# APPENDIX A. SEARCH STRATEGIES

## DATABASE: OVID MEDLINE(R)

1 decision making/ or patient participation/ or directive counseling/
2 decision support technique/
3 (decision making or decision-making or decision support or decis$ aid$ or shared decis$ or shared decision making or informed decision making or valu$ or valu$ clarific$).mp.
4 or/1-3 [decision making search terms]
5 limit 4 to (english language and humans and yr=”1995 -Current”)
6 limit 5 to (“all adult (19 plus years)” or “young adult (19 to 24 years)” or “adult (19 to 44 years)” or “young adult and adult (19-24 and 19-44)” or “middle age (45 to 64 years)” or “middle aged (45 plus years)” or “all aged (65 and over)” or “aged (80 and over)”)
7 limit 5 to (“newborn infant (birth to 1 month)” or “infant (1 to 23 months)” or “preschool child (2 to 5 years)” or “child (6 to 12 years)” or “adolescent (13 to 18 years)”)
8 5 not 7
9 6 or 8 [decision making limited to English, humans, 1995-Current, adult]
10 Randomized controlled trials as topic/
11 Randomized controlled trial/
12 Random allocation/
13 Double blind method/
14 Single blind method/
15 Clinical trial, phase iii.pt.
16 Clinical trial, phase iv.pt.
17 Controlled clinical trial.pt.
18 Randomized controlled trial.pt.
19 ((singl$ or doubl$ or treb$ or trip$) adj (blind$3 or mask$3)).mp.
20 Random$ allocat$.mp.
21 (allocat$ adj2 random$).mp.
22 or/10-21 [RCT terms]
23 Meta analysis/
24 Meta analys$.mp.
25 (systematic adj (review or overview)).mp.
26 meta analysis.pt.
27 or/23-26 [SR/MA terms]
28 (neoplasm$ or cancer$).mp. or exp Neoplasms/ [cancer terms]
29 screen$.mp. or screening/ or cancer screen$.mp. or “Early Detection of Cancer”/
30 colonoscopy/ or sigmoidoscopy/ or colonography, computed tomographic/ or barium sulfate/ or Occult Blood/
31 (fobt or fecal occult or colonoscop$ or sigmoidoscop$ or ct colonograph$ or virtual colonoscop$ or barium enema or lower GI series or lower gastrointestinal series or lower gastrointestinal exam$ or FIT or fecal immunochemical test).mp.
32 vaginal smears/ or DNA Probes, HPV/ or Papillomavirus Infections/ or Human Papillomavirus DNA tests/ or CA-125 Antigen/
33 (pap test$ or pap smear$ or hpv or human papillomavirus or TVUS or (transvag$ adj ultraso$)

or CA-125).mp.
34 mammography/ or (mammography/ and Magnetic Resonance Imaging/) or (MRI mammogra$ or mammogra$).tw. or ultrasonography, mammary/
35 prostate-specific antigen/ or (PSA or prostate specific antigen).tw.
36 Tomography, X-Ray Computed/ or Tomography, Emission-Computed, Single-Photon/ or (computed tomography or tomography).tw.
37 or/29-36 (1087048) [screening terms]
38 9 and 28 and 37
39 38 and 22 [RCTs]
40 38 and 27 [SRs/MAs]

## DATABASE: CINAHL

1 (MM "Decision Making") OR (MM "Decision Making, Clinical") OR (MM "Decision Making, Patient")
2 (MM "Cancer Screening")
3 TX directive counseling OR TX decision support OR TX shared decision OR TX shared OR TX informed OR TX patient participation
4 TX screen* AND TX cancer
5 1 OR 3
6 2 OR 4
7 5 AND 6
8 Narrow by SubjectAge (all adult) AND SubjectMajor (cancer screening)

## DATABASE: PSYCINFO

1 TX Shared OR TX Shared Decision OR TX Decision Support OR TX Informed OR TX Directive Counseling OR TX Decision OR TX Preference OR TX Choice
2 MJ "Cancer Screening"
3 TX PSA OR TX Colonoscopy OR TX Sigmoidoscopy OR TX Colonography OR TX Fecal Occult OR TX FOBT OR TX Pap OR TX cervical OR TX mammography OR TX prostate OR TX tomography
4 1 AND 2 AND 3
5 Narrow by Methodology (treatment outcome/clinical trial), Narrow by Methodology (quantitative study), Narrow by SubjectAge (adulthood [18 yrs & older])
6 (MJ "Decision Making") AND (MJ "Cancer Screening")
7 5 OR 6

# APPENDIX B. EXCLUDED ARTICLES

| Study | Reason for exclusion | Reference |
|---|---|---|
| Adab 2003 | **Decision Action outcome only** | Adab P, Marshall T, Rouse A, Randhawa B, Sangha H, Bhangoo N. Randomised controlled trial of the effect of evidence based information on women's willingness to participate in cervical cancer screening. *J Epidemiol Comm Health*. 2003;57(8):589-93. |
| Agrez 1998 | **Not RCT** | Agrez MV, Coory M, Cockburn J. Population screening for colorectal carcinoma with fecal-occult blood testing: are we sufficiently informed? *Cancer*. 1998;82(10):1803-7. |
| Allen 2010 | **Non-clinic setting** | Allen JD, Othus MK, Hart A Jr, et al. A randomized trial of a computer-tailored decision aid to improve prostate cancer screening decisions: results from the Take the Wheel trial. *Cancer Epidemiol Biomarkers Prev*. 2010;19(9):2172-86. |
| Auvinen 2001 | **Not cancer screening** | Auvinen A, Vornanen T, Tammela TL, et al. A randomized trial of the choice of treatment in prostate cancer: design and baseline characteristics. *BJU Int*. 2001;88(7):708-15. |
| Banks 2014 | **Not cancer screening** | Banks J, Hollinghurst S, Bigwood L, Peters TJ, Walter FM, Hamilton W. Preferences for cancer investigation: a vignette-based study of primary-care attendees. *Lancet Oncol*. 2014;15(2):232-40. |
| Berry 2013 | **Not cancer screening** | Berry DL, et al. The Personal Patient Profile-Prostate decision support for men with localized prostate cancer: A multi-center randomized trial. *Urol Oncol*. 2013; 31(7):1012-1021 |
| Chan 2011 | **Non-clinic setting** | Chan EC, et al. A community-based intervention to promote informed decision making for prostate cancer screening among Hispanic American men changed knowledge and role preferences: a cluster RCT. *Patient Educ Couns*. 2011;84(2):e44-51. |
| Christy 2013 | **Screening promotion** | Christy SM, et al. Promoting colorectal cancer screening discussion: a randomized controlled trial. *Am J Prev Med*. 2013;44(4):325-9. |
| Costanza 2011 | **Not RCT** | Costanza ME, Luckmann RS, Rosal M, et al. Helping men make an informed decision about prostate cancer screening: a pilot study of telephone counseling. *Patient Educ Couns.* 2011;82(2):193–200. |
| Davis 2013 | **Not RCT** | Davis TC, et al. Contrasts in Rural and Urban Barriers to Colorectal Cancer Screening. *Am J Health Behav*. 2013; 37(3):289-298 |
| Dolan 2005 | **Not RCT (secondary observational study from included Dolan 2002)** | Dolan JG. Patient priorities in colorectal cancer screening decisions. *Health Expect*. 2005;8(4):334-44. |
| Dorfman 2010 | **Not RCT (development/usability testing for included Taylor 2013)** | Dorfman CS, et al. The development of a web- and a print-based decision aid for prostate cancer screening. *BMC Med Inform Decis Mak*. 2010;10:12. |
| Driscoll 2008 | **Non-clinic setting** | Driscoll DL, Rupert DJ, Golin CE, McCormack LA, Sheridan SL, Welch BM. Promoting prostate-specific antigen informed decision-making. Evaluating two community-level interventions. *Am J Prev Med*. 2008;35(2):87–94. |
| Edwards 2013 | **Not RCT** | Edwards AGK, et al. Personalised risk communication for informed decision making about taking screening tests. *Cochrane Database Syst Rev.* 2013. 2: CD001865. |
| Edwards 2006 | **Not RCT** | Edwards AGK, et al. Personalised risk communication for informed decision making about taking screening tests. *Cochrane Database Syst Rev.* 2006(4): CD001865. |
| Edwards 2003 | **Not RCT** | Edwards A, et al. Personalised risk communication for informed decision making about entering screening programs. *Cochrane Database Syst Rev.* 2003(1): CD001865. |

| Study | Reason for exclusion | Reference |
|---|---|---|
| Ellison 2008 | **Non-clinic setting** | Ellison GL, Weinrich SP, Lou M, Xu H, Powell IJ, Baquet CR. A randomized trial comparing web-based decision aids on prostate cancer knowledge for African-American men. *J Natl Med Assoc*. 2008;100(10):1139-45. |
| Elwyn 2012 | **Not RCT** | Elwyn G, Rix A, Holt T,et al. Why do clinicians not refer patients to online decision support tool? Interviews with front line clinics in the NHS. *BMJ Open*. 2012; 2 |
| Evans 2007 | **Not RCT (protocol for included Evans 2010)** | Evans R, et al. A randomised controlled trial of the effects of a web-based PSA decision aid, Prosdex. Protocol. *BMC Fam Pract*. 2007;8:58 |
| Feldman-Stewart 2012 | **Not cancer screening** | Feldman-Stewart D, Tong C, Siemens R, et al. The impact of explicit values clarification exercises in a patient decision aid emerges after the decision is actually made: evidence from a randomized controlled trial. *Med Decis Making*. 2012;32(4):616-26. |
| Feng 2013 | **Not RCT** | Feng B, Srinivasan M, Hoffman JR, et al. Physician communication regarding prostate cancer screening: analysis of unannounced standardized patient visits. *Ann Fam Med*. 2013;11(4):315-23. |
| Flight 2012 | **Non-clinic setting** | Flight IH, Wilson CJ, Zajac IT, Hart E, McGillivray JA. Decision Support and the Effectiveness of Web-based Delivery and Information Tailoring for Bowel Cancer Screening: An Exploratory Study. *JMIR Res Protoc*. 2012;1(2):e12. |
| Frosch 2008 | **Not RCT** | Frosch DL, Légaré F, Mangione CM. Using decision aids in community-based primary care: a theory-driven evaluation with ethnically diverse patients. *Patient Educ Couns*. 2008;73(3):490-6. |
| Frosch 2001 | **Not RCT** | Frosch DL, Kaplan RM, Felitti V. Evaluation of two methods to facilitate shared decision making for men considering the prostate-specific antigen test. *J Gen Intern Med*. 2001;16(6):391–8. |
| Flood 1996 | **Not RCT** | Flood AB, et al. The importance of patient preference in the decision to screen for prostate cancer. Prostate Patient Outcomes Research Team. *J Gen Intern Med*. 1996;11(6):342-9. |
| Gattellari 2005 | **Non-clinic setting** | Gattellari M, Ward JE. A community-based randomised controlled trial of three different educational resources for men about prostate cancer screening. *Patient Educ Couns*. 2005;57(2):168-82. |
| Griffith 2008 | **Non-clinic setting** | Griffith JM, Lewis CL, Brenner AR, Pignone MP. The effect of offering different numbers of colorectal cancer screening test options in a decision aid: a pilot randomized trial. *BMC Med Inform Decis Mak*. 2008;8:4. |
| Griffith 2008 | **Not RCT** | Griffith JM, Fichter M, Fowler FJ, Lewis C, Pignone MP. Should a colon cancer screening decision aid include the option of no testing? A comparative trial of two decision aids. *BMC Med Inform Decis Mak*. 2008;8:10. |
| Hall 2011 | **Not cancer screening** | Hall MJ, et al. Effects of a decision support intervention on decisional conflict associated with microsatellite instability testing. *Cancer Epidemiol Biomarkers Prev*. 2011; 20(2):249-54. |
| Han 2013 | **Not RCT** | Han PKJ, et al. National Evidence on the Use of Shared Decision Making in Prostate-Specific Antigen Screening. *Ann Fam Med*. 2013; 11(4) 360-314 |
| Hayat Roshanai 2013 | **Not RCT** | Hayat Roshanai A, Nordin K, Berglund G. Factors influencing primary care physicians' decision to order prostate-specific antigen (PSA) test for men without prostate cancer. *Acta Oncol.* 2013; 52(8):1602-1608. |
| Hayes 2014 | **Not RCT** | Hayes JH, Barry MJ. Screening for Prostate Cancer With the Prostate Specific Antigen Test A Review of Current Evidence. *JAMA*. 2014; 311(11):1143-1149. |
| Holloway 2003 | **Screening promotion** | Holloway RM, et al. Cluster-randomised trial of risk communication to enhance informed uptake of cervical screening. *Br J Gen Pract.* 2003. 53(493):620-5. |

| Study | Reason for exclusion | Reference |
|---|---|---|
| Hooker 2011 | **Not cancer screening** | Hooker GW, et al. Longitudinal changes in patient distress following interactive decision aid use among BRCA1/2 carriers: a randomized trial. *Med Decis Making*. 2011; 31(3):412-21 |
| Ilic 2008 | **Non-clinic setting** | Ilic D, Egberts K, McKenzie JE, Risbridger G, Green S. Informing Men about Prostate Cancer Screening: A Randomized Controlled Trial of Patient Education Materials. *J Gen Intern Med*. 2007; 23(4): 466-471. |
| Inadomi 2012 | **Screening promotion** | Inadomi JM, Vijan S, Janz NK, et al. Adherence to colorectal cancer screening: a randomized clinical trial of competing strategies. *Arch Intern Med*. 2012;172(7):575-82. |
| Jerant 2013 | **Not RCT (secondary study from unpublished RCT)** | Jerant A,, et al. Effects of Tailored Knowledge Enhancement on Colorectal Cancer Screening Preference across Ethnic and Language Groups. *Patient Edu Couns*. 2013;90(1):103-110 |
| Jerant 2007 | **Screening promotion** | Jerant A, Kravitz RL, Rooney M, Amerson S, Kreuter M, Franks P. Effects of a tailored interactive multimedia computer program on determinants of colorectal cancer screening: a randomized controlled pilot study in physician offices. *Patient Educ Couns*. 2007;66(1):67–74. |
| Joseph-Williams 2010 | **Not RCT (secondary observational study from included Evans 2010)** | Joseph-Williams N, et al. Supporting informed decision making online in 20 minutes: an observational web-log study of a PSA test decision aid. *J Med Internet Res*. 2010; 12(2):e15 |
| Kassan 2012 | **Not RCT (secondary observational study from included Taylor 2013)** | Kassan EC, et al. Men's use of an Internet-based decision aid for prostate cancer screening. *J Health Commun*. 2012;17(6):677-97. |
| Katsumura 2008 | **Not RCT** | Katsumura Y, Yasunaga H, Imamura T, Ohe K, Oyama H. Relationship between risk information on total colonoscopy and patient preferences for colorectal cancer screening options: analysis using the analytic hierarchy process. *BMC Health Serv Res*. 2008; 8:106 |
| Kerns 2008 | **Not RCT (secondary observational study from included Krist 2007)** | Kerns JW, Krist AH, Woolf SH, Flores SK, Johnson RE. Patient perceptions of how physicians communicate during prostate cancer screening discussions: a comparison of residents and faculty. *Fam Med*. 2008;40(3):181-7. |
| Kim 2005 | **Not RCT** | Kim J, Whitney A, Hayter S, et al. Development and initial testing of a computer-based patient decision aid to promote colorectal cancer screening for primary care practice. *BMC Med Inform Decis Mak*. 2005;5:36. |
| Korfage 2013 | **Not cancer screening** | Korfage IJ, Fuhrel-Forbis A, Ubel PA, et al. Informed choice about breast cancer prevention: randomized controlled trial of an online decision aid intervention. *Breast Cancer Res*. 2013;15(5):R74. |
| Krist 2007 | **Not RCT (secondary observational study from included Krist 2007)** | Krist AH, Woolf SH, Johnson RE. How physicians approach prostate cancer screening before and after losing a lawsuit. *Ann Fam Med*. 2007;5(2):120-5. |
| Lairson 2011 | **Screening promotion** | Lairson DR, Chan W, Chang YC, del Junco DJ, Vernon SW. Cost-effectiveness of targeted versus tailored interventions to promote mammography screening among women military veterans in the United States. *Eval Program Plann*. 2011;34(2):97–104. |
| Lawrence 2000 | **Not RCT** | Lawrence VA, Streiner D, Hazuda HP, Naylor R, Levine M, Gafni A. A cross-cultural consumer-based decision aid for screening mammography. *Prev Med*. 2000;30(3):200-8. |
| Leader 2012 | **Not RCT (secondary observational study from included Myers 2011)** | Leader A, Constantine Daskalakis C, Braddock III CH, et al. Measuring Informed Decision Making about Prostate Cancer Screening in Primary Care. *Med Decis Making*. 2012; 32(2): 327-36. |
| Legare 2010 | **Not RCT** | Legare F. Ratte S, Stacey D, Kryworuchko J, Gravel K, Graham ID, Turcotte S. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev.* 2010;12(5):CD006732 |

| Study | Reason for exclusion | Reference |
|---|---|---|
| Lerman 1997 | **Not cancer screening** | Lerman C, et al. Controlled trial of pretest education approaches to enhance informed decision-making for BRCA1 gene testing. *J Natl Cancer Inst.* 1997; 89(2):148-57. |
| Lewis 2012 | **Screening promotion** | Lewis CL, Brenner AT, Griffith JM, Moore CG, Pignone MP. Two controlled trials to determine the effectiveness of a mailed intervention to increase colon cancer screening. N C Med J. 2012;73(2):93-8. |
| Lewis 2010 | **Not RCT** | Lewis CL, Golin CE, DeLeon C, et al. A targeted decision aid for the elderly to decide whether to undergo colorectal cancer screening: development and results of an uncontrolled trial. *BMC Med Inform Decis Mak*. 2010;10:54. |
| Lewis 2010 | **Not RCT** | Lewis CL, Pignone MP, Schild L, et al. Effectiveness of a patient and practice-level colorectal cancer screening intervention in health plan members: design and baseline findings of the CHOICE trial. *Cancer.* 2010;116(7):1664–73. |
| Lin 2013 | **Not RCT** | Lin GA, Halley M, Rendle KA, et al. An effort to spread decision aids in five California primary care practices yielded low distribution, highlighting hurdles. *Health Aff (Millwood)*. 2013;32(2):311-20. |
| Linder 2011 | **Not RCT (secondary psychometric study from included Volk 2008)** | Linder SK, Swank PR, Vernon SW, Mullen PD, Morgan RO, Volk RJ. Validity of a low literacy version of the Decisional Conflict Scale. *Patient Edu Couns*. 2011; 85:521-524 |
| Lindbloom 2012 | **Non-clinic setting** | Lindblom K, Gregory T, Wilson C, Flight IH, Zajac I. The impact of computer self-efficacy, computer anxiety, and perceived usability and acceptability on the efficacy of a decision support tool for colorectal cancer screening. *J Am Med Inform Assoc*. 2012;19(3):407-412. |
| McCormack 2011 | **Non-clinic setting** | McCormack L, Treiman K, Bann C, et al. Translating medical evidence to promote informed health care decisions. *Health Serv Res*. 2011;46(4):1200-23. |
| Miller 2011 | **Screening promotion** | Miller DP, Spangler JG, Case D, Goff DC, Singh S, Pignone M. Effectiveness of a Web-Based Colorectal Cancer Screening Patient Decision Aid: A Randomized Controlled Trial in a Mixed-Literacy Population. *Am J Prev Med.* 2011; 40(6):608-615. |
| The Multicentre Australian Colorectal neoplasia Screening Group 2006 | **Non-clinic setting** | Multicentre Australian Colorectal-neoplasia Screening Group. A comparison of colorectal neoplasia screening tests: a multicentre community-based study of the impact of consumer choice. *Med J Aust* 2006;184(11):546-50. |
| Murphy 2014 | **Not RCT** | Murphy DG, et al. The Melbourne Consensus Statement on the early detection of prostate cancer. *BJU Int*. 2014; 113:186-188 |
| Myers 2011 | **Not cancer screening** | Myers RE, et al. A randomized trial of genetic and environmental risk assessment (GERA) for colorectal cancer risk in primary care: trial design and baseline findings. Contemp Clin Trials. 2011;32(1):25-31. |
| Myers 2007 | **Screening promotion** | Myers RE, Sifri R, Hyslop T, et al. A randomized controlled trial of the impact of targeted and tailored interventions on colorectal cancer screening. *Cancer.* 2007;110(9):2083–91. |
| Myers 2005 | **Decision Action outcome only** | Myers RE, et al. Preparing African-American men in community primary care practices to decide whether or not to have prostate cancer screening. J Natl Med Assoc. 2005;97(8): 1143-54. |
| Myers 2005 | **Not RCT** | Myers RE. Decision counseling in cancer prevention and control. *Health Psychol*. 2005;24(4 Suppl):S71–7. |
| Myers 1999 | **Decision Action outcome only** | Myers RE, et al. Adherence by African American men to prostate cancer education and early detection. *Cancer*. 1999;86(1):88-104. |

| Study | Reason for exclusion | Reference |
|---|---|---|
| Nijs 1997 | **Non-clinic setting** | Nijs HG, Tordoir DM, Schuurman JH, Kirkels WJ, Schröder FH. Randomised trial of prostate cancer screening in The Netherlands: assessment of acceptance and motives for attendance. *J Med Screen*. 1997;4(2):102-6. |
| O'Brien 2010 | **Screening promotion** | O'Brien MJ, Halbert CH, Bixby R, Pimentel S, Shea JA. Community health worker intervention to decrease cervical cancer disparities in Hispanic women. *J Gen Intern Med*. 2010;25(11):1186-92. |
| O'Neill 2010 | **Not cancer screening** | O'Neill SC, et al. BRCA1/2 test results impact risk management attitudes, intentions, and uptake. Breast Cancer Res Treat. 2010;124(3):755-64. |
| Pace 2014 | **Not RCT** | Pace LE, Keating NL. A systematic assessment of benefits and risks to guide breast cancer screening decisions. *JAMA*. 2014;311(13):1327-35. |
| Park 2005 | **Screening promotion** | Park S, Chang S, Chung C. Effects of a cognition-emotion focused program to increase public participation in Papanicolaou smear screening. *Public Health Nurs*. 2005;22(4):289-98. |
| Perneger 2011 | **Non-clinic setting** | Perneger TV, Schiesari L, Cullati S, Charvet-Bérard A. Does information about risks and benefits improve the decision-making process in cancer screening - randomized study. *Cancer Epidemiol.* 2011; 35(6):574-9. |
| Pignone 2013 | **Non-clinic setting** | Pignone MP, et al. Comparing 3 techniques for eliciting patient values for decision making about prostate-specific antigen screening: a randomized controlled trial. *JAMA Intern Med*. 2013;173(5):362-8. |
| Pignone 2012 | **Non-clinic setting** | Pignone MP, Brenner AT, Hawley ST, et al. Conjoint analysis versus rating and ranking for values elicitation and clarification in colorectal cancer screening. *J Gen Intern Med.* 2012; 27(1):45–50. |
| Pignone 2011 | **Not RCT** | Pignone MP, Winquist A, Schild L, et al. Effectiveness of a patient and practice-level colorectal cancer screening intervention in health plan members. *Cancer.* 2011;117(15):3252–62. |
| Pignone 2000 | **Decision Action outcome only** | Pignone M, Harris R, Kinsinger L. Videotape-based decision aid for colon cancer screening. A randomized, controlled trial. *Ann Intern Med*. 2000;133(10): 761-9. |
| Price-Haywood 2014 | **Screening promotion** | Price-Haywood EG, Harden-Barrios J, Cooper LA. Comparative effectiveness of audit-feedback versus additional physician communication training to improve cancer screening for patients with limited health literacy. *J Gen Intern Med.* 2014; 29(8):1113-21. |
| Price-Haywood 2010 | **Not RCT (baseline assessments from Price-Haywood 2014)** | Price-Haywood E, Roth KG, Shelby K, Cooper LA. Cancer Risk Communication with Low Health Literacy Patient: A Continuing Medical Education Program. *J Gen Intern Med.* 2010; 25(2): 126-129 |
| Rimer 2001 | **Screening promotion** | Rimer BK, et al. The short-term impact of tailored mammography decision-making interventions. *Patient Educ Couns*. 2001;43(3): 269-85. |
| Rimer 2002 | **Screening promotion** | Rimer BK, et al. Effects of a mammography decision-making intervention at 12 and 24 months. *Am J Prev Med.* 2002;22(4):247-57. |
| Rubel 2010 | **Non-clinic setting** | Rubel SK, et al. Testing the effects of a decision aid for prostate cancer screening. *J Health Comm*. 2010;15(3):307-21. |
| Ruffin 2007 | **Screening promotion** | Ruffin MT 4th, Fetters MD, Jimbo M. Preference-based electronic decision aid to promote colorectal cancer screening: results of a randomized controlled trial. *Prev Med.* 2007;45(4):267-73. |
| Schoenberg 2013 | **Not RCT** | Schoenberg MA, Hamel MB, Davis RB, et al. Development and evaluation of a decision aid on mammography screening for women 75 and older. *JAMA Intern Med*. 2013;174(3):417-24. |
| Schroy 2011 | **Not RCT** | Schroy PC 3rd, Mylvaganam S, Davidson P. Provider perspectives on the utility of a colorectal cancer screening decision aid for facilitating shared decision making. *Health Expect*. 2011;17(1):27-35. |

| Study | Reason for exclusion | Reference |
|---|---|---|
| Sheridan 2004 | **Not RCT** | Sheridan SL, Felix K, Pignone MP, Lewis CL. Information needs of men regarding prostate cancer screening and the effect of a brief decision aid. *Patient Educ Couns*. 2004;54(3):345–51. |
| Smith 2014 | **Non-clinic setting** | Smith SK, Simpson JM, Trevena LJ, McCaffery KJ. Factors Associated with Informed Decisions and Participation in Bowel Cancer Screening among Adults with Lower Education and Literacy. *Med Decis Making*. 2014;34(6):756-72. |
| Smith 2013 | **Not RCT (discussion paper based on Smith 2010)** | Smith SK, Nutbeam D, McCaffery KJ. Insights into the concept and<br><br>measurement of health literacy from a study of shared decision making in a low literacy population. *J Health Psychol*. 2013; 18(8):1011–22. |
| Smith 2012 | **Not RCT (secondary psychometric study from Smith 2010)** | Smith SK, Barratt A, Trevena L, Simpson JM, Jansen J, McCaffery KJ. A theoretical framework for measuring knowledge in screening decision aid trials. *Patient Educ Couns*. 2012. 89(2):330-6. |
| Smith 2010 | **Non-clinic setting** | Smith SK, Trevena L, Simpson JM, Barratt A, Nutbeam D, McCaffery KJ. A decision aid to support informed choices about bowel cancer screening among adults with low education: randomised controlled trial. *BMJ*. 2010;341: c5370. |
| Stalmeier 2009 | **Not cancer screening** | Stalmeier PFM, Roosmalen MS. Concise evaluation of decision aids. *Patient Educ Couns*. 2009;74(1):104-9. |
| Stamatiou 2008 | **Screening promotion** | Stamatiou K, Skolarikos A, Heretis I, Papadimitriou V, Alevizos A, Ilias G, Karanasiou V, Mariolis A, Sofras F. Does educational printed material manage to change compliance with prostate cancer screening? *World J Urol*. 2008;26(4):365-73. |
| Steckelberg 2011 | **Non-clinic setting** | Steckelberg A, Hülfenhaus C, Haastert B, Mühlhauser I. Effect of evidence based risk information on “informed choice” in colorectal cancer screening: randomised controlled trial. *BMJ*. 2011;342:d3193. |
| Stephens 2008 | **Not RCT** | Stephens RL, Xu Y, Volk RJ, Scholl LE, Kamin SL, Holden EW. Influence of a patient decision aid on decisional conflict related to PSA testing: a structural equation model. *Health Psychol*. 2008;27(6):711–21. |
| Street 1998 | **Screening promotion** | Street RL Jr, Van Order A, Bramson R, Manning T. Preconsultation education promoting breast cancer screening: does the choice of media make a difference? *J Cancer Educ*. 1998;13(3):152-61. |
| Taylor 2006 | **Non-clinic setting** | Taylor KL, et al. Educating African American men about the prostate cancer screening dilemma: a randomized intervention. *Cancer Epidemiol Biomarkers Prev*. 2006;15(11):2179-88. |
| Tiller 2006 | **Not cancer screening** | Tiller K, Meiser B, Gaff C, et al. A randomized controlled trial of a decision aid for women at increased risk of ovarian cancer. *Med Decis Making*. 2006;26(4):360-72. |
| Valdez 2001 | **Not RCT** | Valdez A, Banerjee K, Fernandez M, Ackerson L. Impact of a multimedia breast cancer education intervention on use of mammography by low-income Latinas. *J Cancer Educ*. 2001;16(4):221–4. |
| van Roosmalen 2004 | **Not cancer screening** | van Roosmalen MS, et al. Randomized trial of a shared decision-making intervention consisting of trade-offs and individualized treatment information for BRCA1/2 mutation carriers. *J Clin Oncol*. 2004;22(16):3293-301. |
| van Roosmalen 2004 | **Not cancer screening** | van Roosmalen MS, et al. Randomised trial of a decision aid and its timing for women being tested for a BRCA1/2 mutation. *Br J Cancer*. 2004;90(2):333-42. |
| Vernon 2011 | **Screening promotion** | Vernon SW, Bartholomew LK, McQueen A, et al. A randomized controlled trial of a tailored interactive computer-delivered intervention to promote colorectal cancer screening: sometimes more is just the same. *Ann Behav Med*. 2011;41(3):284-99. |

| Study | Reason for exclusion | Reference |
|---|---|---|
| Wahab 2008 | **Screening promotion** | Wahab S, Menon U, Szalacha L. Motivational interviewing and colorectal cancer screening: a peek from the inside out. *Patient Educ Couns*. 2008;72(2):210-7. |
| Weinrich 2008 | **Non-clinic setting** | Weinrich SP. A decision aid for teaching limitations of prostate cancer screening. *JNBNA*. 2008;19(1):1-11. |
| Weinrich 2007 | **Non-clinic setting** | Weinrich SP, Seger R, Curtsinger T, Pumphrey G, NeSmith EG, Weinrich MC. Impact of pretest on posttest knowledge scores with a Solomon Four research design. *Cancer Nurs.* 2007;30(5):E16-28. |
| Wilkinson 2002 | **Not cancer screening** | Wilkinson CR, Williams M. Strengthening patient-provider relationships. *Lippincotts Case Manag*. 2002;7(3): 86-99; quiz 100-2. |
| Williams 2008 | **Non-clinic setting** | Williams RM, Zincke NL, Turner RO, et al. Prostate cancer screening and shared decision-making preferences among African-American members of the Prince Hall Masons. *Psychooncology*. 2008;17(10):1006-13. |
| Williams-Piehota 2008 | **Not RCT (secondary observational study from McCormack 2011)** | Williams-Piehota PA, McCormack LA, Treiman K, Bann CM. Health information styles among participants in a prostate cancer screening informed decision-making intervention. *Health Educ Res*. 2008;23(3):440–53. |
| Wilson 2010 | **Not RCT** | Wilson CJ, Flight IH, Zajac IT, et al. Protocol for population testing of an Internet-based Personalised Decision Support system for colorectal cancer screening. *BMC Med Inform Decis Mak.* 2010;10:50. |
| Wolf 2000 | **Decision Action outcome only** | Wolf AM, Schorling JB. Does informed consent alter elderly patients' preferences for colorectal cancer screening? Results of a randomized trial. *J Gen Intern Med*. 2000;15(1):24-30. |
| Wolf 1996 | **Decision Action outcome only** | Wolf AM, Nasser JF, Wolf AM, Schorling JB. The impact of informed consent on patient interest in prostate-specific antigen screening. *Arch Intern Med*. 1996;156(12):1333-6. |
| Yasunaga 2006 | **Non-clinic setting** | Yasunaga H, Ide H, Imamura T, Ohe K. Benefit evaluation of mass screening for prostate cancer: willingness-to-pay measurement using contingent valuation. *Urology*. 2006;68(5):1046-50. |

# APPENDIX C. PEER REVIEW COMMENTS/AUTHOR RESPONSES

| REVIEWER COMMENT | RESPONSE |
|---|---|
| **1. Are the objectives, scope, and methods for this review clearly described?** | |
| No.<br>Objectives and scope are clearly described.<br>I would like to see more details in the methods section about:<br><br>1) USE OF HEALTH SERVICES. This is eventually defined on P 38, but a more detailed explanation should appear earlier. My first thought was that it was measuring utilization related to undergoing testing.<br><br>2) COMPARATORS: Clarify earlier in the methods section that "usual care" comparators = effectiveness studies, "alternative SDM" = comparative effectiveness studies.<br><br>3) VALUE-CONCORDANCE: Clarify the meaning of the concepts of values clarity and value concordance and explain how these concepts are being measured with the various instruments. Would also suggest explaining a "values clarification exercise." I found the values concepts to be incompletely described and/or used interchangeably, making it difficult to interpret the findings ("clearer values, higher values clarity, "decreased value assessments," "clear values that matched the intention," *etc.*)<br><br>I would suggest explicitly explaining the reason for excluding studies that measured only Decision Action—presumably your reliance on the OSDF framework. I would also have liked to seen the reference list for the studies excluded for this criterion. From reading meta-analyses of cancer screening trials, I know that many RCT of decision aids have been excluded—and I suspect that it was for their limited outcome focus. | Thank you.<br><br>We included more details and definitions throughout the report, including :<br><br>1) Use of health services: We included a definition in both the executive summary (pg 1, paragraph 2) and the main report (pg 12, paragraph 1).<br><br>2) Comparators: We made our language consistent and used effectiveness studies, comparative effectiveness studies, and attention control studies throughout, and included definitions (pg 21 paragraph 1).<br><br>3) Value-concordance: We made our language consistent, using *values clarity* and defining the construct (pg 1 paragraph 2) and describing it with the authors' measurement in a new table with information about measures (Appendix E). We also included a definition of a values clarification exercise (pg 7, paragraph 1).<br><br>We added information on the Ottawa Decision Support Framework and how it guided our review (pg 13 paragraph 3; pg 14 paragraph 1), and why some key decision aid studies were excluded (pg 14 paragraph 1; pg 16 paragraph 5). Additionally, we prepared a table of excluded studies (Appendix B). |
| Yes. In general, the objectives, scope, and methods for this review are clear. However, in the summary, I would add to KQ1 "for cancer screening" after SDM interventions (line 25 p. 1).<br><br>I would also consistently say "SDM interventions" and not just interventions (line 29 p. 1, line 12, p. 2, line 28 p. 11, and others throughout).<br><br>Also, my biggest concern is that the authors should clarify what they mean by SDM and whether they mean any form of SDM or specifically patient decision aids? It seems they mean any form of SDM, but a definition of SDM and SDM interventions is lacking detail in the evidence summary as well as the evidence report. Charles 1997 is cited and later Makoul 2006, both of whom have slightly different definitions of SDM. What about Whitney 2004 who differentiates SDM from informed decision making and informed consent? What about Elwyn, Frosch, *etc.* recent definition of SDM and decision support interventions? Or Elwyn's IPDASi checklist? This is very important to define for readers to better understand the context of the review and to better understand whether key SDM interventions are missing from the review. | Thank you for the suggestion. We made the requested edit throughout the report.<br><br>We added a detailed section on SDM and SDM interventions (pg 12-14), including the scope of our review including definitions, purpose, evidence-based framework utilized (ODSF) (pg 13 paragraph 3; pg 14, paragraph 1), and inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5). It should now be clearer why some key decision aid studies were excluded. Additionally, we prepared a table of excluded studies (Appendix B)<br><br>The reviewer makes a valid point. We edited this sentence (pg 4 paragraph 2) and added context for the interventions throughout the executive summary to improve the clarity. |

| | |
|---|---|
| The authors should specifically refer to the context for their findings when discussing them. For example, line 18, p. 3, should say "whether to be screened for breast cancer…" (the words "for breast cancer" are missing and then it is unclear if it is for another cancer such as CRC). Please check throughout.<br>Some word choice is unclear. E.g. p. 1, line 15, "policy SDM needs…" policy doesn't have needs. SDM interventions could have policy implications but patient and clinical needs are separate from policy implications. This part needs rewording. | Thank you for the suggestion. We made the requested edit throughout the report.<br>Thank you for the suggestion. We reworded this section (pg 1 paragraph 1). |
| Yes. The objectives, scope, and methods are generally well described. Although SDM is defined, there are no explicit criteria that I could find for interventions that are considered SDM interventions. For example, was a criterion for inclusion of a study to have an intervention with an explicit component to encourage collaborative or shared decision making with the clinician (such as coaching patients to speak with their clinician about the decision or the timing of an intervention prior to a clinician visit)? Was the search limited to decision-aids or did it include other interventions that support SDM but may not have incorporated all of the components of a decision aid? Did the investigators seek to identify whether studies documented the occurrence of shared decision-making (through, for example, audio-recordings of the doctor patient interaction or patient self-report of shared decision making)? Or, did the investigators assume that if an intervention was designed with the goal of supporting shared decision-making that shared decision-making occurred? These points highlight the distinction between a review of decision-aid studies and a review of studies designed to support SDM. | Thank you.<br>We added a detailed section on SDM and SDM interventions (pg 12-14), including the scope of our review including definitions, purpose, evidence-based framework utilized (ODSF) (pg 13 paragraph 3; pg 14, paragraph 1), and inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5). |
| Yes | Thank you |
| No. Reading this report makes me appreciate how difficult this topic was to review. The purpose of engaging in shared decision making is not really clearly stated – page 1, line 13 says it's to "improve clinical care" but is the desired outcome to encourage patients to get recommended cancer screening tests or to discourage inappropriate ones or to help them make choices that they're happy with, regardless of whether the healthcare team considers them "right" or "wrong"? Is there evidence that patients aren't making the "best" decisions? The report makes me realize that the whole concept of SDM assumes that people make rational decisions when presented with the evidence and an opportunity to think it through (values clarification, *etc.*) but what if that's not how most people make their decisions? Is it okay for the labeling of a decision as "preference sensitive" to be done by healthcare professionals, rather than by patients? I think so, but perhaps a comment about that should be included.<br>The Ottawa Decision Support Framework is mentioned as the framework used but is not described or explained as to why it was chosen.<br>Some of the studies reviewed seem to have used DAs as stand-alone interventions with patients, without "sharing" the decision with a healthcare provider, even though SDM is described as involving both. For example, the two breast cancer screening SDM trials described on pages 22-23 both involved providing participants with a DA but don't mention discussion of their screening decisions with their healthcare providers. Perhaps these studies are better described as "informed decision making." | We added a detailed section on SDM and SDM interventions (pg 12-14), including the scope of our review including definitions, purpose, evidence-based framework utilized (ODSF) (pg 13-14).<br>We added detailed information on the Ottawa Decision Support Framework, and how it guided our review, (pg 13 paragraph 3, pg 14 paragraph 1).<br>Facilitating informed decision making could be a stand-alone strategy for facilitating the broader goal of SDM, or could be one component of a multi-faceted SDM intervention. We do not exclude SDM interventions restricted to informed decision making processes from the review. We added a detailed section on SDM, and SDM interventions (pg 12-14). Hopefully it is clearer how we conceptualized SDM interventions, and the scope of our review. |

| | |
|---|---|
| The multiple outcomes measured (components of Decision Quality, Decision Impact, and Decision Action) seem to be closely related and a bit hard to differentiate at times. Are they all of equal importance?<br>In the Conclusions paragraph (page 45, lines 31-33), it'd be helpful to say what effect on Decision Quality and Impact would have been expected/ desired from SDM. I assume they should ideally have increased but I'm not sure. | As specified in our revised background section and description of the Ottawa Decision Making Framework, measures of the decision making process (i.e., decision quality and decision impact) receive priority over decision action in selecting studies. We excluded studies that only examined decision action outcomes.<br>In both the Executive Summary and the main report we discuss ideal cancer screening SDM intervention outcomes in SDM interventions (e.g., decrease decisional conflict, increase patient satisfaction, increase knowledge) (pg 1 paragraph 2; pg 13 paragraph 3). |
| No. The objectives, scope, and methods are mostly described well. One exception is that I am unclear by your use of the term SDM interventions. You don't really define it and it's a term commonly used in the literature. I assume you are referring to decision aids and decision support interventions (which becomes clear after the executive summary I am not sure why you are using that term but given its lack of use in the literature you should define it and give examples of what you mean (both in the executive summary and in the main document). Click here to enter text.<br>Also, it may be beneficial to describe a little better the measures used in the studies. | We added a detailed section on SDM and SDM interventions (pg 12-14).<br>We prepared a table describing the measures used in the included studies (Appendix E). |
| Yes. The methods are clearly described. The division into decision quality, decision impact, and decision action doesn't work very well for me but is clearly described. | Thank you |
| **2. Is there any indication of bias in our synthesis of the evidence?** | |
| No | Thank you |
| I am not sure why authors excluded those studies looking at decision action alone. It isn't clear why they chose to include studies that included all three types of outcomes (decision action, decision quality, and decision impact). I would include studies that assessed *any* of the outcomes and just report on those outcomes with slightly different Ns in each. Otherwise they exclude quite a few studies that might be relevant (starting with 2368 hits, going down to 22 unique trials). I now see in the limitations section that the authors state they excluded studies looking at decision action alone because they didn't want to include studies encouraging screening, but with a clear definition of SDM this can be mitigated rather than excluding potentially relevant SDM interventions just because of choice of outcome measures.<br>I am also not sure why authors excluded studies in settings other than primary care or studies in non-clinical settings. This needs clarification. | We added a detailed section on SDM and SDM interventions (pg 12-14), including the scope of our review including definitions, purpose, evidence-based framework utilized (ODSF) (pg 13 paragraph 3; pg 14 paragraph 1), and inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5). Additionally, we prepared a table of excluded studies (Appendix B).<br>We clarified our inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5); to be consistent with the definition guiding this review, which defines SDM as a process that involves interaction between patients and clinical providers, we sought to identify interventions implemented and evaluated in clinical settings where such a dialogue could possibly occur. Clinic settings, either at or shortly before an appointment, were a component to encourage SDM with the clinician. |

| | |
|---|---|
| Study selection in general does not match up with definitions of SDM. So did authors consider an intervention an "SDM intervention" only if it provided both risk and benefit information? What about values clarification? (p. 13, lines 23-29). This again leads back to clarifying what definition they are using.<br>I am not sure whether the list of hand-searched journals is complete. What about BMJ or HEX, for example? | We selected studies based on the stated goals of the interventions and outcomes measured, rather than on content of the intervention per se. There are many ways to facilitate SDM and interventions that increase patient knowledge of risks and benefits, even without explicit values clarification are still SDM interventions. We added a detailed section on SDM and SDM interventions (pg 12-14), and inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), We hope it is now clearer why we included the studies.<br>A complete list of hand-searched journals (including British Medical Journal and Health Expectations) is provided in the Methods section (pg 16 paragraph 3). |
| No | Thank you |
| Yes. The appearance of bias comes from uncertainty in the threshold to conclude SDM interventions for cancer screening do more good than harm. The review notes in Executive Summary Table 1 that 18/19 trials show improved knowledge. If one believes in truly informed consent for screening tests (and national guidelines certainly stress that point, particularly for prostate cancer screening), isn't that the key outcome? In addition, 3/6 trials show an increase in values clarity, 7/13 show a reduction in decisional conflict, 3/6 show reduced use of services, and 1/2 show an increase in decision satisfaction. Moreover, among the prostate trials, 5/9 show a reduction in screening intention, and 7/12 show a reduction in screening test use. These results seem more impressive than the tone of the discussion in the paper suggests, particularly as there seems to be little evidence of harm. | The reviewer makes a valid point. In the discussion we made an effort to emphasize that SDM interventions for cancer screening did more good than harm, while accurately presenting the state of the evidence (pg 49 paragraph 2). |
| No. | Thank you |
| No. More details on your search terms is necessary (perhaps also include in exec summary—found them in main body). I was surprised that none of the following were search terms: decision aids, decision support interventions, patient education, shared decision making. | We added more information about our search in the review (pg 16 paragraphs 2-3) and executive summary (pg 2 paragraph 2) and clarified that the mentioned terms were included. These terms are also presented in Appendix A. |
| No. | Thank you |
| **3. Are there any <u>published</u> or <u>unpublished</u> studies that we may have overlooked?** | |
| Yes. Taylor KL, et al. Decision making in prostate cancer screening using decision aids vs. usual care: a randomized clinical trial. JAMA Intern Med 2013;173:1704. | Thank you for this suggestion. We agreed that this study was overlooked and we included it in the revised report. |
| Yes. What about Jane Kim et al. 2004 BMC Medical Informatics and Decision Making, 5:36, and Carmen Lewis et al. 2010 BMC Medical Informatics and Decision Making (both about colorectal cancer screening decision aids). For decision aids specifically, why not look at the Cochrane Review and then look for RCTs of cancer screening decision aids? Can the authors search Dawn Stacey's review of decision aids for cancer specifically (in CA: A Cancer Journal for Clinicians)? | Thank you for these suggestions. These articles were assessed and excluded during our search; we added more information about our exclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), and we prepared a table of excluded studies (Appendix B).We did use the Cochrane Review, Dr. Stacey's review, as well as others as part of search strategy to identify relevant studies. |

| | |
|---|---|
| No. Not that I am aware of. | Thank you |
| No. | Thank you |
| Yes. There are many studies of decision aids not included in the review – perhaps appropriately, but it's not always clear why some were and some weren't | We added more information about our exclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), and we prepared a table of excluded studies (Appendix B). |
| Dawn Stacey's 2014 Cochrane review of decision aids,<br>Mara Schonberg's 2014 JAMA: IM article on a screening decision aid for women > 75. Maybe John Inadomi's 2012 JAMA: IM article.<br>Sarah Hawley has finished 2 studies looking at CRC screening interventions (one in the VA).<br>Frosch, Legare, Mangione 2008, patient education and counseling (screening in ethnically diverse clinics).<br>Lin et al health Affairs 2013 vol. 32no. 2 311-320 | Thank you for these suggestions. We used Dr. Stacey's review in our search strategy to identify relevant articles and these articles were assessed and excluded during our search; we added more information about our exclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), and we prepared a table of excluded studies (Appendix B).We were unable to include Dr. Hawley's studies as they were unpublished as of July, 2014. |
| Yes. The decision to not include the studies that focus only on decision action doesn't make sense to me, if you want to make conclusions about that set of outcomes. | We aimed to review studies that evaluated the decision making process. Studies that focused on Decision Action did not fit this criterion and were excluded, as well as interventions that promoted screening. We added more information about our exclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), and we prepared a table of excluded studies (Appendix B). |
| **4. Please write any additional suggestions or comments below. If applicable, please indicate the page and line numbers from the draft report.** | |
| P 1, line 22: Typo: Should read that decision quality is characterized by knowledge, value-concordance, and patient role. | Thank you for the suggestions. We made this edit (pg 1 paragraph 2). |
| P 1, line 30: Would suggest just using the phrase "intervention target," the system/organization does not seem to be a population. | We agree with the reviewer and made the requested edit throughout the report. |
| P 3, lines 4-5 (and elsewhere [KQ3]): Would clarify whether results are from lack of effectiveness and/or insufficient sample size. | The reviewer makes a valid point and we clarified this throughout the report. |
| P 10, line 41. USPSTF does not consider barium enema as an acceptable test; would delete or add CT colonography. | We made this edit (pg 13 paragraph 1). |
| | We made this edit (pg 27 paragraph 1). |
| P 24, line 30: CRC screening is also effective in reducing cancer-related mortality and cancer incidence. | We edited the comparative effectiveness trials section to clarify which interventions were favored (pg 32 paragraph 3 – pg 33 paragraph 3) |
| P 37, line 36-8: Which intervention (booklet or pamphlet) was favored for these outcomes? | |
| P 42, line 10: Typo. Should read "decreased their intention to order PSA" | We clarified that the intervention group had a lower intention to order PSA (pg 47 paragraph 2; pg 6 paragraph 3) |

| | |
|---|---|
| Line 14, p. 35: the highest standard in risk communication is not necessarily pictographs…I would rephrase. Newer research suggests bar graphs might be ok, and the most important standard is to use frequencies or percentages rather than RR, AR, NNT, *etc.* Also see Fagerlin et al 2011, JNCI, 10 steps to better risk communication, for a more recent reference.<br><br>Although there is no evidence that more resource intensive SDM interventions do better than less resource intensive SDM interventions, few studies assessed this. I would clarify that throughout the review as it has clear policy implications and it might be premature to say a pamphlet (that might not be read by everyone in standard practice vs. in the context of a voluntary research study) does better than other interventions. Could be added to the conclusions section.<br><br>In general the conclusions are well written and clear. | Thank you for this suggestion. We rephrased to reflect the most current research and included Fagerlin et al 2011 (pg 39 paragraph 2).<br><br>We agree and we clarified throughout the report that conclusions should not be drawn from a single study.<br><br>Thank you |
| There is an error in line 21 when Decision Quality is defined using the same outcomes as Decisional Impact. | We made the requested edit (pg 1 paragraph 2). |
| In the analyses of decision action for SDM interventions for prostate cancer screening, the heterogeneity and differential effects among studies may reflect confounding by the baseline rate. In theory, whether decision action changes and in what direction might depend on whether PSA screening at baseline was overutilized or underutilized. Can the results be stratified based on testing rates in the control group, perhaps comparing the mean baseline rates in the control group for the 7 studies showing a drop in utilization with SDM, versus the 5 showing no effect? | There is a limited range in PSA rates across the prostate cancer studies; the range of mean PSA screening rates is narrow, and thus stratifying would not be a productive. |
| Page 1, lines 21-22: text in the parentheses after Decision Quality and Decision Impact is repeated.<br><br>Page 10, lines 14-16: the sentence starting “SDM involves…” could be better written as “SDM involves integrating the knowledge of health care professionals and the values and preferences of patients to arrive at a final decision.”<br><br>Page 10, line 20: please consider (here and throughout) using the word “use” or “used” rather than “utilization” or “utilized”<br><br>Page 17, lines 25: the definition of “attention control” trials is not provided here, when the term is first used.<br><br>Page 18, Table 1: it’s not clear what the “0” means in this table. Does it mean no effect or not studied or something else?<br><br>Page 24, line 8: are the percents listed (95.5% and 9.3%) correct? They’re described as showing no effect between the 2 groups.<br><br>Page 31, line 20: refer the reader to Appendix C, Table 1 to understand how the risk of bias was determined | We made this edit (pg 1 paragraph 2).<br><br>Thank you for the suggestion. We reworded this paragraph (pg 11 paragraph 1).<br><br>We agree with the reviewer’s suggestion and made the requested clarifications throughout the report.<br><br>We added a definition of ‘attention control trials’ (pg 21 paragraph 1).<br><br>The ‘0’ referred to no effect. However, we made this table consistent with others and added foot notes to all tables.<br><br>The percentages from Mathieu 2007 (9.5% and 9.3%) can be found in Table 4 (pg 76); the text now reads “Mathieu 2007 also measured screening outcomes one month post-intervention and found that SDM had no effect on having made or planning to make a mammography appointment” (pg 26 paragraph 4).<br><br>Thank you for the suggestion. Strength of Evidence and Risk of Bias are described fully in the methods and separately in the results. We added a reference to Appendix F (pg 45 paragraph 2). |

| | |
|---|---|
| The executive summary is hard to understand without context. For example: "A single SDM intervention designed to facilitate decisions about whether women who are younger or older than typically recommended for breast cancer screening should be screened had no effect on decisional conflict." What was the intervention? | The reviewer makes a valid point. We rewrote the executive summary to improve its clarity throughout and added context for interventions. |
| Executive summary table #2: How were these ratings done? Hard to evaluate the table. You discuss the methods in the main body, so maybe just not include the table in the ES unless you provide some detail there. | The reviewer makes a valid point. To improve readability of the Executive Summary, we removed the complete evidence table and included this in the main body where we explained our ratings methods. |
| Another area that needs more research is how to get SDM interventions/decision aid implemented into clinical practice. Often research finds them beneficial in a variety of ways, but once the research staff is no longer engaged (i.e., the research is done), the decision aids never get to patients. How can that change? | The reviewer brings up an interesting point. We addressed implementation challenges in the discussion, citing Dr. Gravel's 2006 review (pg 48 paragraph 3). |
| On page 41 you write: Given the large body of research outlining the most effective ways to communicate risk and decision making theory, it is possible that authors did not report this information. I think you are optimistic. Granted it was 10 years ago, but Fagerlin et al's review of prostate cancer treatment decision aids found that few included any numerical information at all. We are currently reviewing cancer screening guidelines and you would be stunned by the number that don't include numbers (particularly for benefit of screening). | We tempered our optimism and cited the Fagerlin et al review (pg 39 paragraph 2). We look forward to reading the upcoming review of cancer screening guidelines. |
| When discussing previous reviews, you do not cite Stacey et al 2014 Cochrane review of decision aids or the most recent updating of the IPDAS guidelines which will be valuable to you: http://www.biomedcentral.com/bmcmedinformdecismak/supplements/13/S2 | Thank you for the suggestion We included the most recent Cochrane review in our discussion of previous reviews (pg 48 paragraph 2) and discuss IPDAS guidelines in our introduction (pg 13 paragraph 3). We did use these resources reports in our search strategy, but this was not made clear in our report. We have clarified this in the revised report, and added more information about our search strategy (pg 16 paragraphs 2-3). |
| Page 10, lines 32-34 – I think this should be "mortality" rather than "morbidity"; I would say the benefits and harms are closely balanced and that the decision is preference-sensitive (not the balance) | Thank you for the suggestions. In the course of our edits this sentence was deleted. We reworded the section the reviewer referred to. |
| My only other comment is that the text descriptions of the individual studies are long and somewhat hard to read- better to use the tables to convey that information. | Thank you for the suggestion. We edited the text descriptions of the individual studies slightly and directed the reader to evidence tables (Appendix D). |
| **5. Please provide any recommendations on how this report can be revised to more directly address or assist implementation needs.** | |
| Could identify available VA decision support tools (either developed by VA or accessible through CPRS); for example, the recently developed VA decision tool for prostate cancer screening. | We discussed VA-developed decision support tools, both currently available and potential in the future (pg 49 paragraphs 1-2). |
| The report does a good job of highlighting the need for additional studies in lung and cervical cancer and for studies that have a clinician-intervention component | Thank you |
| Given the mostly low-quality evidence, it'd be helpful to say what should be done at present, if anything, about using SDM for cancer screening. | We added additional suggestions and commentary about how to use SDM in cancer screening, despite the quality of evidence (pg 53 paragraph 3). |
| It may be useful to discuss implementation issues outside of cancer screening. Please see France Legare's and Dominick Frosch's work | Thank you for the suggestion. In our discussion we addressed implementation challenges, citing Dr. Gravel's 2006 review (of which Dr. Légaré is a co-author) (pg 53 paragraph 3). |

# APPENDIX D. EVIDENCE TABLES

## BREAST CANCER

**Table 1. Characteristics of Breast Cancer Studies (k=2)**

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | INTERVENTION TARGET | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWLS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Mathieu, 2007[19] (Australia) | Mammography | 70 y/o women in Australia who accessed gov't on line mammography site; 2 screening mammograms in past 5 years; due for next screening within next 3 months; no prior diagnosis of breast cancer | I: Mailed DA (367)<br><br>C: Standard screening brochure (367) | Age: 70 yrs<br>Race/Ethnicity: NR<br>Previous Screen (%): 100 | Australian population screening program, BreastScreen Australia | Immediately, 1 month<br><br>3% did not return questionnaire<br><br>3% did not complete follow-up interview | Sequence generation: adequate<br>Allocation concealment: adequate<br>Blinding: telephone follow-up blinded; other data by self-administered questionnaire<br>Incomplete outcome data: 3% no questionnaire; 11%[a] of questionnaires incomplete; 3% no interview<br>Selective outcome reporting: no<br>**Risk of Bias: Moderate** |
| Mathieu, 2010[20] (Australia) | Mammography | 38-45 y/o women in Australia who accessed gov't web site for mammography; no prior diagnosis of breast cancer | I: Web-based DA (189)<br><br>C: Survey and delayed DA (223) | Age: 42 yrs<br>Race/Ethnicity: NR<br>Previous Screen (%): 11 | Australian population screening program, BreastScreen Australia | Immediately<br><br>19% withdrew or excluded before accessing DA; outcome data for 63% of patients randomized | Sequence generation: adequate<br>Allocation concealment: adequate<br>Blinding: unclear<br>Incomplete outcome data: 37% missing outcome data;61% did not complete informed choice analysis<br>Selective outcome reporting: no<br>**Risk of Bias: Moderate** |

k = number of studies; DA=Decision Aid

[a] Data analysis included all who completed specific sections of the questionnaire

**Table 2. Characteristics of Interventions from Breast Cancer Studies**

| AUTHOR, YEAR | DELIVERY MODE | DELIVERY TIMING and LOCATION | VALUES CLARIFICATION EXERCISE | RISK COMM. METHOD | CONSIDERED HEALTH LITERACY or NUMERACY | RESOURCES (COST, STAFF, PHYSICAL) |
|---|---|---|---|---|---|---|
| Mathieu, 2007[19] | Mailed booklet | Home | Worksheet with examples provided | 1000-face pictograms:<br>Event rate per 1000 women screened every 2 years over 10 years, starting at age 70 | Not specified | Unclear |
| Mathieu, 2010[20] | Website | Home | Worksheet with examples provided | Diagrams as event rates per 1000 women screened every 2 years over 10 years, and per 1000 women who are not screened over 10 years | Not specified | Unclear |

DA=Decision Aid

**Table 3. Decision Quality Outcomes Assessed in Breast Cancer Studies**

| AUTHOR, YEAR | KNOWLEDGE | | PATIENT ROLE IN DECISION | | VALUES CLARITY | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Mathieu, 2007[19] | 76.6% adequate knowledge[a]<br>Informed choice[b]<br>73.5% | 56.9% adequate knowledge<br>$\chi^2$=31.15, p = .02<br>Informed choice<br>48.8%, ($\chi^2$=37.92; P<.001). | - | - | *Clear Values*[c]<br>Mean = 19.51<br>*Decided*<br>Undecided: 4.9%<br>Decided: 95.1% | *Clear Values*<br>Mean = 22.59,<br>$T_{545}$=2.27, p= .02<br>*Decided*<br>Undecided: 10.1%<br>Decided: 89.9%<br>OR 0.32 (0.17, 0.63), P < .001 |
| Mathieu, 2010[20] | Mean 7.35<br>94% adequate[a]<br>Informed choice[b]<br>71% | Mean 6.27, p<.001<br>83% adequate, p<.001<br>Informed choice<br>64%, p=NS | - | - | *Decided*<br>Undecided: 18%<br>Intention – Decided: 82% | *Decided*<br>Undecided: 39%<br>Intention – Decided: 61%<br>$\chi^2$=15.72, P<0.001 |

[a] Adequate knowledge defined as a score of 6/10 or higher
[b] Participants were classified as having made an informed choice if they had either (1) adequate knowledge, positive values towards screening, and intention to attend screening; or (2) adequate knowledge, negative values towards screening, and intention to decline screening
[c] Decisional Conflict Scale – Values Subscale: values considered "clear" if score is ≤ 25

**Table 4. Decision Impact Outcomes Assessed in Breast Cancer Studies**

| AUTHOR, YEAR | DECISIONAL CONFLICT | | USE OF HEALTH SERVICES | | DECISION SATISFACTION | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Mathieu, 2007[19] | *DCS*[a]<br>Mean = 20.06 | *DCS*<br>Mean = 21.89,<br>p= .12 | - | - | - | - |
| Mathieu, 2010[20] | - | - | - | - | - | - |

[a] Decisional Conflict Scale – higher scores indicate greater decisional conflict or uncertainty.

**Table 5. Decision Action Outcomes Assessed in Breast Cancer Studies**

| AUTHOR, YEAR | SCREENING INTENTION | | SCREENING BEHAVIOR | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| Mathieu, 2007[19] | Intention – Stop screening: 9.5%<br>Intention –Continue screening: 85.7%[a] | Intention – Stop screening: 9.3%<br>Intention – Continue screening: 80.6%<br>OR 1.28 (0.63, 2.61), p=.50 | Screened: 5.9%<br>Unscreened, but have made appointment, or planning to make appointment: 75.7%<br>Unscreened: 18.4% | Screened: 7.0%<br>Unscreened, but have made appointment, or planning to make appointment: 74.7%<br>Unscreened : 18.3%<br>P=NS |
| Mathieu, 2010[20] | Intention – Screen: 52%<br>Intention – Not screen: 48%[b]<br>$\chi^2$=4.00, P = .05 | Intention – Screen: 65%<br>Intention – Not screen: 35% | - | - |

[a] Percent of total group (decided and undecided)
[b] Percent of women who had made a decision

# COLORECTAL CANCER

**Table 6. Characteristics of Colorectal Cancer Studies (k=3)**

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | INTERVENTION TARGET | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWLS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Dolan, 2002[21] (United States) | FOBT, FS, FOBT+FS, BE, COL | Men and women at average risk for CRC; CRC screening eligible | I: Interview plus printed DA (N=49)<br><br>C: Interview plus printed educational materials (N=46) | Age (yr): 66.1<br>Gender (Male%): 47.5<br>Race/Ethnicity (%): white 98<br>Previously screened (%): 27.3 | 2 Internal Medicine practices | Follow up<br>1) Immediate<br>2) 2-3 mo. chart review<br><br>1% withdrawals | Sequence generation: Adequate<br>Allocation concealment: Unclear<br>Blinding: Yes (chart review)<br>Incomplete outcome data: No<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |
| Schroy, 2011[22] Schroy, 2012[23] (United States) | FOBT, FS, FOBT+FS, BE, COL | Average risk patient under care of primary care provider at study sites; 50 to 75 years old; no prior CRC screening examinations<br><br>Excluded: prior CRC screening other than FOBT; high-risk conditions (personal history of CRC or polyps, family history of CRC or polyps, chronic IBD); comorbidities that preclude CRC screening by any method | I1: DA plus "Your Disease Risk" tool (YDR)(n=223) (n=280 for Schroy 2012)<br>I2: DA (n=212) (n=269 for Schroy 2012)<br><br>C: Control (modified version of "9 Ways to Stay Healthy and Prevent Disease") (n=231) (n=276 for Schroy 2012) | Schroy 2011<br>Age (yr): 83% <65 years; 17% 65+ years<br>Gender (Male%): 41<br>Race/Ethnicity (%): black 62, white 34, Asian 2<br>Previously screened (%): 14 (FOBT only)<br><br>Schroy 2012<br>Age (yr): 84% <65 years; 16% 65+ years<br>Gender (Male%): 41<br>Race/Ethnicity (%): black 62, white 34, Asian 2<br>Previously screened (%): 13 (FOBT only) | 2 urban ambulatory care clinics (1 private, academic-affiliated, 1 community clinic affiliated with academic clinic)<br><br>50 providers (47 MDs, 3 NPs) participated; pre-study seminars about CRC screening, SDM, overview of study | Schroy 2011<br>Follow up<br>1) Immediate (post-visit)<br>2) Medical record review for screening test ordered (time of review not reported)<br>% withdrawals not reported<br><br>Schroy 2012<br>Follow up<br>12 months post-visit<br>0% withdrawals | Sequence generation: Unclear<br>Allocation concealment: Adequate<br>Blinding: Unclear<br>Incomplete outcome data: No<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |
| Trevena, 2008[24] (Australia) | FOBT | Between 50 and 74 years old<br>Excluded: poor English, significant cognitive impairment, serious physical or mental illness, resident of nursing homes, personal history of colorectal cancer; previous FOBT, FS, or COL (past 2 years); strong family history of CRC | I: DA (age, gender, family history specific) (n=157)<br>C: Government consumer guidelines on FOBT (n=157)<br>Both groups received self-administered questionnaire | Age (yr): 50-54 years 23%; 55-64 years 41%; 65-74 years 35%<br>Gender (Male %): 42<br>Race/Ethnicity (%): NR<br>Previously screened (%): NR | 1 rural and 5 urban family practices | Follow-up: 1 month after mailing<br>14.3% withdrawals | Sequence generation: Adequate<br>Allocation concealment: Adequate<br>Blinding: Participants were blinded to study hypothesis; researchers were blinded to allocations for telephone interviews (questionnaires were self-administered)<br>Incomplete outcome data:<br>Selective outcome reporting:<br>**Risk of Bias: Moderate** |

k = number of studies; BE = barium enema; COL = colonoscopy; CRC = colorectal cancer; DA = decision aid; FOBT = fecal occult blood test; FS = flexible sigmoidoscopy; IBD = inflammatory bowel disease

**Table 7. Characteristics of Interventions from Colorectal Cancer Studies**

| AUTHOR, YEAR | DELIVERY MODE | DELIVERY TIMING and LOCATION | VALUES CLARIFICATION EXERCISE | RISK COMM. METHOD | CONSIDERED HEALTH LITERACY or NUMERACY | RESOURCES (COST, STAFF, PHYSICAL) |
|---|---|---|---|---|---|---|
| Dolan, 2002[21] | Counseling and print | Prior to routine appointment | Analytic hierarchy process | Not specified | Not specified | Study team member-administrated intervention prior to appointment |
| Schroy, 2011[22]<br>Schroy, 2012[23] | DVD | 1 hr prior to prearranged office visit with primary care provider<br><br>Private office | Discrete choice method to identify screening preference | Web-based "Your Disease Risk" (YDR), personalized risk estimates; audio/ visual | Conducted focus groups to determine key factors (including literacy) to include in DA; Prototype modified after usability testing | Research assistants administered pre-test, web-based program |
| Trevena, 2008[24] | Booklet<br>Question set | Home | Personal worksheet required participants to indicate what was important to them | 1000-face diagrams | Readability score: Grade 10 | Unclear |

DA = decision aid

**Table 8. Decision Quality Outcomes Assessed in Colorectal Cancer Studies**

| AUTHOR, YEAR | KNOWLEDGE | | PATIENT'S ROLE IN THE DECISION | | VALUES CLARITY | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Dolan, 2002[21] | - | - | *Perception of how screening decisions were made:*<br>Primarily MD 7 (16.3%)<br>Shared 27 (62.8%)<br>Primarily patient 9 (20.9%) | *Perception of how screening decisions were made:*<br>Primarily MD 6 (13.9%)<br>Shared 22 (51.2%)<br>Primarily patient15 (34.9%), P = .35 | - | - |
| Schroy, 2011[22] | *Baseline*<br>DA+YDR: 7.6 (2.8)*<br>DA: 7.7 (2.9)[a]<br>*Post-visit*<br>DA+YDR: 10.7 (1.8)*<br>DA: 10.9 (1.6)[a]<br>EFFECT sizes (vs control)<br>DA+YDR: d=1.15<br>DA: d=1.27 | *Baseline*<br>Control: 7.5 (2.7)*<br>Overall P=0.91<br>*Post-visit*<br>Control: 8.6 (2.7)*<br>P<0.001 for 2 intervention groups vs control | - | - | - | - |
| Schroy, 2012[23] Continuation of Schroy 2011[22] | *Baseline*<br>DA+YDR: 7.7 (2.9)*<br>DA: 7.9 (2.8)[a]<br>*Post-visit*<br>DA+YDR: 10.7 (1.9)[a]<br>DA: 10.9 (1.6)* | *Baseline*<br>Control: 7.5 (2.8)*<br>Overall P=0.36<br>*Post-visit*<br>Control: 8.6 (2.6)*<br>P <.001 for 2 intervention groups vs control | - | - | - | - |

| AUTHOR, YEAR | KNOWLEDGE | | PATIENT'S ROLE IN THE DECISION | | VALUES CLARITY | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Trevena, 2008[24] | *Adequate knowledge*[b] 28/134 (20.9%); P= .0001<br>*Integrated knowledge and values*‖ 14/134 (10.4%); P= .002 | *Adequate knowledge* 8/137 (5.8%)<br>*Integrated knowledge values*‖ 2/137 (1.5%) | - | - | *Clear values*[c] 83/134 (62%) | *Clear values* 81/137 (59%) P= .63 |

CRC = colorectal cancer; DA = decision aid; DA+YDR = decision aid plus "Your Disease Risk"; MD=physician

[a] 12 item true/false questionnaire about CRC risk factors, rationale and goals of screening, age at which screening should begin; 0 = no correct responses, 12 = all correct responses

[b] Adequate knowledge defined as positive scores for understanding the potential benefits and potential arms of screening; integrated knowledge and values defined as clear values and adequate knowledge

[c] Decisional Conflict Scale – Values Subscale: values considered "clear" if score is ≤ 25

## Table 9. Decision Impact Outcomes Assessed in Colorectal Cancer Studies

| AUTHOR, YEAR | DECISIONAL CONFLICT[a] | | USE OF HEALTH SERVICES | | DECISION SATISFACTION | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Dolan, 2002[21] | 1.83 (0.52)[b] P = .01 effect size=0.29 | 2.03 (0.81) | - | - | - | - |
| Schroy, 2011[22] | - | - | - | - | Mean *SDMP* scores[c] DA + YDR: 50.5 (6.2), N=214 DA: 50.7 (6.2) N=205 | Mean *SDMP* scores Control: 46.7 (7.9) N=217 P <.001 |
| Schroy, 2012[23] Continuation of Schroy, 2011[22] | - | - | - | - | Mean *SDMP* scores[c] DA+YDR: 49.0 (6.2), n=271 DA: 49.7 (6.4), n=262 | Mean *SDMP* scores †† Control: 45.5 (7.8), n=261; P < .001 |
| Trevena, 2008[24] | - | - | - | - | - | - |

[a] Scores are means (standard deviation) unless indicated; DA+YDR = decision aid plus "Your Disease Risk"

[b] Decisional Conflict Scale (low literacy version) - Maximum = 100; 0 = no decisional conflict, 100 = extreme decisional conflict

[c] 12-item Satisfaction with the Decision-Making Process Scale, each item scored from 1 (strongly disagree or "poor") to 5 (strongly agree or "excellent"); maximum score = 60

## Table 10. Decision Action Outcomes Assessed in Colorectal Cancer Studies

| AUTHOR, YEAR | SCREENING INTENTION | | SCREENING BEHAVIOR | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| Dolan, 2002[21] | FOBT 23 (51%)<br>W&S 8 (18%)<br>FOBT+FS 6 (13%)<br>FS 6 (13%)<br>BE 1 (2%)<br>COL 1 (2%) | FOBT 17 (39%)<br>W&S 16 (37%)<br>FOBT+FS 8 (18%)<br>FS 2 (5%)<br>BE 0<br>COL 0<br>All P = ns | FOBT 11 (48%)<br>W&S 8 (100%)<br>FOBT+FS 2 (33%)<br>FS 4 (67%)<br>BE 0<br>COL 1 (100%) | FOBT 6 (35%)<br>W&S 15 (94%)<br>FOBT+FS 7 (88%)<br>FS 1 (50%)<br>BE 0<br>COL 0 |

| AUTHOR, YEAR | SCREENING INTENTION | | SCREENING BEHAVIOR | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| Schroy, 2011[22] | *DA+YDR:*<br>COL 132/223 (60%)<br>FOBT 53/223 (24%)<br>FS 13/223 (6%)<br>FOBT+FS 6/223 (2%)<br>BE 8/223 (4%)<br>None 8/223 (4%)<br>*DA:*<br>COL 120/212 (57%)<br>FOBT 58/212 (28%)<br>FS 11/212 (5%)<br>FOBT+FS 5/212 (3%)<br>BE 9/212 (4%)<br>None 7/212 (3%)<br>P = ns (between groups)<br><br>*Intention to Schedule Screening*†<br>DA+YDR: 4.3 (1.0)<br>DA: 4.4 (1.0)<br><br>*Intention to Complete Screening Test*†<br>DA+YDR: 4.3 (1.0)<br>DA: 4.3 (1.0)<br>EFFECT sizes: Ranged from 0.36 to 0.44 for intention to schedule or complete for 2 intervention groups vs control | NR<br><br>*Intention to Schedule Screening*†<br>Control: 3.9 (1.4)<br>P < .001 vs 2 intervention groups<br><br>*Intention to Complete Screening Test*†<br>Control: 3.9 (1.3)<br>P < .001 vs 2 intervention groups | - | - |
| Schroy, 2012[23]<br>Continuation of Schroy 2011[22]<br>N=825 | *Intention to Schedule Screening*[a]<br>DA+YDR: 4.3 (1.0) (n=280)<br>DA: 4.4 (1.0) (n=269)<br>*Intention to Complete Screening Test*[a]<br><br>DA+YDR: 4.4 (1.0) (n=280)<br>DA: 4.3 (1.0) (n=269)<br>Test Ordered by 12 months After Vsit<br><br>DA+YDR: 73.6%<br>DA: 80.7%<br>DA+YDR vs DA: P = .048 | *Intention to Schedule Screening*<br>Control: 3.9 (1.3) (n=276)<br>P < .001 vs 2 intervention groups<br><br>*Intention to Complete Screening Test*<br>Control: 4.0 (1.3) (n=269)<br>P < .001 vs 2 intervention groups<br><br>*Test Ordered by 12 months Aafter Visit*<br>Control: 71.4%, P = .011 vs DA | *Test Completed by 12 Months After Visit*<br>DA+YDR: 37.1%<br>OR 1.03 (0.72, 1.48) vs control<br><br>DA: 43.1%<br>OR 1.30 (0.90, 1.87) vs control<br>DA+YDR vs DA,<br>P = .153 | *Test Completed by 12 Months After Visit*<br>Control: 34.8%,<br>P = .046 vs DA |
| Trevena, 2008[24] | *Intention to Screen*<br>Baseline<br>142/157 (90.4%)<br>*Post-intervention*<br>117/134 (87.3%) | *Intention to Screen*<br>Baseline<br>139/157 (88.5%)<br>*Post-intervention*<br>124/137 (90.5%), P = .40 | *At One Month Completed FOBT*<br>5.2% | *At One Month Completed FOBT* 6.6%<br>P = .64 |

DA = decision aid; DA+YDR = decision aid plus "Your Disease Risk"; BE = barium enema; COL = colonoscopy; FOBT = fecal occult blood test; FS = flexible sigmoidoscopy; ns = not statistically significant;

[a] 5 point scale with 1 = not at all sure, 5 = completely sure

# PROSTATE CANCER

**Table 11. Characteristics of Prostate Cancer Studies (k=18)**

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Davison, 1999[25] (Canada) | Screening defined as both DRE & PSA | Male patients age 50-79 with a periodic health examination appointment with no prostate cancer diagnosis or evidence of mental confusion. | I: verbal & written information, including prostate cancer screening controversies, pros & cons, encouragement to discuss with MD (n=50)<br>C: Attention control involving discussion about general issues (n=50) | Age(yrs): Mean 62.2<br>50 to 59: 21.5%<br>60 to 69: 17%<br>70 to 79: 12% | 1 family medicine clinic | Immediate<br>Withdrawals: 0% | Sequence generation: Adequate<br>Allocation concealment: Adequate<br>Blinding: no<br>Incomplete outcome data: unclear<br>Selective outcome reporting: unclear<br>**Risk of Bias: Moderate** |
| Evans, 2010[26] (United Kingdom) | PSA | Men aged >50 | I1: Web-based DA, Prosdex (n=89)<br>I2: paper version of Prosdex text (n=86)<br>C1: Questionnaire control group (n=103)<br>C2: no questionnaire control group (n=126) | Age 50-59 65%<br>White 92.9%<br>Black 0.4%<br>Indian 0.4%<br>Mixed Race 1.2%<br>Other 1.1%<br>Mean # previous PSAs 2.15 | 25 General practices from 9 Local Health Board areas in South Wales | Immediate, 6 months<br>Loss to initial follow up:<br>I1: 31% (40/129)<br>I2: 32% (40/126)<br>C1: 19% (24/127)<br>Loss to 6 month follow up:<br>I1: 46% (41/89)<br>I2: 34% (29/86)<br>C1: 33% (34/103)<br>C2: 24% (32/132) | Sequence generation: Adequate<br>Allocation concealment: Adequate<br>Blinding: adequate<br>Incomplete outcome data: Yes<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |
| Frosch, 2003[27] (United States) | PSA | Men aged >50 | I1: Web-based DA (N=114)<br>I2: Video DA (N=112) | Age 62.1<br>White 91.1%<br>African American 0.4%<br>Hispanic 3.5%<br>Asian 3.2%<br>Other 0.4%<br>Mean # previous PSAs 2.15 | 1 Preventive Medicine Clinic | Immediately post-visit<br>Withdrawals:<br>Video 5.7%<br>Web: 17.5% | Sequence generation: Adequate – random number generator<br>Allocation concealment: Adequate<br>Blinding: no<br>Incomplete outcome data: Yes – there was incomplete outcome data, handled by imputing the mean for some and pretest scores for others. This is a less rigorous approach than multiple imputation.<br>Selective outcome reporting: Yes<br>**Risk of Bias: Moderate** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Frosch, 2008[28] (United States) | PSA | Male patients >50 | I1: Web-based Traditional Decision Aid (TDA) (n=155)<br>I2: Web-based Chronic Disease Trajectory Model (DTM) (n=153)<br>I3: combined TDA and DTM (n=152)<br>C: links to public ACS and CDC prostate cancer screening websites (n=151) | Age 58.6<br>White 86%<br>African American 2.8%<br>Hispanic 5.2%<br>Asian 3.9%<br>Other 2.0 %<br>Mean # previous PSAs 3.4 | 1 Preventive Medicine Clinic | Length of follow-up unclear (participants approached "after appointment completed" to assess outcomes)<br>Withdrawals:<br>TDA 23%<br>DTM 25%<br>TDA&DTM 22%<br>Control 34% | Sequence generation: Computer algorithm used to randomize – Adequate<br>Allocation concealment: Adequate<br>Blinding: Unclear whether participants, providers, investigators, and/or outcome assessors were blinded.<br>Incomplete outcome data: Yes – there was incomplete outcome data, handled by imputing the mean for some and pretest scores for others. This is a less rigorous approach than multiple imputation.<br>Selective outcome reporting: Yes<br>**Risk of Bias: Moderate** |
| Gattellari, 2003[29] (Australia) | PSA | Male patients fluent in English, age 40-70 with no prostate cancer diagnosis | I: 32-page (3085 word) Evidence Based booklet distributed in clinic (n=126)<br>C: 968 word pamphlet published by the Australian government (n=122) | Mean Age 54.0<br>Male 100%<br>Previous PSA 36% | Practices of 13 General Practitioners in urban Sydney | Unclear<br>Withdrawal<br>I: 16% (n=106)<br>C: 11% (n=108), NS | Sequence generation: Adequate (pre-randomized code).<br>Allocation concealment: Adequate – pre-randomized assignment concealed from receptionists and General Practitioners by sealed envelope handed to patients.<br>Blinding: Receptionists, general practitioners, and patients were blinded. It is not clear whether individuals conducting analysis were blinded.<br>Incomplete outcome data: Yes –11-16% were not followed up, but no statistically differences across experimental groups on follow-up rates.<br>Selective outcome reporting: unclear<br>**Risk of Bias: Moderate** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Gattelari, 2005[30] (Australia) | PSA | General Practitioners (GPs) who had ordered at least one PSA in past 12 months | I: Mailed information, telephone peer coaching, and education sessions (n=110 practices, 136 GPs)<br>C: Mailed summary of PSA screening guidelines (n=110 practices, 141 GPs) | Age <35 3.3%<br>35-44: 22.7%<br>45-54: 40.8%<br>55-64: 19.8%<br>65+: 11.9%<br>Missing: 1.4%<br>Gender<br>Male: 75.1%<br>Female: 24.9% | Referral network of GPs in New South Wales Australia's most populous state, recruited through large pathology service.<br>220 Clinics | Length of follow-up: 0-6-weeks (depending on outcome)<br>Withdrawals: 1% | Sequence generation: Computer generated random number used to randomize – Adequate<br>Allocation concealment: Adequate – GPs were randomized at the same time, Investigator responsible for randomization not involved in data collection.<br>Blinding: Adequate<br>Incomplete outcome data: Yes – there was incomplete outcome data, but no differences across experimental groups, and only 1% had no data, and outcome-specific missing rates unclear.<br>Selective outcome reporting: unclear<br>**Risk of Bias: Moderate** |
| Kripalani 2007[31] (United States) | PSA, DRE | Men age 45-70; waiting for primary care appointment<br>Excluded: history of prostate cancer, in police custody, not scheduled to see a primary care provider, ill, not fluent in English, corrected visual acuity worse than 20/60 | I1: High-detail patient educational pamphlet, PtEd, to promote shared decision making (n=86)<br>I2: Low-detail 'Talk to doctor" Cue handout (n=81)<br>C: Traditional food pyramid (attention control) (n=83) | Age (yr): 56.5<br>Gender (Male %): 100<br>Race/Ethnicity (%): African American 90.4, white 8.0, other 1.6<br>Previous Screen (%): 68<br>Reading below 9th grade level (%): 79 | One inner-city primary care clinic | Immediately post-visit<br>4% of patients could not be located for post-visit questions | Sequence generation: adequate<br>Allocation concealment: adequate<br>Blinding: health care providers and outcomes assessors were blinded<br>Incomplete outcome data: no<br>Selective outcome reporting: no<br>**Risk of Bias: Low** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Krist, 2007[32] (United States) | PSA | Men age 50 to 70 years; scheduled health maintenance examination<br>Excluded: history of prostate cancer, no Internet access, planned to have blood work before visit, enrolled in another prostate cancer investigation, already enrolled in present study | I1: Web-based decision aid (n=226)<br>I2: Paper version of decision aid (n=196)<br>C: No pre-visit educational material (n=75) | Age (yr): 57<br>Gender (Male %): 100<br>Race/Ethnicity (%): white 91, African American 3<br>Previous Screen (%): 68 (PSA) | One large family practice center with a community-based family practice residency program | Immediately post-visit<br>87% of patients and 91% of physicians completed post-visit questionnaire | Sequence generation: adequate<br>Allocation concealment: adequate<br>Blinding: none<br>Incomplete outcome data: 13% of patients did not complete post-visit questionnaire No<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |
| Lepore, 2012[33] (United States) | PSA | Men 45 to 70 years old, black African descent, accessible by telephone, have a primary care physician<br>Excluded: prostate cancer test in past 12 months, history of prostate cancer | I: tailored telephone education about prostate cancer testing (n=244)<br>C: telephone education about fruit and vegetable consumption (attention control) (n=246)<br>All patients received an educational pamphlet | Age (yr): 55<br>Gender (Male %): 100<br>Race/Ethnicity (%): Caribbean 77<br>Previous Screen (%): 28 | Health insurance company of a healthcare workers' union | Interview 8 months after randomization<br>Claims data collected for 2 years after enrollment<br>59/490 (12%) did not complete second survey; medical claims data available for all patients randomized | Sequence generation: adequate<br>Allocation concealment: adequate<br>Blinding: data collectors were blind to condition<br>Incomplete outcome data: follow-up survey data missing for 12%<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Myers, 2011[34] (United States ) Decision Counseling Trial (DCT) | PSA | Men 50 to 69 years old, no history of prostate cancer or benign prostatic hyperplasia, no PSA test in past 11 months | I: Structured decision counseling session (mean of 28 minutes) about prostate cancer screening plus generic note in medical chart to prompt physician to discuss prostate cancer (n=156)<br>C: practice quality assessment survey (to match face time of intervention group) plus generic note in chart to prompt discussion of prostate cancer screening (n=157)<br>All patients received a 12 page informational brochure on prostate cancer and screening | Age (yr): 56<br>Gender (Male %): 100<br>Race/Ethnicity (%): while 56, non-white 43<br>Previous Screen (%): NR | 2 primary care practice sites | Telephone survey about 7 days after office visit<br>Medical records review about 120 days after visit<br>Primary outcomes: data for 91%<br>IDM outcome: data for 43% (required consent to audiotape)<br>Screening outcome: data for 97% | Sequence generation: unclear<br>Allocation concealment: unclear<br>Blinding: NR<br>Incomplete outcome data: 9% missing data for primary outcome (reasons not reported)<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |
| Partin, 2004[35] Partin 2006[36] (United States) | PSA | Male veterans, age 50 and older, no prostate cancer, scheduled for general internal medicine appointment | I1: pamphlet (developed for study) (n=384)<br>I2: video (23 min; developed by FIMDM) (n=384)<br>C: usual care (n=384) | Age (yr): 68<br>Gender (Male %): 100<br>Race/Ethnicity (%): non-Caucasian 5<br>Previous Screen (%): 70 | General internal medicine clinics at 4 VA facilities | Telephone survey 1 week after visit<br>Medical record review at 2 weeks and 1 year<br>42/1152 (4%) found to be ineligible; 893/1110 (80%) completed follow-up survey | Sequence generation: adequate<br>Allocation concealment: unclear<br>Blinding: providers and outcomes assessors were blinded<br>Incomplete outcome data: outcome data for 76% of patients randomized; explained<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Schapira, 2000[37] (United States) | PSA<br>DRE | Men aged 50 to 80 years; outpatient encounter at VA Medical Center<br><br>Excluded: history of prostate or other cancer, previous prostate ultrasound study or biopsy, cystoscopy, prior prostate surgery, active genitourinary symptoms, cognitive impairment, expected life expectancy <2 years, employee of the VA Medical Center | I: Pamphlet – decision aid with information about screening and treatment (plus educational information included in comparator pamphlet) (8 pages) (n=122)<br><br>C: Pamphlet – basic prostate cancer information (no information on risks and benefits of screening) (5 pages) (n=135) | Age (yr): 70<br>Gender (Male %): 100<br>Race/Ethnicity (%): white 92, black 3<br>Previous Screen (%): NR | VA Medical Center outpatient clinic | Post-intervention<br><br>Follow-up visit 2 weeks after initial study visit | Sequence generation: Unclear<br>Allocation concealment: Unclear<br>Blinding: Unclear<br>Incomplete outcome data: No<br>Selective outcome reporting: Not all items from belief assessment were reported<br>**Risk of Bias: Moderate** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Sheridan, 2012[38] (United States) (NOTE: study was originally designed as 2 studies – 1) intervention vs attention control [highway safety video] and 2) intervention plus additional information on 2 other men's health screening services vs attention control [highway safety video]; results were combined) | PSA | Men who were age-eligible for prostate cancer screening (40-80 years old, no prior history of prostate cancer, seen in the practice for at least 1 year, physician agreed to participate in study<br>Excluded: acute medical visit, evidence of serious medical illness | I: Video, coaching session, brochure (n=60)<br>C: educational video on highway safety (n=70) | Age (yr): 58<br>Gender (Male %): 100<br>Race/Ethnicity (%): white 64, African American 18<br>Previous Screen (%): 52 (44 intervention, 59 control) | 4 Internal medicine practices (1 academic, 1 community in 2 cities) | Follow-up questionnaires a. post-intervention b. post-appointment (same day)<br>Review of medical records approximately 9 months after visit to determine whether screening was done<br>Withdrawals: 2/130 (1.5%) from intervention group | Sequence generation: Adequate<br>Allocation concealment: Unclear<br>Blinding: physicians were unaware of patient group assignment<br>Incomplete outcome data: Yes – no data from 2 patients<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |
| Taylor, 2013[39] (United States) | PSA, DRE | Men age 45-70, English speaking, ability to provide informed consent, independent living, appointment in next 24 months<br>Excluded: history of prostate cancer | I1: Web DA (n=625)<br>I2: Print DA (n=628)<br>C: UC (n=626) | Age (yr): 56.9<br>Gender (Male %): 100<br>Race/Ethnicity (%): white 56.2, African American 39.9, other 3.9<br>Previous Screen (%): 86.3 | 3 health systems in 1 city | Follow up at 1 month and 13 months<br>Retention rate 1 month 89%, 13 months 84% | Sequence generation: Adequate<br>Allocation concealment: Unclear<br>Blinding: yes<br>Incomplete outcome data: Yes – Retention rate 1 month 89%, 13 months 84%<br>Selective outcome reporting: No<br>**Risk of Bias: Low** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Volk, 1999[40] Volk, 2003[41] (1 year follow-up) (United States) | PSA | Men 45-70 years old, no history of prostate cancer | I: Educational video (from Foundation for Informed Medical Decision Making, Inc.) and accompanying brochure (n=80)<br>C: No intervention before visit; brochure sent after 2 week follow-up assessment (n=80) | Age (yr): 59<br>Gender (Male %): 100<br>Race/Ethnicity (%): white 61, African American 19, Mexican American 16 other 4<br>Previous Screen (%): 41 | Family medicine clinic | Videotape evaluated after viewing<br>2 week follow-up assessment (Volk 1999)<br>1 year follow-up[ assessment (Volk 2003)<br>Withdrawals at 2 weeks: 2/160 (1.3%) from intervention group<br>Withdrawals at 1 year (total): 23/160 (14%) | Sequence generation: Adequate<br>Allocation concealment: Adequate<br>Blinding: Physicians were unaware of patient assignment; interviewers and patients were not blinded<br>Incomplete outcome data: Yes – no data from 2 intervention group patients (1 died, 1 unavailable)<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |
| Volk, 2008[42] (United States) | PSA | Men 50 to 70 years old if not African American (40 to 70 if African American), visit to clinic for non-acute care, no history of prostate cancer | I: Interactive multimedia decision aid (n=224; 76 at low literacy site, 148 at high literacy site)<br>C: Audiobooklet without interactivity and entertainment factors (n=226; 73 at low literacy site, 153 at high literacy site) | *Patients completing 2 week follow-up*<br>n=89 at low literacy site<br>Age (yr): 56<br>Gender (Male %): 100<br>Race/Ethnicity (%):African American 73, , Hispanic 9, white 18<br>Previous Screen (%): 37<br>n=263 at high literacy site<br>Age (yr): 57<br>Gender (Male %): 100<br>Race/Ethnicity (%):African American 17 , Hispanic 8, white 65<br>Previous Screen (%): 75% | General medicine clinic at publicly funded hospital (low health literacy site) and university-affiliated family medicine clinic (high health literacy site) | Post-intervention and 2 weeks<br>Withdrawals: 13/450 (2.9%) at post-intervention follow-up<br>85/437 (19%) at 2 week follow-up<br>98/450 (21.8%) total (including 16% from high literacy site and 40% from low literacy site) | Sequence generation: Unclear<br>Allocation concealment: Unclear<br>Blinding: Unclear<br>Incomplete outcome data: Total of 21.8% lost at 2 week follow-up<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Watson, 2006[43] (United Kingdom) | PSA | Men age 40 to 75 years, no history of prostate cancer | I: Copy of brief patient decision aid and questionnaire (n=980 randomized; 468 analyzed)<br>C: Questionnaire only (n=980 randomized, 522 analyzed) | Age (yr): sample was stratified by age group (40-49, 50-59, 60-69, 70-75)<br>Gender (Male %): 100<br>Race/Ethnicity (%): white 97%, black 1%, Asian 1%<br>Previous Screen (%): 16 | 11 general practices in England and Wales | Intervention and control components were sent to patients followed by a single reminder<br>5.6% did not receive intervention<br>54% of delivered questionnaires were returned and eligible<br>7 questionnaires (of 475 returned by intervention group) were excluded; no exclusions in control group | Sequence generation: Adequate<br>Allocation concealment: Adequate (mailed intervention)<br>Blinding: N/A – self-administered questionnaire<br>Incomplete outcome data: Yes<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |

| AUTHOR, YEAR (COUNTRY) | SCREENING OPTIONS | TARGET POPULATION | INTERVENTION (I) (n) COMPARATOR (C) (n) | SAMPLE CHARACTERISTICS | SETTING | LENGTH OF FOLLOW-UP % WITHDRAWALS | RISK OF BIAS |
|---|---|---|---|---|---|---|---|
| Wilkes, 2013[44] (United States) | PSA | Men age 55 to 65 years, no serious comorbidity, English speaking | I1: Interactive Web-based educational program (MD-Ed); 30 min (19 waiting areas; 41 physicians with 246 patients)<br>12: MD-Ed plus Web-based patient activation (30 min) (MD-Ed+A) (19 waiting areas; 36 physicians with 113 patients)<br>C. usual practice (17 waiting areas; 43 physicians with 353 patients)<br>All patients had access to CDC brochure in waiting area | *Patients (n=581 analyzed)*<br>Age (yr): 63<br>Gender (Male %): 100<br>Race/Ethnicity (%): 82% white, 8% Hispanic, 8% African American, 5% Asian<br>Previous Screen (%): 83% | 2 large primary care networks associated with academic medical center, 2 staff model HMOs; 1 medical group practice network (all in California) | Length of follow-up: Varied (study complete after standardized patient visit)<br>Withdrawals: No physicians withdrew, 15 (12.5%) did not start intervention and were analyzed with usual practice group<br>14% of patients did not return questionnaire or had incomplete data; additional 5% were found to have prior prostate cancer; 33 patients of physicians who did not start intervention were analyzed with usual practice group | Sequence generation: Adequate<br>Allocation concealment: Adequate<br>Blinding: patients were not aware of physician assignment (cluster randomized trial with waiting areas randomized); physicians were not aware of which patients were involved in the study or who completed the educational program<br>Incomplete outcome data: Yes; 14% of patients did not return questionnaire and 5% who returned questionnaire had prior prostate cancer<br>Selective outcome reporting: No<br>**Risk of Bias: Moderate** |

k = number of studies; DA=Decision Aid; DRE = digital rectal examination; FIMDM = Foundation for Informed Medical Decision Making, Inc.; HMO = health maintenance organization; PSA = prostate-specific antigen

**Table 12. Characteristics of Interventions from Prostate Cancer Studies**

| AUTHOR, YEAR | DELIVERY MODE | DELIVERY TIMING and LOCATION | VALUES CLARIFICATION EXERCISE | RISK COMM. METHOD | CONSIDERED HEALTH LITERACY or NUMERACY | RESOURCES (COST, STAFF, PHYSICAL) |
|---|---|---|---|---|---|---|
| Davison, 1999[25] | Verbal & written | Before a periodic health examination (PHE)<br>in clinic | None | Not clear | Not clear | Not clear |
| Evans, 2010[26] | Web / text of web | Identified from patient registry but not tied to appointment<br>At home | Decision stacker (web) | Not clear | Not clear | Not clear |
| Frosch, 2003[27] | Web version of video DA | Before health appraisal appointment<br>Anywhere (web)<br>in clinic (video) | None | Not clear | Not clear | Not clear |
| Frosch, 2008[28] | Internet (4 conditions) | 2-3 weeks before Health Appraisal appointment<br>Anywhere | DTM: Time trade off exercise and visual analog ratings | Not clear | Not clear | Not clear |
| Gattellari, 2003[29] | Print – distributed in clinic | Prior to appointment<br>in general practice clinic | Social matching - Series of statements consistent with PSA- - determine which statements "sound like them" | Pictograms and flow diagrams | Flesch-Kinkaid grade level for intervention booklet =7.3<br>Flesch-Kinkaid level for comparison booklet 11.2 | Not clear |
| Gattelari, 2005[30] | Audio, video information packages; Booklets and peer coaching | Not tied to a specific appointment<br>Unclear | None | Not clear | Not clear | Medical peer educators to deliver peer coaching sessions |
| Kripalani, 2007[31] | Pamphlets (High-detail, low-detail) | In waiting room before appointment | No | Pictograph | Written at 6th grade level, designed for low-literacy patients; assessed subject literacy | Trained interviewers |
| Krist, 2007[32] | Internet or paper version | Within 2 weeks of visit<br>Home | None | Not clear | Not clear | Not clear |

| AUTHOR, YEAR | DELIVERY MODE | DELIVERY TIMING and LOCATION | VALUES CLARIFICATION EXERCISE | RISK COMM. METHOD | CONSIDERED HEALTH LITERACY or NUMERACY | RESOURCES (COST, STAFF, PHYSICAL) |
|---|---|---|---|---|---|---|
| Lepore, 2012[33] | Telephone (Initial 20 min call, brief follow-up call approx. 1 week later) | Health insurance o appointment<br>Home | Interventionists described 5 potential risks and 5 potential benefits of testing and asked participant after each one whether the information influenced interest in getting tested | Not clear | Pamphlet was designed for men with low literacy<br>Knowledge test items were piloted to ensure comprehension | Telephone interventionists (graduate level health-educators) |
| Myers, 2011[34] | Face-to-face counseling session | Scheduled visit for non-acute care<br>Clinic | Counseling session included discussion of factors influencing screening decision and relative influence and strength | Not clear | Not clear | Study nurse educator (training sessions and patient sessions) |
| Partin, 2004[35]<br>Partin, 2006[36] | Video or pamphlet | Mailed 2 weeks before appointment<br>Home | None | Not clear | Pamphlet written at 6th grade level<br>Video designed for 100% comprehension at 10th grade level | Not clear |
| Schapira, 2000[37] | Pamphlet | 2 weeks before appointment with physician or research physicians<br>Clinic | None | Pictograph to show frequencies of outcomes per 100 men | Research assistant present and available to answer questions when patients read pamphlets<br>Assessment tools were pilot-tested | Research assistant present |
| Sheridan, 2012[38] | 1. Video (12 minutes)<br>2. Coaching session (8 minutes) led by trained health counselor<br>3. Supplemental brochure | 1 hour prior to appointment<br>Private room at the clinic | a. In video: social matching with 2 men making opposite decisions using the same facts<br>b. In coaching session: men to read series of 2 opposing statements and chose which best represented their thinking | Not clear | Not clear | 1 hour educational session for physicians<br>8 min coaching time |
| Taylor, 2013[39] | Web-based or Print DA | Reviewed at home | Yes | Pictographs | DAs have 8th grade reading level; assessed health-related numeracy | Not clear |

| AUTHOR, YEAR | DELIVERY MODE | DELIVERY TIMING and LOCATION | VALUES CLARIFICATION EXERCISE | RISK COMM. METHOD | CONSIDERED HEALTH LITERACY or NUMERACY | RESOURCES (COST, STAFF, PHYSICAL) |
|---|---|---|---|---|---|---|
| Volk, 1999[40]<br>Volk, 2003[41] (1 year follow-up) | Video (20 min)<br>Or brochure on risks & benefits | Before scheduled office visit<br>In clinic | None | Not clear | Knowledge assessment tool written at 5th grade reading level; Spanish version available if patient requested | Office visit for video |
| Volk, 2008[42] | "Edutainment" decision aid combining storyline with factual medical information | Before scheduled office visit<br>In clinic | Social-matching – patient asked to pick character who most resembles how they feel | Not clear | Had low health literacy and high health literacy sites | Not clear |
| Watson, 2006[43] | Printed material | Not associated with a visit<br>Reviewed at home | None | Not clear | "conformed to accepted standards for the provision of patient information;" decision aid was field-tested with the target population | Not clear |
| Wilkes, 2013[44] | Interactive Web-based education program | Physician education prior to all patient visits (location not specified)<br>Patient education 60 min prior to visit (in clinic) | Educational programs included questions about individual's values and preferences | Visual risk comparison diagrams (MD and patient programs)<br>Vignettes for potential harms (patient program) | Not specified | Research associate to assist patients in completing Web-based program<br>Standardized patients (8 actors, 20 hours of training each, 120 physician visits) |

**Table 13. Decision Quality Outcomes Assessed in Prostate Cancer Studies**

| AUTHOR, YEAR | KNOWLEDGE | | PATIENT ROLE IN DECISION | | VALUES CLARITY | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Davison, 1999[25] | - | - | Active 31/50 (62%)<br>Passive 9/50 (18%)<br>Collaborative 10/50 (20%)<br>Z=-4.07, P < .001 | Active 11/50 (22%)<br>Passive 19/50 (38%)<br>Collaborative 20/50 (40%) | - | - |
| Evans, 2010[26] | *Mean (Range -12 to +12)*<br>Prosdex 4.90<br>Paper 5.40<br>Prosdex vs paper U/mn=0.47 (95%CI 0.39, 0.55), P = .48 | Questionnaire control group (QCG) 2.17<br>Prosdex vs QCG U/mn=0.70 (95%CI=0.62, 0.76), P < .001 | - | - | - | - |
| Frosch, 2003[27] | *Knowledge about prostate cancer screening and testing (0-5 scale):*<br>Pretest 1.84 (0.10)<br>Posttest 1.92 (0.90) | Pretest 2.90 (0.12)<br>Posttest 3.47 (0.12)<br>P < .001 | - | - | - | - |
| Frosch, 2008[28] | Mean (SD) – imputed<br>TDA 8.14 (0.15)<br>DTM 7.69 (0.15)<br>Combined 7.71 (0.15)<br><br>Mean (SD) – complete data<br>TDA 8.65 (0.18)<br>DTM 8.03 (0.18)<br>Combined 8.03 (0.18) | Mean (SD) – imputed<br>7.24 (0.16)<br><br>Mean (SD) – complete data<br>7.49 (0.19) | - | - | *DCS Values clarity subscale*<br>TDA 32.25<br>DTM 36.62<br>Combined 38.24<br><br>TDA vs other groups, P < .05 | *DCS Values clarity subscale*<br>37.93 |
| Gattellari, 2005[29] | Mean<br>6.1 | 4.8<br>P ≤ .001 | *Decisional Control-Patient passive*<br>5/135 (3.7) | *Decisional Control-Patient passive*<br>35/139 (25.2)<br>OR=0.11 (0.04-0.31), P < .001 | - | - |
| Gattellari, 2003[30] | Mean % correct = 50% (no SD provided)<br>P = .049 | Mean % correct = 45% | - | - | Mean (SD)<br>Pretest 2.2 (1.31)<br>Posttest 1.7 (1.4-2.0) | Mean (SD)<br>Pretest 2.4 (1.33)<br>Posttest 1.4 (1.0-1.6) |

| AUTHOR, YEAR | KNOWLEDGE | | PATIENT ROLE IN DECISION | | VALUES CLARITY | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Kripalani, 2007[31] | - | - | *Frequency of prostate cancer discussion with health care provider*<br>PtEd: 50.0%, aOR=1.92 (95%CI 1.01, 3.65), P < .05<br>Cue: 58.0%, aOR=2.39 (95%CI=1.26, 4.52), P = .008<br>*Proportion of patients who initiated the discussion:*<br>PtEd: 47.6%, P < .01<br>Cue: 40.0%, P < .01 | *Frequency of prostate cancer discussion with health care provider*<br>Control: 37.3, P = .03<br>*Proportion of patients who initiated the discussion:*<br>Control: 9.7% | - | |
| Krist, 2007[32] | *% of knowledge questions answered correctly:*<br>Web-based: 69%<br>Brochure: 69% | *% of knowledge questions answered correctly:*<br>Control: 54%<br>P < .001 vs either Web-based or brochure interventions | *CPS (n=431)*<br>Web-based: increased involvement in relative to control (P = .03)<br>A (Complete patient control) = 17%<br>B = 39%<br>C (Collaborative) = 36%<br>D = 3%<br>E (Complete physician control) = 5%<br>Brochure: increased involvement relative to control (P = .03)<br>A = 23%<br>B = 31%<br>C = 36%<br>D = 4%<br>E = 6% | *CPS*<br>Control:<br>A (Complete patient control) = 11%<br>B = 34%<br>C(Collaborative) = 36%<br>D = 10%<br>E (Complete physician control) = 9% | - | |
| Lepore, 2012[33] | *% Correct*<br>Pretest 51.7% (SE 0.012)<br>Posttest 61.6% (SE 0.009) | *% Correct*<br>Pretest 49.6% (SE 0.012)<br>Posttest 54.7% (SE 0.009)<br>Condition by time interaction; P < .001 | *Talked to MD about PC screening*<br>Intervention: 34/215 (15.8%)<br>Exp(B) 2.127, P < .001 | *Talked to MD about PC screening*<br>Control: 18/216 (8.3%) | - | - |
| Myers, 2011[34] | *10 items, range 1 to 10*<br>Baseline: 3.8 (1.9)<br>Endpoint : 5.3 (2.0) | Baseline: 3.6 (2.1)<br>Endpoint: 4.4 (2.1);<br>P = .001 | - | - | - | - |

| AUTHOR, YEAR | KNOWLEDGE | | PATIENT ROLE IN DECISION | | VALUES CLARITY | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Partin, 2004[35]<br>Partin, 2006[36] | *10 items, range 1 to 10*<br>Pamphlet: 7.3 [7.0, 7.5]; P = .001 vs control<br>Video: 7.4 [7.2, 7.7];<br>P = .03 vs control | Usual care: 6.9 [6.7, 7.1] | *Discussed PSA*<br>Video: 35%<br>P = .33 vs control<br>Pamphlet: 41%<br>P = .03 vs control | *Discussed PSA*<br>Control: 32% | - | - |
| Schapira, 2000[37] | *18 items*<br>Baseline: 11.7 (2.4)<br>Post-intervention: 15 (2.3) | *18 items*<br>Baseline: 11.4 (2.4);<br>P = .32<br>Post-intervention: 14.1 (2.7); P < .01 | - | - | - | - |
| Sheridan, 2012[38] | *% men have "key knowledge" (correct responses to 4 key questions)*<br>47% (27/58) | *% men have "key knowledge" (correct responses to 4 key questions)*<br>13% (9/70)<br>Absolute difference 34% [95%CI 19, 50]<br>aRR 4.28 [95% CI 2.30, 6.45] | *% men reporting shared decisions, post-visit*<br>74% (28/38) | *% men reporting shared decisions, post-visit*<br>76% (39/51)<br>Absolute difference -3% [95% CI -21, +15%]<br>aRR 0.96 [95%CI 0.67, 1.15] | *'PSA is a Decision' score*<br>64% (37/58) | *'PSA is a Decision' score*<br>23% (16/70)<br>Absolute difference 41% [95% CI 25, 57%]<br>aRR 2.79 [95%CI 1.96, 3.47] |
| Taylor, 2013[39] | *PCa screening knowledge, mean (SD)*<br>*1 mo*<br>Web DA: 13.5 (3.4)<br>Print DA: 13.5 (3.5)<br>Print vs web P = .90<br>*13 mo*<br>Web DA: 12.6 (3.4)<br>Print DA: 12.7 (3.3)<br>Print vs web P = .65 | *PCa screening knowledge, mean (SD)*<br>*1 mo*<br>11.1 (3.1)<br>UC vs web P = .001<br>UC vs print P = .001<br>*13 mo*<br>11.0 (3.0)<br>UC vs web P = .001<br>UC vs print P = .001 | - | - | - | - |
| Volk, 1999[40]<br>Volk, 2003[41] (1 year follow-up) | Baseline: 2.7 (of 10 questions) correct<br>2 weeks: 4.8<br>Change: +2.1, P = .001<br>1 year follow-up: 3.8 (of 10 questions) correct | Baseline: 2.8 (of 10 questions) correct<br>2 weeks: 3.1<br>Change: +0.3, P = .19<br>1 year follow-up: reported unchanged<br>Across data collection periods: P < .001 for group differences | - | - | - | - |

| AUTHOR, YEAR | KNOWLEDGE | | PATIENT ROLE IN DECISION | | VALUES CLARITY | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Volk, 2008[42] | Both low- and high-literacy site patients had significant improvements in knowledge regardless of decision aid received; no significant differences between the decision aids in subject's knowledge gains | | *PSAS-Low Literacy Site*[a]<br>Total: 1.66 [1.56, 1.76]<br>*PSAS-High Literacy Site*[a]<br>Total: 2.41 [2.34, 2.47] | *PSAS-Low Literacy Site*<br>Total: 1.75 [1.67,1.84]; P=0.15<br>*PSAS-High Literacy Site*<br>Total: 2.45 [2.39, 2.47]; P = .38 | - | - |
| Watson, 2006[43] | *U.K. specific measure developed for the study (12 items)*<br>Median 9.0 (range 0-12) | *U.K. specific measure developed for the study (12 items)*<br>Median 3.0 (range 0-12); P < .0001) | Patient makes decision: 106/985 (11%)<br>Patient makes decision after considering doctor's opinion: 421/985 (43%)<br>Shared decision: 324/985 (33%)<br>Doctor makes final decision after considering patient's opinion: 64/985 (6%)<br>Doctor makes decision: 70/985 (7%) | | Decisional balance score (mean)<br>-3.5 (SE 0.9) | +3.3 (SE 0.8);<br>P < .0001 indicating less favorable assessment of the "pros" of screening vs the "cons" in the intervention group |
| Wilkes, 2013[44] | - | - | *Physician report: Change in Shared Decision Making (Kaplan Scale), sum mean score (SD)*<br>MD-Ed: 0.2 (1.5)<br>(AMD -0.05 [-0.72, 0.61] vs control)<br>MD-Ed+A: 0.1 (1.5)<br>(AMD -0.10 [-0.77, 0.56] vs control)<br><br>*Patient report: Perception of shared decision making post-visit*[b]<br>MD-Ed: 11.4 (3.0)<br>(AMD -0.29 [-1.30, 0.71] vs control)<br>MD-Ed+A: 12.3 (3.0)<br>(AMD 0.87 [-0.17, 1.90] vs control) | *Physician report: Change in Shared Decision Making (Kaplan Scale), sum mean score (SD)*<br>Control: 0.2 (1.5)<br><br>*Patient report: Perception of shared decision making post-visit*<br>Control: 11.8 (3.0) | - | - |

aOR = adjusted odds ratio; aRR = adjusted risk ratio; AMD = adjusted mean difference; NR = not reported; MD-Ed = physician education; MD-Ed+A = physician education with patient activation

[a] Low literacy version of Patient Self-Advocacy Scale (PSAS) used at low literacy site; standard 12-item version used at high literacy site; lower scores indicate greater self-advocacy but scores across sites should not be compared

[b] Kaplan shared decision making instrument (modified to be specific for prostate cancer screening); sum of 4 elements; 4=strongly disagree, 16=strongly agree

**Table 14. Decision Impact Outcomes Assessed in Prostate Cancer Studies**

| AUTHOR, YEAR) | DECISIONAL CONFLICT[a] | | USE OF HEALTH SERVICES | | DECISION SATISFACTION | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Davison, 1999[25] | 28.52<br>Effect size:<br>*Z*= -3.602, P < .00001 | 35.20 | - | - | - | - |
| Evans, 2010[26] | Prosdex 40.37<br>Paper 38.49<br>Prosdex vs paper U/mn=0.56 (95%CI=0.47-0.64), P = .18 | QCG 47.73<br>Prosdex vs control U/mn=0.32 (95%CI=0.25-0.40), P < .001 | - | - | - | - |
| Frosch, 2003[27] | - | - | - | - | - | - |
| Frosch, 2008[28] | *DCS subscale scores*<br>Feel informed<br>TDA 23.4<br>DTM 27.23<br>Combined 27.3<br>Value clarity<br>TDA 32.3<br>DTM 36.6<br>Combined 38.2<br>Feel supported<br>TDA 30.5<br>DTM 33.8<br>Combined 35.4 | *DCS subscale scores*<br>Feel informed<br>29.7<br>Value clarity<br>37.9<br>Feel supported<br>35.2<br>P < .05 TDA vs other groups for 3 subscales | - | - | - | - |
| Gattellari, 2003[29] | *DCS Uncertainty subscale mean* 8.1 (no sd) p=.93<br>*Factors contributing to uncertainty subscale mean* 21.6 (no SD)<br>P ≤ .001 | *DCS Uncertainty subscale mean* 8.1<br>*Factors contributing to uncertainty mean* 24.3 | - | - | - | - |
| Gattellari, 2005[30] | *Mean score (range 9-45)*<br>*No SD provided*<br>25.4 (95%CI 24.5-26.3) | *Mean score (range 9-45)*<br>*No SD provided*<br>27.8 (95%CI 26.6-29.0), P = .0002 | - | - | - | - |
| Kripalani, 2007[31] | - | - | - | - | - | - |
| Krist, 2007[32] | Web-based: 1.55 (range 1, 2.7)<br>Brochure: 1.54 (range 1, 2.8) | Control: 1.58 (range 1, 3.2)<br>p=NS vs intervention groups | *Patient report of minutes discussing PCa, mean*<br>Internet: 5.1 (range 0, 15)<br>Brochure: 5.3 (range 0, 25) | *Patient report of minutes discussing PCa, mean*<br>UC: 5.2 (range 0, 20)<br>NS | - | - |
| Lepore, 2012[33] | 34.15 (SE 1.64) | 39.85 (SE 1.64)<br>F(1,427)=6.05, P < .05 | | | - | - |

| AUTHOR, YEAR) | DECISIONAL CONFLICT[a] | | USE OF HEALTH SERVICES | | DECISION SATISFACTION | |
|---|---|---|---|---|---|---|
| | Intervention | Control | Intervention | Control | Intervention | Control |
| Myers, 2011[34] | *0-4 (higher scores indicated higher decisional conflict)*<br>*0.29 (0.34)* | 0.32 (0.49)<br>P = .62 | - | - | - | - |
| Partin, 2004[35]<br>Partin, 2006[36] | - | - | - | - | - | - |
| Schapira, 2000[37] | - | - | - | - | - | - |
| Sheridan, 2012[38] | - | - | - | - | - | - |
| Taylor, 2013[39] | *1 mo*<br>Web DA: 12.7 (21.0)<br>Print DA: 12.2 (19.3)<br>Print vs web P = .70<br>*13 mo*<br>Web DA: 11.4 (19.5)<br>Print DA: 10.7 (16.9)<br>Print vs web P = .61 | *1mo*<br>20.0 (23.7)<br>UC vs web P = .001<br>UC vs print P = .001<br>*13 mo*<br>15.0 (21.2)<br>UC vs web P = .001<br>UC vs print P = .001 | - | - | *Satisfaction with Decision Scale*[b]; % high satisfaction:<br>*1 mo*<br>Web DA: 52.2<br>Print DA: 60.4<br>Print vs web P = .01<br>*13 mo*<br>Web DA: 50.4<br>Print DA: 55.7<br>Print vs web P = .10 | *Satisfaction with Decision Scale*; % high satisfaction:<br>*1 mo*<br>45.5<br>UC vs web P = .001<br>UC vs print P = .03<br>*13 mo*<br>49.8<br>UC vs web P = .85<br>UC vs print P = .06 |
| Volk, 1999[40]<br>Volk, 2003[41] (1 year follow-up) | - | - | - | - | *SWD*[b]<br>Mean = 24.3 [23.7, 25.0] | *SWD*<br>Mean = 23.8 [22.9, 24.7] NS |
| Volk, 2008[42] | *Low Literacy Site DCS*[c]<br>Total: 12 [5, 19]<br>*High Literacy Site DCS*[c]<br>Total: 13 [10, 15] | *Low Literacy Site DCS*<br>Total: 22 [15, 28];<br>P = .04<br>*High Literacy Site DCS*<br>Total: 15 [13, 17];<br>P = .15 | - | - | - | - |
| Watson, 2006[43] | - | - | - | - | - | - |
| Wilkes, 2013[44] | - | - | - | - | - | - |

DA = decision aid; NA = not applicable; SA = strongly agree; SD = strongly disagree

[a] Scores are mean of Decisional Conflict Scale (DCS) unless otherwise noted; higher scores indicate greater decisional conflict

[b] Satisfaction with Decision Scale (SWD): 6 items, 5 point scale

[c] Low literacy version (10 item) of DCS used at low literacy site; standard 16-item version used at high literacy site; scores across sites should not be compared

**Table 15. Decision Action Outcomes Assessed in Prostate Cancer Studies**

| AUTHOR, YEAR | SCREENING INTENTION | | SCREENING BEHAVIOR | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| Davison, 1999[25] | - | - | DRE and PSA: 28% | DRE and PSA: 21%<br>"no significant differences" |
| Evans, 2010[26] | *% men who were very likely to or definitely would get PSA*<br>Prosdex: 40 (n=89)<br>Paper: 53 (n=86)<br>Prosdex vs paper: U/mn=0.43 (95%CI 0.35, 0.51), P = .10 | *% men who were very likely to or definitely would get PSA*<br>QCG: 58 (n=103)<br>Prosdex vs QCG: U/mn=0.40 (95%CI 0.32, 0.48), P = .02 | *6 month PSA uptake - % (n)*<br>Prosdex: 3.1 (4/127)<br>Paper: 9.1 | *6 month PSA uptake - % (n)*<br>QCG: 8.9 (11/123)<br>Prosdex vs QCG: Pearson chi-square P = .014<br>No QCG: 1.6 (2/126) |
| Frosch, 2003[27] | | | 91.9% PSA request | 81.5% PSA request<br>P < .05 |
| Frosch, 2008[28] | - | - | *Reduction in PSA sx pre-post (%)*<br>TDA 9.1<br>DTM 8.7<br>Combined 5.3 | *Reduction in PSA sx pre-post (%)*<br>3.3<br>Single intervention vs combined or control group (OR=3.31, 95% CI 1.01, 10.74, P = .047) |
| Gattellari, 2005[29] | *Would not opportunistically discuss PSA*<br>112/135 (83)<br>*Would not opportunistically sx*<br>102/135 (75.6)<br>*Would not order PSA for men with LUTS*<br>90/135 (66.7) | *Would not opportunistically discuss PSA*<br>93/140 (66.4)<br>*Would not opportunistically sx*<br>41/140 (29.3)<br>*Would not order PSA for men with LUTS*<br>4/140 (2.9) | *Median # tests ordered per provider (IQR)*<br>1 (0-2) | *Median # tests ordered per provider (IQR)*<br>2 (0-5)<br>RR 0.52 (95% CI 0.38, 0.75), P = .0004 |
| Gattellari, 2003[30] | Definitely interested in PSA in next 12 months 27/106 (26%)<br>Quite a lot 11/106 (11%)<br>Somewhat 19/106 (18%)<br>Definitely not interested in PSA in next 12 months 23/106 (22%) | Definitely interested in PSA in next 12 months 25/108 (23%)<br>Quite a lot 14/108 (13%)<br>Somewhat 21/108 (20%)<br>Definitely not interested in PSA in next 12 months 25/108 (23%) | - | - |
| Kripalani, 2007[31] | - | - | *PSA test ordered, % (N)*<br>PtEd 14.1% (12)<br>vs control: aOR=7.62, 95%CI 1.62, 35.83, P = .01<br>Cue 12.3% (10)<br>vs control: aOR=5.86, 95%CI 1.24, 27.81, P = .03<br>*DRE documented, % (N)*<br>PtEd 4.7% (4)<br>vs control: aOR=0.85, 95%CI 0.21, 3.37, P = .81<br>Cue 6.2% (5)<br>vs control: aOR=1.04, 95%CI 0.29, 3.76, P = .95 | *PSA test ordered, % (N)*<br>2.4% (2)<br>*DRE documented, % (N)*<br>6.0 (5) |

| AUTHOR, YEAR | SCREENING INTENTION | | SCREENING BEHAVIOR | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| Krist, 2007[32] | - | - | *PSA test ordered*<br>Web-based<br>Patient report: 86%<br>Physician report: 86% (P = .06 vs control)<br>Brochure<br>Patient report: 83%<br>Physician report: 85% (P = .04 vs control) | Control<br>Patient report: 85%<br>Physician report: 94% (P = .06 for patient vs physician) |
| Lepore, 2012[33] | Plan to test for prostate cancer<br>Pretest: 61%<br>Posttest: 81% | Plan to test for prostate cancer<br>Pretest: 59%<br>Posttest: 81%<br>P = ns | *Verified PSA*<br>1 year: 45%<br>2 year: 63% | *Verified PSA*<br>1 year: 46%<br>2 year: 67%<br>P = ns |
| Myers, 2011[34] | - | - | *Within 120 days of visit*<br>63% (n=152)<br>*Visit with physician aware of screening controversy:* 64%<br>*Visit with physician unaware of screening controversy*: 60% | *Within 120 days of* visit<br>71% (n=153)<br>OR 0.67 [0.41, 1.08]; P = .102<br>*Physician aware of controversy:* 81% (P = .004)<br>*Physician unaware of controversy:* 50% (P = .37) |
| Partin, 2004[35]<br>Partin, 2006[36] | Intend to have PSA in next year<br>Video: 63%; P < .05 vs control<br>Pamphlet: 65%; P < .05 vs control | Control: 74% | *PSA within 2 weeks*<br>Video: 29%<br>Pamphlet: 28%<br>*PSA within 1 year*<br>Video: 70%<br>Pamphlet: 67% | *PSA within 2 weeks*<br>Control: 29%<br>*PSA within 1 year*<br>Control: 69%<br>All P = ns |
| Schapira, 2000[37] | - | | *Prostate cancer screening completed*<br>82% | 84% (P = .60) |
| Sheridan, 2012[38] | 26/58 (45%) | 55/70 (79%)<br>Absolute difference -34% [-50, -18]<br>aRR 0.18 [0.06, 0.48] | *After visit*<br>4/58 (11%)<br>*At 9 month review*<br>11/58 (19%) | *After visit*<br>16/70 (31%)<br>Absolute difference -21% [-38, -4]<br>aRR 0.42 [0-.14, 1.24]<br>*At 9 month review*<br>29/70 (41%)<br>Absolute difference -22% [-38, -7]<br>aRR 0.76 [0.50, 0.97] |
| Taylor, 2013[39] | - | - | *Self-reported screening (PSA or DRE), % (n)*<br>Web DA: 59.3 (258)<br>Print DA: 59.5 (282)<br>Web vs Print P = .95 | *Self-reported screening (PSA or DRE), % (n)*<br>56.3 (281)<br>Wed vs UC P = .35<br>Print vs UC P = .25 |

| AUTHOR, YEAR | SCREENING INTENTION | | SCREENING BEHAVIOR | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| Volk, 1999[40] Volk, 2003[41] (1 year follow-up) | Preferring to have PSA test<br>Baseline: 62/78 (79%)<br>2 weeks: 48/78 (62%)<br>P = .01 | Preferring to have PSA test<br>Baseline: 62/80 (78%)<br>2 weeks: 64/80 (80%)<br>P = .82<br>Absolute difference 18.5% [4.6, 32.4]; P = .009 | *During 1 year follow-up*<br>DRE: 26/70 (37%)<br>PSA: 24/70 (34%) | *During 1 year follow-up*<br>DRE: 26/67 (39%); P = .84<br>PSA: 37/67 (55%); P = .01 |
| Volk, 2008[42] | - | - | - | - |
| Watson, 2006[43] | 119/465 (25.6%) reported positive testing intentions | 149/512 (29.1%) reported positive testing intentions<br>OR 0.82 [0.61, 1.09]; P = .17 | - | - |
| Wilkes, 2013[44] | - | - | Reported that PSA tests were ordered for 32% of patients overall with similar frequency among groups | |

k = number of studies; DRE = digital rectal examination; FOBT = fecal occult blood test; W&S = wait and see; BE = barium enema; COL = colonoscopy; PSA = prostate specific antigen; ns = not statistically significant; OR = odds ratio; aOR = adjusted odds ratio; aRR = adjusted risk ratio; sx = screen

# APPENDIX E. DECISION QUALITY AND DECISION IMPACT MEASURE PATTERNS IN INCLUDED STUDIES

| Measure | Measure Description | SDM Intervention ↑ | No Intervention Effect | SDM Intervention ↓ |
|---|---|---|---|---|
| **Decision Quality** | | | | |
| *Knowledge* | | | | |
| Investigator-developed measure | (number of items) | Evans 2010 (12)[26]<br>Frosch 2003 (5)[28]<br>Gattellari 2005 (7)[29]<br>Lepore 2012 (14)[33]<br>Mathieu 2007 (10)[19]<br>Mathieu 2010 (10)[20]<br>Myers 2011 (10)[34]<br>Schapira 2000 (18)[37]<br>Schroy 2011/2012 (12)[22,23]<br>Taylor 2013 (18)[39]<br>Trevena 2008 (10)[24]<br>Watson 2006 (18)[43] | | |
| Previously validated index (Radosevich 2004)[46] | 10 items; sum of correct responses | Frosch 2008[28]<br>Partin 2004/2006[35,36]<br>Sheridan 2012 (4 items)[38] | | |
| PC-Know (O'Dell 1999);[47] developed for Volk 1999/2003[40,41] | 10 items; scored % of correct answers | Krist 2007[32]<br>Gattellari 2003[29]<br>Volk 1999/2003[40,41] | Volk 2008[42] | |
| *Values Clarity* | | | | |
| Decision Conflict Scale: Values Subscale (O'Connor 1995)[54] | 0-100; values considered "clear" if score is ≤ 25 | Frosch 2008[28] | Trevena 2008[24] | Mathieu 2007[19] |
| Decisional Balance Score (created by authors) | 12 items; Summary measure | Watson 2006[43] | | |
| Dormandy Scale (Dormandy 2006)[48] | 0-100; score≥ 50 = positive mamm. attitudes, score < 50 = negative mammo. attitudes | | Mathieu 2010[20] | |
| Indecision about screening intention | Made a decision about intention | | | Mathieu 2007[19]<br>Mathieu 2010[20] |
| Strength of agreement with PSA, modified from previous attitude measures (Rakowski 1997)[49] | range -5 to +5 | | Gattellari 2003[29] | |
| "PSA is a Decision" item (1 of 3) (McCormack 2011)[50] | 1 item; 5 responses | Sheridan 2012[38] | | |

| Measure | Measure Description | SDM Intervention ↑ | No Intervention Effect | SDM Intervention ↓ |
|---|---|---|---|---|
| *Patient's Role in Decision* | | | | |
| Control Preferences Scale (CPS) (Degner 1992)[51] | 1 item; 5 responses reflecting SDM preference | Davison 1999[25]<br>Gattellari 2005[30]<br>Krist 2007[32] | Sheridan 2012[38]<br>Watson 2006[43] | |
| Discussed PSA | | Kripalani 2007[31]<br>Lepore 2012[33]<br>Partin 2004/2006[35,36] | | |
| Modified from Kaplan's SDM instrument (Kaplan 1995)[45] | Perception of SDM<br>4 4-point scales | | Wilkes 2013[44] | |
| Patient Self Advocacy Scale (PSAS) (Brashers 1999)[52] | 12 item; 5 point scale | | Volk 2008[42] | |
| Patient perception of how screening decision was made (Strull 1984)[53] | 1 item; 5 responses | | Dolan 2002[21] | |
| **Decision Impact** | | | | |
| *Decision Conflict* | | | | |
| Decision Conflict Scale (DCS) (O'Connor 1995)[54] | 16-item; 0 = no decisional conflict, 100 = extreme decisional conflict | | Krist 2007[32]<br>Mathieu 2007[19]<br>Myers 2011[34]<br>Volk 2008[42a] | Davison 1999[25]<br>Dolan 2002[21]<br>Evans 2010[26]<br>Frosch 2008[28]<br>Gattellari 2003[29]<br>Lepore 2012[33]<br>Taylor 2013[39]<br>Volk 2008[42a] |
| Provider Decision Process Assessment Instrument (Dolan 1999)[55] | Extent to which GPs experience uncertainty; 9 items (range 9-45) | | | Gattellari 2005[30] |
| *Decision Satisfaction* | | | | |
| Satisfaction with the Decision-Making Process Scale (SDMP) (Barry 1997)[56] | 12-item; scores range from 5 to 60 | Schroy 2011/2012[22,23] | | |
| Satisfaction with Decision (SWD) (Holmes-Rovner 1996)[57] | 6-item; 5 point responses | Taylor 2013[39b] | Taylor 2013[39b]<br>Volk 1999/2003[40,41] | |
| *Use of Services* | | | | |
| Consultation length | Minutes | | Krist 2007[32] | |

[a] High literacy version of DCS no intervention effect; low literacy version of DCS intervention group lower DCS score
[b] Intervention group had higher SWD scores at time 1 (1 month), but no significant difference at time 2 (13 months)

# APPENDIX F. STRENGTH OF EVIDENCE

| Outcome Category | Outcome (# of Studies Reporting) | Results<br>Shared Decision Making vs Control | Risk of Bias | Consistency | Directness | Precision | Strength of Evidence |
|---|---|---|---|---|---|---|---|
| ***Breast Cancer (k=2)*** | | | | | | | |
| **Decision Quality**<br>***Overall Strength of Evidence: Low*** | **Knowledge (2)** | 77% (Intervention) vs 57% (Control); P = .02 (Mathieu 2007)[19]<br>94% (Intervention) vs 83% (Control); P < .001 (Mathieu 2010)[20] | Moderate (2) | Consistent (based on direction) | Direct | Precise (based on p-values) | Moderate |
| | **Values Clarity (2)** | Means: 19.5 (Intervention) vs 22.6 (Control); P = .02 (Mathieu 2007)[19]<br>Positive values: 79% (Intervention) vs 79% (Control); p=ns (Mathieu 2010)[20] | Moderate (2) | Inconsistent | Direct | Imprecise | Low |
| | **Patient's Role in Decision (0)** | | | | | | Insufficient |
| **Decision Impact**<br>***Overall Strength of Evidence: Insufficient*** | **Decisional Conflict (1)** | Means: 20.1 (Intervention) vs 21.9 (Control); P = .12 (Mathieu 2007)[19] | Moderate | NA | Direct | Unclear | Low |
| | **Use of Services (0)** | | | | | | Insufficient |
| | **Decision Satisfaction (0)** | | | | | | Insufficient |
| **Decision Action**<br>***Overall Strength of Evidence: Low*** | **Screening Intention (2)** | OR=1.28 [0.63, 2.61]; P = .50 (Mathieu 2007)[19]<br>Intention to Screen: 52% (Intervention) vs 65% (Control); P = .05 (Mathieu 2010)[20] | Moderate (2) | Inconsistent | Direct | Imprecise | Low |
| | **Screening Behavior (1)** | Screened: 6% (Intervention) vs 7% (Control); p=ns (Mathieu 2007)[19] | Moderate | NA | Direct | Unclear | Low |
| ***Colorectal Cancer (k=3)*** | | | | | | | |
| **Decision Quality**<br>***Overall Strength of Evidence: Low*** | **Knowledge (2)** | DA: SMD=1.06 [0.88, 1.24] (Schroy 2012)[23]<br>DA+YDR: SMD=0.92 [0.75, 1.10] (Schroy 2012)[23]<br>RR 3.58 [1.69, 7.57] (Trevena 2008)[24] | Moderate (2) | Consistent (based on direction) | Direct | Precise | Moderate |
| | **Values Clarity (1)** | 62% vs 59%, P = .63 (Trevena 2008)[24] | Moderate | NA | Direct | Unclear | Low |
| | **Patient's Role in Decision (1)** | Perception of how screening decision were made:<br>Shared: RR=1.23 [0.85, 1.78] (Schroy 2012)[23]<br>Physician: RR=1.17 [0.43. 3.19] (Schroy 2012)[23]<br>Patient: RR 0.60 [0.29, 1.22] (Schroy 2012)[23] | Moderate | NA | Direct | Imprecise | Low |
| **Decision Impact**<br>***Overall Strength of Evidence: Low*** | **Decisional Conflict (1)** | SMD=-0.29 [-0.74, 0.15] (Dolan 2002)[21] | Moderate | NA | Direct | Imprecise | Low |
| | **Use of Services (0)** | | | | | | Insufficient |
| | **Decision Satisfaction (1)** | DA: SMD=0.59 [0.41, 0.78] (Schroy 2012)[23]<br>DA+YDR: SMD=0.50 [0.32, 0.67] (Schroy 2012)[23] | Moderate | NA | Direct | Precise | Low |

| Outcome Category | Outcome (# of Studies Reporting) | Results<br>Shared Decision Making vs Control | Risk of Bias | Consistency | Directness | Precision | Strength of Evidence |
|---|---|---|---|---|---|---|---|
| **Decision Action**<br>***Overall Strength of Evidence: Low*** | **Screening Intention (3)** | RR=0.48 [0.23, 1.00] (Dolan 2010)[21]<br>DA: SMD=0.30 [0.11, 0.49] (Schroy 2012)[23]<br>DA+YDR: SMD=0.40 [0.21, 0.59] (Schroy 2012)[23]<br>RR=0.96 [0.89, 1.05] (Trevena 2008)[24] | Moderate (3) | Inconsistent | Direct | Imprecise | Low |
| | **Screening Behavior (3)** | RR=0.94 [0.57, 1.53] (Dolan 2012)[21]<br>DA: RR=1.24 [1.00, 1.53] (Schroy 2012)[23]<br>DA+YDR: RR=1.07 [0.86, 1.33] (Schroy 2012)[23]<br>Completed FOBT: 5.2% (Intervention) vs 6.6% (Control); P = .64 (Trevena 2008)[24] | Moderate (3) | Inconsistent | Direct | Imprecise | Low |
| ***Prostate Cancer (k=18)*** | | | | | | | |
| **Decision Quality**<br>***Overall Strength of Evidence: Moderate*** | **Knowledge (12)**<br>**Did not include Gattellari 2205 (MDs)**<br>**Volk 2008 (No data – reported improved knowledge with no difference between 2 decision aids)**<br>**Frosch 2003 (Comparison of 2 DAs with greater knowledge in video DA group)** | SMD=0.29 [0.02, 0.56] (Gattellari 2003)[29]<br>SMD=0.36 [0.11, 0.60] (Schapira 2000)[37]<br>48% vs, 31%; P < .001 (Volk 1999/2003)[40,41]<br>Median difference 4.0 [4.0, 5.0] (Watson 2006)[43]<br>Means: 4.90 (Prosdex) vs 5.40 (Paper version) vs 2.17 (Control); P < .001 for Prosdex vs Control (Evans 2010)[26]<br>SMD=0.46 [0.23, 0.69] (Internet vs Control) (Frosch 2008)[28]<br>SMD=0.26 [0.03, 0.48] (CDTM vs Control) (Frosch 2008)[28]<br>Means: 69% (Internet) vs 69% (Brochure), 54% (Control); both P < .001 vs Control (Krist 2007)[32]<br>SMD=0.44 [0.20, 0.67] (Myers 2011)[34]<br>SMD=0.24 [0.10, 0.38] (Video vs UC) (Partin 2004)[35]<br>SMD=0.18 [0.03, 0.32] (Pamphlet vs UC) (Partin 2004)[35]<br>61.6 (Intervention) vs 54.7 (Control); P < .001 (Lepore 2012)[33]<br>AD=34% [19, 50] (Sheridan 2012)[38]<br>SMD=0.54 [0.42, 0.66] (Taylor 2013 Print)[39]<br>SMD=0.50 [0.38, 0.62] (Taylor 2013 Web)[39] | Moderate (11)<br>Low (1) | Generally Consistent (based on direction) | Direct | Generally Precise | Moderate |
| | **Values Clarity (4)** | 1.7 (Intervention) vs 1.4 (Control); P = .056 (Gattellari 2003)[29]<br>-3.5 (Intervention) vs +3.3 (Control) ( P < .0001); SMD==0.37 [-0.50,-0.24] (Watson 2006)[43]<br>Means: 32.3 (Traditional DA) vs 36.6 (CDTM) vs 37.9 (Control); P < .05 TDA vs others (Frosch 2008)[28]<br>RR=2.79 [1.96, 3.47] (Sheridan 2012)[38] | Moderate (4) | Inconsistent | Direct | Imprecise | Low |
| | **Patient's Role in Decision (7)**<br>**Did not include Gattellari 2005 (MDs)**<br>**Volk 2008 (Comparison of 2 DAs with no significant difference)**<br>**Watson 2006 (Baseline only)** | RR=1.28 [1.03, 1.59] (Partin 2004, Pamphlet)[35]<br>RR=1.09 [0.87, 1.37] (Partin 2004, Video)[35]<br>RR=1.55 [1.11,2.17] (Kripalani 2007 Cue)[31]<br>RR=1.34 [0.94,1.90] (Kripalani 2007 Patient Ed)[31]<br>RR=1.22 [0.91, 1.63] (Krist 2007 Active Internet vs UC)[32]<br>RR=1.17 [0.87, 1.58] (Krist 2007 Active Brochure vs UC)[32]<br>Means: 11.4 (MD-Ed) vs 12.3 (MD-Ed+A) vs 11.8 (UC); p=ns (interventions vs control) (Wilkes 2013)[44]<br>RR=2.82 [1.60, 4.96] (Davison 1999 Active)[25]<br>RR=0.90 [1.11, 3.25] (Lepore 2012)[33]<br>RR=0.96 [0.76, 1.23] (Sheridan 2012)[38] | Moderate (6)<br>Low (1) | Inconsistent | Direct | Imprecise | Low |

| Outcome Category | Outcome (# of Studies Reporting) | Results<br>Shared Decision Making vs Control | Risk of Bias | Consistency | Directness | Precision | Strength of Evidence |
|---|---|---|---|---|---|---|---|
| **Decision Impact** ***Overall Strength of Evidence: Low*** | **Decisional Conflict (8)**<br>**Did not include Volk 2008 (Comparison of 2 DAs with significant difference at low literacy site)**<br>**Gattellari 2005 (MDs)** | SMD=0.00 [-0.27, 0.27] (Gattellari 2003)[29]<br>Means: 40.4 (Prosdex) vs 38.5 (Paper version) vs 47.7 (Control); P < .001 (Prosdex vs Control) (Evans 2010)[26]<br>Mean of Reported DCS subscale scores: 28.7 (I1) vs 32.5 (I2) vs 34.3 (UC); P < .05 for I1 vs Control (Frosch 2008)[28]<br>Means: 1.6 (Internet) vs 1.5 (Brochure) vs 1.6 (UC); p=ns (Krist 2007)[32]<br>SMD=-0.07 [-0.30, 0.16] (Myers 2011)[34]<br>Means: 28.5 (Intervention) vs 35.2 (Control); P < .0001 (Davison 1999)[25]<br>SMD=-0.24 [-0.43, -0.05] (Lepore 2012)[33]<br>SMD=-0.22 [-0.34, -0.10] (Taylor 2013 Print)[39]<br>SMD=-0.18 [-0.30, -0.05] (Taylor 2013 Web)[39] | Moderate (7)<br>Low (1) | Inconsistent | Direct | Imprecise | Low |
| | **Use of Services (1)** | Means: 5.1 (Internet) vs 5.3 (Brochure) vs 5.2 (UC); p=ns (Krist 2007)[32] | Moderate (1) | NA | Direct | Precise | Low |
| | **Decision Satisfaction (2)** | Means: 24.3 (Intervention) vs 23.8 (Control); p=ns (Volk 1999/2003)[40,41]<br>RR=1.12 [0.99, 1.26] (Taylor 2012 Print)[39]<br>RR=1.01 [0.89, 1.15] (Taylor 2012 Web)[39] | Moderate (1)<br>Low (1) | Consistent | Direct | Precise | Low |

| Outcome Category | Outcome (# of Studies Reporting) | Results<br>Shared Decision Making vs Control | Risk of Bias | Consistency | Directness | Precision | Strength of Evidence |
|---|---|---|---|---|---|---|---|
| **Decision Action** ***Overall Strength of Evidence: Low*** | **Screening Intention (7)**<br>**Did not include Gattellari 2005 (MDs)** | RR=1.02 [0.88, 1.18] (Gattellari 2003)[29]<br>RR=0.77 [0.63, 0.95] (Volk 1999)[40]<br>RR=0.88 [0.72, 1.08] (Watson 2006)[43]<br>Means: 40% (Prosdex) vs 53% (Paper) vs 58% (Control); P = .02 (Prosdex vs Control) (Evans 2010)[26]<br>RR=0.69 [0.51, 0.94] (Evans 2010 Prosdex vs Control)[26]<br>RR=0.90 [0.69, 1.18] (Evans 2010 Paper vs Control)[26]<br>RR=0.85 [0.76, 0.95] (Video vs UC) (Partin 2004)[35]<br>RR=0.89 [0.80, 0.99] (Pamphlet vs UC) (Partin 2004)[35]<br>RR=1.00 [0.91, 1.09] (Lepore 2012)[33]<br>RR=0.57 [0.42, 0.78] (Sheridan 2012)[38] | Moderate (7) | Inconsistent | Direct | Generally Precise | Low |
| | **Screening Behavior (10)**<br>**Did not include Davison 1999 (No statistical test of results possible)**<br>**Frosch 2003 (Comparison of 2 DAs with significantly fewer PSAs in video group)**<br>**Frosch 2008 (Reduction in PSA pre to post)**<br>**Wilkes 2013 (Overall PSA ordering; no data for groups)**<br>**Gattellari 2005 (MDs)** | RR=0.98 [0.88, 1.09] (PSA+DRE) (Schapira 2000)[37]<br>RR=0.62 [0.42, 0.92] (PSA) (Volk 1999)[40]<br>RR=0.96 [0.62, 1.47] (DRE) (Volk 1999)[40]<br>Means: 3% (Prosdex) vs 9% (Paper) vs 9% (Control); P = .014 (Prosdex vs Control) (Evans 2010)[26]<br>RR=0.35 [0.12, 1.08] (Evans 2012 Prosdex vs Control)[26]<br>RR=1.02 [0.46, 2.26] (Evans 2012 Paper vs Control)[26]<br>RR=0.91 [0.84, 0.99] (Internet vs UC) (Krist 2007)[32]<br>RR=0.90 [0.83, 0.98] (Brochure vs UC) (Krist 2007)[32]<br>RR=5.12 [1.18, 22.67] (Kripalani 2007 PSA Cue vs UC)[31]<br>RR=5.86 [1.35, 25.38] (Kripalani 2007 PSA Patient Ed vs UC)[31]<br>RR=1.02 [0.31, 3.41] (Kripalani 2007 DRE Cue vs UC)[31]<br>RR=0.78 [0.22, 2.81] (Kripalani 2007 DRE Patient Ed vs UC)[31]<br>RR=0.88 [0.75, 1.04] (Myers 2011)[34]<br>RR=0.96 [0.86, 1.07] (Video vs UC) (Partin 2004)[35]<br>RR=0.96 [0.86, 1.07] (Pamphlet vs UC) (Partin 2004)[35]<br>RR=0.94 [0.82, 1.08] (Lepore 2012)[33]<br>RR=0.46 [0.25, 0.83] (Sheridan 2012)[38]<br>RR=1.01 [0.91, 1.13] (Taylor 2012 Print)[39]<br>RR=0.97 [0.86, 1.08] (Taylor 2012 Web)[39] | Moderate (8)<br>Low (2) | Inconsistent | Direct | Generally Precise | Low |

k = number of studies; ns = not statistically significant; SMD = standard mean difference; RR = risk ratio; AD = absolute difference; UC = usual care; DA = decision aid; YDR = "Your Disease Risk"; CDTM = Chronic Disease Trajectory Model; MD-Ed = Physicians participated in Web-based educational program ; MD-Ed+A = Physician Web-based educational program plus activated patients (patients who viewed different but related educational program); C1 = control with survey; I1 = traditional decision aid; I2 = chronic disease trajectory model

[a] Standard mean differences and risk ratios were calculated for inclusion on the strength of evidence table if authors provided data necessary for these calculations.

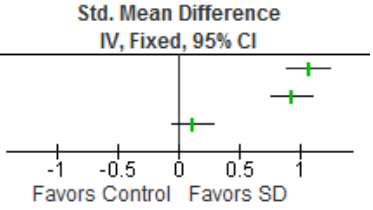
# APPENDIX G. FOREST PLOTS FOR STRENGTH OF EVIDENCE ANALYSIS

## COLORECTAL CANCER

### 1. Knowledge

*Knowledge: CRC Risk Factors*[a,b,c]

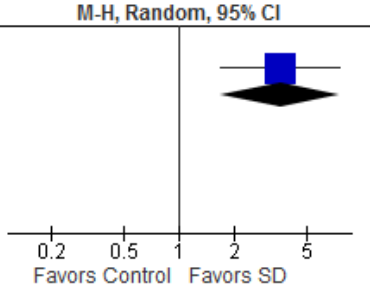
| Study or Subgroup | Shared Decision Mean | SD | Total | Control Mean | SD | Total | Std. Mean Difference IV, Fixed, 95% CI |
|---|---|---|---|---|---|---|---|
| Schroy 2012 DA | 10.9 | 1.6 | 269 | 8.6 | 2.6 | 276 | 1.06 [0.88, 1.24] |
| Schroy 2012 DA+YDR | 10.7 | 1.9 | 280 | 8.6 | 2.6 | 276 | 0.92 [0.75, 1.10] |
| Schroy DA vs DA+YDR | 10.9 | 1.6 | 269 | 10.7 | 1.9 | 280 | 0.11 [-0.05, 0.28] |




[a] Range 0-None Correct to 12-All Correct)
[b] First two comparisons versus control
[c] Schroy 2012[23]

*Adequate Knowledge*[a]

| Study or Subgroup | Shared Decision Events | Total | Control Events | Total | Weight | Risk Ratio M-H, Random, 95% CI |
|---|---|---|---|---|---|---|
| **2.2.1 Adequate Knowledge** | | | | | | |
| Trevena 2008 | 28 | 134 | 8 | 137 | 100.0% | 3.58 [1.69, 7.57] |
| **Subtotal (95% CI)** | | **134** | | **137** | **100.0%** | **3.58 [1.69, 7.57]** |
| Total events | 28 | | 8 | | | |
| Heterogeneity: Not applicable | | | | | | |
| Test for overall effect: Z = 3.34 (P = 0.0008) | | | | | | |



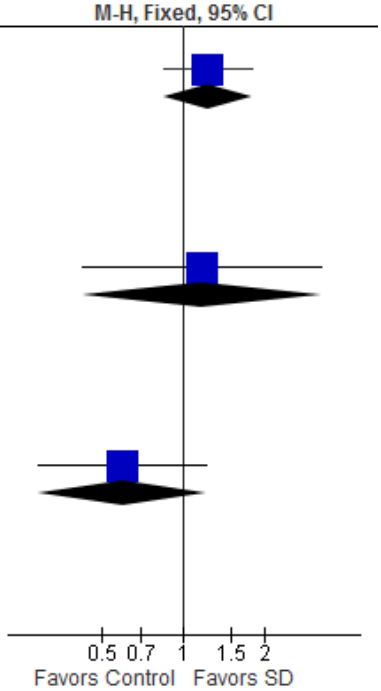

Test for subgroup differences: Not applicable

[a] Trevena 2008[24]

## 2. Patient's Role in Decision

*Perception of How Screening Decisions Were Made*[a]

| Study or Subgroup | Shared Decision Events | Total | Control Events | Total | Weight | Risk Ratio M-H, Fixed, 95% CI |
|---|---|---|---|---|---|---|
| **1.5.1 Shared** | | | | | | |
| Dolan 2002 | 27 | 43 | 22 | 43 | 100.0% | 1.23 [0.85, 1.78] |
| **Subtotal (95% CI)** | | **43** | | **43** | **100.0%** | **1.23 [0.85, 1.78]** |
| Total events | 27 | | 22 | | | |
| Heterogeneity: Not applicable | | | | | | |
| Test for overall effect: Z = 1.08 (P = 0.28) | | | | | | |
| **1.5.2 Primarily physician** | | | | | | |
| Dolan 2002 | 7 | 43 | 6 | 43 | 100.0% | 1.17 [0.43, 3.19] |
| **Subtotal (95% CI)** | | **43** | | **43** | **100.0%** | **1.17 [0.43, 3.19]** |
| Total events | 7 | | 6 | | | |
| Heterogeneity: Not applicable | | | | | | |
| Test for overall effect: Z = 0.30 (P = 0.76) | | | | | | |
| **1.5.3 Primarily patient** | | | | | | |
| Dolan 2002 | 9 | 43 | 15 | 43 | 100.0% | 0.60 [0.29, 1.22] |
| **Subtotal (95% CI)** | | **43** | | **43** | **100.0%** | **0.60 [0.29, 1.22]** |
| Total events | 9 | | 15 | | | |
| Heterogeneity: Not applicable | | | | | | |
| Test for overall effect: Z = 1.41 (P = 0.16) | | | | | | |



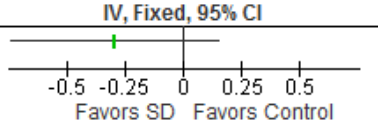

Test for subgroup differences: Chi² = 3.10, df = 2 (P = 0.21), I² = 35.5%

[a] Dolan 2002[21]

## 3. Decisional Conflict

*Decisional Conflict Scale (Lower Score = Better Decision Making Process)*[a,b]

| Study or Subgroup | Shared Decision Mean | SD | Total | Control Mean | SD | Total | Std. Mean Difference IV, Fixed, 95% CI |
|---|---|---|---|---|---|---|---|
| Dolan 2002 | 1.83 | 0.52 | 41 | 2.03 | 0.81 | 37 | -0.29 [-0.74, 0.15] |



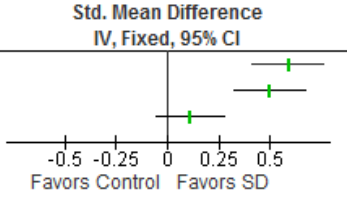

[a] Note: scores reversed from how reported in paper so effect size is now a negative number)

[b] Dolan 2002

## 4. Decision Satisfaction

*Satisfaction with the Decision-Making Process Scale (SDMP)*[a,b,c]

| Study or Subgroup | Shared Decision Mean | SD | Total | Control Mean | SD | Total | Weight | Std. Mean Difference IV, Fixed, 95% CI |
|---|---|---|---|---|---|---|---|---|
| Schroy 2012 DA | 49.7 | 6.4 | 262 | 45.5 | 7.8 | 261 | | 0.59 [0.41, 0.76] |
| Schroy 2012 DA+YDR | 49 | 6.2 | 271 | 45.5 | 7.8 | 261 | | 0.50 [0.32, 0.67] |
| Schroy DA vs DA+YDR | 49.7 | 6.4 | 262 | 49 | 6.2 | 271 | | 0.11 [-0.06, 0.28] |




[a] 12 items, each scored from 1 (strongly disagree or "poor") to 5 (strongly agree or "excellent") with a maximum score of 60

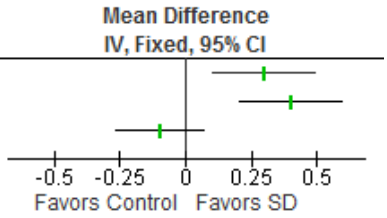
[b] First two comparisons versus control

[c] Schroy 2012[23]

## 5. Screening Intention

### *Intention to Complete Screening Test*[a,b,c]

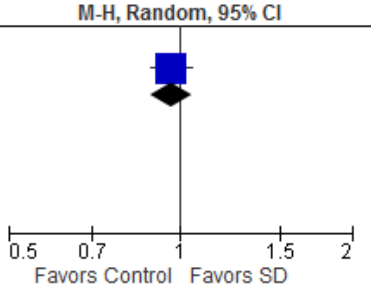
| Study or Subgroup | Shared Decision Mean | SD | Total | Control Mean | SD | Total | Mean Difference IV, Fixed, 95% CI |
|---|---|---|---|---|---|---|---|
| Schroy 2012 DA | 4.3 | 1 | 269 | 4 | 1.3 | 276 | 0.30 [0.11, 0.49] |
| Schroy 2012 DA+YDR | 4.4 | 1 | 280 | 4 | 1.3 | 276 | 0.40 [0.21, 0.59] |
| Schroy DA vs DA+YDR | 4.3 | 1 | 269 | 4.4 | 1 | 280 | -0.10 [-0.27, 0.07] |




[a] 5 point scale (1 not sure to 5 completely sure)
[b] First two comparisons versus control
[c] Schroy 2012[23]

### *Screening Intention*[a]

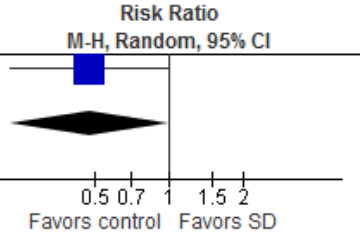
| Study or Subgroup | Shared Decision Events | Total | Control Events | Total | Weight | Risk Ratio M-H, Random, 95% CI |
|---|---|---|---|---|---|---|
| **2.12.2 Intention to Screen: Post-intervention** | | | | | | |
| Trevena 2008 | 117 | 134 | 124 | 137 | 100.0% | 0.96 [0.89, 1.05] |
| **Subtotal (95% CI)** | | **134** | | **137** | **100.0%** | **0.96 [0.89, 1.05]** |
| Total events | 117 | | 124 | | | |
| Heterogeneity: Not applicable | | | | | | |
| Test for overall effect: Z = 0.84 (P = 0.40) | | | | | | |
| Test for subgroup differences: Not applicable | | | | | | |




[a] Trevena 2008[24]

### *Intention to Screen*[a]

| Study or Subgroup | Shared Decision Events | Total | Control Events | Total | Weight | Risk Ratio M-H, Random, 95% CI |
|---|---|---|---|---|---|---|
| Dolan 2002 | 8 | 45 | 16 | 43 | 100.0% | 0.48 [0.23, 1.00] |
| **Total (95% CI)** | | **45** | | **43** | **100.0%** | **0.48 [0.23, 1.00]** |
| Total events | 8 | | 16 | | | |
| Heterogeneity: Not applicable | | | | | | |
| Test for overall effect: Z = 1.96 (P = 0.05) | | | | | | |

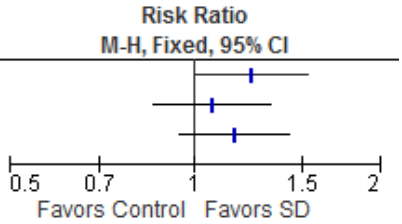



[a] Dolan 2002[21]

## 6. Screening Behavior

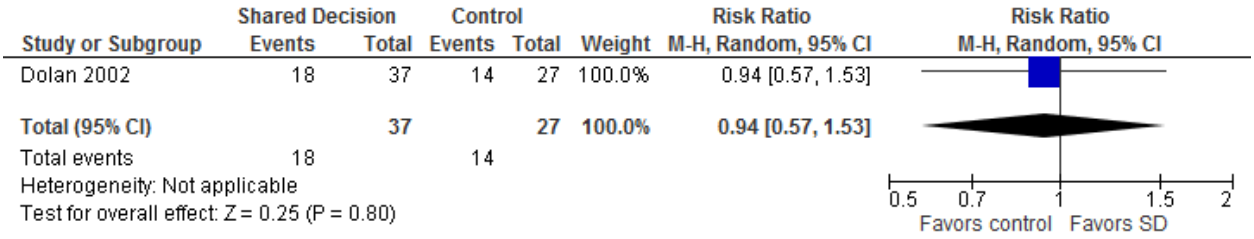
### *Test Completed by 12 Months after Visit*[a,b]

| Study or Subgroup | Shared Decision Events | Total | Control Events | Total | Risk Ratio M-H, Fixed, 95% CI |
|---|---|---|---|---|---|
| Schroy 2012 DA | 116 | 269 | 96 | 276 | 1.24 [1.00, 1.53] |
| Schroy 2012 DA+YDR | 104 | 280 | 96 | 276 | 1.07 [0.86, 1.33] |
| Schroy DA vs DA+YDR | 116 | 269 | 104 | 280 | 1.16 [0.95, 1.43] |




[a] First two comparisons versus control
[b] Schroy 2012[23]

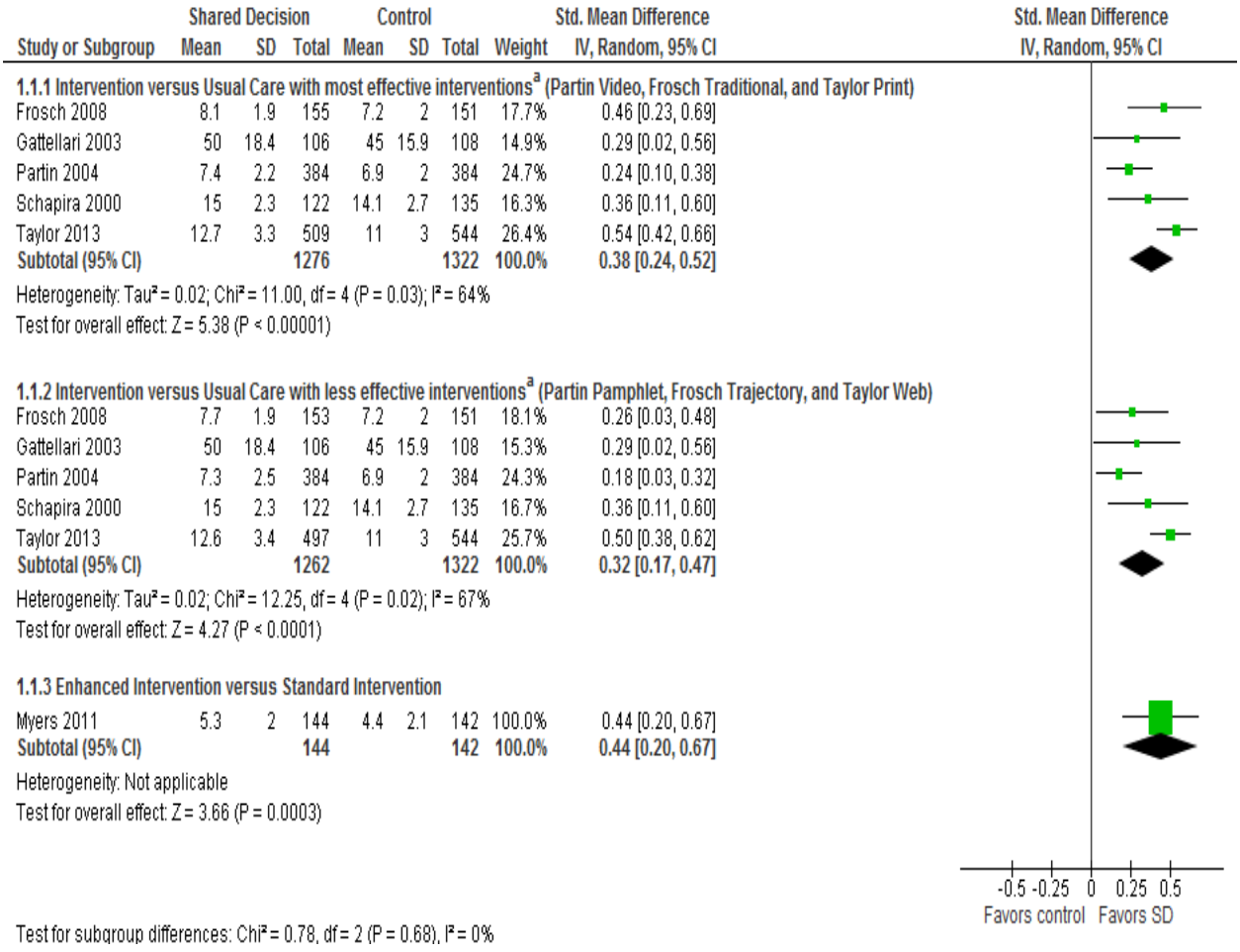
### *Screening Completed*[a]




[a] Dolan 2002[21]

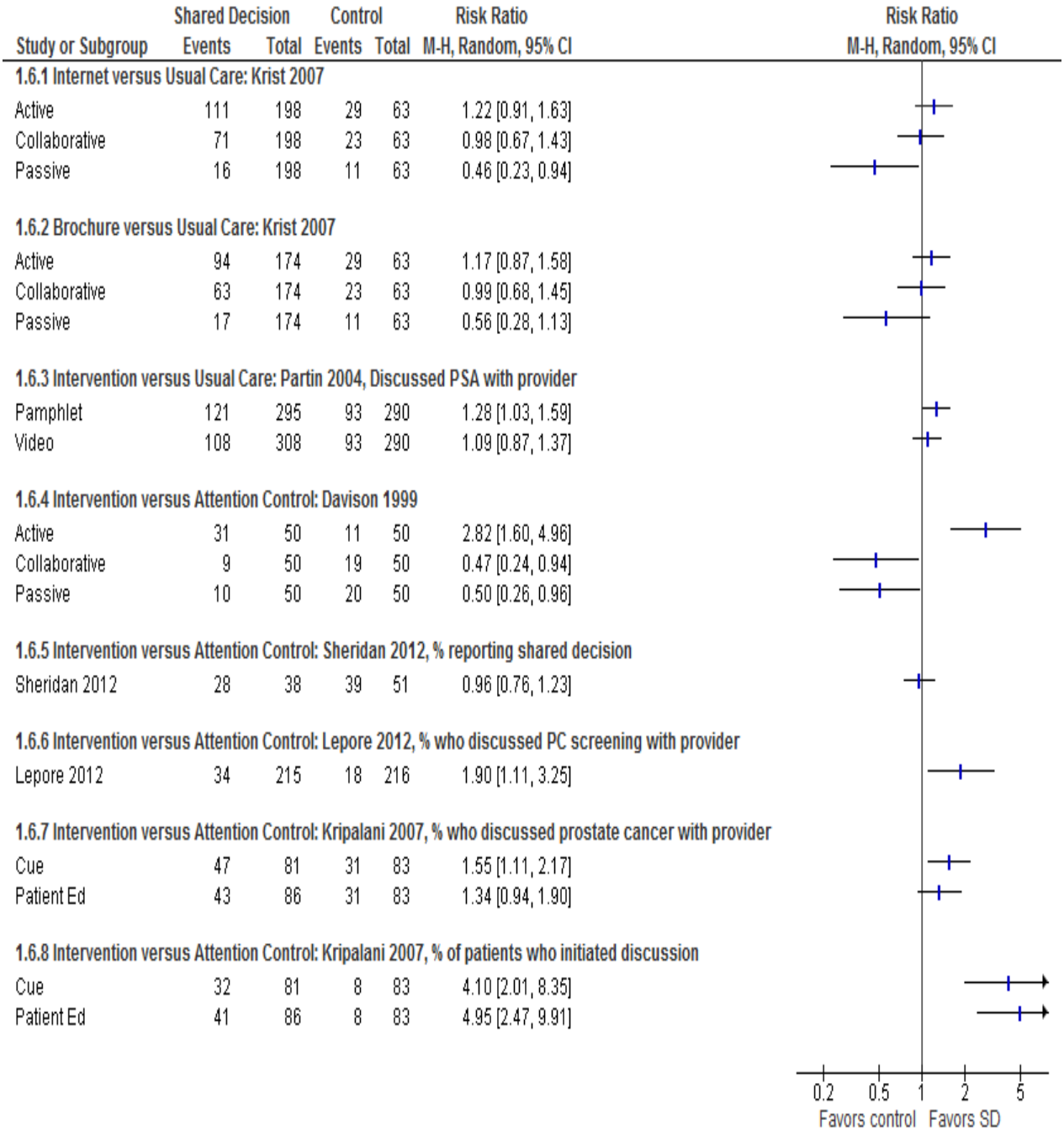
## PROSTATE CANCER

### 1. Knowledge[a,b]



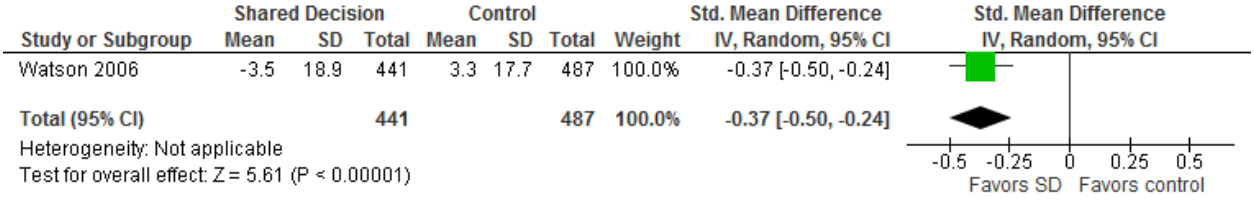

[a] Multi-armed trials
[b] Frosch 2008,[28] Gattellari 2003,[29] Partin 2004,[35] Schapira 2000,[37] Taylor 2013,[39] Myers 2011[34]

## 2. Patient's Role in the Decision - Usual Care Trials[a]



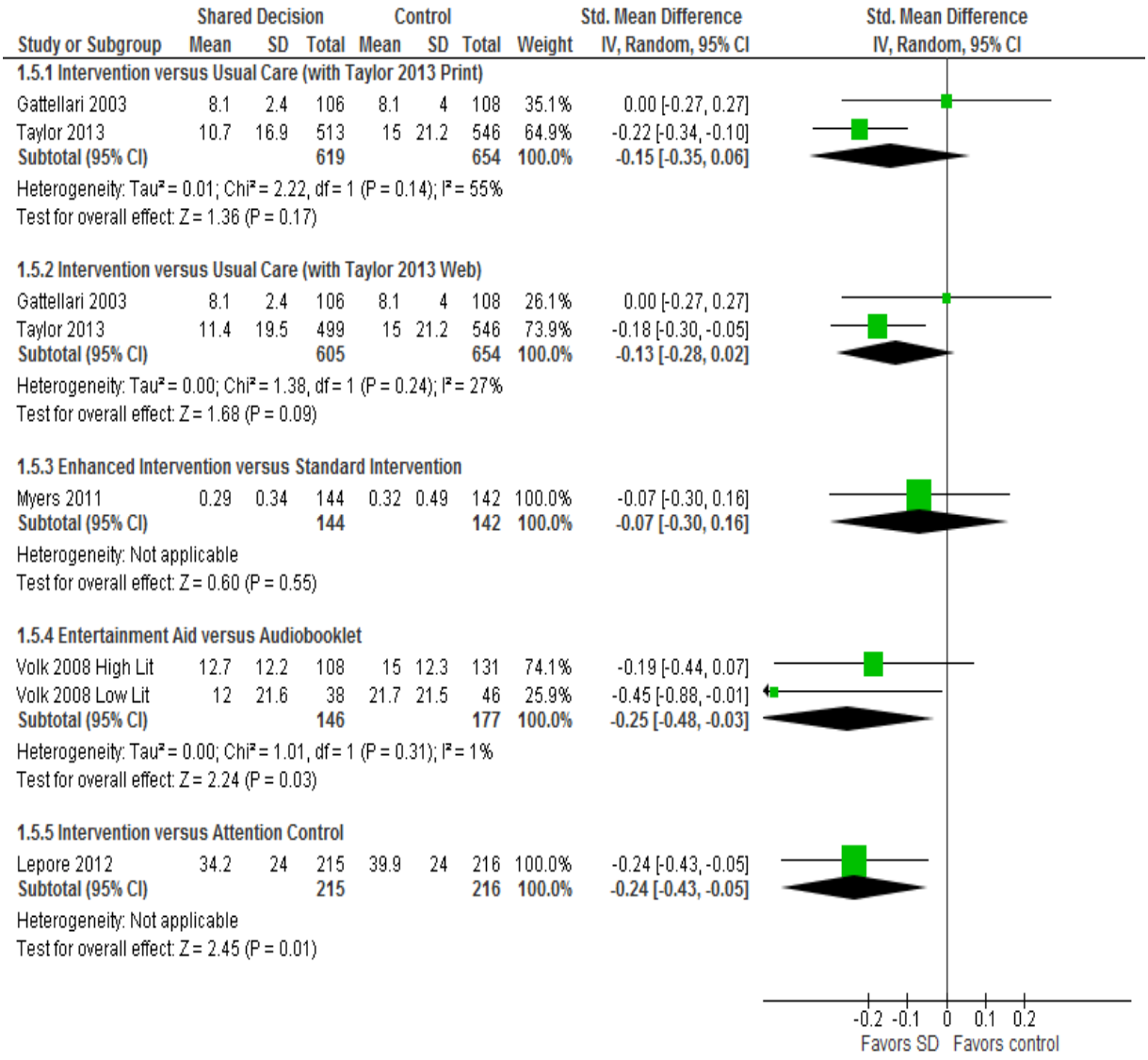

[a] Krist 2007,[32] Partin 2004,[35] Davison 1999,[25] Sheridan 2012,[38] Lepore 2012,[33] Kripalani 2007[31]

## 3. Value's Clarity[a]



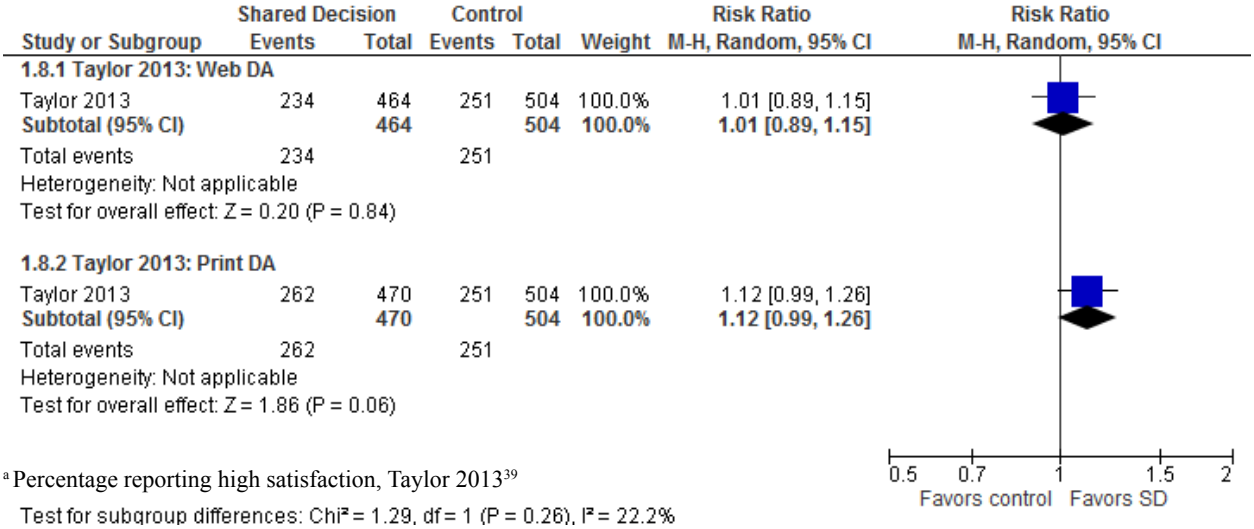

[a] Watson 2006[43]

## 4. Decision Conflict - Usual Care Trials[a]




[a] Gattellari 2003,[29] Taylor 2013,[39] Myers 2011,[34] Volk 2008,[42] Lepore 2012[33]

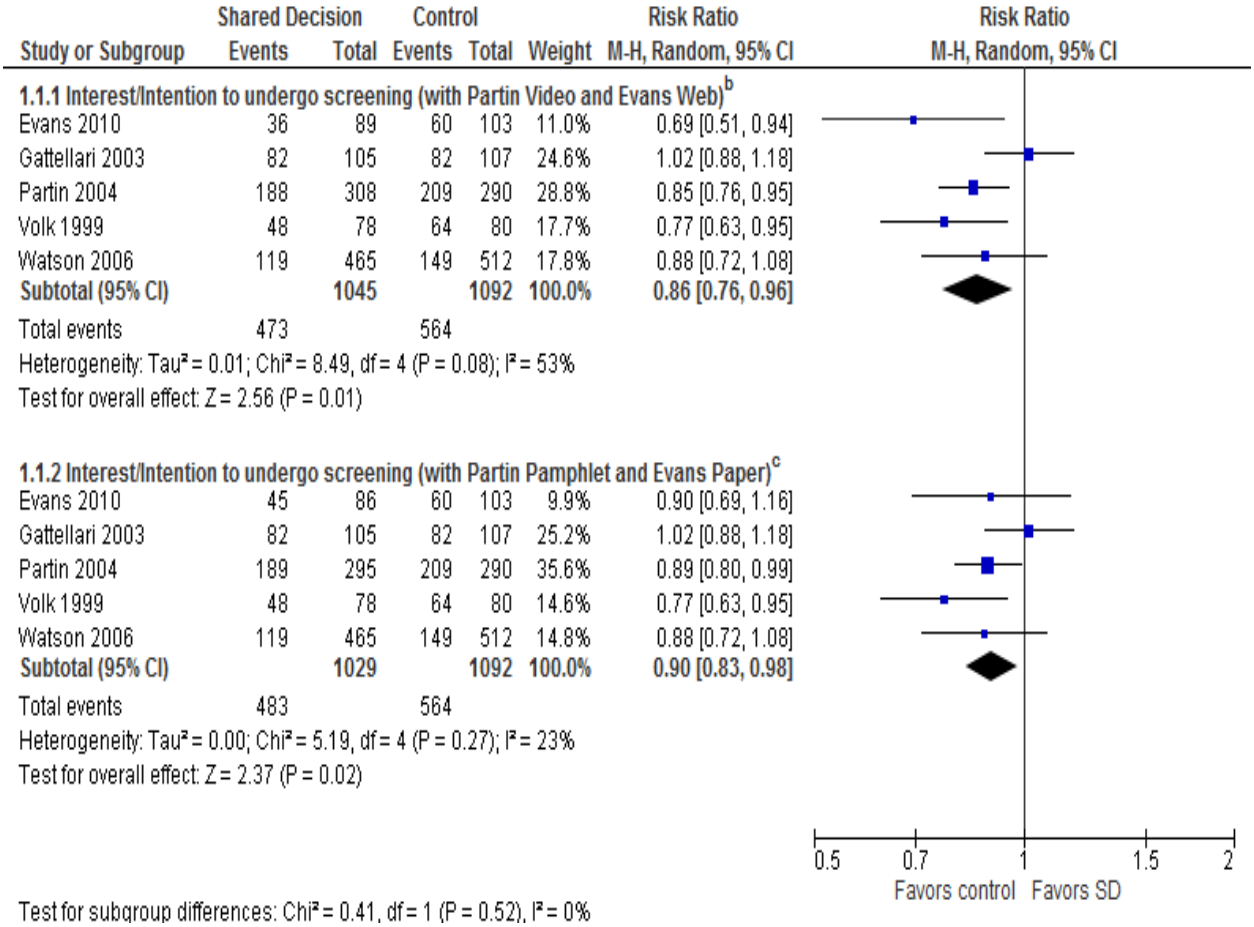
## 5. Decision Satisfaction[a]




[a] Percentage reporting high satisfaction, Taylor 2013[39]

Test for subgroup differences: Chi² = 1.29, df = 1 (P = 0.26), I² = 22.2%

## 6. Screening Preference/Intention - Usual Care Trials[a]




Test for subgroup differences: Chi² = 0.41, df = 1 (P = 0.52), I² = 0%

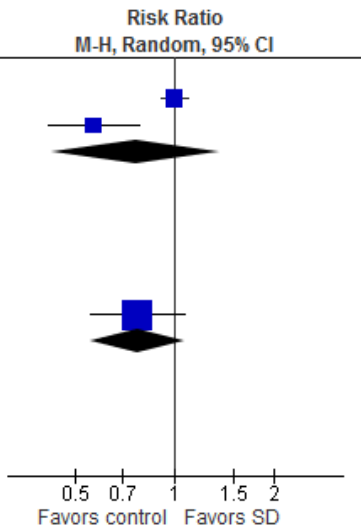
[a] Evans 2010,[26] Gattellari 2003,[29] Partin 2004,[35] Volk 1999,[40] Watson 2006[43]

[b] Includes Evans and Partin studies with significant or more significant results.

[c] Includes Evans and Partin studies with non-significant or less significant results.

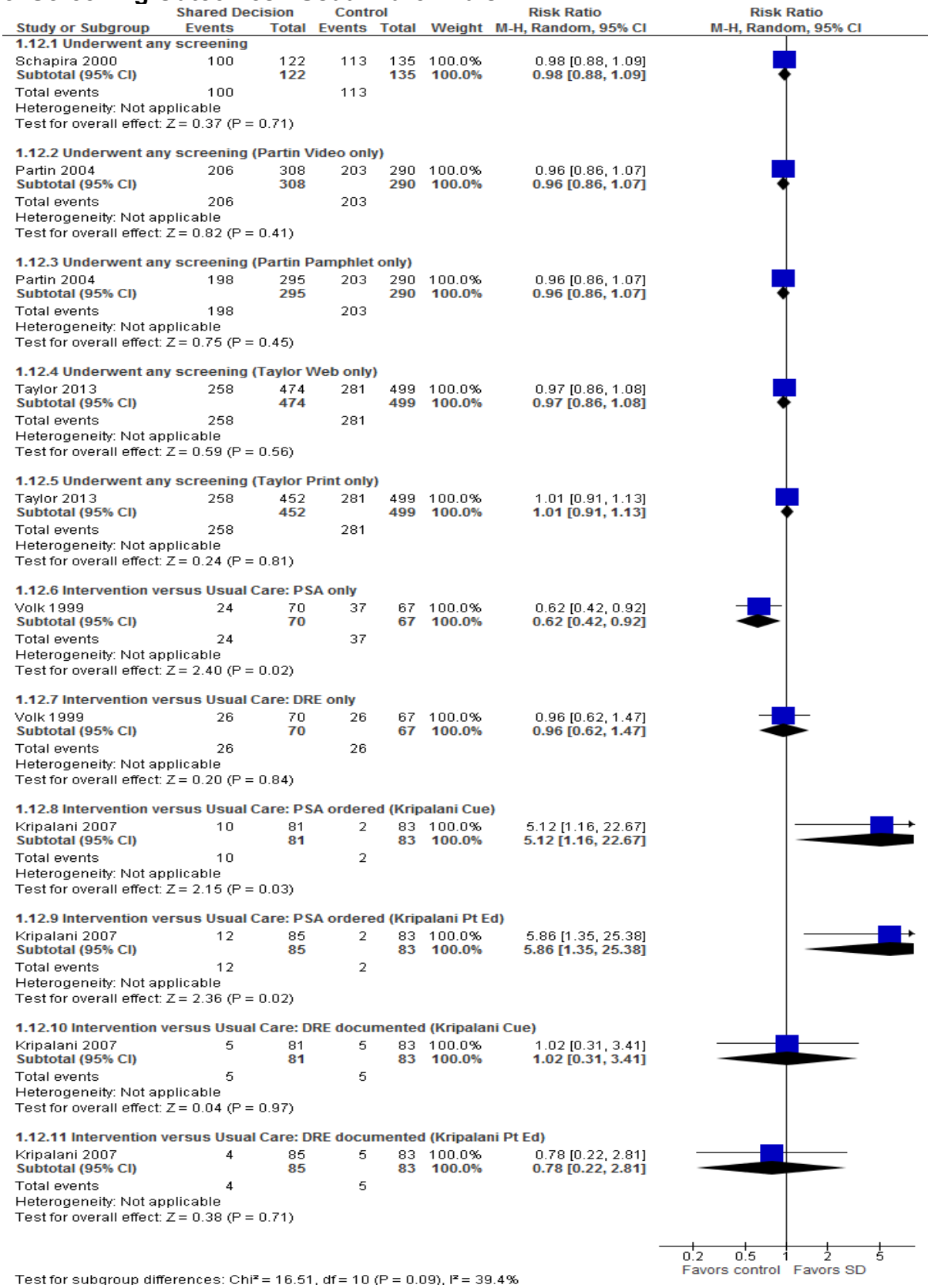
## 7. Screening Preference/Intention - Other Trials[a]

| Study or Subgroup | Shared Decision Events | Total | Control Events | Total | Weight | Risk Ratio M-H, Random, 95% CI |
|---|---|---|---|---|---|---|
| **1.11.1 Intervention versus Attention Control: Interest/Intention to undergo screening - Yes** | | | | | | |
| Lepore 2012 | 174 | 215 | 175 | 216 | 53.2% | 1.00 [0.91, 1.09] |
| Sheridan 2012 | 26 | 58 | 55 | 70 | 46.8% | 0.57 [0.42, 0.78] |
| **Subtotal (95% CI)** | | **273** | | **286** | **100.0%** | **0.77 [0.43, 1.38]** |
| Total events | 200 | | 230 | | | |
| Heterogeneity: Tau² = 0.16; Chi² = 13.02, df = 1 (P = 0.0003); I² = 92% | | | | | | |
| Test for overall effect: Z = 0.88 (P = 0.38) | | | | | | |
| **1.11.2 Evans 2010: Web versus paper decision aid** | | | | | | |
| Evans 2010 | 36 | 89 | 45 | 86 | 100.0% | 0.77 [0.56, 1.07] |
| **Subtotal (95% CI)** | | **89** | | **86** | **100.0%** | **0.77 [0.56, 1.07]** |
| Total events | 36 | | 45 | | | |
| Heterogeneity: Not applicable | | | | | | |
| Test for overall effect: Z = 1.56 (P = 0.12) | | | | | | |
| Test for subgroup differences: Chi² = 0.00, df = 1 (P = 0.99), I² = 0% | | | | | | |



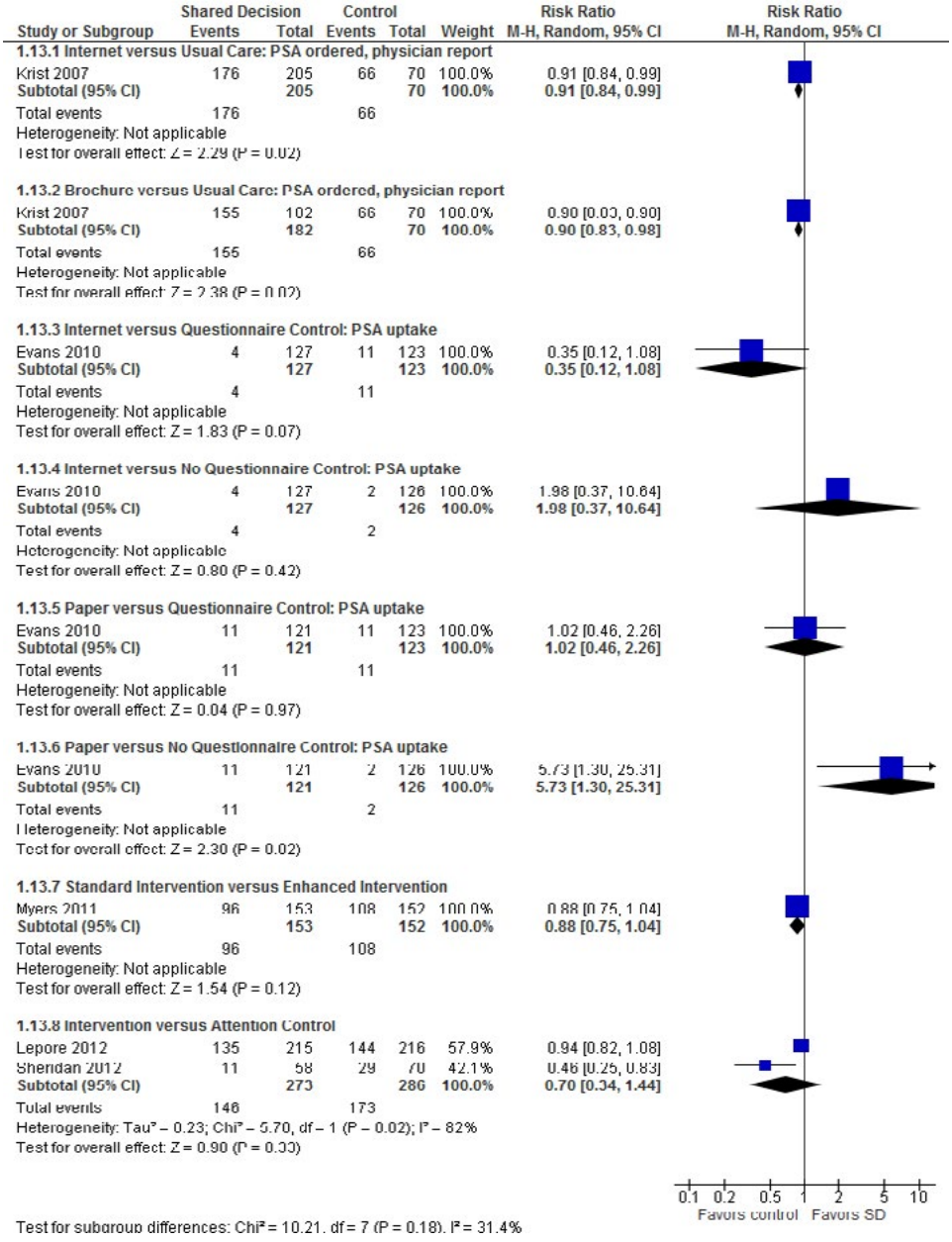

[a] Lepore 2012,[33] Sheridan 2012,[38] Evans 2010[26]

## 8. Screening Outcomes - Usual Care Trials[a]




[a] Schapira 2000,[37] Partin 2004,[35] Taylor 2013,[39] Volk 1999,[40] Kripalani 2007[31]

## 9. Screening Outcomes - Other Trials[a]




[a] Krist 2007,[32] Evans 2010,[26] Myers 2011,[34] Lepore 2012,[33] Sheridan 2012[38]