Appendix E – Clinical evidence tables

Alegria 2018

Alegria, 2018

Bibliographic Reference	Alegria, Margarita; Nakash, Ora; Johnson, Kirsten; Ault-Brutus, Andrea; Carson, Nicholas; Fillbrunn, Mirko; Wang, Ye; Cheng, Alice; Harris, Treniece; Polo, Antonio; Lincoln, Alisa; Freeman, Elmer; Bostdorf, Benjamin; Rosenbaum, Marcos; Epelbaum, Claudia; LaRoche, Martin; Okpokwasili-Johnson, Ebele; Carrasco, MaJose; Shrout, Patrick E; Effectiveness of the DECIDE Interventions on Shared Decision Making and Perceived Quality of Care in Behavioral Health With Multicultural Patients: A Randomized Clinical Trial.; JAMA psychiatry; 2018; vol. 75 (no. 4); 325-335

Study details

Component	Third person support and Patient activation
Study type	Randomised controlled trial
Study location	Boston, Massachusetts
Study setting	13 behavioural health clinics in Massachusetts that serve low income patients. Clinics offered individual and group psychotherapy and pharmacologic services.
Study dates	Recruitment: September - November 2013. Final follow-up September 2016.
Duration of follow-up	3 years
Sources of funding	Patient Centered-Outcomes Research Institute (PCORI)
Inclusion criteria	Criteria 1 No previous exposure to DECIDE-PA intervention Age 18 to 80 years Language English, Spanish or Mandarin speaking

Exclusion criteria	Clinical/Disease diagnosis Positive screening for mania, psychosis, suicide ideation, or cognitive impairment.
Sample size	Intervention: 157 patients, 40 clinicians Control: 155 patients, 34 clinicians
Loss to follow-up	Intervention: 11 lost to follow-up Usual care: 10 lost to follow-up
% Female	Clinicians: 76% female Patients: 68% female
Mean age (SD)	Mean age of clinicians: 39.8 years (12.5) Mean age of patients: 44 years (15)
Outcome measures	Outcome 1 SDM-Q-9: 9 item shared decision making questionnaire Outcome 2 OBOM SDM: OPTION-12 Outcome 3 Kim alliance scale Outcome 4 Perceptions of care survey - global evaluation of care Outcome 5 Working alliance inventory

Study arms

DECIDE-PC (N = 197) 3 areas of patient-centred communication in promoting SDM: 1) perspective talking, 2) attributional errors and 3) receptivity to patient participation and collaboration. Clinicians attended a 12-hour workshop and a total of 6 coaching sessions.

Usual care (N = 189)

Patients continued usual treatment, completed 3 assessments and had a recorded clinical session.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(No baseline imbalance but no explanation of concealment or randomisation methodology even with protocol.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Lack of detail around randomisation concealment and methodology even in protocol. OBOM is some concerns, PROM would be high)*
	Overall Directness	Directly applicable

Aljumah 2015

Aljumah, 2015

Bibliographic Reference	Aljumah, K; Hassali, M A; Impact of pharmacist intervention on adherence and measurable patient outcomes among depressed patients: a randomised controlled study.; BMC psychiatry; 2015; vol. 15; 219

Study details

Component	Third person support
Study type	Randomised controlled trial
Study location	Riyadh, Saudi Arabia
Study setting	One Psychiatric Hospital
Study dates	February 2014 and July 2014
Duration of follow-up	3 months
Sources of funding	NR
Inclusion criteria	Criteria 1 No history of psychosis or bipolar disorders Criteria 2 No drug or dependency history Criteria 3 No cognitive impairment that may hinder the assessment. Age 18 to 60 Clinical/Disease presentation Newly diagnosed with an MDD, according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th Ed (DSM-IV; 1994)
Exclusion criteria	Criteria 1 No response at any level to the antidepressant within 8 weeks of recruitment.

Sample size	239
Loss to follow-up	Intervention arm: 9 Control arm: 10
% Female	Intervention: 55.5% Control: 53.6%
Mean age (SD)	18-30 years: Int: 32 (19.1%), Ctrl: 27 (24.5%) 31-40 years: Int: 31 (28.2%), Ctrl: 35 (31.8%) 41-50 years: Int: 27 (24.5%) Ctrl: 27 (24.5%) 51-60 years: Int: 20 (18.2%) Ctrl: 21 (19.1%)
Outcome measures	Outcome 1 OBOM SDM: OPTION 12 Outcome 2 Beliefs: Beliefs about Medicine Questionnaire (BMQ) - general and specific Outcome 3 Treatment Satisfaction Questionnaire for Medication (TSQM 1.4)

Study arms

Usual Pharmacy + SDM (N = 119) SDM competency framework, designed specifically for depressed patients. Also pre-meeting PDA.
Usual care and standard communication. (N = 120)

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Whilst not clear if randomisation was blinded prior to allocation research assistant assigning to groups was blinded)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(Whilst paper states non-adherence isn't due to significant side effects they fail to report what this dropout was for, reason for dropout could differ between arms despite numbers being similar.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Issues around dropouts and not reporting reasons for them.)*
	Overall Directness	Direct

Berger-Hoger 2019

Berger-Hoger, 2019

Bibliographic Reference	Berger-Hoger, Birte; Liethmann, Katrin; Muhlhauser, Ingrid; Haastert, Burkhard; Steckelberg, Anke; Nurse-led coaching of shared decision-making for women with ductal carcinoma in situ in breast care centers: A cluster randomized controlled trial.; International journal of nursing studies; 2019; vol. 93; 141-152

Study details

Component	Third person support and Preference/value elicitation
Study type	Cluster randomised controlled trial
Study location	Germany
Study setting	Sixteen centres were recruited in the Federal States Schleswig- Holstein, Hamburg, Lower Saxony, Hessen and North Rhine-Westphalia.
Study dates	February 2015 and January 2016
Duration of follow-up	2 months
Sources of funding	German Federal Ministry of Health
Inclusion criteria	Age 18 years and older Clinical/Disease presentation Primary histologically confirmed ductal carcinoma in situ.
Exclusion criteria	Criteria 1 Pregnant Criteria 2 Had a known BRCA 1/2 mutation or had a previous diagnosis of breast cancer or DCIS (irrespective of ipsi- or contralateral).
Sample size	Intervention: 28 physicians, 16 specialised nurses, 36 patients Control: 25 physicians, 15 specialised nurses, 28 patients
Loss to follow-up	None reported.
% Female	Physicians: Intervention: 78% Control: 92% Patients: not reported

Mean age (SD)	Physicians: Intervention: 44.6 (7.7) Control: 41.3 (9.7) Patients: not reported
Condition specific characteristics	Title Grading of carcinoma: Intervention: 1 (5/34), 2 (20/34), 3 (8/34), unknown (1/34). Control: 1 (1/27), 2 (15/27), 3 (10/27), unknown (1/27). Title 2 History of cancer (except breast cancer): Intervention: 3/32, control: 1/28
Outcome measures	Outcome 1 Decisional conflict Outcome 2 Multifocal approach to sharing Decision-Making (MAPPIN-Q)

Study arms

Decision coaching (N = 36) Patients were provided with the decision aid (a), at least one nurse-led decision coaching session (b) and a final shared decision making physician encounter (c). The decision aid presents information on the disease, its natural course and probabilities of the benefits and harms of the treatment options. Decision coaching: the nurse supported the woman's decision-making process in a structured manner, taking the six steps of shared decision making (Kasper et al., 2012) into consideration. Consultation: the preferred option was discussed, open questions were clarified, and arrangements made for further treatment or watchful waiting.
Standard Care (N = 28) Women did not receive additional information or counselling. Usually, standard care comprises one or two physician encounters to inform women about their diagnosis and to get informed consent to the treatment recommended by the tumour board.

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Some concerns
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Some concerns *(Patients were recruited by the participating physicians.)*
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Some concerns *(Only some information available at patient level, all outcomes available at cluster level.)*
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Some concerns *(For objective measures)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(For objective measures. patients were recruited by the participating physicians.)*
	Overall Directness	Directly applicable

Brown 2004

Brown, 2004

Bibliographic Reference	Brown, Rhonda F; Butow, Phyllis N; Sharrock, Merin Anne; Henman, Michael; Boyle, Fran; Goldstein, David; Tattersall, Martin H N; Education and role modelling for clinical decisions with female cancer patients.; Health expectations : an international journal of public participation in health care and health policy; 2004; vol. 7 (no. 4); 303-16

Study details

Component	Pre-consultation interventions
Study type	Randomised controlled trial (RCT)
Study location	Sydney, Australia
Study setting	6 teaching hospitals
Study dates	NR
Duration of follow-up	2 weeks
Sources of funding	National Health and Medical Research Council of Australia (Grant No. 970735).
Inclusion criteria	Criteria 1 not too ill to complete questionnaire Criteria 2 Women Age over 16 Language Able to speak and read English
Exclusion criteria	Criteria 1 NR
Sample size	65
Loss to follow-up	3 at post-consultation 12 before 2-week questionnaire

% Female	100%
Mean age (SD)	Intervention: 51 (12) Control: 54 (13)
Outcome measures	Outcome 1 Decisional conflict: DCS Outcome 2 Satisfaction: Patient satisfaction with consultation scale Outcome 3 Practitioner satisfaction

Study arms

Booklet intervention (N = 30) 8-page booklet titled 'How treatment decisions are made' which describes decision making in the context of evidence-based medicine, treatment options and patient preferences. Provided to patients before oncologist consultation. 15 min videotapes were made of the 8 experienced medical oncologists participating in the study discussing treatment options.
Control booklet (N = 30)

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(Increased baseline anxiety in control group. So high risk for this measure. Some concerns for others as despite no reported randomisation baseline characteristics did not suggest issue.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Evidence loss to follow-up balanced across arms. Not large chance of missingness being related to true value)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Downgraded from High on subjectivity was only two results, also rest of measurement process robust with multiple objective coders and recorded appointments)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(High concerns for anxiety but not outcome we are focusing on, objective measurement was robust despite breaking of measurer blinding in two cases, reporting of everything other than randomisation is good.)*
	Overall Directness	Direct

Causarano 2015

Causarano, 2015

Bibliographic Reference Causarano, Natalie; Platt, Jennica; Baxter, Nancy N; Bagher, Shaghayegh; Jones, Jennifer M; Metcalfe, Kelly A; Hofer, Stefan O P; O'Neill, Anne C; Cheng, Terry; Starenkyj, Elizabeth; Zhong, Toni; Pre-consultation educational group intervention to improve shared decision-making for postmastectomy breast reconstruction: a pilot randomized controlled trial.; Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer; 2015; vol. 23 (no. 5); 1365-75

Study details

Component	Third person support

Study type	Randomised controlled trial
Study location	Toronto, Canada
Study setting	Tertiary cancer centre
Study dates	January to July 2013
Duration of follow-up	post-intervention.
Sources of funding	Funding was received from the Physician Services Incorporated Foundation
Inclusion criteria	Criteria 1 Women Criteria 2 undergone mastectomy referred to one of three plastic surgeons for consultation of delayed postmastectomy breast reconstruction Age ≥18 years
Exclusion criteria	Criteria 1 could not understand or speak English Criteria 2 seeking consultation for breast revision or nipple reconstruction only Criteria 3 a previous consultation with a plastic surgeon Criteria 4 cognitive impairment or uncontrolled psychiatric diagnosis Clinical/Disease diagnosis Active or atypical breast cancer
Sample size	41
Loss to follow-up	0 but 2 excluded from analysis
% Female	100%
Mean age (SD)	Intervention: 50.9 (5.5) Control: 51.5 (9.1)
Outcome measures	Outcome 1 Decisional Conflict: DCS

	Outcome 2 Self-efficacy: DSE Outcome 3 PROM SDM: CPS Outcome 4 PROM SDM: Decision-making (M-PICS) Outcome 5 Other: Satisfaction with information

Study arms

Intervention (N = 21) pre-consultation educational group intervention in addition to receiving routine education.
Control (N = 20) routine education only

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Decisional conflict imbalanced at baseline and our key outcome of interest)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low

Section	Question	Answer
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Obvious implications of receiving an education intervention, people may feel compelled to show they've learned something.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(PROMs only and patient cannot be blinded to these. Could be bias by receiving educational intervention.)*
	Overall Directness	Direct

Cheng 2019

Cheng, 2019

Bibliographic Reference Cheng, Li; Sit, Janet W H; Choi, Kai-Chow; Chair, Sek-Ying; Li, Xiaomei; Wu, Yuning; Long, Junhong; Yang, Hui; The effects of an empowerment-based self-management intervention on empowerment level, psychological distress, and quality of life in patients with poorly controlled type 2 diabetes: A randomized controlled trial.; International journal of nursing studies; 2019; 103407

Study details

Component	Patient activation
Study type	Randomised controlled trial
Study location	Xi'an, China
Study setting	two tertiary teaching hospitals

Study dates	April 2014 to October 2015
Duration of follow-up	3 months
Sources of funding	This research was supported by the Hong Kong Ph.D. Fellowship Scheme.
Inclusion criteria	Criteria 1 accessible by telephone Criteria 2 cognitively intact (indicated by Abbreviated Mental Test score of 6 or above). Age Adult Clinical/Disease presentation type 2 diabetes with Haemoglobin A1c (HbA1c) over 58 mmol/mol,
Sample size	242
Loss to follow-up	Intervention: 17 Control: 20
% Female	Intervention: 23.14% Control: 28.93%
Mean age (SD)	Intervention: 56.13 (10.72) Control: 53.91 (13.01)
Outcome measures	Outcome 1 Diabetes related distress, Emotional distress, Physician-related distress, Regimen-related distress, Interpersonal distress. Outcome 2 QoL: ADDQoL Outcome 3 Other: Empowerment level

Study arms

Empowerment program (N = 121) 6-week empowerment-based transitional care program with significant emphasis on establishing personally meaningful goals, facilitating collaborative partnership and shared decision making, resolving life-disease conflicts via situational reflection.
Control (N = 121) Two general health education classes and post-discharge social calls on top of routine care.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Low
	Overall Directness	Directly applicable

Collinsworth 2018

Collinsworth, 2018

Bibliographic Reference	Collinsworth, Ashley W; Brown, Rachel M; James, Cameron S; Stanford, Richard H; Alemayehu, Daniel; Priest, Elisa L; The impact of patient education and shared decision making on hospital readmissions for COPD.; International journal of chronic obstructive pulmonary disease; 2018; vol. 13; 1325-1332

Study details

Component	Third person support
Study type	Randomised controlled trial
Study location	Dallas, USA
Study setting	community hospital in a low-income suburb
Study dates	August 20, 2014 to February 7, 2016
Duration of follow-up	6 months
Sources of funding	GSK (GSK study ID: HO-13-13904)
Inclusion criteria	Criteria 1 access to a telephone Age >=40 years Clinical/Disease presentation diagnosis of COPD at least 24 hours after admission
Exclusion criteria	Criteria 1 primary diagnosis of asthma at the time of admission Criteria 2 history of pulmonary tuberculosis or respiratory cancer Criteria 3 been referred to hospice care Criteria 4 used a ventilator in hospital for >10 days Criteria 5 primary language that was not English or Spanish

Sample size	308
Loss to follow-up	Intervention: 89 Control: 119 No reason: Intervention: 12, Control: 5
% Female	Intervention: 85 (60.3%) Control: 95 (56.9%)
Mean age (SD)	Interview: 70.0 (11.9) Control: 70.9 (12.5)
Outcome measures	Outcome 1 Patient activation measure.

Study arms

CCC (COPD Chronic Care): (N = 141) SDM self-management planning took place in the hospital and lasted 15-30 minutes. Aims to help patients choose and focus on strategies that they perceived were most important to maintaining their health and preventing readmission. These strategies included further discussions of COPD symptoms, medication management, appropriate diet and nutrition, stress and coping, and smoking cessation activities.
Control (N = 167) COPD education prior to discharge and follow-up data collection call at 6 months post-discharge.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Concerns as alternating assignment to randomisation easy to guess.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Large dropout numbers with unclear reasoning why, dropout differed between intervention and control.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(PROM patient activation could be influenced by patients own opinions of their conduct.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Serious concerns around very high dropout rate and reasoning does not shed light on cause of these.)*
	Overall Directness	Directly applicable

Deen 2012

Deen, 2012

Bibliographic Reference	Deen, Darwin; Lu, Wei Hsin; Weintraub, Miranda Ritterman; Maranda, Michael J; Elshafey, Suzanne; Gold, Marthe R; The impact of different modalities for activating patients in a community health center setting.; Patient education and counseling; 2012; vol. 89 (no. 1); 178-83

Study details

Component	Patient activation
Study type	Randomised controlled trial
Study location	New York, USA
Study setting	Single health centre
Study dates	Over a 6 month period
Duration of follow-up	Same day
Sources of funding	Support for this project was provided by the Foundation for Informed Medical Decision Making
Inclusion criteria	Criteria 1 Age 18 and over
Sample size	279
Split between study groups	see arm data
Loss to follow-up	NA
% Female	Total: 176 (63.1%) Control: 37 (53.6%) PDA: 44 (63.8%) PAI: 43 (58.9%)
Mean age (SD)	NA
Outcome measures	Outcome 1 Patient activation measure

Study arms

Decision aid and patient activation (N = 68) Both interventions
Patient activation (N = 73) The objective of the intervention is to help individuals understand the importance of asking questions to inform potential medical decisions. The discussion that arises from the intervention focuses on non-medical decisions that individuals routinely make and then identifies questions that inform those routine decisions. It goes on to link the process of asking questions to decisions that are made during doctor visits and uses that preparation to assist with generating questions for their impending doctor visit.
Patient decision aid (N = 69) ‘‘Getting The Health Care that’s Right for You’’, was developed by the Foundation for Informed Medical Decision Making, to impart general information to patients about their role in gaining information and care within a medical setting.
Control (N = 69) Doctor visit

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(No info on randomisation and baseline characteristics varied)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	High *(Blinding not possible with these interventions)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(No information about the number of participants excluded in the analysis in the study arms. Exclusion of participants after the randomisation may not preserve the benefit of randomisation.)*

Section	Question	Answer
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Whilst outcome measurement used means that results were not as effective, the sample population seemed evenly distributed in regards to patient activation across arms. Effect of this would be to lessen intervention effect.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(No protocol but no apparent reporting bias.)*
Overall bias and Directness	Risk of bias judgement	High *(Concerns around elimination of patients post-randomization and applicability of sample population affecting results.)*
	Overall Directness	Directly applicable

Denig 2014

Denig, 2014

Bibliographic Reference	Denig, Petra; Schuling, Jan; Haaijer-Ruskamp, Flora; Voorham, Jaco; Effects of a patient oriented decision aid for prioritising treatment goals in diabetes: pragmatic randomised controlled trial.; BMJ (Clinical research ed.); 2014; vol. 349; g5651

Study details

Component	Preference/value elicitation
Study type	Cluster randomised controlled trial
Study location	North Netherlands
Study setting	Primary care, 18 general practices

Study dates	April 2011 and August 2012
Duration of follow-up	6 months
Sources of funding	ZonMW—the Netherlands Organisation for Health Research and Development.
Inclusion criteria	Criteria 1 type 2 diabetes
Exclusion criteria	Criteria 1 >65 years old Clinical/Disease diagnosis Experienced a stroke, heart failure, angina pectoris, or a terminal illness
Sample size	344
Loss to follow-up	Intervention: 4 + 22 with incomplete outcomes Control: 3 + 9 with incomplete outcomes
% Female	Intervention: 94 (42%) Usual care: 54 (46%)
Mean age (SD)	Intervention: 61.8 (8.5) Usual care: 61.5 (8.5)
Outcome measures	Outcome 1 Diabetes empowerment scale: Setting and achieving goals, Readiness to change, Psychosocial management Outcome 2 Beliefs about medication questionnaire: Necessity, concerns, overuse, harm Outcome 3 PEQD (quality of diabetes care) Outcome 4 Problem area in diabetes Outcome 5 EQ5D-NL

Study arms

Intervention (N = 225) We developed a decision aid for people with diabetes, which presents individually tailored information on risks and treatment options for multiple risk factors. Specific risk factors included HbA1c, systolic blood pressure, low density lipoprotein cholesterol, and smoking. In short, the aid focuses on shared goal setting and decision making, particularly with respect to the drug treatment of risk factors
Usual care (N = 119) Regular quarterly check-up, including any education, information, or additional consultations as deemed necessary by their healthcare provider

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(No info on allocation randomisation and issues with baseline imbalances)*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	High *(Missing outcome data greater in intervention group)*
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(PROMs with no ability to blind)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Lack of randomisation with imbalance at baseline,*

Section	Question	Answer
		large amount of missing outcome data in intervention arm, PROM outcomes that cannot be blinded)
	Overall Directness	Direct

Dillon 2017

Dillon, 2017

Bibliographic Reference	Dillon, Ellis C; Stults, Cheryl D; Wilson, Caroline; Chuang, Judith; Meehan, Amy; Li, Martina; Elwyn, Glyn; Frosch, Dominick L; Yu, Edward; Tai-Seale, Ming; An evaluation of two interventions to enhance patient-physician communication using the observer OPTION5 measure of shared decision making.; Patient education and counseling; 2017; vol. 100 (no. 10); 1910-1917

Study details

Component	Pre-consultation intervention, Preference/value elicitation, Patient activation
Study type	Cluster randomised controlled trial
Study location	Northern California, USA
Study setting	Four primary care clinics
Study dates	NR
Duration of follow-up	NR
Sources of funding	Patient-Centered Outcomes Research Institute (PCORI)
Inclusion criteria	None reported
Sample size	40

Split between study groups	NR
Loss to follow-up	NR
% Female	65%
Mean age (SD)	Mean = 51.4 years to 60.4 years in groups
Outcome measures	Outcome 1 OPTION

Study arms

Open communication (N = 10) Physician coaching and patient activation: 1) a brief introductory animated video, 2) Standardised Patient Instructor communication coaching for PCPs, and 3) a Visit Companion Booklet that instructed patients to write down their health concerns before the appointment, write down their next steps during the appointment, and to “teach back” the plan out loud to their PCP to make sure they are on the same page.
AskShareKnow (N = 10) An existing tool encouraging patients to ask questions. Patients received a flyer prior to their appointment that encouraged them to ask their primary care providers (PCPs) three questions: 1) What are my options?, 2) What are the possible benefits and risks of each option?, and 3) How likely are the benefits and risks of each option to occur?
Open Communication and ASK combined (N = 10)
Usual care (N = 10) No additional training, although some PCPs may have had prior training in SDM.

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(No information on sequence generation)*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Some concerns *(No information regarding recruitment and randomisation order and timing)*
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Some concerns *(outcome assessors not blinded but difficult with these interventions)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *No information on sequence generation, No information regarding recruitment and randomisation order/timing. Unblinded assessors.*
	Overall Directness	Directly applicable

Dobke 2008

Dobke, 2008

Bibliographic Reference	Dobke, M.K.; Bhavsar, D.; Gosman, A.; De Neve, J.; De Neve, B.; Pilot trial of telemedicine as a decision aid for patients with chronic wounds; Telemedicine and e-Health; 2008; vol. 14 (no. 3); 245-249

Study details

Component	Third person support
Study type	Randomised controlled trial
Study location	San Diego, California, USA
Study setting	Plastic surgery dept, University hospital.
Study dates	January 2003 through December 2005
Duration of follow-up	2 weeks
Sources of funding	NR
Inclusion criteria	Criteria 1 patients with problematic, nonhealing wounds referred to the wound care program and surgical consultant by their primary care physicians Criteria 2 alert and intellectually interactive
Exclusion criteria	Criteria 1 NA
Sample size	30
Loss to follow-up	NR
% Female	53%
Mean age (SD)	Intervention: 54.9 (± 10.8) Control: 53.9 (± 10.4)
Outcome measures	Outcome 1 Decisional conflict: DCS Outcome 2 SDM satisfaction: Satisfaction with decision making scale

Study arms

Telemedicine consultation (N = 15) wound assessment, rationale for suggested wound management, prevention and benefits of surgery. Communicated by field wound care nurse.
Control (N = 15) No telemedicine contact

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Patient recorded outcome measures)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(patient recorded outcome measures when patients were aware of the intervention)*
	Overall Directness	Directly applicable

Doherty 2018

Doherty, 2018

Bibliographic Reference	Doherty, Michael; Jenkins, Wendy; Richardson, Helen; Sarmanova, Aliya; Abhishek, Abhishek; Ashton, Deborah; Barclay, Christine; Doherty, Sally; Duley, Lelia; Hatton, Rachael; Rees, Frances; Stevenson, Matthew; Zhang, Weiya; Efficacy and cost-effectiveness of nurse-led care involving education and engagement of patients and a treat-to-target urate-lowering strategy versus usual care for gout: a randomised controlled trial.; Lancet (London, England); 2018; vol. 392 (no. 10156); 1403-1412

Study details

Component	Third person support
Study type	Randomised controlled trial
Study location	East Midlands
Study setting	General practice
Study dates	March 21, 2013 to Oct 25, 2016.
Duration of follow-up	2 years
Sources of funding	Research funding from AstraZeneca for the Sons of Gout study. Consultation fees from AstraZeneca, Grunenthal, and Mallinckrodt.
Inclusion criteria	Criteria 1 fulfilled 1977 American College of Rheumatology gout classification criteria. Criteria 2 reported at least one gout flare in the previous 12 months Criteria 3 indicated willingness for further contact Age >21
Exclusion criteria	Criteria 1 not meeting the 1977 American College of Rheumatology gout classification criteria Criteria 2 inability to consent

	Criteria 3 terminal or severe illness
Sample size	517
Loss to follow-up	Intervention: 18 Control: 43
% Female	Intervention: 10% Control: 11%
Mean age (SD)	Intervention: 62.01 (10.81) Control: 63.69 (11.91)
Outcome measures	Outcome 1 QoL: SF-36 physical component Outcome 2 QoL: SF-36 Mental Component

Study arms

Nurse individualised package of care (N = 255) holistic assessment, discussion of illness perceptions, and full information on gout and encouraged them to share in decision making.
Control (N = 262) Usual GP-led care: gout information booklet.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Randomising by CCG is a systematic randomisation and could be worked out or compromised)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(attrition in control arm much higher than intervention. Reasons unclear and imputation assumed randomness.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Unblinded study with QoL outcomes.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Unblinded study looking at QoL outcomes which are questionnaire based.)*
	Overall Directness	Direct

Granados-Santiago 2019

Granados-Santiago, 2019

Bibliographic Reference	Granados-Santiago, M.; Valenza, M.C.; Lopez-Lopez, L.; Prados-Roman, E.; Rodriguez-Torres, J.; Cabrera-Martos, I.; Shared decision-making and patient engagement program during acute exacerbation of COPD hospitalization: A randomized control trial; Patient Education and Counseling; 2019

Study details

Component	Preference/value elicitation
Study type	Randomised controlled trial
Study location	Granada, Spain
Study setting	hospital
Study dates	NR
Duration of follow-up	3 month
Sources of funding	Fundación Progreso y Salud (FPS), Boehringer Ingelheim España, S.A, and Oximesa, Praxair
Inclusion criteria	Criteria 1 patients hospitalized due to AECOPD
Exclusion criteria	Criteria 1 inability to provide informed consent Criteria 2 the presence of psychiatric or cognitive disorders Criteria 3 progressive neurological disorders Criteria 4 organ failure Criteria 5 cancer Criteria 6 inability to cooperate
Sample size	42
Loss to follow-up	Error in report: reported all patients dropped out, so not reported follow up values.
% Female	NR
Mean age (SD)	Control: 74.20 (9.25) Intervention: 69.33 (9.89)
Outcome measures	Outcome 1

	QoL: EuroQol 5d Outcome 2 Knowledge: COPD-Q

Study arms

SDM-PE (N = 21) Tailored programme focusing on COPD self-management. Included: pharmacological management, symptomatic control, and healthy lifestyle promotion.
Control (N = 21) Standard treatment (medical and pharmacological care)

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Low
	Overall Directness	Directly applicable

Hacking 2013

Hacking, 2013

Bibliographic Reference	Hacking, Belinda; Wallace, Louise; Scott, Sarah; Kosmala-Anderson, Joanna; Belkora, Jeffrey; McNeill, Alan; Testing the feasibility, acceptability and effectiveness of a 'decision navigation' intervention for early stage prostate cancer patients in Scotland – a randomised controlled trial; Psycho-Oncology; 2013; vol. 22 (no. 5); 1017-1024

Study details

Component	Third person support
Study type	Randomised controlled trial (RCT)
Study location	Scotland
Study setting	Prostate cancer patient at general hospital
Study dates	between January 2009 and August 2010
Duration of follow-up	3 months
Sources of funding	Macmillan Cancer Support funded this study in its entirety. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The trial is registered with NHS Lothian. Project ID Number: 2008/W/ON/26.
Inclusion criteria	Criteria 1 patients who had just received a diagnosis of localised or early stage primary prostate cancer, those who had a decision to make regarding cancer management and who were referred to a specialist urology consultant

Exclusion criteria	Criteria 1 patients with any cognitive or sensory impairment, which impeded participation in the trial, and those who had already opted for active monitoring or to commence hormone treatment at diagnosis.
Sample size	123
Loss to follow-up	NR
% Female	0
Mean age (SD)	Intervention: 65.4 Control: 64.5
Outcome measures	Outcome 1 Decision self-efficacy Outcome 2 Decisional conflict Outcome 3 Decisional regret

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Unblinded subjective outcomes)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Subjective unblinded outcomes)*
	Overall Directness	Directly applicable

Hamann 2011

Hamann, 2011

Bibliographic Reference	Hamann, Johannes; Mendel, Rosmarie; Meier, Anna; Asani, Florim; Pausch, Esther; Leucht, Stefan; Kissling, Werner; "How to speak to your psychiatrist": shared decision-making training for inpatients with schizophrenia.; Psychiatric services (Washington, D.C.); 2011; vol. 62 (no. 10); 1218-21

Study details

Component	Patient activation
Study type	Randomised controlled trial
Study location	Munich, Germany
Study setting	University psychiatric hospital
Study dates	May 2009 to February 2010
Duration of follow-up	6 months
Sources of funding	This work was supported by research project grant 2168-1746.1/2007 from the German-Israeli Foundation for Scientific Research and Development.
Inclusion criteria	Criteria 1 capable of tolerating a 60-minute interactive patient group Age 18-60 Clinical/Disease presentation with schizophrenia or schizoaffective disorder according to the ICD-10
Sample size	51
Loss to follow-up	Intervention: 7 Control: 6
% Female	38 (62%)
Mean age (SD)	40.7±11.7
Outcome measures	Outcome 1 Autonomy Preference index (M+/-SD) Outcome 2 Responsibility for decision making Outcome 3 Decision self-efficacy scale Outcome 4 Beliefs in medication questionnaire

	Outcome 5 Satisfaction (with treatment) Outcome 6 Multidimensional Health Locus of Control Scale Outcome 7 Trust in physician scale Outcome 8 physician rated decision capacity Outcome 9 physician rated therapeutic alliance Outcome 10 Difficult doctor-patient relationship questionnaire

Study arms

Patient SDM training (N = 32) five one-hour sessions for a group of five to eight patients. The content of the training was derived from theoretical considerations about patients' contributions to the shared decision making process, from an adaptation of related approaches from somatic medicine, and from pilot testing the training. The training sessions included motivational aspects (such as prospects of participation) and behavioural aspects (including role-play exercises). The training emphasized interaction between moderators and patients as well as mutual support. All sessions were led by a psychiatrist and a psychologist, neither of whom were in charge of the specific care of these patients.
Control (N = 29) Patients in the control condition participated in a five-session cognitive training group.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(No randomisation info, imbalances at baseline with no explanation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(Lack of information about type on analysis done)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Very little information on why data is missing and how this was addressed)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(PROM outcomes with unblinded assessors)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(No randomisation info, lack of info on analysis type, no information on dropout reasons or missing data, PROM outcomes with unblinded assessors)*
	Overall Directness	Directly applicable

Hamann 2020

Hamann, 2020

Bibliographic Reference	Hamann, J.; Holzhuter, F.; Blakaj, S.; Becher, S.; Haller, B.; Landgrebe, M.; Schmauss, M.; Heres, S.; Implementing shared decision-making on acute psychiatric wards: A cluster-randomized trial with inpatients suffering from schizophrenia (SDM-PLUS); Epidemiology and Psychiatric Sciences; 2020; e137

Study details

Component	Patient activation
Study type	Randomised controlled trial (RCT)
Study location	Germany
Study setting	12 acute psychiatric wards
Study dates	NR
Duration of follow-up	6 months
Sources of funding	Janssen Cilag supported the trial with an unrestricted grant (to Dr Hamann and Dr Heres). The company had no influence on the design of the trial, the collection, analysis and interpretation of the data. The development of the intervention was not influenced by the sponsor of the study. Intervention development and trial design were conducted solely by the authors and sponsorship was established on the basis of an 'investigator-initiated trial'.
Inclusion criteria	Criteria 1 Inpatient status of participating ward Criteria 2 Capable of participating in 60 min group intervention Criteria 3 Can provide written informed consent Age 18-65 Clinical/Disease presentation Diagnosis of schizophrenia or schizoaffective disorder
Exclusion criteria	Criteria 1 Insufficient mental capacity

	Criteria 2 Insufficient German proficiency
Sample size	161
Loss to follow-up	NR
% Female	Intervention: 52% Control: 47%
Mean age (SD)	Intervention: 42.1 (12.9) Control: 41.4 (13.9)
Outcome measures	Outcome 1 PROM SDM: SDM-Q-9 Outcome 2 Helping alliance scale clinician and patient (P/C) Outcome 3 Patient satisfaction (ZUF) Outcome 4 Camberwell assessment of need Outcome 5 Wellbeing (WHO-5) Outcome 6 Quality of Life – EUROHIS-QoL

Study arms

SDM-plus (N = 257) SDM-PLUS aims to empower health care staff and patients alike with regard to SDM-specific communication techniques. 2014). The two principal investigators provided interactive workshops on SDM-PLUS techniques to treatment teams. The two half-day workshops were based on a power point presentation and written case vignettes for role plays and took place in the respective psychiatric hospitals. It was mandatory that all physicians (residents and consultants) of intervention wards and as many members of the nursing team as possible participated in both workshops. Patients were provided with group training in SDM (Hamann et al., 2011) and the use of question prompt sheets for ward rounds and individual consultations. Throughout the study period, this group training was offered twice a week for all wards and it was ensured that all intervention group patients participated at least in two group sessions.
Control (N = 130) Staff (and patients) from the control wards acted under TAU conditions but were offered SDM-PLUS training after the end of the study.

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low

Section	Question	Answer
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(Unblinded subjective outcomes)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Unblinded subjective outcomes)*
	Overall Directness	Directly applicable

Henselmans 2019

Henselmans, 2019

Bibliographic Reference Henselmans, I.; van Laarhoven, H.W.M.; van Maarschalkerweerd, P.; de Haes, H.C.J.M.; Dijkgraaf, M.G.W.; Sommeijer, D.W.; Ottevanger, P.B.; Fiebrich, H.-B.; Dohmen, S.; Creemers, G.-J.; de Vos, F.Y.F.L.; Smets, E.M.A.; Effect of a Skills Training for Oncologists and a Patient Communication Aid on Shared Decision Making About Palliative Systemic Treatment: A Randomized Clinical Trial; Oncologist; 2019

Study details

Component	Preference/value elicitation
Study type	Randomised controlled trial

	patients/oncologists randomised separately
Study location	The Netherlands.
Study setting	medical oncology departments of three academic and three non-academic hospitals.
Study dates	November 2015 to August 2016 + Follow up
Duration of follow-up	post-appointment
Sources of funding	van Laarhoven research funding: Bayer, BMS, Celgene, Janssen, Eli Lilly and Company, Nordic Pharma, Phillips, Roche.
Inclusion criteria	Clinical/Disease presentation diagnosed with metastatic or inoperable tumours for which survival curves indicate a median life expectancy of 6 months
Sample size	194
Loss to follow-up	Intervention: 25 Control: 22
% Female	49%
Mean age (SD)	63.6 (11.2)
Outcome measures	Outcome 1 OBOM SDM: OPTION-12 Outcome 2 OBOM SDM: 4SDM Outcome 3 PROM SDM: SDMQ-9 patient Outcome 4 Satisfaction: patient satisfaction Outcome 5 Decisional conflict: DCS Outcome 6 Quality of life (global health subscale of EORTC)

Study arms

Patient communication intervention only (N = 50) Education about SDM, Question prompt list, value clarification methods, info about treatment options
Oncologist SDM training only (N = 48) The training (10 hours) was based on a model with four essential SDM steps [4]: (A) set the SDM agenda, (B) inform about the options and pros and cons, (C) explore patients values and support preference construction, (D) make or defer a decision in agreement. The training aimed to address oncologists' knowledge, attitude, and skills and was provided in small groups (three to six participants) by an experienced trainer in two sessions, both 3.5 hours, with preferably 2 weeks in between.
Patient communication aid and oncologist SDM training (N = 47)
Neither intervention (N = 49)

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Potential concern: another clinician was added after randomisation to balance groups, so there must've been knowledge of randomisation make up, but this randomisation was done by independent researcher.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Main outcomes OBOMs, still concerns with PROMs)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns *(Concerns regarding modification of oncologist number post-randomisation, allows risk of modifying end results)*
	Overall Directness	Directly applicable

Ishii 2017

Ishii, 2017

Bibliographic Reference	Ishii, Mio; Okumura, Yasuyuki; Sugiyama, Naoya; Hasegawa, Hana; Noda, Toshie; Hirayasu, Yoshio; Ito, Hiroto; Feasibility and efficacy of shared decision making for first-admission schizophrenia: a randomized clinical trial.; BMC psychiatry; 2017; vol. 17 (no. 1); 52

Study details

Component	Third person support
Study type	Randomised controlled trial
Study location	Shizuoka, Japan
Study setting	psychiatric ward
Study dates	June 4, 2013 - September 29, 2015
Duration of follow-up	6 months
Sources of funding	Health and Labor Sciences Research Grant for Comprehensive Research on Disability Health and Welfare from the Japanese Ministry of Health, Labour and Welfare
Inclusion criteria	Criteria 1 no history of psychiatric admission Age

	16 - 65 Clinical/Disease presentation diagnosis of schizophrenia spectrum disorder (including schizophrenia, schizotypal, and delusional disorders
Exclusion criteria	Criteria 1 moderate to profound mental retardation Criteria 2 organic mental disorders Criteria 3 inability to converse in japanese Criteria 4 severe conceptual disorganization
Sample size	24
Loss to follow-up	2
% Female	31.8% (7)
Mean age (SD)	39.1 (11.7)
Outcome measures	Outcome 1 Satisfaction: CSJ-8

Study arms

SDM intervention (N = 11) 15 - 20 min weekly intervention. consists of three sequential elements: assessing patient's perceptions on their on-going treatments by a self-report questionnaire; sharing patients' and medical staffs' perceptions on the treatments in a 15-20-min meeting; and patients together with medical staff deciding on a care plan for the next week.
Usual care (N = 13) Text-based decision aid

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(Lack of information around blinding, possibly low if this isn't a committee concern.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Lack of information about blinding of outcome assessing coupled with PROM outcome leads to high risk of bias here.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Lack of blinding coupled with patient reported outcomes)*
	Overall Directness	Directly applicable

Joosten 2008

Joosten, 2008

Bibliographic Reference	Joosten E; de Weert G; Sensky T; van der Staak C; de Jong C; Effect of shared decision-making on therapeutic alliance in addiction health care.; Patient preference and adherence; 2008; vol. 2

Study details

Component	Preference/value elicitation
Study type	Randomised controlled trial
Study location	Netherlands
Study setting	Three addiction treatment centres
Study dates	January 2005 to May 2006
Duration of follow-up	3 months
Sources of funding	Dutch Ministry of Health, Welfare and Sports (VWS) and the Dutch Organization for Health Research and Development (ZonMW).
Inclusion criteria	Criteria 1 dependent on psychoactive substances Criteria 2 needed inpatient treatment programs
Exclusion criteria	Criteria 1 under 18 years Criteria 2 insufficient knowledge of the Dutch language Criteria 3 severe psychiatric co-morbidity that would preclude to take part in the process of SDM and adherence to the protocol Criteria 4 no informed consent to participate in the study.
Sample size	212
Loss to follow-up	65
% Female	I: 33.4% C: 24.1%
Mean age (SD)	Intervention: 40.7 (10.3) Control: 41.2 (11.1)

Outcome measures	Outcome 1 Patient HAQ (alliance questionnaire) Outcome 2 Clinician HAQ (alliance questionnaire)

Study arms

SDMI (N = 107) SDMI contains 5 sessions. In the introduction session (session I), at the beginning of the treatment, the clinician introduces the procedure of SDMI to the patient. At the end of this session the patient is handed over the questionnaire and Q-sort cards. One week after the introduction session (session II), patient's treatment goals and expectations are explored and compared with the clinician's perception as described in the results of his questionnaire. Similarities and differences between clinician's and patient's perceptions are discussed. Based on this discussion, the treatment contract is completed. During the interim evaluation (session III), halfway through the treatment, the goals and expectations are explored again with the questionnaire and the results are discussed again and adapted to the treatment development if necessary. At the end of the treatment program, a final evaluation (session IV) takes place, based on goals and expectations as put down in the treatment contract. In addition, new goals and expectations are explored on basis of the completed questionnaire and ranked Q-sort cards handed out before this session. In the case of discontinuation of treatment before the interim or final evaluation, if possible, an exit interview with the same content as the final evaluation is carried out. A follow-up evaluation (session V) is carried out three months after treatment. In this follow-up meeting the goals and expectations are evaluated which were agreed on during the latest evaluation.
Control (N = 105) Clinicians in the control condition also used MI. In the experimental condition, MI was offered in a structured way by protocol to explore and compare indicated treatment goals and finally to reach an agreement on these goals.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(lack of info on dropouts but balanced)*

Section	Question	Answer
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(PROM outcomes with unblinded participants)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Some concerns about missing data, PROM data for SDM outcomes)*
	Overall Directness	Directly applicable

Kravitz 2018

Kravitz, 2018

Bibliographic Reference Kravitz, Richard L; Schmid, Christopher H; Marois, Maria; Wilsey, Barth; Ward, Deborah; Hays, Ron D; Duan, Naihua; Wang, Youdan; MacDonald, Scott; Jerant, Anthony; Servadio, Joseph L; Haddad, David; Sim, Ida; Effect of Mobile Device-Supported Single-Patient Multi-crossover Trials on Treatment of Chronic Musculoskeletal Pain: A Randomized Clinical Trial.; JAMA internal medicine; 2018; vol. 178 (no. 10); 1368-1377

Study details

Component	Documentary interventions
Study type	Randomised controlled trial
Study location	California, USA
Study setting	Primary care, Family medicine clinic, Veteran affairs, Air force base.
Study dates	January 2016 - May 2017

Duration of follow-up	6 months
Sources of funding	National institute of nursing research. National centre for advancing the translational sciences of the national institutes of health.
Inclusion criteria	Criteria 1 musculoskeletal pain for at least 6 weeks at the time of screening Criteria 2 has smartphone or tablet with a data plan Criteria 3 score of 4 or higher out of 10 on at least 1 item of 3 item pain, enjoyment and general activity questionnaire. Age 18-75 Language Can read and speak english
Exclusion criteria	Criteria 1 Cancer treatment within the past 5 years Criteria 2 Life expectancy less than 2 years Criteria 3 Evidence of drug or alcohol abuse. Clinical/Disease diagnosis psychological disorder (eg. dementia, memory loss, psychosis)
Sample size	215
Loss to follow-up	Intervention N = 4 Control N = 6
% Female	47%
Mean age (SD)	55.5 years (+/- 11.1)
Outcome measures	Outcome 1 Pain interference, pain intensity Outcome 2 Global physical health, Global mental health, analgesic adherence Outcome 3 Patient satisfaction questionnaire with pain information, with medical care, with pain medication.

Study arms

n-of-1 trial supported by mobile health app (N = 108) The clinician patient dyad selected from 1 of 8 treatment categories, duration of treatment period and paired comparisons. Parameters sent to app on patients mobile device, which alerted patient when to take each treatment and record daily questionnaire. Review visit of dyad at end of trial.
Control (N = 107) Attendance of baseline clinic where they completed assessments in the waiting room under the supervision of the study research assistant.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(not enough info about outcome to determine objectivity)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(not enough info about outcome to determine objectivity)*
	Overall Directness	Directly applicable

Krones 2008

Krones, 2008

Bibliographic Reference	Krones, Tanja; Keller, Heidemarie; Sonnichsen, Andreas; Sadowski, Eva-Maria; Baum, Erika; Wegscheider, Karl; Rochon, Justine; Donner-Banzhoff, Norbert; Absolute cardiovascular disease risk and shared decision making in primary care: a randomized controlled trial.; Annals of family medicine; 2008; vol. 6 (no. 3); 218-27

Study details

Component	Preference/value elicitation
Study type	Cluster randomised controlled trial
Study location	Hessen, Germany
Study setting	primary care; ambulatory care
Sample size	1132
Outcome measures	Outcome 1 Patient participation scale Outcome 2 SDM-Q Outcome 3 Joint process between healthcare professionals and patients to make decisions

Study arms

Multifaceted SDM intervention (N = 550)

A simple, evidence-based decision aid (ARRIBA-Herz) to help physicians achieve the double paradigm shift toward shared decision making and global CVD risk.

Control (N = 582)

Single intervention (control): placebo educational meeting Quote: ”Family doctors in the control arm were offered seminars on defined alternative topics that would not interfere with CVD prevention.“

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(Lack of information available regarding randomisation methodology.)*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	High *(Large amount of practices switched groups)*
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(Participant recorded outcome measure)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Lack of randomisation information, large amount of arm switching, and PROM.)*

Section	Question	Answer
	Overall Directness	Direct

Landrey 2013

Landrey, 2013

Bibliographic Reference	Landrey, Alison R; Matlock, Daniel D; Andrews, Laura; Bronsert, Michael; Denberg, Tom; Shared decision making in prostate-specific antigen testing: the effect of a mailed patient flyer prior to an annual exam.; Journal of primary care & community health; 2013; vol. 4 (no. 1); 67-74

Study details

Component	Pre-consultation interventions
Study type	Randomised controlled trial
Study location	Colorado, USA
Study setting	general internal medicine practices
Study dates	October 2009 - August 2010
Duration of follow-up	2 weeks
Sources of funding	Health Literacy Award from the American College of Physician's Foundation. National Institutes on Aging.
Inclusion criteria	Criteria 1 50-74

	Criteria 2 scheduled to have an annual health maintenance exam
Exclusion criteria	Criteria 1 PSA test within the past 12 months Clinical/Disease diagnosis history of prostate cancer, or any other diagnosis of cancer, terminal illness or dementia
Sample size	303
Loss to follow-up	Intervention: 9 Control: 11 Survey outcomes: Intervention: 71 Control: 80
% Female	All men
Mean age (SD)	Intervention: 62.2 (No SD) Control: 62.4 (No SD)
Outcome measures	Outcome 1 PROM SDM: CPS Outcome 2 PROM SDM: Patient-Provider PSA discussion (EHR documentation) Outcome 3 Disease: Patient PSA testing preference (EHR documentation) Outcome 4 Other: Flyer acceptability

Study arms

Mailed Flyer (N = 145) basic information about the PSA test, prostate cancer, and risks and benefits of screening, and encouraged patients to talk with their providers about whether a PSA test was appropriate for them
Usual care (N = 158) No flyer

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Lack of information about randomisation)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(For non-survey outcomes)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(Lack of evidence around how missing data was accounted for.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Patient-reported outcomes with known information.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(patient reported outcomes concern as cannot blind. Survey outcomes v high risk of bias)*
	Overall Directness	Directly applicable

Ledford 2018

Ledford, 2018

Bibliographic Reference	Ledford, Christy J W; Womack, Jasmyne J; Rider, Heather A; Seehusen, Angela B; Conner, Stephen J; Lauters, Rebecca A; Hodge, Joshua A; Unexpected Effects of a System-Distributed Mobile Application in Maternity Care: A Randomized Controlled Trial.; Health education & behavior : the official publication of the Society for Public Health Education; 2018; vol. 45 (no. 3); 323-330

Study details

Component	Patient activation Documentary intervention
Study type	Randomised controlled trial
Study location	Georgia, Nevada, Virginia: USA
Study setting	Women's health and family medicine departments of one community hospital and two medical centres.
Study dates	Screening: May to November 2015.
Duration of follow-up	36 weeks (PIPC) 32 weeks (PAM)
Sources of funding	This work was supported by the U.S. Department of Defense (FAM 81-3193).
Inclusion criteria	None reported
Exclusion criteria	Criteria 1 conditions that would elevate the patient's care to complicated obstetrics care (e.g., cardiovascular disease, diabetes mellitus, renal disorder, etc.
Sample size	205
Loss to follow-up	None
% Female	100% (study of pregnant women)
Mean age (SD)	Overall: 26.60 (SD 4.85)

	Control: 26.74 (SD 4.62) Intervention: 26.46 (SD 5.09)
Outcome measures	Outcome 1 Patient activation measure: 13 likert types

Study arms

Mobile app (N = 120) The mobile app used in this study was designed for the same two purposes and contained identical content, though via a mobile design interface (available on both Android and iOS platforms).
Notebook control (N = 121) The spiral notebook is designed for two purposes: (1) patient education of what happens throughout pregnancy and (2) patient record keeping of her own pregnancy experience, including space for recording weight, blood pressure, and journaling.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Block randomisation occurred post recruitment and assessors were blinded until moment of assignment.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Doctors may have edited their practice if they noticed method by which patient was collecting clinical info, but there is no evidence of this. (Could feasibly change to some concerns))*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Paper collected data on patients who did not complete treatment and*

Section	Question	Answer
		concluded missingness was not related to condition. Also dropout rates similar to other psychological studies.)
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Hard to not be aware of mobile intervention.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Difficult to blind intervention)*
	Overall Directness	Directly applicable

McBride 2016

McBride, 2016

Bibliographic Reference	McBride, E; Hacking, B; O'Carroll, R; Young, M; Jahr, J; Borthwick, C; Callander, A; Berrada, Z; Increasing patient involvement in the diabetic foot pathway: a pilot randomized controlled trial.; Diabetic medicine : a journal of the British Diabetic Association; 2016; vol. 33 (no. 11); 1483-1492

Study details

Component	Third person support Preference/value elicitation
Study type	Randomised controlled trial
Study location	Edinburgh, UK

Study setting	One diabetes foot clinic.
Study dates	Recruitment: 01/07/14 and 31/03/15
Duration of follow-up	3 months (2 weeks)
Sources of funding	NHS Lothian and NHS Education for Scotland
Inclusion criteria	Clinical/Disease presentation Patients with any type of diabetes
Exclusion criteria	Criteria 1 unable to give informed consent Criteria 2 displayed a severe ischemic foot ulcer Criteria 3 identifiable severe psychiatric morbidity Criteria 4 younger than 16 years old
Sample size	56
Loss to follow-up	7
% Female	Control: 73.1% Intervention: 73.3%
Mean age (SD)	Control: 59.5 (9.9) Intervention: 62.5 (14.98)
Outcome measures	Outcome 1 Decision self-efficacy Outcome 2 Decisional conflict: DCS Outcome 3 Decisional regret Outcome 4

	Quality of life: HR-QoL

Study arms

Decision navigation (N = 30) Facilitate shared decision making between a healthcare professional and patient in practice. The main component of decision navigation takes the form of an interview between the patient and a trained 'Navigator' in order to form a consultation plan (written summary) of the patients' questions/concerns relating to their care and treatment. Consultation plan is then used within a routine appointment as an agenda with a healthcare professional. Audio recordings and a written document of the information discussed are generated and given to the patient.
Usual care (N = 26) 1) formal assessment of ulcer, 2) treatment plan, 3) patient received treatment advice, 4) patient attended clinic

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Imputed data is last observation carried forward, not reported which arm dropouts occurred in. No reasons given for dropouts.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(PROM measures and unblinded)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High *(Issues around missing outcome reasons and PROM unblinded)*
	Overall Directness	Directly applicable

Metz 2019

Metz, 2019

Bibliographic Reference	Metz, Margot J; Veerbeek, Marjolein A; Twisk, Jos W R; van der Feltz-Cornelis, Christina M; de Beurs, Edwin; Beekman, Aartjan T F; Shared decision-making in mental health care using routine outcome monitoring: results of a cluster randomised-controlled trial.; Social psychiatry and psychiatric epidemiology; 2019; vol. 54 (no. 2); 209-219

Study details

Component	Documentary interventions
Study type	Cluster randomised controlled trial
Study location	Netherlands
Study setting	Multi-centre: 14 teams (7 intervention, 7 control) of 4 specialist mental health care organisations).
Study dates	October 2015 - March 2017
Duration of follow-up	6 months
Sources of funding	National Network for Quality Development in mental health care (grant number PV140003).
Inclusion criteria	Criteria 1 Teams (in centres) which are participating in the Dutch Breakthrough ROM network (project).
Sample size	186

Loss to follow-up	Intervention: 13 patients Control: 15 patients
% Female	59% in total study population
Mean age (SD)	47.2 (18.0)
Outcome measures	Outcome 1 Decisional conflict Outcome 2 Working alliance inventory Outcome 3 Outcome questionnaire Outcome 4 Manchester Short Quality of Life Measurement (MANSA-VN-16)

Study arms

Shared decision making using Routine Outcome Monitoring (SDMR) (N = 94) Implementation of routine outcome monitoring (ROM) involving 5 steps: 1) introduction (expectations about shared process, discussion, connect with patients wishes and goals, explain ROM), 2) Give meaning to ROM, 3) explore options, 4) weight options and 5) shared decision. Prior to the study, of the intervention teams underwent a 1- day training in applying SDMR in clinical practice.
Control (N = 92) No further information provided

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low

Section	Question	Answer
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Some concerns *(Lack of ability to blind, unclear what effect this may have had on team allocation)*
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(Lack of blinding and patient reported outcomes.)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns
	Overall Directness	Directly applicable

Muscat 2019

Muscat, 2019

Bibliographic Reference	Muscat, Danielle M; Morony, Suzanne; Trevena, Lyndal; Hayen, Andrew; Shepherd, Heather L; Smith, Sian K; Dhillon, Haryana M; Luxford, Karen; Nutbeam, Don; McCaffery, Kirsten J; Skills for Shared Decision-Making: Evaluation of a Health Literacy Program for Consumers with Lower Literacy Levels.; Health literacy research and practice; 2019; vol. 3 (no. 3suppl); 58-s74

Study details

Component	Health literacy
Study type	Cluster randomised controlled trial
Study location	NSW, Australia
Study setting	Technical and Further Education (TAFE) institutes
Study dates	2014
Duration of follow-up	6 months
Sources of funding	NR
Inclusion criteria	Criteria 1 students Age over 16
Exclusion criteria	Criteria 1 NR
Sample size	141
Loss to follow-up	unclear as both randomised and non-randomised combined.
% Female	79%
Mean age (SD)	47.9 (13.2)
Outcome measures	Outcome 1 Literacy: Health literacy skills (conceptual knowledge, health numeracy, graphical numeracy) Outcome 2 Other: Types of questions considered important Outcome 3 PROM SDM: CPS Outcome 4 Decisional conflict: Sure

Study arms

HL+SDM (N = 76) HL programme adapted from the United Kingdom Skilled for Health program with added 6-hour SDM component that aimed to build students' skills and self-efficacy to participate in health care decision-making.
Control (N = 60) Standard Language, literacy, and numeracy (LLN)

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(Study only partially randomised)*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	High *(Some patients randomised)*
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	High *(No definition between randomised and non-randomised dropouts)*
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(PROM outcome measures)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Whilst randomised results presented separately there are non-randomised data in analysis and the risk of extra bias occurring here is high.)*
	Overall Directness	Directly applicable

Myers 2011

Myers, 2011

Bibliographic Reference	Myers, Ronald E; Daskalakis, Constantine; Kunkel, Elisabeth J S; Cocroft, James R; Riggio, Jeffrey M; Capkin, Mark; Braddock, Clarence H 3rd; Mediated decision support in prostate cancer screening: a randomized controlled trial of decision counseling.; Patient education and counseling; 2011; vol. 83 (no. 2); 240-6

Study details

Component	Third person support and Preference/value elicitation
Study type	Randomised controlled trial
Study location	Philadelphia, USA
Study setting	Two primary care practice sites.
Study dates	2003 and 2007
Duration of follow-up	6 months
Sources of funding	AAMC/CDC cooperative agreement grant MM-0554-03.
Inclusion criteria	Criteria 1 Male Criteria 2 no history of prostate cancer Criteria 3 benign prostatic hyperplasia (BPH) Criteria 4 did not have a PSA test in the previous 11 months Age

	50-69
Exclusion criteria	Criteria 1 nr
Sample size	313
Loss to follow-up	0
% Female	0
Mean age (SD)	50-59: Control: 113 (72%), Intervention: 103 (66%) 60-69: Control: 44 (28%), Intervention: 53 (34%)
Outcome measures	Outcome 1 Decisional conflict: DCS Outcome 2 Knowledge: patient knowledge Outcome 3 Other: Informed decision-making

Study arms

Enhanced intervention (N = 156) Nurse-led decision counselling. Nurse educator reviewed the prostate cancer screening brochure and elicited factors that were likely to influence the participant's screening decision, along with their relative influence and strength. The nurse educator then used a hand-held computer with a pre-programmed algorithm to compute each participant's decision preference score, which reflected his decision preference direction and strength.
Standard intervention (SI) (N = 157) Nurse educator placed a generic note on the SI Group participant's medical chart to prompt the patient's physician to discuss prostate cancer screening

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(Lack of info around randomisation)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(Patients switch group and lack of information around analysis.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Varies, subset of outcomes were randomised but main outcomes are PROMs)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Lack of information on randomisation OBOM better than PROM outcomes)*
	Overall Directness	Directly applicable

Nayak 2019

Nayak, 2019

Bibliographic Reference Nayak, J.G.; Scalzo, N.; Chu, A.; Shiff, B.; Kearns, J.T.; Dy, G.W.; Macleod, L.C.; Mossanen, M.; Ellis, W.J.; Lin, D.W.; Wright, J.L.; True, L.D.; Gore, J.L.; The development and comparative effectiveness of a patient-centered prostate biopsy report: a prospective, randomized study; Prostate Cancer and Prostatic Diseases; 2019

Study details

Component	Pre-consultation interventions
Study type	Randomised controlled trial
Study location	Washington, USA
Study setting	"clinic"
Study dates	Enrolment: From June 2015 until September 2017
Duration of follow-up	1 day
Sources of funding	Pacific Northwest Prostate Cancer SPORE (P50-CA097186) and the Institute for Prostate Cancer Research.
Inclusion criteria	Criteria 1 patients who had undergone a prostate biopsy that was positive for adenocarcinoma Criteria 2 presented to the clinic to review the results and discuss management options
Exclusion criteria	Criteria 1 failed questionnaire
Sample size	79
Loss to follow-up	NR
% Female	0
Mean age (SD)	Intervention: 64.5 (6.7) Control: 64.5 (6.2)
Outcome measures	Outcome 1 Patient activation: PAM Outcome 2 PROM SDM: patient-centred decision making Outcome 3 Self-efficacy: PEPPI-5 Outcome 4 PROM SDM: PDMS

Study arms

PCPR (N = 39) patients were given standard report with patient centred report: set up using expert panel and patient advisory board.
Control (N = 40) Standard report alone

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	High
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Patient reported outcomes with knowledge of interventions)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Concerns both with type of analysis (non-respondents excluded) and PROM outcomes*
	Overall Directness	Directly applicable

O’Leary 2016

O'Leary, 2016

Bibliographic Reference	O'Leary, Kevin J; Killarney, Audrey; Hansen, Luke O; Jones, Sasha; Malladi, Megan; Marks, Kelly; M Shah, Hiren; Effect of patient-centred bedside rounds on hospitalised patients' decision control, activation and satisfaction with care.; BMJ quality & safety; 2016; vol. 25 (no. 12); 921-928

Study details

Component	Documentary interventions
Study type	Cluster randomised controlled trial
Study location	Illinois, USA
Study setting	Four similar nonteaching hospitalist service units in a large urban hospital.
Study dates	12 May 2014 - 31 January 2015
Duration of follow-up	NR
Sources of funding	The Globe Foundation.
Inclusion criteria	Criteria 1 none
Exclusion criteria	Criteria 1 Disorientation Criteria 2 preferred language was not English
Sample size	493
Loss to follow-up	NR
% Female	Intervention: 124 (56.6%) Control: 148 (54.0%)
Mean age (SD)	Post-discharge patient satisfaction survey respondents:

	Control: 65.3 (15.8) Intervention: 63.4 (16.7)
Outcome measures	Outcome 1 Patient activation measure Outcome 2 nurses', physicians' and advanced practice providers' (APP) perceptions of PCBR using a survey developed for this study Outcome 3 satisfaction: post-discharge patient satisfaction survey items related to teamwork, involvement in decisions and overall care. Outcome 4 Control preferences scale: CPS Outcome 5 Declined to participate Outcome 6 Withdrew from study

Study arms

Implement patient-centred bedside round (N = 219) Daily, interprofessional rounds conducted at the bedside, designed with input from patients, family members and frontline professionals.
Control (N = 274)

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low

Section	Question	Answer
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Some concerns *(No reporting on randomisation order.)*
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	High *(Over half of patients in intervention arm did not have PCBR (54%))*
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(High but with caveat of study type making blinding very difficult)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *T*
	Overall Directness	Directly applicable

Rahn 2018

Rahn, 2018

Bibliographic Reference	Rahn, A. C; Kopke, S; Backhus, I; Kasper, J; Anger, K; Untiedt, B; Alegiani, A; Kleiter, I; Muhlhauser, I; Heesen, C; Nurse-led immunotreatment DEcision Coaching In people with Multiple Sclerosis (DECIMS)-Feasibility testing, pilot randomised controlled trial and mixed methods process evaluation.; International Journal of Nursing Studies; 2018; vol. 78; 26-36

Study details

Component	Third person support
Study type	Randomised controlled trial
Study location	Multiple, Germany
Study setting	Two multiple sclerosis university centres.
Study dates	March 2014 - March 2016
Duration of follow-up	post-intervention, 2 weeks
Sources of funding	German Ministry of Education and Research within the KKNMS (01GI1206)
Inclusion criteria	Criteria 1 were facing a decision on starting or switching a first line treatment and had internet access. Age 18 or older Clinical/Disease presentation had suspected or relapsing remitting multiple sclerosis
Exclusion criteria	Criteria 1 secondary-progressive or primary-progressive multiple sclerosis as well as any other suspected central nervous system disease Criteria 2 facing a decision on escalation immunotreatment or on symptomatic treatment Criteria 3 severe cognitive deficit or major psychiatric illness affecting information uptake.
Sample size	73
Loss to follow-up	15
% Female	Intervention: 68% Control: 80%
Mean age (SD)	Intervention: 38.3 (9) Control: 36.2 (11)
Outcome measures	Outcome 1 Choice: Informed choice using multi-dimensional measure of informed choice (MMIC)

	Outcome 2 Decisional conflict: DCS Outcome 3 PROM SDM: CPS (subscale - trust)

Study arms

Decision coaching for multiple sclerosis nurses: 6 steps of SDM (N = 38) (1) reviewing the problem, (2) key message, (3) information about pros and cons of each option, (4) expectations of the patient, (5) decision, and (6) arrangements. Use of online treatment information platform: DECIMS-Wiki: aims to provide information on several relevant topics on multiple sclerosis, but mainly focusses on treatment options. Final physician consultation.
Control (N = 35) DECIMS-Wiki and final physician consultation.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(High dropout rate but no clear reason what part of the intervention would cause this.)*

Section	Question	Answer
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Patient recorded outcome measures. No ability to blind.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Patient recorded outcome measures and large amounts of missing data)*
	Overall Directness	Directly applicable

Raue 2019

Raue, 2019

Bibliographic Reference	Raue, P.J.; Schulberg, H.C.; Bruce, M.L.; Banerjee, S.; Artis, A.; Espejo, M.; Catalan, I.; Romero, S.; Effectiveness of Shared Decision-Making for Elderly Depressed Minority Primary Care Patients; American Journal of Geriatric Psychiatry; 2019; vol. 27 (no. 8); 883-893

Study details

Component	Third person support and preference/value elicitation
Study type	Randomised controlled trial
Study location	New York City, USA
Study setting	Mental Health Centre
Study dates	April 2010 - November 2014
Duration of follow-up	12 weeks

Sources of funding	National Institute of Mental Health
Inclusion criteria	Criteria 1 scoring 10 or higher on medical staff or research assistant (RA)- administered Patient Health Questionnaire-9 Criteria 2 not receiving antidepressant medication or psychotherapy within past month Language Can read and speak Spanish.
Exclusion criteria	Criteria 1 bipolar, psychotic, dementia according to medical records Criteria 2 current substance abuse disorders via Structured Clinical Interview for Axis I Diagnostic and Statistical Manual of Mental Disorders (SCID)
Sample size	202
Loss to follow-up	Intervention: N = 41 Control: N = 32
% Female	81.2%
Mean age (SD)	72.1 (+/- 5.5)
Outcome measures	Outcome 1 HAM-D Outcome 2 Cornell Service Use Index Outcome 3 Satisfaction with decision making scale

Study arms

SDM (N = 114) patients were provided access to nurse-administered SDM. Consisted of a 30 minute in-person meeting followed by 2 weekly 10 −15 minute telephone calls.
Usual care (N = 88)

physicians engaged patients in depression treatment decisions as part of routine care		
Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(No information on how randomisation took place)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(No blinding but deviations unlikely to differ in real world situations.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(Large amount of missing data but balanced across groups.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(PROM unblinded)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Lack of data on randomisation, patient reported? outcome.)*
	Overall Directness	Directly applicable

Shepherd 2011

Shepherd, 2011

Bibliographic Reference	Shepherd, Heather L.; Barratt, Alexandra; Trevena, Lyndal J.; McGeechan, Kevin; Carey, Karen; Epstein, Ronald M.; Butow, Phyllis N.; Del Mar, Chris B.; Entwistle, Vikki; Tattersall, Martin H.N.; Three questions that patients can ask to improve the quality of information physicians give about treatment options: A cross-over trial; Patient Education and Counseling; 2011; vol. 84 (no. 3); 379-385

Study details

Component	Pre-consultation intervention
Study type	RCT
Study location	Australia
Study setting	Simulated patients in family practices
Study dates	NR
Duration of follow-up	Recorded appointments
Sources of funding	Macmillan Cancer Support funded this study in its entirety.
Sample size	36
Loss to follow-up	NR
% Female	NA
Mean age (SD)	NA

Outcome measures	Outcome 1 OBOM SDM - OPTION 12 Outcome 2 Assessing communication about evidence and patient preferences (ACEPP)

Study arms

Ask3Questions (N = 18) Designed to prompt physicians to provide information that patients need to make an informed choice between treatment options. 1. What are my options? 2. What are the possible benefits and harms of those options? 3. How likely are the benefits and harms of each option to occur? Elicits the minimum information needed for decision-making under conditions of uncertainty and to help organize the information that physicians give patients.
Control (N = 18) Presented with same symptoms but did not ask the three questions

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low

Section	Question	Answer
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Low
	Overall Directness	Partially applicable *(Simulated patients)*

Shepherd 2019

Shepherd, 2019

Bibliographic Reference	Shepherd, S.C.; Hacking, B.; Wallace, L.M.; Murdoch, S.E.; Belkora, J.; Randomised controlled trial of a repeated consultation support intervention for patients with colorectal cancer; Psycho-Oncology; 2019; vol. 28 (no. 4); 702-709

Study details

Component	Third person support
Study type	Randomised controlled trial (RCT)
Study location	Scotland
Study setting	Colorectal cancer clinic of a tertiary cancer centre
Study dates	January 2011 to January 2014
Duration of follow-up	3 months
Sources of funding	Funding for this study was provided by Macmillan Cancer Care, NHS Lothian, and Coventry University, United Kingdom. We acknowledge and thank all patients and staff. Immense thanks go to Sarah Scott and Dr. Deborah Bowyer, the Navigators within this study
Inclusion criteria	Criteria 1 Colorectal cancer patients considering oncology treatment
Exclusion criteria	Criteria 1 Non-English speaking Criteria 2 People with a limited capacity of ability to understand or engage fully with intervention Clinical/Disease diagnosis previous cancer diagnosis
Sample size	137
Loss to follow-up	NR

% Female	Intervention: 35.8% Control: 42.6%
Mean age (SD)	Intervention: 62.7 (SD 11.35) Control: 61.5 (11.99)
Outcome measures	Outcome 1 Decision self-efficacy Outcome 2 Decisional conflict Outcome 3 Decisional regret Outcome 4 Prepared for decision-making Outcome 5 Anxiety: HADS Outcome 6 Depression: HADS

Study arms

Decision navigation (N = 137) Two “navigators” delivered the intervention, 1. Consultation planning: Prior to the clinic appointment participant and Navigator created a list of prioritised questions and important information for the medical consultation, usually over the phone. This plan was shared with both patient and clinician before the appointment and a printed version was provided at the appointment. 2. Summary and audio recording: The Navigator attended three clinic appointments with the participant to type notes and audio record. Participants received the plain language typed summary, approved by the attending clinician, (sent within 1

week) and audio recording of their consultation via audio disk (provided immediately). Each navigator accompanied participants to up to three appointments over a 6-month period: 1. Initial medical consultation; the first appointment in which chemotherapy as an option is discussed and planned. 2. Second medical consultation; a review of the ongoing treatment. 3. Third medical consultation; a review following the end of first line treatment.

Control arm (N = 67)

Usual care participants were informed, and subsequent contact was limited to answering questions about and delivery of questionnaires.

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(Unblinded subjective outcomes)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	High *(Unblinded subjective outcomes)*
	Overall Directness	Directly applicable

Sheridan 2012

Sheridan, 2012

Bibliographic Reference	Sheridan, Stacey L; Golin, Carol; Bunton, Audrina; Lykes, John B; Schwartz, Bob; McCormack, Lauren; Driscoll, David; Bangdiwala, Shrikant I; Harris, Russell P; Shared decision making for prostate cancer screening: the results of a combined analysis of two practice-based randomized controlled trials.; BMC medical informatics and decision making; 2012; vol. 12; 130

Study details

Component	Preference/Values elicitation

	Third person support
Study type	Randomised controlled trial (RCT)
Study location	North Carolina, USA
Study setting	One academic and one community practice
Study dates	March 2005 and April 2006
Duration of follow-up	post-visit
Sources of funding	Centres for Disease Control and Prevention (CDC, #TS0845).
Inclusion criteria	Criteria 1 no prior history of prostate cancer, Criteria 2 seen in the practice for at least one year Criteria 3 physician agreed to participate in the study Age 40-80
Exclusion criteria	Criteria 1 presenting for an acute medical visit or if they had evidence of a serious medical illness (e.g. intensive care hospitalization within the last 6 months, more than 2 hospitalizations in the last 6 months)
Sample size	130
Loss to follow-up	2

% Female	0
Mean age (SD)	Control: 58 (41 – 74) Intervention: 57 (41-78)
Outcome measures	Outcome 1 PROM SDM: : Preferred participation in decision-making (self-made measure) Outcome 2 Knowledge: : knowledge about screening (self-made measure)

Study arms

Video PDA and counselor (N = 94) Video patient decision aid and counsellor delivered coaching to answer additional screening question clarify values and prepare to discuss screening
Control (N = 92) Educational video on highway safety

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Patient reported outcome measure: unable to blind)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Patient recorded outcome measures: unblinded* *(Two trials that were combined into meta-analysis)*
	Overall Directness	Directly applicable

Swoboda 2017

Swoboda, 2017

Bibliographic Reference	Swoboda, Christine M; Miller, Carla K; Wills, Celia E; Impact of a goal setting and decision support telephone coaching intervention on diet, psychosocial, and decision outcomes among people with type 2 diabetes.; Patient education and counseling; 2017; vol. 100 (no. 7); 1367-1373

Study details

Component	Third person support
Study type	Randomised controlled trial
Study location	Northwest USA
Study setting	NR
Study dates	January 2014 to July 2015
Duration of follow-up	16 weeks
Inclusion criteria	Criteria 1 overweight or obese Criteria 2 have 1 additional risk factor for CVD, including: LDL-cholesterol 100 mg/dl, triglycerides 150 mg/dl, blood pressure 130/ 80 mmHg, and/or A1C 6.5% Age 40 - 75 Clinical/Disease presentation diagnosed with T2DM 1 year
Exclusion criteria	Criteria 1 type 1 or gestational diabetes Criteria 2 body mass index (BMI) > 50 kg/m2 Criteria 3 pregnant/trying to become pregnant/ lactating Criteria 4 reported other medical concerns requiring dietary treatment Criteria 5 unable to perform physical activity without a physician's recommendation Criteria 6 may have had clinically significant depression (a score 10 on the Patient Health Questionnaire-8)

Sample size	54
Loss to follow-up	6
% Female	Intervention: 67.6% Control: 70.6%
Mean age (SD)	Control: 55.41 (7.82) Intervention: 56.76 (7.35)
Outcome measures	Outcome 1 Decisional conflict: DCS Outcome 2 Other: Decisional confidence scale Outcome 3 SDM Satisfaction: Satisfaction with decision scale

Study arms

Decision support and goal-setting intervention. (N = 37) 16-week decision support and goal setting intervention. One Motivational interview and decision support session followed by seven bi-weekly telephone coaching calls with the aim of encouraging lifestyle change through smart target, goal-setting and decision making.
Attention control (N = 17) The attention control (AC) group received calls and completed data collection on the same schedule as the intervention groups to control for contact time. AC participants received a guide to local health care resources and completed interviews that focused on discussion of community and public health resources. No coaching or goal setting occurred with these participants.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Lack of info on randomisation but sequence concealed.)*

Section	Question	Answer
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	High *(Unclear what type on analysis was undertaken. Arms combined post randomisation)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Attrition bias not stratified between arms.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Unblinded subjective outcome assessment)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	High *(Two arms combined in final data analysis.)*
Overall bias and Directness	Risk of bias judgement	High *(Arms combined post randomisation for analysis, arms very different sizes as result. Type of analysis unclear. No imputation of dropout data. subjective outcome measurement without blinding.)*
	Overall Directness	Directly applicable

Timmers 2018

Timmers, 2018

Bibliographic Reference Timmers, Thomas; Janssen, Loes; Pronk, Yvette; van der Zwaard, Babette C; Koeter, Sander; van Oostveen, Dirk; de Boer, Stefan; Kremers, Keetie; Rutten, Sebastiaan; Das, Dirk; van Geenen, Rutger Ci; Koenraadt, Koen Lm; Kusters, Rob; van der Weegen, Walter; Assessing the Efficacy of an Educational Smartphone or Tablet App With Subdivided and Interactive Content to Increase Patients' Medical Knowledge: Randomized Controlled Trial.; JMIR mHealth and uHealth; 2018; vol. 6 (no. 12); e10742

Study details

Component	Pre-consultation interventions
Study type	Cluster randomised controlled trial
Study location	Netherlands
Study setting	4 non-academic teaching hospitals, 1 general hospital, and 1 specialized orthopedic clinic
Study dates	April and September 2017
Duration of follow-up	1-day post consultation
Inclusion criteria	Criteria 1 referred by their GP because of knee complaints indicating OA Criteria 2 in the possession of an email address and a smartphone or tablet. Age >40 Language Fluent in Dutch
Sample size	307
Loss to follow-up	50
% Female	Control: 54.1% Intervention: 50%
Mean age (SD)	Control: 61.75 (8.54) Intervention: 62.27 (8.32)
Outcome measures	Outcome 1 Knowledge: Perceived knowledge Outcome 2 Other: Satisfaction with information (self-developed questionnaire) Outcome 3 Other: Satisfaction with knowledge Outcome 4 Other: Need for more information (self-developed questionnaire)

Study arms

Patient's Journey App (N = 148) Send information about disease to patients daily in lead up to consultation, information consists of: Treatment options, risk, rehabilitation and expectancies. Knowledge assessed inf form of quiz.
Control (N = 159) Standard education.

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Large amounts of missing data in both arms, imbalanced, not explained how this was accounted for)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(subjective outcomes with patients aware of their intervention)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Large amounts of missing data in both arms, PROM unblinded)*

Section	Question	Answer
	Overall Directness	Direct

van Roosmalen 2004

van Roosmalen, 2004

Bibliographic Reference van Roosmalen, M S; Stalmeier, P F M; Verhoef, L C G; Hoekstra-Weebers, J E H M; Oosterwijk, J C; Hoogerbrugge, N; Moog, U; van Daal, W A J; Randomized trial of a shared decision-making intervention consisting of trade-offs and individualized treatment information for BRCA1/2 mutation carriers.; Journal of clinical oncology : official journal of the American Society of Clinical Oncology; 2004; vol. 22 (no. 16); 3293-301

Study details

Component	Preference/value elicitation
Study type	Randomised controlled trial
Study location	Netherlands
Study setting	Family Cancer Clinics of the University Hospitals
Study dates	Recruitment: March 1999 - November 2001
Duration of follow-up	9 months
Sources of funding	Dutch Cancer Society (grant No. 98-1585),
Inclusion criteria	Criteria 1 chosen to undergo DNA testing Criteria 2 BRCA1/2 mutation was found.
Exclusion criteria	Criteria 1 unable to give informed consent

	Criteria 2 insufficient knowledge of the Dutch language Criteria 3 diagnosed with distant metastases, Criteria 4 undergone both bilateral mastectomy and oophorectomy Criteria 5 had been treated with chemotherapy, radiotherapy, or surgery for breast/ovarian cancer less than 1 month before blood sampling
Sample size	88
Loss to follow-up	1
% Female	100%
Mean age (SD)	Intervention: 39.1 (9.7) Control: 39.9 (10.4)
Outcome measures	Outcome 1 Other: Wellbeing: anxiety (spielberger state-trait anxiety inventory), depression (centre for epidemiologic studies depression scale), intrusive and avoidance of thoughts about cancer in family (impact of event scale) Outcome 2 Choice: Strength of treatment preference Outcome 3 Participation: perceived participation in DM (problem-solving DM scale) Outcome 4 disease: weighing treatment advice Outcome 5 Other: preferred preference and support and advice from specialists

Study arms

SDMI (N = 44) Trained research assistant - interval of 1 to two weeks. In the first session, individual values for treatment options were assessed using time trade-offs. In second session, TTO repeated by telephone.

Usual care (N = 44)		
Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Seems no-one was blinded to intervention assignment)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(subjective patient responses and unblinded intervention.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Patient reported outcomes with unblinded patients, some concerns due to non-blinding to intervention assignment)*
	Overall Directness	Directly applicable

Walczak 2017

Walczak, 2017

Bibliographic Reference	Walczak, Adam; Butow, Phyllis N; Tattersall, Martin H N; Davidson, Patricia M; Young, Jane; Epstein, Ronald M; Costa, Daniel S J; Clayton, Josephine M; Encouraging early discussion of life expectancy and end-of-life care: A randomised controlled trial of a nurse-led communication support program for patients and caregivers.; International journal of nursing studies; 2017; vol. 67; 31-40

Study details

Component	Third person support, Preference/value elicitation and Patient activation
Study type	Randomised controlled trial
Study location	Sydney, Australia
Study setting	six cancer treatment centres
Study dates	NR
Duration of follow-up	1 month
Inclusion criteria	Criteria 1 medical oncology patients with various advanced, incurable cancer diagnoses and an oncologist-assessed 2–12 month life expectancy Age adult Language English speaking
Sample size	110
Loss to follow-up	30
% Female	32.7%
Mean age (SD)	64.4 (11.09)
Outcome measures	Outcome 1 Other: Patient communication self-efficacy (PEPPI) Outcome 2 QoI: Patient QoL (FACT-G) Outcome 3 PROM SDM: Control preferences scale

Study arms

Nurse led communication support program (N = 61)

Two senior nurses each received approximately 40 h of training to deliver the two CSP sessions: 1) an approximately 45 min face to face meeting and 2) an approximately 15 min telephone booster session. Patients attended face-to-face meetings at cancer treatment centres approximately 1 week before a follow-up oncology consultation. A QPL designed for patients (and caregivers) with advanced, incurable cancer was introduced by the nurse and systematically explored to identify questions participants felt were relevant to them. A single telephone booster session was completed 1 to 2 weeks after patients' first oncology consultation following the face-to-face meeting.		
Usual care (N = 49)		
Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Lots of missing data with no reasoning, lot more dropout in intervention arm.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Subjective outcomes with unblinded assessors)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Lots of missing data and subjective unblinded proms.)*
	Overall Directness	Directly applicable

Wilkes 2013

Wilkes, 2013

Bibliographic Reference	Wilkes, Michael S; Day, Frank C; Srinivasan, Malathi; Griffin, Erin; Tancredi, Daniel J; Rainwater, Julie A; Kravitz, Richard L; Bell, Douglas S; Hoffman, Jerome R; Pairing physician education with patient activation to improve shared decisions in prostate cancer screening: a cluster randomized controlled trial.; Annals of family medicine; 2013; vol. 11 (no. 4); 324-34

Study details

Component	Preference/value elicitation and Patient activation
Study type	Cluster randomised controlled trial
Study location	California, USA
Study setting	2 large primary care networks associated with an academic medical centre, 2 staff model health maintenance organizations, and a medical group practice network
Study dates	May 2007 and December 2008
Duration of follow-up	some time 12 months after first appointment
Sources of funding	Centers for Disease Control and Prevention (CDC).v grant 1 RO1 PH000019-01
Inclusion criteria	Criteria 1 lacked serious comorbidity (including any known cancer) Age 55-65 Language Speak English
Sample size	705
Loss to follow-up	108
% Female	0
Mean age (SD)	Control: 63 (7)

	MD-Ed: 63 (7) MD-Ed + PA 64 (7)
Outcome measures	Outcome 1 Other: patients perception of shared decision making, measured by summing 4, 4-point scales derived from Kaplan's validated shared decision-making instrument simulated patients) Outcome 2 Other: achievement of information (CISQ)

Study arms

Physician education and patient activation (N = 113) Patients viewed a different, but related, program that both provided information and encouraged them to participate actively in the decision to pursue prostate cancer screening: The patient program includes video vignettes to depict the potential harms for 2 scenarios: (1) not having prostate cancer screening (a regretful patient dying of advanced prostate cancer), and (2) having prostate cancer screening with a false-positive result (a regretful patient with impotence from an ostensibly nontherapeutic prostatectomy).
Physician education alone (N = 239) The physician program allows a user to adjust any of the underlying model assumptions and instantly view how that affects a given patient's 10-year risk.
usual care (N = 353)

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low

Section	Question	Answer
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	High *(Large amounts of imbalanced missing data,)*
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(Subjective outcome measurement, not done at same time in every arm. Inappropriate analysis)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Large amounts of missing data imbalanced across arms, subjective data with patients not recorded at exactly the same timepoints)*
	Overall Directness	Directly applicable

Wilson 2010

Wilson, 2010

Bibliographic Reference	Wilson, Sandra R; Strub, Peg; Buist, A Sonia; Knowles, Sarah B; Lavori, Philip W; Lapidus, Jodi; Vollmer, William M; Better Outcomes of Asthma Treatment (BOAT) Study, Group; Shared treatment decision making improves adherence and outcomes in poorly controlled asthma.; American journal of respiratory and critical care medicine; 2010; vol. 181 (no. 6); 566-77

Study details

Component	Preference/value elicitation
Study type	Randomised controlled trial
Study location	USA, multiple locations
Study setting	five clinical sites
Study dates	NR
Duration of follow-up	1 year
Sources of funding	Supported by National Institutes of Health grants R01 HL69358 and R18 HL67092.
Inclusion criteria	Criteria 1 evidence of poorly controlled asthma Age 18 - 70 Clinical/Disease presentation Asthma (not well controlled)
Exclusion criteria	Criteria 1 intermittent asthma (brief exacerbations or symptoms less than once/wk) Criteria 2 COPD or emphysema diagnosis Criteria 3 insufficient pulmonary function reversibility (for ex-/current smokers and those without regular controller use) Criteria 4 regular use of oral corticosteroids Criteria 5 current asthma care management
Sample size	612
Loss to follow-up	SDM: 22 CDM: 24 UC: 15

% Female	UC: 57.4% CDM: 55.9% SDM: 56.4%
Mean age (SD)	SDM: 45.7 6 13.3 CDM: 46.9 +/- 12.1 Usual care: 45.1 +/- 12.4
Outcome measures	Outcome 1 Asthma related QoL Outcome 2 Patient-perceived roles in treatment decision making

Study arms

SDM intervention (N = 204) The SDM model implemented the four key defining features described by Charles and colleagues. The care manager elicited the patient's goals for treatment and relative priorities regarding symptom control, regimen convenience, avoidance of side effects, and cost. The patient was then shown a list of the full range of regimen options for all levels of asthma severity, based on the then-current national asthma guidelines and KP pharmacopeia. These options differed with respect to the number and type(s) of medications, dosing, and schedule. Using a simple worksheet, the patient and clinician then compared the pros and cons of all of the options the patient wished to consider, which included the option of continuing the patient's current de facto regimen (i.e., how they were using their current asthma medications) to arrive at a treatment that best accommodated the patient's and care manager's goal
Clinician decision making (N = 204)

Eliciting patient history, patient instructed in the correct use of medications. Written asthma management and action plan created, barriers addressed with motivational interviewing. identical to SDM in format, content, and all patient education handouts and worksheets, except for the process by which treatment was decided.
Usual care control (N = 204) Usual care

Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(Some missing non-imputed data but balanced across groups)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(PROM outcomes with unblinded assessors)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Only high due to PROM outcome measures, some missing data but not due to true value.)*
	Overall Directness	Directly applicable

Yamaguchi 2017

Yamaguchi, 2017

Bibliographic Reference	Yamaguchi, Sosei; Taneda, Ayano; Matsunaga, Asami; Sasaki, Natsuki; Mizuno, Masashi; Sawada, Yumiko; Sakata, Masuhiro; Fukui, Satoe; Hisanaga, Fumie; Bernick, Peter; Ito, Junichiro; Efficacy of a Peer-Led, Recovery-Oriented Shared Decision-Making System: A Pilot Randomized Controlled Trial.; Psychiatric services (Washington, D.C.); 2017; vol. 68 (no. 12); 1307-1311

Study details

Component	Third person support and Preference/value elicitation
Study type	Randomised controlled trial
Study location	Tokyo, Japan
Study setting	Two outpatient sites (one outpatient psychiatric clinic and one psychiatric hospital)
Study dates	July 2014 - March 2016
Duration of follow-up	6 months
Sources of funding	Grant in aid from the Japanese ministry of education, culture, sports, science and technology.
Inclusion criteria	Criteria 1 regularly received medical care from one of the four participating doctors at the two sites Criteria 2 received services from case managers in either a psychiatric day care or visiting nurse program Age >20
Exclusion criteria	Criteria 1 primary ICD-10 diagnosis of substance abuse, dementia, or neurotic disorder
Sample size	43
Loss to follow-up	1.7% (N=1 intervention)

% Female	Intervention: 38.5% Control: 44.5%
Mean age (SD)	Intervention: 39.38 (± 11.60) Control: 38.19 (± 9.45)
Outcome measures	Outcome 1 clinical outcomes (weight, symptoms, overall functioning, medication side effects and adherence, service satisfaction) Outcome 2 related outcomes (quality of life, recovery stage). Outcome 3 Decision support centre fidelity scale: The scale consisted of 13 items, with scores ranging from 13 to 65. Higher scores indicated closer adherence to the CommonGround approach. Outcome 4 SDM-18: based on the Elements of Informed Decision Making Scale, which has nine items identifying whether a clinical decision is present and assessing quality of the clinical decision in a medical consultation. Outcome 5 STAR-clinician Outcome 6 STAR-patients Outcome 7 IPC: Interpersonal Processes of Care Survey Short Form Outcome 8 Patient activation measure

Study arms

shared decision making system (intervention) group (N = 26) A comprehensive shared decision making system based on the CommonGround approach and incorporating peer support and a computerized decision aid [SHARE]
Treatment as usual (control) (N = 27) Usual medical consultation with the same doctors as the intervention group

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Research team members performed the ratings, although they were not independent assessors trained for fidelity assessment. Objective but not skilled assessors. Bias lower for SDM outcomes as these are not clinician reported like the health outcomes.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Measurement of outcome not blinded: Objective measures of SDM used)*
	Overall Directness	Directly applicable