 month (median: 1 week) about fruit and vegetable consumption + educational pamphlet (mailed); N=246	Ottawa Decision Support Framework (ODSF)

					literacy educational pamphlet (mailed), titled "Prostate Cancer: Your Life-You Decide" about advantages and disadvantages of prostate cancer testing, prostate cancer risk factors and prostate cancer tests, potential risks and benefits of testing; N=244		
Myers, 2011 [47]	USA RCT, parallel Between 2003 and 2007 Funding: non-profit	Primary care practice, 2	Men 50 to 69 years old, with no history of prostate cancer or benign prostatic hyperplasia, who had no PSA test in past 11 months	n.r.	1) Enhanced intervention: 28-min (mean) structured decision counselling session (about prostate cancer screening) + generic note in medical chart to prompt physician to discuss prostate cancer + 12-page informational brochure (on prostate cancer and screening); N=156	1) Standard intervention: practice quality assessment survey (to match face time of intervention group) + generic note in chart to prompt discussion of prostate cancer screening + 12-page informational brochure (on prostate cancer and screening); N=157	Decision Counselling Theory (as mediated decision support to inform SDM)
Evans, 2010 [48]	UK (South Wales) RCT, parallel Period, n.r. Funding: non-profit	General practices from nine local health board areas, 25	Men 50 to 75 years old, who had not had a PSA test or prostate cancer, and able to use a computer and read English	Men participants who could not read English, those whose general practice records indicated that they had previously had prostate cancer or a PSA test	1) Web-based DA, Prosdex interactive program (online program on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance); N=129	1) Paper version of Prosdex text (online DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer program; summary); N=126 2) Control questionnaire; N=127 3) Control no questionnaire (received nothing); N=132	Informed Decision Making Measure
Stamatiou, 2008 [49]	GRC RCT, parallel Apr 2004 to 2006 Funding: n.r.	Primary care institutions	Men 50 to 86 years old, who had a scheduled primary care appointment for various medical conditions except prostate-related conditions	Appointment for prostate-related conditions	1) Pre-test interview with the physician + additional printed written information in the form of an 554 words double-sided a3 sheet illustrated educational leaflet "prostate cancer screening"; N=548	1) Usual care: pre-test interview with the physician with physician's advice during interview in the examination room; N=587	Patient-Centred Approach
Frosch, 2008 [50]	USA RCT, parallel Mar 2005 to May 2006 (recruitment) Funding: non-profit	Preventive medicine clinic (Kaiser Permanente), 1	Men older than 50 years, who made an appointment at the clinic, and who had broadband Internet access at home or at work, and with informed consent	n.r.	1) Web-based traditional DA (TDA) with information on the clinical problem, outcome options and probabilities, others' opinions; N=155	1) Web-based Chronic Disease Trajectory Model (CDTM) with information on the clinical problem, outcome options and probabilities, others' opinions, and with explicit values clarification (utilities for	Unclear/n.r.

						<p>outcomes associated with prostate cancer); N=153</p> <p>2) Combined TDA and CDTM (n=151) with explicit values clarification (utilities for outcomes associated with prostate cancer); N=152</p> <p>3) Links to public ACS and CDC prostate cancer screening websites; N=151</p>	
Volk, 2008 [51]	<p>USA</p> <p>RCT, parallel</p> <p>Jan 2004 to Feb 2006 (data collection)</p> <p>Funding: non-profit</p>	<p>General medicine clinic from publicly funded hospital (low health literacy site), 1</p> <p>University affiliated family medicine clinic (high health literacy site), 1</p>	<p>Men 40 to 70 years old if African-American, or aged 50 to 70 years if not African-American, who visited clinic for non-acute care, with no history of prostate cancer</p>	n.r.	<p>1) Interactive and entertainment multimedia DA (edutainment DA with tailored computerized program with information options' outcomes, clinical problem, explicit values clarification, others' opinion, guidance); N=224</p>	<p>1) Audio booklet without interactivity and entertainment factors; N=226</p>	<p>Edutainment Decision Aid Model (EDAM)</p>
Krist, 2007 [52, 53] (Woolf, 2005)	<p>USA</p> <p>RCT, parallel</p> <p>Jun 2002 to Jun 2004</p> <p>Funding: non-profit</p>	<p>Suburban family practice centre, 1</p>	<p>Men 50 to 70 years old with a scheduled health maintenance examination</p>	<p>Men with history of prostate cancer, lacked internet access, planned on having blood work before their visit, were enrolled in another prostate cancer investigation, or had already been enrolled in the study</p>	<p>1) Web-based DA (about options' outcomes, clinical problem, outcome probability); N=226</p>	<p>1) 4-page pamphlet (mailed) paper version of web-based DA (with same information as web-based da); N=196</p> <p>2) usual care with no pre-visit educational material; N=75</p>	<p>US Preventive Services Task Force (USPSTF)</p>
Kripalani, 2007 [54]	<p>USA</p> <p>RCT, parallel</p> <p>Jun-Jul 2003 (enrollment)</p> <p>Funding: non-profit</p>	<p>Teaching hospital, 1</p>	<p>Men 45 to 70 years old, waiting for primary care appointment</p>	<p>Men enrolled previously, had history of prostate cancer as determined by a focused review of the patient's electronic medical record, in police custody, arrived ill on a stretcher, not scheduled to see a primary care provider (i.e. Nurse-only visits, medical student appointments, and refill pickups were excluded) for a full visit, not fluent in English on face-to-face screening, corrected visual acuity worse than 20/60 as assessed by a pocket vision screening card</p>	<p>1) 6th grade level high-detail two-sided patient educational pamphlet to promote SDM; N=101</p>	<p>1) 5th grade level low-detail one-sided 'talk to your doctor' cue handout; N=101</p> <p>2) Pictured traditional food pyramid (attention control); N=101</p>	<p>Unclear/nr</p>

Partin, 2006 [55, 56] (Partin, 2004)	USA RCT, parallel Apr-Jun 2001 (recruitment) Funding: non-profit	General internal medicine Veterans' Affair Medical clinic, 4	Men veterans of at least 50 years of age, with no prostate cancer, scheduled for general internal medicine appointment at one of the four participating centres between April and June 2001	n.r.	1) 10th grade level 23-min mailed video "The PSA Decision: What YOU Need to Know" (developed by FIMDM); N=384	1) 6th grade level mailed pamphlet (developed for study); N=384 2) Usual care and whatever decision-making support provided in routine appointments; N=384	Social Cognitive Theory
Watson, 2006 [57]	UK (England and Wales) RCT, parallel Jan-Aug 2004 (recruitment) Funding: n.r.	General practices, 11	Men 40 to 75 years old, with no history of prostate cancer	n.r.	1) Brief patient DA leaflet ('PSA testing for prostate cancer—an information sheet for men considering a PSA test'; options' outcomes, clinical problem, outcome probability) + questionnaire; N=980	1) Control questionnaire only; N=980	DA production conformed to accepted standards for the provision of patient information
Myers, 2005 [58]	USA RCT, parallel Aug 1999 to Jul 2000 Funding: non-profit	Community-based primary care practice, 3	Men older than 40 (final sample: 40 to 69) years, of African-American origin, from the participating practices, with no history of prostate cancer or benign prostate hyperplasia, who had not undergone a prostate biopsy or prostate ultrasound, had visited one of the participating practices within two years prior to study initiation, and had contact information available at the practice and informed consent	n.r.	1) Enhanced intervention: informational booklet (mailed) (about prostate cancer options' outcomes) + decision education session (about clinical problem, explicit values clarification, guidance/coaching) by telephone (patients contacted by trained health educator by telephone 1 month after booklet mailing; N=121	1) Standard intervention: informational booklet (about prostate cancer clinical problem and options' outcomes); N=121	US Preventive Services Task Force (USPSTF)
Gatellari, 2003 [59]	AUS RCT, parallel Period, n.r. Funding: non-profit	Urban general practices, 13	Men 40 to 70 years old, sufficiently fluent in English, not diagnosed with prostate cancer, from 13 general practitioners (GPs) in urban Sydney	n.r.	1) Evidence-based booklet, 7.3-level Flesch–Kincaid, 32-page, 3085-word (with essential content to inform decision making about PSA screening, in quantitative data form with maximised readability; includes a section for patients to write down the questions they might have for their doctors and another section suggesting patients to discuss or ask questions to their doctors); N=126	1) Pamphlet, 11.2-level Flesch–Kincaid, 968-word, published by the Australian government (information to advise men of the agreed policy about PSA screening, in non-numerical data form); N=122	Unclear/n.r.
Frosch, 2003 [60, 61] (Frosch, 2001)	USA RCT, parallel	Preventive medicine clinic, 1	Men older than 50 years, who made an appointment at the clinic, who had broadband	n.r.	1) 47-slide, 25-30 min, web-based DA (without pause) mirroring videotape DA content; N=114	1) 23-minute video DA (dialog about options' outcomes, clinical problem, outcome	Unclear/n.r.

	Period, n.r. Funding: non-profit		Internet access at home or at work and informed consent			probability, others' opinions; N=112	
Volk, 2003 [62, 63] (Volk, 1999)	USA RCT, parallel Feb-Jun 1997 (enrollment) Funding: non-profit	University family medicine clinic, 1	Men 45 to 70 years old, with no history of prostate cancer and who presented for care at the participating centres, or patients with urinary incontinence or erectile dysfunction	n.r.	1) 20-minute educational videotape " the PSA decision: what you need to know" (developed by the foundation for informed medical decision making, Inc.) + accompanying brochure; N=80	1) No intervention at baseline (before visit) + brochure after 2 week follow-up; N=80	Shared Decision Making Approach
Schapiro, 2000 [64]	USA RCT, parallel Period, n.r. Funding: non-profit	Veterans' Affair Medical Center Outpatient Clinic, 1	Men 50 to 80 years old with an outpatient (encounter) visit between 1990 to 1995 at the participating centre	Men with history of prostate or other cancer, previous prostate ultrasound study or biopsy, cystoscopy, prior prostate surgery, active genitourinary symptoms, cognitive impairment (defined by a mini-mental state examination score of 23 or less), an anticipated life expectancy of less than two years, or who were currently employed by the Veterans' Affair Medical Center	1) 8-page DA pamphlet with information about screening and treatment + educational (basic prostate cancer) information included in the comparator 5-page pamphlet; N=122	1) 5-page written pamphlet with basic information about prostate cancer (no information on risks and benefits of screening); N=135	Health Belief Model Theory
Davison, 1999 [65]	CAN RCT, parallel Period, n.r. Funding: non-profit	Family medical teaching Centre, 1	Men 50 to 79 years old, with a periodic health examination appointment with no previous history of prostate cancer or evidence of mental confusion, able to read, speak and write English; men previously screened for prostate cancer were also included	n.r.	1) Verbal and written information (about prostate cancer screening controversies, pros and cons of having DER and/or PSA) with encouragement to discuss with family physician and to participate in making a screening decision to the extent patients were comfortable); N=50	1) Attention control: discussion about general issues (prior to medical appointment and about the same length of time than intervention group); N=50	Unclear/n.r.

Wolf, 1998 [66, 67] (Wolf, 1996)	USA RCT, parallel Jun 1994 to Mar 1995 (recruitment) Funding: non-profit	University family practices, 4	Men of at least 50 years of age, English speakers visiting their primary care physicians for outpatient appointments, with no personal history of prostate cancer and who had not been screened with PSA, and with informed consent	Men with prior PSA screening and personal history of prostate cancer	1) Scripted overview of PSA screening; N=103	1) Brief control message about PSA availability; N=102	Health Belief Model Theory
TREATMENT							
Chabrera, 2015 [68]	SPN RCT, parallel Jun 2011 to Jun 2013 Funding: non-profit	University hospital, 1 Oncology institutes, 2	Men older than 45 years, newly diagnosed in the early stages of localized prostate cancer (T1Y2/N0/M0), not receiving therapeutic treatment for prostate cancer, and able to read and write in Spanish	Men having a primary tumor type different from prostate cancer, having been diagnosed for any type of cognitive deterioration, psychiatric or addictive disorders that would preclude taking part in the process of shared decision making, and unwillingness to give informed consent to participate in the study; and patients with stage t1an0m0 tumours, because their treatment consists of active follow-up until signs of disease progression, and hence there is no real choice of treatment	1) Printed booklet DA for localised prostate cancer with values' clarification exercises and with preparation material for consultation; N=73	1) Standard information for localised prostate cancer; N=74	Ottawa Decision Support Framework (ODSF)
Berry, 2013 [69-71] (Berry, 2012; Bosco, 2012)	USA RCT, parallel Mar 2007 to Nov 2009 Funding: non-profit	Veterans' Affair hospital, 3 University cancer centre, 1 Cancer centre institute, 2	Men older than 40 years, with T1 or T2, histologically-proven localised prostate cancer, were consulting with specialists who perceived that each participant was a candidate for at least 2 treatment options, and had not begun therapy	Men with advanced disease or those who had received prior treatment	1) Tailored internet aid: baseline validated questionnaires with the P3P assessment component and research measures + P3P printed education and text and interactive web video coaching tailored to patients' personal profile (video on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (list of questions to ask doctor and automated summary); N=266	1) Website links to prostate cancer information: baseline validated questionnaires with the P3P assessment component and research measures + links to established information websites about prostate cancer; N=228	Ottawa Decision Support Framework (ODSF)

Hacking, 2013 [72]	UK (Scotland) RCT, parallel Jan 2009 to Aug 2010 (eligibility assessment) Funding: non-profit	General hospital, 1	Men who had just received a diagnosis of localised or early stage primary prostate cancer, those who had a decision to make regarding cancer management and who were referred to a specialist urology consultant; age not used as inclusion criteria; final sample 65.4 and 67.2 for intervention and control group respectively	Men with any cognitive or sensory impairment, which impeded participation in the trial, and those who had already opted for active monitoring or to commence hormone treatment at diagnosis	1) DA coaching - decisional navigator by telephone or in person to guide patients in preparing for a consultation (by identifying and framing key questions and concerns regarding cancer management options) to generate a tailored personal consultation plan for the appointment; N=63	1) Usual care pathway for prostate cancer patients meeting with a specialist consultant to discuss treatment options within a month of diagnosis; N=60	Situation, choices, objectives, people, evaluation, and decisions checklist (scoped)
van Tol-Geerdink, 2013 [73]	NLD RCT, parallel Mar 2008 to Feb 2011 Funding: non-profit	University medical centre, 1 General hospitals, 2	Men with primary localized prostate cancer (T1–3a0m0), intending to be treated and eligible for both radiotherapy and radical prostatectomy; age not selected as inclusion criteria; final sample age: 64 (SD5) years	Men with contra-indications for surgery (based on for example age or cardiovascular problems) or external radiotherapy (based on for example Crohn's disease), mental or cognitive problems as assessed by the physician, inadequate knowledge of the Dutch language or a preference for active surveillance. We excluded active surveillance patients because our decision aid did not include risk information on this option. Brachytherapy was offered only to a selected group of patients. Exclusion criteria for brachytherapy were a small or large prostate volume (<20 ml or >50 ml), PSA > 15, Gleason >7 and/or severe urinary symptoms (requiring medication or, if available, IPSS > 12 and/or Qmax < 15 ml/s).	1) DA consultation in semi-structured interview with researcher to provide information + discussion of treatment choice with (their) specialists; N=163	1) Usual care: discussion of treatment choice with (their) specialists; N=77	Ottawa Decision Support Framework (ODSF)
Huang, 2014 [74-76] (Auvinen, 2004; Auvinen, 2001)	FIN RCT, parallel Period, n.r. Funding: non-profit	University hospitals, 2 General hospitals, 2	Men with new histologically confirmed prostate cancer (between September 1993 and November 1994), with the ability to complete the study questionnaire, as judged by the urologist in charge of treatment, with no exclusion	Men with inability to participate because of dementia or strongly impaired general condition, and patients with stage t1a0m0 tumours, because their treatment consists of active follow-up until signs of	1) Enhanced participation: extensive consultation with urologist where patient-defined own role in treatment choice actively emphasised (with discussions about various aspects of available treatment options, including survival rate, adverse	1) Standard treatment protocols; N=106	Unclear/n.r.

			criteria based on age of the patient or extent of the disease; severe coronary heart disease for major surgery was not regarded as an exclusion criterion	disease progression, and hence there is no real choice of treatment	effects and cost, and the patient's opinion about the aims of treatment and willingness to accept potential side-effect) + oral and written structured information about treatment options; N=104		
Feldman-Stewart, 2012 [77-79] (Feldman-Stewart, 2004; Feldman-Stewart, 2001)	CAN RCT, parallel Period, n.r. Funding: non-profit	Cancer clinic centres, 4	Men older than 40 years, with newly diagnosed prostate cancer with low- or intermediate-risk early-stage disease (stage T1 or T2, prostate-specific antigen <20 and Gleason <8), visiting the cancer clinic for their first consultation and faced with making a treatment decision, understood English well-enough to complete the DA	Men with a cognitive or emotional challenge that would preclude him from using the patient DA in a meaningful manner or that it would be potentially harmful or upsetting to him, in the opinion of the treating physician	1) Computer DA and interview with well-structured information with Value Clarification Exercises (Val Ex); N=81	1) Computer DA and interview with well-structured information with general questions (selection of attributes); N=75	Differentiation and Consolidation Theory
Taylor, 2010 [80]	USA RCT, parallel Sep 2002 to Nov 2004 Funding: non-profit	University hospital, 1 Hospital centre, 1 Local prostate cancer support groups and newsletters	Men with newly diagnosed, early-stage prostate cancer (T1-T2N0M0; any Gleason score), English speakers, with absence of cognitive impairment, no prostate cancer history, treatment decision not yet made, and treatment choice not limited by comorbidities or age; no exclusion criteria based on age; final sample age: 64.6 (SD9.4) years	n.r.	1) 4hr information CD-Room + 3 interactive Decision Tools; N=66 (95 CD users)	1) Information only; N=66 (25 non-CD users)	Unclear/n.r.
Mishel, 2009 [81]	USA RCT, parallel Period, n.r. Funding: non-profit	Cancer centre, 2 Community hospital, 3 Veterans' Affairs Medical Center, 1	Men with staging (t1a, b, c or T2a or b); Gleason score less than 10; PSA level less than 20; at least 10 days before the treatment consultation appointment; no major cognitive impairment; ability to read; access to a telephone; no prior cancer history; and a primary support person designated by the patient who was willing to participate in the study	Men with advanced disease beyond stage t2b	1) Treatment supplemented: DVD + Booklet + 4 Telephone calls by (trained) nurse to both patients and patient primary supporting person (e.g. Spouse); N=89	1) Treatment direct: DVD + Booklet + 4 Telephone calls by (trained) nurse to patients only; N=93 2) control - usual care (?): handout on staying healthy during treatment; N=74	Uncertainty Illness Theory

Hack, 2007 [82]	CAN RCT, parallel Feb-Dec 2001 Funding: non-profit	Tertiary oncology clinic treatment facilities, 4	Men older than 18 years, newly diagnosed with prostate cancer, who were presenting to a tertiary oncology clinic for their primary treatment consultation, discerned to be free of any cognitive impairment that would disable them from providing informed consent	n.r.	1) Audiotape: a) audio recording of clinical encounter audio-taped and given to patient (t2); b) audio recording of clinical encounter: audio-taped and offered patient the choice of receiving audiotape or not (t3); N=214	1) No audiotape: a) audio recording of clinical encounter: audio-taped and not given to patient (t1); b) standard care: consultation not audio-taped; N=211	Unclear/n.r.
Davison, 2007 [83]	CAN RCT, parallel Period, n.r. Funding: non-profit	Prostate education and research centre within a general hospital, 1	Men newly diagnosed with localised prostate cancer, with biopsy-proven early-stage prostate cancer, who were aware of their diagnosis, had their initial urologic treatment consultation, not scheduled for definitive treatment within the next 4 weeks, and able to read and write English; age not selected as inclusion criteria; final sample 62.4 years (SD6.9); partners were included in the sessions if they accompanied the patient	n.r.	1) Individualized information printout based on information preferences and patient's disease characteristics + Written information package + Telephone by Research Nurse approximately 4 weeks later + Encouragement to bring their significant others to the appointment who were also included in the sessions; N=162	1) Generic information videotape + written information package + telephone by research nurse approximately 4 weeks later + encouragement to bring their significant others to the appointment who were also included in the sessions; N=162	The Decision Support Framework (by O'Connor)
Feldman-Stewart, 2006 [84]	CAN RCT, parallel Period, n.r. Funding: non-profit	Ambulatory cancer centres, 3	Men with stage 1 or 2 prostate cancer, PSA <20, Gleason score <8, emotionally and cognitively capable of completing the task (judged by the oncologist), and judged by themselves as being able to read English. Family members were eligible if they were older than 18 years	n.r.	1) 8th grade-Flesch-Kincaid CCE information booklet, developed by authors at cancer centre and designed for patients with low or intermediate risk disease; N=152	1) Standard information booklet routinely provided to patients, developed by AstraZeneca; N=156	Unclear/n.r.
Davison, 1997 [85]	CAN RCT, parallel Period, n.r. Funding: non-profit	Community clinic with practicing urologists, 1	Men newly diagnosed with prostate cancer, having been told their diagnosis: not having had their initial treatment consultation, able to read, speak, and write English, and with no evidence of mental confusion; age not selected as inclusion criteria; final sample age range: 41-81	n.r.	1) Empowerment intervention (interview preparing for consultation): Written information package (five brochures about prostate cancer) + Questions List to ask physicians (with discussion with investigator with additional questions prompted from discussions added to list) + Blank audiotape (to record consultation)	1) Written information package (five brochures about prostate cancer) + package content shown + recommendation to read the information before or after the initial treatment consultation with their physician + social component in the interview; N=30	Self-Efficacy Theory within The Empowerment Model (by Conger and Kanungo)

					+ Encouragement to participate in decision-making, and to bring their spouse/significant other(s) to the treatment consultation; N=30		
SCREENING AND TREATMENT							
Wilt, 2001 [86]	USA RCT, parallel Oct to Nov 1998 Funding: n.r.	Primary care clinic at a Veterans' Affairs Medical Center, 1	Men of at least 50 years of age, attending a primary care clinic at a Veterans' Affairs Medical Center	n.r.	1) 7th grade Fleisch-Kincaid Question and answer two-sided printed sheets; N=275	1) Usual care (control) alone; N=275	Unclear/n.r.