National Institute for Health and Care Excellence

Final

Shared decision making

[B] Evidence review for interventions to support effective shared decision making

NICE guideline NG197

Evidence reviews underpinning recommendations 1.2.1 to 1.2.18 and research recommendations in the NICE guideline

June 2021

Final

These evidence reviews were developed by the NICE Guideline Updates Team

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive. All NICE guidance is subject to regular review and may be updated or withdrawn.

Copyright

ISBN: 978-1-4731-4145-2

Contents

Interventions to support effective shared decision making

Review question

What are the core components of interventions that support shared decision making?

Introduction

Shared decision making is a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care, now or in the future (for example, through advance care planning). It involves healthcare professionals working together with people who use services and their families and carers to choose tests, treatments, management or support packages, based on evidence and informed personal preferences, health beliefs, and values. This involves making sure the person has a good understanding of the risks, benefits and possible consequences of different options through discussion and information sharing.

Although the benefits of shared decision making are increasingly being recognised it is not yet routinely practised in every setting, and definitions of what constitutes shared decision making can vary. National surveys have shown that many inpatients want to be more involved in decisions about their care (45% and over 30% of primary care patients [CQC inpatient survey 2019]. The GP survey 2020 suggests 93% of patients in primary care are as involved as they want to be in their care, but there are still opportunities for more evidence around the best ways to perform and implement SDM.

A landmark ruling was made in 2015 by the UK Supreme Court following the Montgomery v Lanarkshire case. A new legal standard set out that adults ‘of sound mind’ are entitled to make informed decisions when giving or withholding consent to treatment or diagnosis. Consent ‘must be obtained before treatment interfering with bodily integrity is undertaken’, and it should only be gained when patients have shared a decision informed by what is known about the risks, benefits and consequences of all reasonable NHS treatment options. It is the healthcare professional’s duty to ‘take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.’

The aim of this review is to explore the effectiveness of the key components of interventions that support SDM, as defined by the SDM committee in earlier meetings.

PICO table

Table 1: PICO table for interventions that support shared decision making

Type of review	Effectiveness review

Population	Inclusion: • Adults using healthcare services (and their families, carers and advocates • healthcare providers
Intervention	Interventions to increase effective shared decision: • Pre-consultation interventions • Interventions to improve health literacy • Preference/value elicitation • Third person support • Patient activation • Documentary interventions
Comparators	• Head to head trials with other interventions from the list above. • No intervention/normal care • Sham intervention
Outcomes	**Primary** Engagement in shared decision making by healthcare providers and people who use healthcare services and their families, carers and advocates, measured using an objective observer-based outcome measure (OBOM). OBOMs are instruments used by a third observer to capture the decision-making process during an encounter between a healthcare professional and a patient/family caregiver when facing health treatment or screening decisions. **Secondary** Engagement in shared decision making by healthcare providers and people who use healthcare services and their families, carers and advocates, measured using a subjective measure (Patient Reported Outcome Measure). PROMs are instruments that collect information directly from patients. The measurement is recorded without amendment or interpretation by a clinician or other observer. Wellbeing and quality of life (including physical health, mental health and social wellbeing) using validated QoL measures. Changes in knowledge, intentions, culture, norms, ability and confidence in relation to undertaking shared decision making among healthcare providers and people who use healthcare services and their families, carers and advocates, as defined by the authors Satisfaction with shared decision making of people who use healthcare services (including perceptions of how satisfied they are from their family members, carers and advocates) using PROMs Unintended consequences (for example, decisional regret) using PROMs
Study types	• RCTs • Systematic reviews of RCTs

Methods and process

This evidence review update was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A

A broad range of interventions are used to improve or enable shared decision making. For the purposes of this guideline the committee was tasked with identifying the key interventions that were likely to be part of an effective SDM A sub-group of the committee, led by an academic expert in SDM prepared a paper for the committee (Appendix I) as a basis for the committee to discuss and agree the key components of SDM. On the basis of those discussions, the committee advised that the most relevant interventions to support SDM were:

- Pre-consultation interventions
- Interventions to improve health literacy
- Preference/value elicitation
- Third person support
- Patient activation
- Documentary interventions

For further details of the methods used see appendix B.

The search strategies used in this review are detailed in appendix C.

Declarations of interest were recorded according to NICE's 2018 conflicts of interest policy.

Clinical evidence

Included studies

A systematic search was carried out to identify randomised controlled trials (RCTs) and systematic reviews of RCTs that met the criteria set out in the PICO table. This was an overarching search for all six SDM components: pre-consultation intervention, health literacy, preference/value elicitation, third person support, patient activation, and documentary interventions.

The search found 9,879 references from both original searches (up to 13th January 2020) and rerun searches (up to 18th August 2020) (see Appendix C for the literature search strategy) along with an additional 28 identified from searching of included systematic reviews.

In total, 151 references were identified for potential inclusion at title and abstract level for all components and were examined in full text. At full text, 86 references were excluded, leaving 65 includes 29 systematic reviews and 40 primary studies.

The 29 systematic reviews were checked for missed primary studies. 127 studies from the systematic reviews were screened, and 28 primary studies were put into the main screen. Between both the systematic review check and main screen, 40 primary studies were identified and included in this review.

A detailed study flow can be found in Appendix D

References for included studies can be found in Appendix H.

Excluded studies

Details of studies excluded at full text, with reasons for exclusion, is given in Appendix G.

Summary of clinical studies included in the evidence review

A list of studies and their components are presented in Table 2.

40 primary studies were included in this review, and were stratified into 6 distinct components, or a combination of these 6. There were 10 cluster RCTs and 30 individual RCTs. Studies were not pooled in meta-analysis as committee agreed with NICE team heterogeneity of populations and outcomes was too high.

Table 2: List of study components

Note that Dillon 2017 is listed in 3 categories so total numbers do not equal numbers of included studies.

Component(s)	Study name
Pre-consultation interventions (6 studies)	Brown 2004
	Dillon 2017
	Landrey 2013
	Nayak 2019
	Shepherd 2011
	Timmers 2018
Interventions to improve Health literacy (1 study)	Muscat 2019
Preference/value elicitation (7 studies)	Denig 2014
	Granados-Santiago 2019
	Henselmans 2019
	Joosten 2008
	Krones 2008
	van Roosmalen 2004
	Wilson 2010
Patient activation (4 studies)	Cheng 2019
	Deen 2012
	Dillon 2017

Component(s)	Study name
	Hamann 2011
	Hamann 2020
Third person support (9 studies)	Aljumah 2015
	Collinsworth 2019
	Dobke 2008
	Doherty 2018
	Hacking 2011
	Ishii 2017
	Rahn 2018
	Shepherd 2018
	Swoboda 2017
Documentary interventions (3 studies)	Kravitz 2018
	Metz 2019
	O'Leary 2016
Patient activation + Pre-consultation interventions (1 study)	Dillon 2017
Patient activation + Documentary intervention (1 study)	Ledford 2018
Preference/value elicitation + Patient activation (1 study)	Wilkes 2013
Third person support + Preference/value elicitation (7 studies)	Berger-Hoger 2019
	Causarano 2015
	McBride 2016
	Myers 2011
	Raue 2019
	Sheridan 2012
	Yamaguchi 2017
Third person support + Preference/value elicitation + Patient activation (1 study)	Walczak 2017

See appendix E for full evidence tables.

Summary of results

Pre-consultation interventions

Pre-consultation interventions were categorised as material aiming to provide the patient a "primer" of information before a consultation, to be read, viewed or listened to alone without a third parties input. These materials would often describe potential patient preferences, or encourage and explain shared decision making, but stop short of eliciting values/preferences or full patient activation. The complexity of these interventions ranged from a simple form to more complex interventions such as a digital app which could provide daily notifications.

Table 3: Summary of study characteristics – Pre-consultation Interventions

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Brown 2004	RCT	2	Australia	65	Booklet intervention	Control booklet	Teaching hospitals – Cancer patients
Dillon 2017 – arm 1 vs UC	Cluster RCT	2	USA	20	AskShareKnow	Usual care	Four primary care clinics – General patients
Landrey 2013	RCT	2	USA	303	Mailed flyer	No flyer	General practice – General patients
Nayak 2019	RCT	2	USA	79	Patient centred prognosis report	Standard report	Prostate cancer clinic – Prostate cancer patients
Shepherd 2011	RCT	2	Australia	36	Ask3questions	No intervention	Simulated patients at family practices
Timmers 2018	RCT	2	Netherlands	307	"Patient's journey" app	Standard education	Teaching hospitals, general hospital, orthopaedic clinic – Patients with knee complaints

Table 4: Intervention descriptions from papers – Pre-consultation interventions

Brown 2004 Booklet intervention	An eight-page booklet titled "How treatment decisions are made" was developed in consultation with an international panel of experts in the fields of evidence-based medicine, psycho-oncology and consumer involvement. The package was designed to operate as an "advanced organizer" that lays the framework for the patient's understanding of the overall structure of the decision-making process. The package was designed to provide both a structuring of knowledge regarding clinical decision-making and sufficient cues to activate the learning achieved in the context of the consultation. The booklet described decision-making in the context of evidence-based medicine, treatment options and patient preferences. It describes: (a) the importance of evaluating treatments before they are

	widely used, using historical examples where failure to do so resulted in medical disasters, (b) different stages of research which are conducted to evaluate the safety and efficacy of new treatments; (c) levels of evidence, (d) how the doctor decides which treatment to recommend, (e) the importance of patient involvement in treatment decision-making, if that is desired and (f) a list of suggested questions to ask the doctor about treatment options.
Dillon 2017 AskShareKnow	Patients in the ASK arm received a flyer prior to their appointment that encouraged them to ask their primary care physicians 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?
Landrey 2013 Mailed flyer	The flyer was developed by the study authors with feedback by internal medicine physicians at the University of Colorado. Written at a fourth grade (9 – 10 years old) level, it provided basic information about the Prostate Specific Antigen (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.
Nayak 2019 Patient centered prognosis report	The objective of this study was to create a patient-centered prostate biopsy report and compare its effectiveness with standard pathology reports in a randomized setting. It hypothesized that the patient-centered prostate biopsy report would improve patient understanding regarding the diagnosis. A web-based survey was constructed where a multidisciplinary team of experts rank-ordered a list of key prostate pathology report elements. Patient Advisory Board Authors met with a Patient Advisory Board comprising local prostate cancer survivors from the University of Washington to identify patient-centered design and syntax that incorporated the previously identified key elements into a prostate biopsy pathology report. This information was then used to draft multiple candidate patient-centered pathology reports (PCPRs). The questions consisted of: Why do we do biopsies? What did it[the biopsy] show? How much cancer is there? How bad is it? What is the overall risk to my life? Was there anything else?

Shepherd 2011 Ask3Questions	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.
Timmers 2018 “Patient Journey” app	The Patient Journey app (Interactive Studios, Rosmalen, The Netherlands) was used as the intervention. By using push notifications, it actively offered patients information about knee osteoarthritis (OA), (conservative and operative) treatment options, risks, rehabilitation, and expectancies in a subdivided (daily) and categorized (per theme) manner. Information was presented on an interactive timeline using text, photos, and video content. Interactive quiz-like questions were used to test their knowledge, providing direct feedback on the given answer. The content for the app was compiled based on the input of 10 orthopaedic surgeons from various hospitals, the Dutch option grid for knee OA, and information booklets from 3 participating hospitals. The 5 most important topics, as agreed upon by the surgeons, were (1) knee anatomy and the origin of the complaints, (2) different types of conservative and operative treatments, (3) risks of surgery, (4) rehabilitation after total knee replacement, and (5) expectations after total knee replacement. These topics also formed the base for the questionnaires addressing perceived and actual knowledge Patients used the app in the 7 days before the first consultation with their orthopaedic surgeon. During the first 5 days, information concerning the 5 most important topics was provided, whereas on days 6 and 7, a summary as well as practical information on how to prepare for the consultation itself were provided. Patients received daily push notifications at 10:00 am. During the study, no changes or revisions to the app took place.

Table 5: Summary of GRADE - Pre-consultation Interventions

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Brown 2004 – Decisional conflict: DCS – post-consultation	60	MD 1.20 (-0.83, 3.23)	+/- 1.50	Low	Could not differentiate
Brown 2004 – Satisfaction: Patient satisfaction – post-consultation	60	MD -0.10 (-1.12, 0.92)	+/- 1.10	Low	Could not differentiate
Brown 2004 – Depression (Beck depression Inventory) - 6 months	**60**	**MD 1.90 (0.21, 3.59)**	**+/- 0.70**	**Low**	**Effect (Favours Control)**
Brown 2004 – Anxiety (Spielberger State-Trait Anxiety Inventory) - 6 months	60	MD -1.30 (-7.10, 4.50)	+/- 4.70	Low	Could not differentiate
Dillon 2017 (Arm 1) – OPTION 5 – ASK vs Usual Care	20	MD 1.90 (-3.40, 7.20)	+/- 3.02	Very low	Could not differentiate
Landrey 2013 – PROM SDM: CPS (preferred active role in SDM)	283	RR 0.98 (0.91, 1.05)	0.80 , 1.25	Low	No meaningful difference
Nayak 2019 – CARE: empathy	79	MD -1.40 (-4.47, 1.67)	+/- 2.85	Very low	Could not differentiate
Nayak 2019 – self-efficacy: PEPPI-5	79	MD 0.40 (-1.46, 2.26)	+/- 1.95	Very low	Could not differentiate
Nayak 2019 – PROM SDM: PDMS	79	MD 1.00 (-10.07, 12.07)	+/- 13.55	Low	No meaningful difference
Shepherd 2011 – OBOM SDM: OPTION	**36**	**MD 4.70 (2.30, 7.10)**	**+/- 1.84**	**Moderate**	**Effect (Favours intervention)**
Shepherd 2011 – Communication about evidence and patient preferences: ACEPP	**36**	**MD 11.50 (5.10, 17.90)**	**+/- 4.90**	**Moderate**	**Effect (Favours intervention)**
Timmers 2018 – Actual Knowledge (self-developed questionnaire)	**213**	**MD 9.00 (7.06, 10.94)**	**+/- 3.40**	**Low**	**Effect (Favours intervention)**
Timmers 2018 – Perceived knowledge (self-developed questionnaire)	**213**	**MD 3.50 (1.92, 5.08)**	**+/- 2.05**	**Very low**	**Effect (Favours intervention)**
Timmers 2018 – Satisfaction with information (self-developed questionnaire)	**213**	**MD 1.70 (1.05, 2.35)**	**+/- 1.25**	**Very low**	**Effect (Favours intervention)**
Timmers 2018 – Satisfaction with knowledge (self-developed questionnaire)	**213**	**MD 1.40 (0.69, 2.11)**	**+/- 1.25**	**Very low**	**Effect (Favours intervention)**

Interventions to improve health literacy

Only one specific health literacy intervention was found, whilst many interventions looked at increasing patient knowledge of disease this was done in a more general “patient educational” manner and did not seek to address “health literacy” specifically in regards to SDM.

Table 6: Summary of study characteristics - Interventions to improve health literacy

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Muscat 2019	Cluster RCT	2	Australia	65	Booklet intervention	Control booklet	Teaching hospitals - Students

Table 7: Intervention descriptions from papers – Interventions to improve health literacy

Muscat 2019 Booklet intervention	Authors developed a health literacy program for adults with lower literacy to be run through established adult learning programs in New South Wales (NSW), Australia. The program was adapted from the United Kingdom Skilled for Health program to focus on Australian public health priorities and included 30 health topics (10 core units and 20 elective units). They added a core 6-hour SDM component that aimed to build students' skills and self-efficacy to participate in health care decision-making. SDM content was developed in collaboration with an adult education expert and revised on the basis of feedback from three adult education teachers.

This high risk of bias study did not present data in a way that could be extractable into GRADE, but was the best available evidence for the health literacy component. The significance reported below is form the paper itself.

There was no significant difference in the number of patients with adequate overall health literacy skills (i.e., achieved the a priori competence threshold of 9 of 14 items correct) between the health literacy training and standard language literacy numeracy training arms ($p = .426$). [Sample size 80]

Health literacy training participants were significantly more likely to consider questions about options, the benefits and harms of options, and the personal likelihood of the benefits and harms of different options to be important compared to standard language, literacy and numeracy training participants (all $p < .01$). [Sample size 95]

There was no significant difference in the number of patients indicating a patient-involved decision making preference to experience decisional conflict between the health literacy training and standard language literacy numeracy training arms .($p = .870$ and $p= .129$).

Preference/value elicitation

Preference and value elicitation concerned ensuring the patient's desires in the consultation were recorded in some way during the clinical encounter, and foster a more patient-inclusive way of deciding on treatments. Preference value elicitation was often used in conjunction with risk communication and patient decision aids to help the patient understand what treatment option they feel is best. This took various forms, both methodologically (including question prompt lists, time trade offs, and value clarification methods) and in terms of method of delivery (electronic, paper-based). Most preference elicitation methods were clinician-led, with one being clearly situated in a patient self-management scheme. Some preference/value elicitations took place over several sessions, with the dyad returning to ensure preferences and values had not changed.

Table 8: Summary of study characteristics - Preference/value elicitation

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Denig 2014	Cluster RCT	2	Netherlands	344	"Decision aid" with shared goal setting	Usual care	Primary care general practices – Diabetes patients
Granados-Santiago 2019	RCT	2	Spain	42	COPD self-management programme	Usual care	Hospital – hospitalised patients with COPD exacerbations
Henselmans 2019	RCT	4	Netherlands	194	Patient communication, oncologist SDM training, both	Usual care	Hospital oncology departments – patients with metastatic or inoperable tumours
Joosten 2008	RCT	2	Netherlands	147	5 part SDM reporting – multiple preference discussions	Motivational interviewing	Addiction treatment centres – inpatients dependent on psychiatric substances
Krones 2008	Cluster RCT	2	Germany	550	Multifaceted SDM intervention	Placebo educational meeting	Primary care, Ambulatory care – patients with cardiovascular issues
van Roosmalen 2004	RCT	2	Netherlands	88	Individual value assessment	Usual care	Family cancer clinic – patients with higher risk of breast cancer
Wilson 2010	RCT	3	USA	612	Eliciting patient treatment goals and priorities	Clinicians decision making / Usual care	Five clinical sites - Asthma patients

Table 9: Intervention descriptions from papers – Preference/value elicitation

Denig 2014 "Decision aid" with shared goal-setting	The authors 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. The aid focuses on shared goal-setting and decision-making, particularly with respect to the drug treatment of risk factors. The decision aid shows several graphs using individually tailored information. Graphs are then presented showing potential risk reductions with possible treatment options and questions posed to the patient. Key features, identified as being relevant for productive patient-provider interaction, included a personal status report including test results and current drug treatment; the presentation of tailored information on achievable treatment goals and possible treatment options for specific risk factors; a combination of graphs and text using natural frequencies for outcome probabilities; the presentation

	of pros and cons of all treatment options; and asking patients to think about treatment options. The aid retrieves clinical information directly from the electronic medical record to be used by patients before a regular quarterly check-up and discussed jointly with their healthcare provider during the consultation to help them prioritise on treatment that will maximise relevant outcomes. The software is integrated in the electronic medical record for additional data entry or corrections. The software is complemented with a set of treatment cards that can be used during consultation, summarising the positive and side effects of the various treatment options, including doing nothing. The patients were asked to come to the practice 15 minutes in advance to go through the information, either in print or on the computer. During the consultation, healthcare providers were expected to support patients to think about treatment goals and options, making use of the computer screen or printed version of the information. When appropriate, healthcare providers could present and compare specific treatment options using the treatment cards. The consultation ideally was to be concluded with clear action points. At the end of the consultation, the printed version was to be distributed to all intervention patients. When the regular scheduled time was too short, a further consultation could be planned to finalise the shared decision making.
Granados-Santiago 2019 COPD self-management programme	All patients included in the intervention group received an individualized SDM-PE program added to the standard treatment during the hospitalization period. The program was tailored to meet the needs of each patient. The SDM-PE program was developed focusing on chronic obstructive pulmonary disease (COPD) self-management goals, although other characteristics such as health care competence were also considered taking into account the clinical profile of patients and their priorities, interests, and preferences. The key elements of each SDM-PE program are 1. Evaluate and identify COPD self-management goals, 2. Health care team counsels a proposal strategy about patient's care 3. Discuss strategies with patients, where COPD patients have opportunities to make decisions regarding their preferences and interests 4. Deliver information, training and feedback on selected goals *5.* Accomplishment analyse of planned objective *[sic]*

	The SDM-PE program goals included pharmacological management, symptomatic control, and healthy lifestyle promotion. The decision-making process was developed collaboratively among professionals and patients by providing information, explaining the advantages and disadvantages, and promoting the active role of COPD patients. The contents of the program were developed jointly with each patient in a problem-solving format in order to detect potential misbeliefs, considering the best available evidence concerning the risks and benefits of each option.
Henselmans 2019 Patient communication & oncologist SDM training	The patient communication aid (PCA) was developed based on examples, interviews with patients and (bereaved) relatives, and a pilot. It encompasses a paper brochure containing education about SDM, a question prompt list (QPL), and value clarification methods (VCMs). The brochure presents the treatment options: disease-targeted treatment and best supportive care. The subsequent QPL is a structured list of example questions patients can ask their physician. QPLs have been shown to stimulate question asking and putting difficult issues, such as prognosis, on the agenda. The last part contains VCMs, which are often used in decision aids to help patients in constructing a treatment preference. The VCM included open-ended questions about values, narratives of fictive patients expressing their values, and scaling items requiring the weighing of opposing values. Patients were encouraged to share their answers with their oncologist.
Joosten 2008 5 part SDM intervention – multiple preference discussions	This 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. Three months before the start of the study clinicians of the experimental condition were trained in the SDMI protocol and in selected aspects of motivational interviewing techniques.
Krones 2008 Multifaceted SDM intervention	The counselling was structured according to the 6 steps also included in a decision aid. The patient's perspective on prevention of cardiovascular disease (CVD) (step 1, agree on task; step 2, talking about subjective risk) was addressed first, and patients were invited to a shared decision making process. Physicians then calculated each patient's absolute risk for stroke and myocardial infarction on the basis of an adapted Framingham algorithm with the decision aid. Individual prognosis was compared with age- and sex-adjusted population risk. For patients in secondary prevention, we assumed about 50% absolute risk for stroke or myocardial infarction in the next 10 years. This assumption was based on a secondary prevention trial calculating a relative risk reduction of preventive measures amounting 40% overall. Individual prognosis was displayed through marked smiley faces. The possible effects of single or multiple interventions were calculated by applying the specific relative risk reduction on the calculated and demonstrated absolute risk, which was visually supported by smileys being crossed out, ie, events prevented. Physicians were taught to calculate and show the effect of several preventive measures simultaneously.
Van Roosmalen 2004 Individual value assessment	The SDMI was provided by a trained research assistant and consisted of three sessions with an interval of 1 to 2 weeks. In the first session, individual values for the treatment options (screening and prophylactic surgery) were assessed in a face-to-face interview by use of the TTO method. In the second session, the TTO interview was repeated by telephone. The questions asked in the face-to-face and telephone interview were identical. In a previous study, in a comparable study sample. Many women commented that the trade-off task led to a thoughtful evaluation of the health outcomes and considered the trade-off to be relevant. In the third session, individualized treatment information was shared with the women using two bar charts, one for life expectancy and one for quality adjusted life expectancy. The bar charts presented the treatment options relative to each other.

	The TTO interview started with an introduction, an example, and a flow-chart in which the women had to answer a series of questions. The value assessment started as follows: the health states following the treatment options were described in bulletpoint format on laminated cards, and the women were asked to rank them in order of preference. Values for each health state were then elicited with a flow-chart using the TTO method. Women were asked to choose between two certain options. Option 1 is to continue living with prophylactic surgery for a fixed time t (such as the rest of life until age 80 years). Option 2 is to continue living with screening for a time x less than t. Using forced choices, authors found how many years (x) in the health state screening was equivalent to a defined time (t) in the poorer health state prophylactic surgery. Time was used as the unit of comparison. By comparing the two times x and t, the value for each health state could be calculated. The TTO value for prophylactic surgery was calculated as (x/t).
Wilson 2010 Eliciting patient treatment goals and priorities	Two protocols. **SDM** Describe the shared decision making approach, identify patient goals and preferences. Summarize patient goals and preferences. Discuss regimen options and their relative merits in terms of patient goals and preferences. Negotiate a decision about treatment regimen. **CDM** No identification of patient preferences Clinician recommends new regimen based on guidelines

Table 10: Summary of GRADE - Preference/value elicitation

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Denig 2014 – Diabetes empowerment scale (setting and achieving goals)	315	MD 0.04 (-0.06, 0.13)	+/- 0.20	Low	No meaningful difference
Denig 2014 – Diabetes empowerment scale (readiness to change)	315	MD -0.02 (-0.10, 0.07)	+/- 0.19	Low	No meaningful difference
Denig 2014 – Diabetes empowerment scale (psychosocial management)	312	MD -0.00 (-0.09, 0.08)	+/- 0.19	Low	No meaningful difference
Denig 2014 – PEQD (patient's evaluation of quality of diabetes care)	313	MD -0.73 (-4.18, 2.72)	+/- 7.40	Low	No meaningful difference

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Denig 2014 – EQ5d-NL	308	MD -0.01 (-0.04, 0.02)	+/- 0.06	Low	No meaningful difference
Granados-Santiago 2019 – QoL: EuroQoL 5D – 3 months	42	MD -8.28 (-23.24, 6.68)	+/- 10.29	Moderate	Could not differentiate
Granados-Santiago 2019 – Patient knowledge: COPD-Q – 3 months	**42**	**MD 3.88 (3.17, 4.59)**	**+/- 0.81**	**High**	**Effect (Favours intervention)**
Granados-Santiago 2019 – Anxiety/Depression (Hospital Anxiety and Depression Scale (HADS) – 3 months	42	MD -0.13 (-0.44, 0.18)	+/- 0.36	Moderate	Could not differentiate
Henselmans 2019 – PDA, no training vs no PDA, no training – OPTION-12	99	MD 0.38 (-5.06, 5.82)	+/- 7.20	Moderate	No meaningful difference
Henselmans 2019 – PDA, no training vs no PDA, no training – 4 SDM	99	MD 1.09 (-1.00, 3.18)	+/- 2.68	Low	Could not differentiate
Henselmans 2019 – PDA, no training vs no PDA, no training – patient reported SDM	99	MD 2.31 (-1.66, 6.28)	+/- 5.07	Low	Could not differentiate
Henselmans 2019 – PDA, no training vs no PDA, no training – satisfaction: patient satisfaction	99	MD -2.73 (-9.31, 3.85)	+/- 7.84	Low	Could not differentiate
Henselmans 2019 – PDA, no training vs no PDA, no training – oncologist satisfaction	99	MD 2.25 (-2.25, 6.75)	+/- 5.41	Low	Could not differentiate
Henselmans 2019 – PDA, no training vs no PDA, no training – Decisional conflict: patient DC	99	MD 2.34 (-1.32, 6.00)	+/- 4.04	Low	Could not differentiate
Henselmans 2019 – PDA, no training vs no PDA, no training – patient QoL – 3 month	99	MD 2.40 (-5.09, 9.89)	+/- 9.60	Low	Could not differentiate
Henselmans 2019 – Training, PDA vs Training, No PDA – OPTION-12	95	MD 0.34 (-5.09, 5.77)	+/- 7.09	Moderate	No meaningful difference
Henselmans 2019 – Training, PDA vs Training, No PDA – 4 SDM	95	MD 0.87 (-0.97, 2.71)	+/- 2.44	Low	Could not differentiate
Henselmans 2019 – Training, PDA vs Training, No PDA – patient reported SDM	95	MD 0.92 (-1.98, 3.82)	+/- 3.50	Low	Could not differentiate
Henselmans 2019 – Training, PDA vs Training, No PDA – satisfaction: patient satisfaction	95	MD 0.05 (-7.55, 7.65)	+/- 9.23	Moderate	No meaningful difference
Henselmans 2019 – Training, PDA vs Training, No PDA – oncologist satisfaction	95	MD -2.49 (-8.02, 3.04)	+/- 6.20	Low	Could not differentiate
Henselmans 2019 – Training, PDA vs Training, No PDA – Decisional conflict: patient DC	95	MD -0.30 (-3.79, 3.19)	+/- 4.07	Moderate	No meaningful difference

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Henselmans 2019 – Training, PDA vs Training, No PDA – patient QoL – 3 month	95	MD 0.90 (-7.15, 8.95)	+/- 10.40	Moderate	No meaningful difference
Joosten 2008 – Patient Health alliance questionnaire – 3 months	103	MD -0.50 (-2.49, 1.49)	+/- 2.80	Low	No meaningful difference
Joosten 2008 – Clinician Health alliance questionnaire – 3 months	95	MD 1.60 (-0.35, 3.55)	+/- 2.70	Very low	Could not differentiate
Joosten 2008 – Health alliance questionnaire difference score – 3 months	**88**	**MD -3.30 (-6.02, -0.58)**	**+/- 3.65**	**Very low**	**Less than MID (Favours intervention)**
Krones 2008 – Shared decision making (patient participation scale) (PROM, continuous)	1132	MD 1.72 (1.22, 2.22)	+/- 2.25	Low	No meaningful difference
Van Roosmalen 2004 – Decision uncertainty: DCS – uncertainty subscale	80	MD -0.20 (-0.62, 0.22)	+/- 0.50	Very low	Could not differentiate
Van Roosmalen 2004 – General health	88	MD -0.30 (-0.99, 0.39)	+/- 0.65	Very low	Could not differentiate
Van Roosmalen 2004 – Anxiety (Spielberger State-Trait Anxiety Inventory state anxiety subscale)	86	SMD -0.18 (-0.60, 0.25)	+/- 0.50	Very low	Could not differentiate
Van Roosmalen 2004 – Depression (Center for Epidemiologic Studies Depression Scale)	86	MD -2.00 (-5.13, 1.13)	+/- 3.65	Very low	Could not differentiate
Van Roosmalen 2004 – Shared decision making (PROM, continuous)	78	SMD 0.30 (-0.14, 0.75)	+/- 0.50	Very low	Could not differentiate
Wilson 2010 – Patient-perceived roles in treatment decision-making	**408**	**MD 0.60 (0.45, 0.75)**	**+/- 0.45**	**Low**	**Effect (Favours intervention)**

Patient activation

Patient activation took two forms in the studies identified. Longer form patient specific training around encouraging self-management and self-motivation, and briefer interventions in which patients were not only encouraged to ask questions but “teach back” the concepts to their practitioner, which differs from the more straightforward question prompts seen in pre-consultation interventions. The key thread through all these interventions was “motivation” and the aim that the healthcare user would continue the practices they had learned after the intervention and subsequent consultation.

Table 11: Summary of study characteristics - Patient activation

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Cheng 2019	RCT	2	China	242	6-week patient empowerment program	General education (control)	Two tertiary teaching hospitals – General patients
Deen 2012	RCT	4	USA	279	Patient activation intervention with or without a patient decision aid	(Doctor visit) Control	Single health centre – General patients
Dillon 2017 – arm 2 vs UC	Cluster RCT	2	USA	20	OpenCommunication: physician coaching and activation tool	Usual care	Four primary care clinics – General patients
Hamann 2011	RCT	2	Germany	51	Patient training on participating in SDM	Cognitive reports (control)	University psychiatric hospital – patients with schizophrenia or schizoaffective disorder
Hamann 2020	Cluster RCT	2	Germany	161	SDM plus	Control	12 acute psychiatric wards

Table 12: Intervention descriptions from papers – Patient activation

Cheng 2019 6-week patient empowerment program	*A brief intake session: Assessing patients needs and setting personally meaningful goals.* • Discussing role and responsibilities of patients in diabetes care, • Assessing patients' self-management behaviors • Discussing patients' unique experience of poor glycemic control, • Identifying patients' needs and priorities, • Eliciting patients' self-motivational statements, • Framing collaborative self-management goals, • Knowledge and competence workbooks were provided to patients at the end of the brief intake session. *Two face to face group sessions: Establishing self-efficacy: culturally-tailored knowledge acquisition* • Discussing culturally-tailored self-management knowledge, including diet management, medication adherence, Self-Monitoring of Blood Glucose (SMBG),

	exercise, and foot care, prevention and early detection of complications; • Advocating flexible dietary principle (including a hand portion guide, the food pyramid, food exchange, low glycemic index food, healthy cooking, eating outside within collective cultural circumstances, and understanding food nutrition labels); • Advocating stepwise approximation strategy to an ideal, culturally acceptable eating plan; • Discussing cost-effective SMBG plan (including focused and staggered SMBG plan, SMBG plan when experiencing aberrations), strategies to interpret the SMBG results and make adjustment accordingly; • Facilitating recognition of personal and social resources; Assisting patients to manage uncertainty around diabetes and self-management; • Experience sharing and discussion from peers; Supporting patient initiatives for change *Two phone-based individual consultation sessions: Establishing self-efficacy: skills training and taking action* • Encouraging to build supportive relationships with family members; • Assessing individuals' self-management performances in real life; • Encouraging expression of concerns and responding to patients' emotions; • Practicing the learned skills (including goal setting, action planning, problem-solving, reflection, relapse prevention, and healthy coping); • Encouraging participation in decision-making and establishing self-efficacy; • Maintaining physical and emotional stability; • Developing a personalized self-management action plan and addressing patients' priorities *Two phone-based maintenance sessions: Taking actions and reflecting*

	• Reflecting self-management experience and goal achievements in the past six weeks • Recognizing the strengths, weaknesses, opportunities, and obstacles • Refining long-term goal setting and action plans • Discussing available personal, community, and social resources to facilitate the continuity of self-care. *Six phone-based telephone follow-up counselling sessions: Reinforcement* • Monitoring patients' self-care progress • Facilitating patients to review the material provided (knowledge and competence workbooks) • Providing informative and emotional support to help patients solve problems in a collaborative manner
Deen 2012 Patient activation intervention with or without a patient decision aid	In conjunction with collaborators from the Right Question Project authors developed a brief Patient Activation Intervention (PAI). 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. For the current study they tested the effectiveness of a generally activating decision aid developed by the Foundation for Informed Decision Making.
Dillon 2017 OpenCommunication: physician coaching and activation tool	The OpenComm intervention involved (1) a brief introductory animated video, (2) Standardized 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.
Hamann 2011 Patient training on participating in SDM	The training consisted of 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 was in charge of the specific care of these patients.
Hamann 2020 SDM-plus	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.

Table 13: Summary of GRADE: Patient activation

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Cheng 2019 – Empowerment level (Diabetes empowerment scale short form) - 1 week	209	MD 0.16 (0.01, 0.31)	+/- 0.28	Moderate	Less than MID (Favours intervention)
Cheng 2019 – Empowerment level (Diabetes empowerment scale short form) - 3 months	201	MD 0.18 (0.02, 0.33)	+/- 0.28	Moderate	Less than MID (Favours intervention)
Cheng 2019 – Diabetes related distress (diabetes distress scale) – 1 week	209	MD -0.13 (-0.27, 0.01)	+/- 0.26	Moderate	Could not differentiate
Cheng 2019 – Diabetes related distress (diabetes distress scale) – 3 months	201	MD -0.18 (-0.35, -0.01)	+/- 0.31	Moderate	Less than MID (Favours intervention)
Cheng 2019 – Quality of life (audit diabetes dependent quality of life) – 1 week	209	MD 1.62 (-2.72, 5.95)	+/- 7.99	High	No meaningful difference
Cheng 2019 – Quality of life (audit diabetes dependent quality of life) – 3 months	201	MD 4.15 (1.29, 7.01)	+/- 5.17	Moderate	Less than MID (Favours intervention)
Deen 2012 PA vs doctor visit – Patient activation	142	MD 0.51 (-1.43, 2.45)	+/- 2.83	Low	No meaningful difference

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Deen 2012 PA vs doctor visit – Decision self-efficacy	35	MD 2.13 (-9.13, 13.39)	+/- 9.64	Very low	Could not differentiate
Deen 2012 PDA vs doctor visit - Patient activation	138	MD -0.38 (-2.21, 1.45)	+/- 2.83	Low	No meaningful difference
Deen 2012 PDA vs doctor visit - Decision self-efficacy	36	MD 4.83 (-6.94, 16.60)	+/- 9.64	Very low	Could not differentiate
Deen 2012 PA and PDA vs doctor visit – Patient activation	137	MD 0.23 (-1.63, 2.09)	+/- 2.83	Low	No meaningful difference
Deen 2012 PA and PDA vs doctor visit – Decision self-efficacy	32	MD 6.40 (-5.85, 18.65)	+/- 9.64	Very low	Could not differentiate
Deen 2012 PA vs PDA – Patient activation	142	MD 0.89 (-0.99, 2.77)	+/- 2.64	Very low	Could not differentiate
Deen 2012 PA vs PDA – Decision self-efficacy	41	MD -2.70 (-11.35, 5.95)	+/- 7.70	Very low	Could not differentiate
Deen 2012 PA vs PA and PDA – Patient activation	141	MD 0.28 (-1.64, 2.20)	+/- 2.73	Low	No meaningful difference
Deen 2012 PA vs PA and PDA – Decision self-efficacy	37	MD -4.27 (-13.55, 5.01)	+/- 7.78	Very low	Could not differentiate
Deen 2012 PA and PDA vs PDA – Patient activation	137	MD 0.61 (-1.19, 2.41)	+/- 2.64	Low	No meaningful difference
Deen 2012 PA and PDA vs PDA – Decision self-efficacy	38	MD 1.57 (-8.33, 11.47)	+/- 7.70	Very low	Could not differentiate
Dillon 2017 – OPTION 5 – Opencomm vs usual care	20	MD 4.05 (-2.11, 10.22)	+/- 3.52	Low	Could not differentiate
Hamann 2011 – Shared decision making (PROM, continuous)	61	SMD -0.18 (-0.68, 0.32)	+/- 0.50	Very low	Could not differentiate
Hamann 2011 – Satisfaction with treatment	61	SMD -0.32 (-0.83, 0.19)	+/- 0.50	Very low	Could not differentiate
Hamann 2011 – Decision self-efficacy	61	SMD 0.04 (-0.46, 0.55)	+/- 0.50	Very low	Could not differentiate
Hamann 2020 - PROM SDM: SDM-q-9 Perceived involvement in DM	322	MD 1.07 (0.39, 1.75)	+/- 1.56	Very low	Less than MID (Favours intervention)
Hamann 2020 - Patient measure of therapeutic relationship: Helping alliance scale (HAS-P)	322	MD -0.42 (-0.94, 0.10)	+/- 1.19	Low	No meaningful difference
Hamann 2020 - Clinician measure of therapeutic relationship: Helping alliance scale (HAS-C)	322	MD 3.04 (1.69, 4.39)	+/- 3.09	Very low	Less than MID (Favours intervention)

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Hamann 2020 - Patient satisfaction with treatment (ZUF8)	322	MD -0.79 (-1.91, 0.33)	+/- 2.56	Low	No meaningful difference
Hamann 2020 - Camberwell assessment of need self-report questionnaire (unmet need)	322	MD 3.96 (-10.32, 18.24)	+/- 32.68	Low	No meaningful difference
Hamann 2020 - wellbeing (WHO-5)	322	MD 1.59 (-1.47, 4.65)	+/- 7.00	Low	No meaningful difference
Hamann 2020 - Quality of life: EUROHIS-QOL	322	MD 1.07 (0.39, 1.75)	+/- 1.56	Very low	Less than MID (Favours intervention)

Third person support

Third party support was observed in the included studies in two forms, one being a team of third party members supporting the patient in a group setting, and the other being a non-doctor third party individual priming or supporting the patient, preparing them for a consultation setting. Third parties were mostly nursing staff but also included pharmacists, therapists, and dietitians.

Table 14: Summary of study characteristics - Third person support

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Aljumah 2015	RCT	2	Saudi Arabia	239	Usual pharmacy and SDM competency framework	Usual care	Psychiatric hospital – patients with depression
Collinsworth 2019	RCT	2	USA	308	SDM self-management	COPD education (Control)	community hospital in a low-income suburb - COPD patients
Dobke 2008	RCT	2	USA	30	Telemedicine consultation	No telemedicine contact	Plastic surgery dept of hospital – patients on a wound care program
Doherty 2018	RCT	2	UK	517	Nurse individualised packaged of care	Control	General practice – patients with gout
Hacking 2013	RCT	2	Scotland	123	Decision navigation	Usual care	Prostate cancer clinic

Ishii 2017	RCT	2	Japan	24	SDM model program	Text-based decision aid	Psychiatric ward – patients with schizophrenia spectrum disorder
Rahn 2018	RCT	2	Germany	73	Nurses trained in decision coaching	Usual care	Multiple sclerosis centres – multiple sclerosis patients
Shepherd 2018	RCT	2	Scotland	137	Decision navigation	Usual care	Colorectal cancer clinic of tertiary cancer centre
Swoboda 2017	RCT	2	USA	54	Decision-support and goal-setting intervention	Attention control	No specific setting – Overweight or obese type-2 diabetes patients

Table 15: Intervention descriptions from papers – Third person support

Aljumah 2015 Usual pharmacy and SDM competency framework	During the intervention, pharmacists followed the SDM competency framework, which was designed specifically for depressed patients, to ensure all aspects of SDM were implemented for each patient. Before the SDM session started, the research team distributed a decision aid to patients in the intervention group. The intervention focused on enhancing patients' involvement in decision making by assessing their beliefs and knowledge about antidepressants. The average duration of the first SDM session (baseline) was 15 min, and the second session (final session) lasted 10 min (at 3-month follow-up).
Collinsworth 2019 SDM self-management	The COPD education and SDM self-management planning took place in the hospital and lasted 15–30 minutes. The registered respiratory therapist used SDM principles 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. The therapist would then help the participants to create a COPD self-management plan. These patients also received follow-up phone calls lasting 5–10 minutes from the RRT at 3–7 days and 1, 2, and 6 months post-hospital discharge. These calls were guided by a structured checklist

	and included discussions about COPD exacerbations, health care utilization, the patient's self-management plan, further education, and coaching.
Dobke 2008 Telemedicine consultation	The telemedicine consult included (1) wound assessment, (2) rationale for the suggested wound management with emphasis on wound risk projections, and (3) prevention and benefits of surgical intervention. This was communicated to the patient by the field wound care nurse.
Doherty 2018 Nurse individualized package of care	As part of an individualised package of care, the nurses provided patients with holistic assessment, discussion of illness perceptions, and full information on gout (nature, causes, associations, consequences, and treatment options), and encouraged them to share in decision making. Patients were given the Arthritis Research UK gout information booklet. Follow-up assessments and measurement of serum urate concentrations were done as often as required by the nurse. Telephone contact (eg. to review serum urate results) could be substituted for face-to-face visits, and home visits were permitted (eg for older patients). If the nurses had questions about gout management, they could seek advice from a study rheumatologist. All contacts with participants were logged.
Hacking 2013	Intervention group patients met with their navigator by telephone or in person prior to their specialist treatment consultation. The aim of this meeting was to assist patients in identifying and framing key questions and concerns regarding cancer management options to generate a personal consultation plan for the appointment. Authors trained navigators in existing methods for non-directive interviewing and low-inference paraphrasing and summarising. The navigator produced a draft consultation plan and, after incorporating patient edits, gave copies to the physician in advance.
Ishii 2017 SDM model program	Participants received the SDM model program in addition to usual psychiatric inpatient care. The SDM model program is a 15–20-min weekly intervention during the acute psychiatric ward stay, and its development has been detailed previously. The 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. As a medical team, a primary physician, a primary nurse, and others participated in the meetings. To improve adherence and quality of the intervention, independent

	supervisors managed intervention schedules, facilitated meetings, and educated medical staff. First, participants are asked to complete a six-item self-reported questionnaire that assesses patients' perceptions of their treatment at the time. The questionnaire is an initial intervention tool allowing patients to express themselves more easily and prepare for the following session. Each question is written in a simple sentence, and is designed to be answered using a five-point Likert scale. In order to avoid perceived pressure from staff, the patient is asked to answer in private setting or with the help of a staff member if the patient requests assistance. Second, to discuss patients' and medical teams' perceptions of treatment, patients in the SDM intervention attend a group session. The members of each session are the patient, medical team (i.e. the primary doctor, the primary nurse, and other staff), and a facilitator from the supervision team. Regarding the questionnaire that the patient has answered, the patient and at least three ward staff members discuss for 15–20 minutes the on-going treatment, including medication, ward circumstances, and treatment goals. A facilitator from the study supervision team presides, trying to create a comfortable atmosphere both for the patient and staff members. Other participants are free to discuss their own views and preferences regarding the treatment. Third, all the session's participants draft the care plan sheet in order to outline clearly what they have shared in the session. The sheet displays the treatment information at that point in time, including remaining symptoms, diagnosis, the patient's condition, medication, problems at the ward and solutions, activities, and the goal of hospital treatment.
Rahn 2018 Nurses trained in decision coaching	The intervention consists of up to three coaching sessions, access to the DECIMS-Wiki and up to two physician consultations. The decision coaching sessions are structured following the six steps of shared decision making: (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. Patient workbooks, one on first line treatment and one for people with multiple sclerosis considering a treatment change as well as a coaching guide were developed to support and guide the decision coaching. The DECIMS-Wiki aims to provide information on several relevant topics on multiple sclerosis, but mainly focusses on treatment options. The content was built on former developed evidence-based patient information brochures and literature searches.

	Information on benefits and side effects on all available drugs are provided. Therefore, bar charts on disability progression and relapses were developed to display the absolute risk reduction for each immunotreatment option. The comprehension of the bar charts was evaluated in a randomised controlled trial (Kasper et al., 2016). People with multiple sclerosis received login details and a user guide after they filled in the baseline questionnaires. The DECIMS-Wiki was also used during coaching sessions (see above). The coaching process finishes with up to two physician consultations, where the final decision is made. All physicians received an information package on SDM (information sheet, paper and video on SDM) at the beginning of the study. Otherwise consultations were conducted as usual.
Shepherd 2018	Decision Navigation N = 65 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.
Swoboda 2017 Decision-support and goal-setting intervention	Intervention participants received one baseline in-person goal-setting and decision coaching session to encourage lifestyle change followed by seven biweekly coaching calls delivered by the same interventionist, a registered dietitian. Tailored, self-set goals and action plans pertaining to diet and/or physical activity were established using a motivational interviewing approach.

	The intervention did not assign concrete goals; instead, participants were guided toward making personalized goals consistent with their preferences and risk factors. Participants were instructed to set "SMART" (i.e., specific, measurable, attainable, realistic, and timely) goals and received a copy of self-set goals and action plans. Multiple goal group participants established one diet and one physical activity goal during the first session, and subsequently set goals in both domains during every coaching call. Those in the single goal group set a goal for either a diet- or physical activity-related behaviour during the first session based on individual preference. Single goal group members were instructed to set a new goal following goal attainment or alter an existing goal for one behavioural domain at a time at each subsequent call to promote goal mastery. During each coaching call, the participant discussed their success with self-set goals and created new or modified existing goals. A new goal was established following attainment of an existing goal. If a goal was not achieved, problem solving for minimizing barriers toward goal attainment occurred or an alternate goal was established, supported by decision coaching for working through decisional conflict as relevant. Goals and action plans were emailed to participants after each coaching session. Detailed notes were written following each coaching call to record new goals established, changes in diet and physical activity achieved during the previous two weeks, and personal, social and environmental factors that influenced goal attempts.

Table 16: Summary of GRADE – Third person support

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Aljumah 2015 – Beliefs about medicine (patients beliefs about medicine questionnaire) – 6 months	**220**	**MD -2.76 (-3.83, -1.69)**	**+/-2.21**	**Low**	**Effect (Favours control)**
Aljumah 2015 – Treatment satisfaction (Treatment Satisfaction questionnaire for medication (TSQM 1,4) – 6 months	220	MD 5.82 (2.61, 9.03)	+/-6.70	Low	Less than MID (Favours intervention)
Aljumah 2015 – Depression (Montgomery-Asberg scale) – 6 months	220	MD -0.21 (-3.45, 3.03)	+/-6.27	Moderate	No meaningful difference
Aljumah 2015 – Quality of life: EQ-5D – 6 months	220	MD 0.02 (-0.08, 0.12)	+/-0.19	Moderate	No meaningful difference
Collinsworth 2018 – Patient activation (PAM)	100	MD -0.17 (-0.54, 0.20)	+/-0.48	Very low	Could not differentiate

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Collinsworth 2018 – COPD assessment test score – 6 months	**100**	**MD -4.89 (-8.44, -1.34)**	**+/-3.89**	**Very low**	**Effect (Favours intervention)**
Dobke 2008 – Decisional conflict: DCS	**30**	**MD -21.00 (-23.33, -18.67)**	**+/-2.13**	**Low**	**Effect (Favours intervention)**
Dobke 2008 – SDM satisfaction (satisfaction with decision making scale)	**30**	**MD -1.40 (-2.27, -0.53)**	**+/-0.82**	**Very low**	**Effect (Favours control)**
Doherty 2018 – QoL: SF-36 Physical component – 2 years	517	MD 3.58 (0.86, 6.30)	+/-7.40	Low	No meaningful difference
Doherty 2018 – QoL: SF-36 mental component – 2 years	517	MD -1.10 (-3.19, 0.99)	+/-4.63	Low	No meaningful difference
Hacking 2013 – Decision self-efficacy - post intervention	90	MD 6.10 (0.13, 12.07)	+/-8.70	Very Low	Less than MID (Favours intervention)
Hacking 2013 – Decision self efficacy - 6 months	90	MD 6.30 (0.47, 12.13)	+/-8.30	Very Low	Less than MID (Favours intervention)
Hacking 2013 - Decisional conflict - post intervention	101	MD -0.16 (-0.40, 0.08)	+/-0.32	Very Low	Could not differentiate
Hacking 2013 - Decision conflict - 6 months	101	MD -0.23 (-0.46, -0.00)	+/-0.32	Very Low	Could not differentiate
Hacking 2013 – Decision regret - 6 months	102	MD -6.30 (-12.20, -0.40)	+/-8.00	Very Low	Less than MID (Favours intervention)
Ishii 2017 – Satisfaction: CSJ-8 – discharge	24	MD 1.60 (-1.46, 4.66)	+/-1.85	Very low	Could not differentiate
Ishii 2017 – Global assessment of functioning – discharge	24	MD 7.80 (-4.42, 20.02)	+/-9.45	Very low	Could not differentiate
Rahn 2018 – MAPPIN'SDM (physician consultation) – patient	**59**	**MD 0.30 (0.04, 0.56)**	**+/-0.20**	**Very low**	**Effect (Favours intervention)**
Rahn 2018 – MAPPIN'SDM (physician consultation) – physician	**55**	**MD 0.30 (0.06, 0.54)**	**+/-0.25**	**Very low**	**Effect (Favours intervention)**
Rahn 2018 – Decisional conflict (DCS) – patient	59	MD 0.30 (0.03, 0.57)	+/-0.30	Very low	Less than MID (Favours control)
Rahn 2018 – Decisional conflict (DCS) – physician	**55**	**MD 0.40 (0.09, 0.71)**	**+/-0.35**	**Very low**	**Effect (Favours control)**

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Rahn 2018 – PROM SDM (control preferences subscale – trust)	54	MD -1.60 (-7.26, 4.06)	+/- 4.60	Very low	Could not differentiate
Shepherd 2018 - Decision self-efficacy post-intervention	90	MD 6.10 (0.13, 12.07)	+/- 8.70	Very low	Less than MID (Favours intervention)
Shepherd 2018 - Decision self-efficacy 6 months (DSE scale)	90	MD 6.30 (0.47, 12.13)	+/- 8.30	Very low	Less than MID (Favours intervention)
Shepherd 2018 - Decisional conflict post-intervention	101	MD -0.16 (-0.40, 0.08)	+/- 0.32	Very low	Could not differentiate
Shepherd 2018 - Decisional conflict 6 months (DCS scale)	101	MD -0.23 (-0.46, -0.00)	+/- 0.32	Very low	Less than MID (Favours intervention)
Shepherd 2018 - Decision regret 6 months	102	MD -6.30 (-12.20, -0.40)	+/- 8.00	Very low	Less than MID (Favours intervention)
Shepherd 2018 - Decision self-efficacy post third consultation	**66**	**MD 9.47 (3.15, 15.79)**	**+/- 7.70**	**Very low**	**Effect (Favours intervention)**
Shepherd 2018 - Decisional conflict 3 months	69	MD -0.22 (-0.47, 0.03)	+/- 0.27	Very low	Could not differentiate
Shepherd 2018 - Decisional regret 3 months	68	MD -9.71 (-18.67, -0.75)	+/- 11.43	Very low	Less than MID
Shepherd 2018 - preparation for decision making	**72**	**MD 29.56 (17.15, 41.97)**	**+/- 15.98**	**Low**	**Effect (Favours intervention)**
Shepherd 2018 - Anxiety (HADS-A) 3 months	68	MD -0.33 (-2.41, 1.75)	+/- 2.23	Very low	Could not differentiate
Shepherd 2018 - Depression (HADS-D) 3 months	68	MD -0.33 (-2.02, 1.36)	+/- 1.91	Very low	Could not differentiate
Swoboda 2017 – Depression: PHQ-8 – 16 weeks	53	MD 0.37 (-2.64, 3.38)	+/- 2.90	Very low	Could not differentiate
Swoboda 2017 – Diabetes self-efficacy – 16 weeks	53	MD 0.92 (-0.29, 2.13)	+/- 1.10	Very low	Could not differentiate
Swoboda 2017 – Diabetes empowerment – 16 weeks	53	MD 0.53 (-0.04, 1.10)	+/- 0.52	Very low	Could not differentiate
Swoboda 2017 – Diabetes distress – 16 weeks	53	MD -0.16 (-0.54, 0.22)	+/- 0.32	Very low	Could not differentiate

Documentary intervention

Documentary interventions approached enabling SDM by focusing on the collection of ongoing data and how this then feeds back into the shared-decision making process, whether this be through a "trial" of treatments concluding in a patient-clinician discussion (such as physician prompts), or incorporating more SDM into aspects of care that are already performed in practice (such as routine outcome monitoring and bedside rounds).

Table 17: Study characteristics – Documentary interventions

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Kravitz 2018	RCT	2	USA	215	N of 1 trial	Baseline clinics	Veterans family medicine clinic – patients with chronic musculoskeletal pain
Metz 2019	Cluster RCT	2	Netherlands	186	Routine outcome monitoring	No ROM (Control)	Mental health clinic – any admitted patients
O'Leary 2016	Cluster RCT	2	USA	493	Patient centred-bedside rounds	No PCBR (Control)	General hospitals – general patients

Table 18: Intervention descriptions from papers – Documentary interventions

Kravitz 2018 N of 1 trial	Based on the clinician's judgment and the patient's preferences, the clinician-patient dyad selected from 9 treatment categories including current therapy and no therapy. Short-acting opioids were included as options because they are in common use in primary care and because it was believed that some patients might benefit from eliminating them. Treatment regimens for comparison (eg, treatment A and treatment B) could be single agents or combinations. Trials could be structured to compare treatments between categories or treatments within category. Dyads also chose the duration of each treatment period (1 or 2 weeks), the number of paired comparisons (2, 3, or 4), and the start date. Trials could last 4, 6, 8, or 12 weeks. Trial parameters were sent to the Trialist app on the patient's mobile device. The system randomly chose a balanced treatment sequence (eg, ABAB); alerted the patient when to begin each treatment; and sent a

	daily questionnaire covering pain on average, pain interference with enjoyment of life, and pain interference with daily activities (each self-assessed over the past 24 hours), as well as 5 potential adverse effects of treatment (drowsiness, fatigue, constipation, sleep problems, and cognitive impairment). At trial completion, patients were asked to meet with their clinician for a results review visit to discuss the n-of-1 trial experience while addressing any new or ongoing clinical concerns. Each dyad was provided graphs depicting their n-of-1 trial results, which were generated by comparing outcomes between regimens (treatment A vs treatment B), first descriptively and then using Bayesian models yielding absolute differences with 95% credible intervals and probabilities of small, medium, and large effects. To aid in interpretation, physicians had access to online instructional videos. Patients unable to schedule a results review visit within 8 weeks of n-of-1 trial completion could review results by telephone or email.
Metz 2019 ROM	The intervention teams, which participated for a full year in the QIC program, implemented a model with five steps to apply SDMR as a personalized source of information. Main component of this intervention was the implementation of routine outcome measures (ROM), tailored to the patient group, in routine clinical practice. In addition, prior to the study, the clinicians of the intervention teams underwent a 1-day training in applying SDMR in clinical practice. Over the course of this study, the clinicians of all the intervention teams received one central booster session, and additionally intervention teams organized their own local, regular supervision sessions. The researcher attended the supervision sessions of each team twice, aiming to monitor intervention integrity. A comprehensive description of the intervention can be found elsewhere.
O'Leary 2016 PCBR	Patient centred bedside rounds: Encounters including two physicians plus a nurse or other care provider discussing the case at the patient's bedside. Researchers assembled working groups on two intervention units, consisting of professionals and patient/family members, to determine the optimal timing, duration and format for PCBR. Nurses and hospitalists rounded together in PCBR using a communication tool to provide a framework for discussion and unit leaders joined PCBR to provide coaching during initial weeks of implementation.

Table 19: Summary of GRADE – Documentary interventions

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Kravitz 2018 – Shared decision making (PROM, continuous) consumer assessment of healthcare providers and systems survey– 12 months	215	MD 9.40 (0.05, 18.75)	+/- 17.48	Very low	Less than MID (Favours intervention)
Kravitz 2018 – patient satisfaction with care	170	MD 6.19 (-0.98, 13.36)	+/- 11.91	Very low	Could not differentiate
Kravitz 2018 – Health-related quality of life (physical)	170	MD 1.64 (-0.25, 3.53)	+/- 3.14	Very low	Could not differentiate
Kravitz 2018 – Health-related quality of life (mental) (PROMIS Global Health Scale)	170	MD 2.45 (0.11, 4.79)	+/- 4.52	Very low	Less than MID (Favours intervention)
Metz 2019 – Health-related quality of life	186	MD -0.05 (-0.32, 0.22)	+/- 0.47	Low	No meaningful difference
Metz 2019 – Alliance	186	MD -0.03 (-0.29, 0.23)	+/- 0.44	Low	No meaningful difference
Metz 2019 – Decisional conflict	186	MD -0.15 (-5.31, 5.01)	+/- 8.26	Low	No meaningful difference
Metz 2019 – Shared decision making (PROM, continuous) – SDM-Q-9 (patient) – 2 months	175	MD 7.56 (0.48, 14.64)	+/- 12.82	Low	Less than MID (Favours intervention)
O'Leary 2016 – Concordance between experienced role and preferred role in SDM	236	RR 0.99 (0.91, 1.08)	0.80 , 1.25	Low	No meaningful difference
O'Leary 2016 – Patient activation	236	MD 0.69 (-2.82, 4.20)	+/- 6.87	Low	No meaningful difference
O'Leary 2016 – Satisfaction (overall)	236	RR 1.14 (0.76, 1.70)	0.80 , 1.25	Very Low	Could not differentiate

Multiple components

Some studies featured multiple of the outlined SDM components in such a way that no single component took overall precedent, and thus these have been presented as combined interventions so as to appraise the relevant component effects.

Multiple components – Patient Activation and pre-consultation interventions

One study combined a brief pre-intervention question prompt list with a more in-depth patient activation "teach back" tool.

Table 20: Summary of study characteristics - Patient Activation and pre-consultation interventions

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Dillon 2017 – Arm 3 vs UC	Cluster RCT	2	USA	20	OpenCommunication + AskShareKnow	Usual care	Four primary care clinics – General patients

Table 21: Intervention descriptions from papers – Patient Activation and pre-consultation interventions

Dillon 2017 OpenCommunication: physician coaching and activation tool; AskShareKnow: Patient activation tool Combined intervention	The OpenComm and ASK interventions each incorporated a tool designed to promote SDM and communication between primary care providers (PCPs) and patients. The OpenComm intervention involved (1) a brief introductory animated video, (2) Standardized 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. Patients in the ASK arm received a flyer prior to their appointment that encouraged them to ask their 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?

Table 22: Summary of GRADE - Patient Activation and pre-consultation interventions

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Dillon 2017 – OPTION 5 – OpenComm + ASK vs Usual care	20	MD -2.29 (-7.35, 2.78)	+/- 2.89	Low	Could not differentiate

Multiple components – Patient activation and documentary intervention

One study aimed to use a more modern version of a tool to "activate" patients and enable them to document more of their information through journaling that they could then bring to the appointment.

Table 23: Summary of study characteristics - Patient activation and documentary intervention

Author	Study type	Arms	Country	N	Intervention	Control	Setting
Ledford 2018	RCT	2	USA	205	Mobile SDM app	Notebook SDM	Women health/ family medicine departments – patients requiring complicated obstetrics care

Table 24: Intervention descriptions from papers – Patient activation and documentary intervention

Ledford 2018 Mobile SDM app	The control (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. 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).

Table 25: Summary of GRADE - Patient activation and documentary intervention

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Ledford 2018 – change in Patient activation (PAM) – 32 weeks	205	MD -4.35 (-8.24, -0.46)	+/- 7.36	Low	Less than MID (Favours control)

Multiple components – Preference/value elicitation and Patient activation

One study looked at the combined effect of preference elicitation using risk trade-offs with an activating intervention using videos of actors as patients going through a similar decision with branching outcomes.

Table 26: Summary of study characteristics - Preference/value elicitation and Patient activation

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Wilkes 2013	Cluster RCT	3	USA	705	Physician education on preference elicitation and patient activation, Phys-ed alone	Usual care	2 primary care networks – prostate cancer patients

Table 27: Intervention descriptions from papers – Preference/value elicitation and Patient activation

Wilkes 2013 Physician education on preference elicitation and patient activation, Phys-ed alone	Physicians in both intervention arms participated in an interactive Web-based educational program. In one intervention arm physicians saw only the educational program (MD-Ed). The other intervention also including activated patients (MD-Ed+A), who 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 intervention consisted of two 30-minute interactive educational Web-based programs on prostate cancer screening, one for physicians and another for patients. Each program reviews the importance of prostate cancer in men's health, limitations of PSA screening for prostate cancer, the risk trade-off inherent to the decision to do prostate cancer screening, and the central importance of each individual's values and preferences. The patient program includes video vignettes to depict the potential harms for two scenarios: (1) not having prostate cancer screening and (2) having prostate cancer screening with a false-positive result.

Table 28: Summary of GRADE - Preference/value elicitation and Patient activation

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Wilkes 2013 – overall PSA SDM (patient self-report)	581	MD 0.87 (-0.17, 1.91)	+/- 3.20	Low	No meaningful difference
Wilkes 2013 – overall PSA SDM (physician self-report)	120	MD -0.10 (-0.77, 0.57)	+/- 0.86	Low	No meaningful difference

Multiple components – Third person support and patient activation

The only patient third party intervention that made clear mention of patient activation.

Table 29: Summary of study characteristics - Third person support and patient activation

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Alegria 2018	Crossover trial	2	USA	312	DECIDE-PC patient centred communication	Usual care	Behavioural health clinics – general patients

Table 30: Intervention descriptions from papers – Third person support and patient activation

Alegria 2018 DECIDE-PC patient centred communication	The patient training consisted of three 60-minute sessions balancing didactics with opportunities to engage, role-play, and reflect on activation. Bachelor's-level care managers delivered the intervention under supervision from licensed, bilingual clinicians. The first session (decisions and agency) educated patients about their role, choices, and agency in clinical visits. The second session (role, process, and reason) taught skills to understand treatment decisions. The third session (self-efficacy and consolidation) encouraged patients to ask questions about conditions and treatment options.

Table 31: Summary of GRADE - Third person support and patient activation

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Alegria 2018 – Shared decision making (OBOM, continuous) – targeting patients – OPTION 12	312	MD 0.36 (-2.70, 3.42)	+/- 6.89	Moderate	No meaningful difference
Alegria 2018 – Shared decision making (PROM, continuous) – targeting patients – SDM-Q-9 (patient)	312	MD 1.45 (-2.80, 5.70)	+/- 9.58	Low	No meaningful difference
Alegria 2018 – Shared decision making (OBOM, continuous) – int targeting professionals – OPTION 12	74	MD 4.52 (0.27, 8.77)	+/- 4.65	Low	Less than MID (Favours intervention)
Alegria 2018 – Shared decision making (PROM, continuous) –targeting professionals - SDM-Q-9 (professional)	74	MD -0.86 (-5.09, 3.37)	+/- 4.63	Very low	Could not differentiate

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Alegria 2018 – Shared decision making (OBOM, continuous) – targeting both – OPTION 12	312	MD 2.52 (-3.46, 8.50)	+/- 13.47	Moderate	No meaningful difference
Alegria 2018 – Shared decision making (PROM, continuous) – targeting both – SDM-q-9 (patient)	312	MD 4.78 (-4.26, 13.82)	+/- 20.36	Low	No meaningful difference

Multiple components – Third person support and preference/value elicitation

Many studies combined a third person support intervention with eliciting patient preferences. With the third person support seen as a separate space to elicit patient preferences, presumably freeing up the consultation for the act of shared decision making. Third person supporters were again mostly nurses but also included health counsellors, peer support specialists and social workers.

Table 32: Summary of study characteristics - Third person support and preference/value elicitation

Author	Study type	Arms	Country	N	Intervention	Control	Setting and population
Berger-Hoger 2019	Cluster RCT	2	Germany	64	Decision coaching	Standard care	Breast care centers – patients with carcinomas
Causarano 2015	RCT	2	Canada	41	Patient educational intervention	Routine education	Tertiary cancer centre – patients who have had a mastectomy
McBride 2016	RCT	2	UK	56	Decision navigation	Usual care	Diabetes foot clinic – patients with diabetes
Myers 2011	RCT	2	USA	313	Nurse led decision counselling	Normal physician discussion (control)	Primary care practice sites – patients going for prostate

							cancer screening
Raue 2019	RCT	2	USA	202	Nurse administered SDM	Usual care	Mental health centre – elderly depressed minority patients
Sheridan 2012	RCT	2	USA	130	Video PDA and counsellor	Control	Prostate cancer patients academic and community practice
Yamaguchi 2017	RCT	2	Japan	43	CommonGround SDM system	Usual care	Psychiatric clinic and psychiatric hospital

Table 33: Intervention descriptions from papers – Third person support and preference/value elicitation

Berger-Hoger 2019 Decision coaching	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). a) The evidence-based patient decision aid presents information on the disease, its natural course and probabilities of the benefits and harms of the treatment options. The options of watchful waiting and breast conserving therapy without radiation were included in the decision aid. After informed consent for study participation was obtained, nurses instructed women on the decision-coaching procedures and handed out the decision aid and a decision guidance, which is a value clarification tool targeted to the decision to be made (nurse-led first contact). In addition, nurses arranged an appointment for the decision coaching within one week. Nurse-led decision coaching: At the next appointment, the nurse supported the woman's decision-making process in a structured manner, taking the six steps of shared decision making into consideration: 1. Definition of the problem requiring a decision-making process. 2. Shared decision making key message (There is more than one option, and the best option

	depends on how the patients value the evidence, the benefits and harms considering their expectations and preferences.). 3. Information about the options, including benefits and harms based on evidence-based patient information. 4. Clarifying patient's values and preferences. 5. Decision-making (optional to postpone the decision). 6. Arrangements. To support the decision coaching consultation prompt cards for nurses and information sheets with essential information on the four treatment options outlined in the decision aid were also developed. Structured physician's consultation: Once a woman was aware of her treatment preferences, the nurse arranged the consultation with the physician, in which the preferred option was discussed, open questions were clarified, and arrangements made for further treatment or watchful waiting.
Causarano 2015 Patient educational intervention	The conceptual framework for the intervention was based on the Ottawa Decision Support Framework that combines concepts and theories from general psychology, social psychology, decision analysis, decisional conflict, values, social support, and self-efficacy to reduce decisional conflict. The intervention aims to manage unrealistic expectations, clarify personal values, improve knowledge about the complex surgical options, risks and benefits, probable outcomes, and alternatives to surgery, and provide social/peer support. Five patients, a plastic surgeon, a nurse specialist, a social worker, and two peer support patients participated in each intervention. The intervention incorporated key components of shared decision making (patient-physician involvement and expression of preferences) and decision support (information provision, values clarification, and patient involvement). Their description of decision support was as follows: 1. Personal value and preference clarification 2. Provision of options, risks, benefits, probability of alternatives 3. Guidance in deliberation and communications of decisions 4. Dyadic peer support provided by volunteer patients

McBride 2016 Decision navigation	Navigators assist patients in creating a personalised consultation plan for key medical consultations. This clearly communicates to physicians the patient's unique preferences, questions and concerns about the treatment, while also explicitly clarifying the patients' preference for involvement in decision making. Patients are provided with personalised information in the form of an audio recording of the physician–patient discussion and a typed consultation summary. The aim of DN is to facilitate the exchange of information and the patient–physician partnership, enabling patients to make informed decisions consistent with their personal preferences. This intervention combines two components. Making a list of questions and audio recordings and summaries. 'Decision navigation' (DN) is a multi-component intervention designed to facilitate shared decision making between a healthcare professional and patient in practice. It is built on techniques which have been shown to increase patient involvement in question asking and improve information recall. The main component of DN 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. This 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. DN has previously been shown to enhance decisional confidence and certainty, as well as reduce decisional regret, in newly diagnosed prostate cancer patients faced with treatment choices.
Myers 2011 Nurse-led decision counselling	The nurse educator met intervention group men at the office visit, reviewed the content of a mailed booklet, and conducted a structured decision counselling session about prostate cancer screening. In this session, the 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. The nurse educator then explained and discussed the score with the participant and verified participant agreement with the derived preference. Nurse educators were trained to adopt a neutral stance regarding the performance of prostate cancer screening. The nurse educator also placed a generic note on each intervention group participant's medical chart to prompt the physician to discuss prostate cancer screening.
Raue 2019 Nurse administered SDM	Four registered nurses employed by Lincoln provided the manualized SDM intervention under regular supervision by the Principal Investigator (PI). SDM consisted of a 30 minute in-person meeting followed by 2 weekly 10 −15 minute telephone calls. Nurses first discussed the patient's depressive symptoms and provided psychoeducation. They elicited patients' treatment experiences, preferences, and concerns regarding various treatment approaches. Nurses used decision aid materials to further clarify patients' values by discussing the effectiveness, speed of onset, side effects, and costs associated with both antidepressant medication and psychotherapy. Nurses provided psychoeducational handouts for patients and family members to review at home. Nurses assisted with appointment scheduling and addressed practical barriers to care such as transportation as needed or referred patients to in-house social work. During follow-up calls, if patients encountered difficulty because of poor motivation, stigma, poor access, high cost, or lack of service availability, nurses attempted to address unresolved treatment barriers and re-engaged patients in SDM processes. The PI conducted training in SDM by manual review, demonstrations, and role plays over 1 month. Nurses were required to receive global adherence scores of 3 ("adequate") to final role plays, according to the SDM Adherence Form that uses a 0−5 point scale evaluating SDM tasks described earlier.
Sheridan 2012 Video PDA and counsellor	Intervention consisted of two components, a video-based decision aid for patients and a coaching session for patients. This information was framed in the context of information about the prevalence of cardiovascular disease and colon cancer, the certain benefit of

	screening for these diseases, and the options and attributes of common screening tests and treatments for these diseases. The 12-minute video-based decision aid for patients was designed with three main objectives: 1) to provide the core information men would need to make an informed decision about prostate cancer screening, 2) to model the process of deciding whether or not to be screened, and 3) to help men begin to clarify their values and make a decision. The video showed four men engaged in an impromptu discussion about prostate cancer screening with their doctor. The 8-minute coaching tool employed scripted materials delivered by a trained health counsellor. It had three main objectives: 1) to answer men's additional questions about prostate cancer screening, 2) to help men further clarify their values for prostate cancer screening, and 3) to prepare men to discuss prostate cancer screening with their doctor. Authors addressed additional questions they anticipated men might have through a supplemental brochure. The brochure reinforced and expanded on content presented in the video and Copies of relevant brochures were given to each man to take home. Men clarified their values for prostate cancer screening using a process in which they rated and then ranked the relative importance of several factors in their decision making. Men were first asked to read a series of two opposing statements about each decision factor and choose which statement best represented their own feeling about that factor To help men prepare for discussions about prostate cancer screening with their doctor, we first asked men to consider how involved they'd like to be in decision making about prostate cancer screening. We then delivered scripted counselling on how to address barriers to communication. Men received counselling on as many barriers as they endorsed. Following counselling, men received a "list pad" which summarized key messages and encourage men to write down questions to ask their doctor.
Yamaguchi 2017 SHARE Commonground SDM system	The primary aim of SHARE is to facilitate the process in which patients and doctors make treatment decisions together, rather than to provide proper treatment information with the patient.

	The general framework of SHARE was developed focusing on recovery goals and self-management, like the CommonGround approach. Detailed contents and individual items where users rate their concerns about health status and medications in SHARE were developed by using Substance Abuse and Mental Health Services Administration guidelines after discussion among study team members. Another difference from CommonGround was that SHARE has self-rated items for problems with community life (e.g., home, job, or interpersonal relationships), which fit the Japanese context. Authors provided three two-day training sessions to peer support specialists, doctors, and case managers during the study period. Participants who were assigned to the intervention group met with peer support specialists, who helped them use SHARE by sharing their own recovery experiences. SHARE guided patients in identifying personal values and treatment preferences. Before medical consultations, patients also used SHARE to rate their condition and concerns about community life. During medical consultations, doctors were strongly encouraged to confirm the patient's personal recovery goals and the number of times the patient performed key behaviours identified in the program. Doctors then proceeded with their medical consultation on the basis of the participant's condition and concerns as entered in SHARE. In addition, as part of shared decision making, doctors were expected to discuss treatment or self-management behaviours based on the participant's individual personal recovery goals. At the end of the medical consultation, the patient and the doctor determined the treatment (such as medication type and timing/use of medication) or self-management behaviour for follow-up at the next consultation, after which the doctor confirmed shared decision making content with the patient and entered it into SHARE.

Table 34: Summary of GRADE - Third person support and preference/value elicitation

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Berger-Hoger 2019 – OBOM SDM: MAPPIN-Q	**64**	**MD 1.88 (1.26, 2.50)**	**+/- 0.63**	**Moderate**	**Effect (Favours intervention)**

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Berger-Hoger 2019 – Decisional conflict (DCS) (patient)	65	MD -0.03 (-7.79, 7.73)	+/- 9.07	Moderate	No meaningful difference
Berger-Hoger 2019 – Decisional conflict (DCS) (physician)	66	MD -1.74 (-16.80, 13.32)	+/- 18.36	Moderate	No meaningful difference
Berger-Hoger 2019 – Knowledge: Patient informed choice (%)	**64**	**MD 47.66 (12.64, 82.68)**	**+/- 35.46**	**Low**	**Effect (Favours intervention)**
Berger-Hoger 2019 – Duration of consultation (minutes)	**64**	**MD 33.80 (19.16, 48.44)**	**+/- 7.61**	**Moderate**	**Effect (Favours control)**
Causarano 2015 – Decision self-efficacy	39	MD 0.60 (-6.53, 7.73)	+/- 4.90	Very low	Could not differentiate
Causarano 2015 – Other: Satisfaction with information provided	39	MD 1.50 (-7.22, 10.22)	+/- 7.50	Very low	Could not differentiate
Causarano 2015 – PROM SDM: Decision making – M-PICS	39	SMD -0.44 (-1.08, 0.19)	+/- 0.50	Very low	Could not differentiate
Causarano 2015 – Decisional conflict: DCS	**39**	**MD -13.40 (-25.61, -1.19)**	**+/- 8.00**	**Very low**	**Effect (Favours intervention)**
Mcbride 2016 – Decision self-efficacy – 12 weeks	56	MD 5.66 (-2.12, 13.44)	+/- 7.92	Very low	Could not differentiate
Mcbride 2016 – Decisional conflict: DCS – 12 weeks	50	MD 5.19 (-3.21, 13.59)	+/- 7.56	Very low	Could not differentiate
Mcbride 2016 – Decisional regret – 12 weeks	47	MD 2.00 (-6.17, 10.17)	+/- 8.50	Very low	Could not differentiate
Mcbride 2016 – HR-QoL – 12 weeks	52	MD 5.52 (-6.14, 17.18)	+/- 11.39	Very low	Could not differentiate
Myers 2011 – Decisional conflict: DCS	288	MD -0.03 (-0.13, 0.07)	+/- 0.24	Low	No meaningful difference
Myers 2011 – Knowledge: Patient knowledge of prostate cancer screening	288	MD 0.70 (0.24, 1.16)	+/- 0.95	Very low	Less than MID (Favours intervention)
Raue 2019 – Patient satisfaction with decision	202	MD -0.04 (-0.12, 0.04)	+/- 0.17	Low	No meaningful difference
Raue 2019 – Depression (continuous) HAM-D	**202**	**MD 0.90 (0.65, 1.15)**	**+/- 0.45**	**Low**	**Effect (Favours control)**

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Sheridan 2012 – PROM SDM: number with preferred participation in decision-making (unadjusted)	89	RR 0.93 (0.72, 1.20)	0.80, 1.25	Very low	Could not differentiate
Sheridan 2012 – Knowledge: number having key knowledge about screening (self-made questionnaire)	**128**	**RR 3.62 (1.85, 7.07)**	**0.80, 1.25**	**Low**	**Effect (Favours intervention)**
Sheridan 2012 – Men reporting a shared decision	89	RR 0.96 (0.76, 1.23)	0.80, 1.25	Very low	Could not differentiate
Sheridan 2012 – Men agreeing a screening test is a decision	**128**	**RR 2.79 (1.74, 4.47)**	**0.80, 1.25**	**Low**	**Effect (Favours intervention)**
Yamaguchi 2017 – Shared decision making (OBOM, continuous) – targeting both – SDM-18	**37**	**MD 2.24 (1.40, 3.08)**	**+/- 0.66**	**Moderate**	**Effect (Favours intervention)**
Yamaguchi 2017 – Shared decision making (PROM, continuous) – SDM-q-9	53	MD 6.50 (-1.58, 14.58)	+/- 5.41	Low	Could not differentiate
Yamaguchi 2017 – Satisfaction with consultation	53	MD 1.74 (-0.73, 4.21)	+/- 2.38	Low	Could not differentiate
Yamaguchi 2017 – Patient-physician communication (IPC Interpersonal Processes of Care Survey) – 6 months	**53**	**MD 3.63 (1.10, 6.16)**	**+/- 2.27**	**Low**	**Effect (Favours intervention)**
Yamaguchi 2017 – Health-related quality of life (mental)	53	MD 1.00 (-1.71, 3.71)	+/- 2.53	Low	Could not differentiate
Yamaguchi 2017 – Health-related quality of life (physical)	53	MD 0.96 (-2.21, 4.13)	+/- 2.49	Low	Could not differentiate

Multiple components – Third Person Support + Preference/Value Elicitation + Patient Activation

This intervention combined a third person supporter (Nurse), motivating patient to participate, and eliciting patient preferences regarding questions to ask in an SDM setting.

Table 35: Summary of study characteristics - Third Party Support + Preference/Value Elicitation + Patient Activation

Author	Study type	Arms	Country	N	Intervention	Control	Setting
Walczak 2017	RCT	2	Australia	110	Nurse led communication support program	Usual care	Cancer treatment centres

Table 36: Intervention descriptions from papers – Third Party Support + Preference/Value Elicitation + Patient Activation

Walczak 2017 Nurse led communication support program	The communication support program aimed to increase 'Autonomous Motivation' to discuss prognosis and end of life care and self-perceived 'Competence' to undertake discussions. Oncologists were cued to endorse question prompt list use and question asking to address social support needs (Relatedness) prescribed by this theory. The overall goal of the intervention was to increase participants' ability and motivation to discuss prognosis and end-of-life care early in their final year of life. Patients attended face-to-face meetings at cancer treatment centres approximately 1 week before a follow-up oncology consultation. Caregivers joined where practical. 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. Participants were also given a DVD discussing advanced care planning and further information about documenting wishes for care. Finally, participants were prompted to select 1–3 questions to ask at the next consultation. A single telephone booster session was completed 1 to 2 weeks after patients' first oncology consultation following the face-to-face meeting. This session sought to reinforce the content of the face-to-face meeting and to help patients prepare for communication in future consultations using the QPL. Nurses verbally cued oncologists to endorse QPL use and question asking immediately prior to the consultation following the face-to-face session. Oncologists also received a postcard with suggested endorsement phrasing.

Table 37: Summary of GRADE - Third Party Support + Preference/Value Elicitation + Patient Activation

Study name	Sample size	Final effect estimate	MIDs	Quality	Interpretation of effect
Walczak 2017 – Other: Patient communication self-efficacy (PEPPI)	79	MD 1.16 (-0.27, 2.59)	+/- 1.75	Very low	Could not differentiate
Walczak 2017 – QoL: Patient QoL (FACT-G)	79	MD -6.89 (-14.65, 0.87)	+/- 9.40	Very low	Could not differentiate

Recommendations supported by this evidence review

This evidence review supports recommendations 1.2.1 to 1.2.18 and the research recommendation on interventions to support effective shared decision making.

The committee's discussion of the evidence

Outcomes that matter most

The committee understood that NICE have already agreed, as part of their social value judgements, that Shared Decision Making (SDM) is a vital aspect of healthcare. It focused on finding the most effective way to encourage the use of SDM in healthcare situations. The committee's aim is that this guideline will aid in the implementation of SDM for those who are not sure of the best way to practice it. This section of the guideline seeks to inform people using and providing healthcare services of specific components of interventions that will help ensure SDM takes place.

The committee agreed, as per other reviews in this guideline, that observer-based outcome measures of SDM (Such as OPTION-5) where SDM was rated by a third party, not a member of the patient-clinician dyad, were the most valuable outcomes when seeing if SDM was occurring and how high quality the SDM was. This was followed by participant-recorded shared-decision making outcomes such as SDM-Q-9 or COMRADE. These outcomes were directly measuring participants' perceptions of SDM but at a greater risk of bias due to the inability of the assessor to be blinded.

With regard to secondary outcomes, the committee wished to highlight that outcomes such as decisional conflict and duration of consultation favoring control did not mean that SDM was not occurring or led to worse outcomes, and may just highlight that more in depth discussions are taking place. Conflict about decisions reached during SDM was described as a potentially realistic outcome. The committee stated that a shared decision may validly lead to greater 'conflict' (i.e. uncertainty about what the best decision is for the individual) if the service user has become more knowledgeable about the options, and lack of clear-cut benefit (e.g. prostate cancer screening or treatment options) or if the healthcare provider and service user have different opinions.

Quality of the evidence

Many studies were downgraded due to a lack of objective outcome measures of SDM, the nature of interventions to improve SDM mean it is difficult to blind to, and thus any studies without objective measures were at risk of bias due to the "measurement of outcome" domain. Reporting in these studies was also poor, particularly of randomisation procedures.

Two studies had the combination of moderate quality evidence and outcomes measuring SDM (Yamaguchi and Berger-Hoger, both under the "Third-person support and preference/value elicitation" header.)

Whilst one study (Granados-Santiago) had high quality evidence, this was in a disease-knowledge related outcome, and thus was not used to form recommendations.

Only ten papers had primary SDM outcomes and a meaningful effect or lack thereof. Landrey and Nayak both had "no meaningful difference" in SDM outcomes for the "pre-consultation interventions" group.

The committee noted the lack of evidence focusing on ethnic minorities, persons with lower health literacy, less experience of using digital technologies (e.g. some older patient groups), more co-morbidities, people from lower income backgrounds, and other groups who have been less likely to engage with SDM and made a research recommendation in this area.

The committee agreed it would like to see more evidence regarding documentary interventions for patients, for example a written record or audio recording of consultations. It believed this might help patients recall what had occurred in consultations and help encourage SDM, however it did not prioritise this as a research recommendation.

Benefits and harms

The committee structured recommendations according to before, during and after appointments because, from their experience, it would be easier for practitioners to apply the recommendations in a meaningful way if they follow the care pathway.

In the committee's view, shared decision making should be treated as a continuing process rather than a one-off event. Using a combination of interventions or components is likely to be most effective because no single intervention can be a one-size-fits-all solution, and the evidence supported this. The best available evidence was for multicomponent ('complex') rather than individual interventions.

The committee wanted to highlight that interventions will need to be tailored to specific settings and populations, for example how the SHARE intervention in Yamaguchi et al. was modified to better fit the needs of the Japanese population. This could be undertaken by individual clinicians or at a departmental or organizational level.

The committee agreed that the evidence showed digital technology (such as that used in the SHARE tool by Yamaguchi) could potentially be used to support shared decision making, by providing the healthcare provider and the person using services with knowledge of past decisions, past preferences, values, and other information discussed during appointments.

Before appointments

There was some evidence of effectiveness for offering interventions before appointments. Even though the studies that looked specifically at pre-appointment interventions did not show an increase in shared decision making, there was some evidence that these kinds of interventions increased people's knowledge and their satisfaction with their appointment. The committee agreed that while knowledge alone is not enough for shared decision making, it is a necessary part of it. Supporting evidence also came from studies looking at other types of interventions ('third person support' and 'preference/value elicitation') that were offered before appointment. Some of these included observer-based outcome measures of shared decision making (a more direct measure of shared decision making). The committee acknowledged that while service user preferences/values could not be elicited prior to consultation, they could be encouraged to think about them and bring these thoughts to the consultation.

The committee recommended third party support only for people who might need additional support to engage in shared decision making. This was because the evidence was not strong enough to offset the potentially large resource impact of putting in place a third person support intervention as standard.

During appointments

In the evidence, the studies looking at what was effective in shared decision making showed the strongest support for expectation, value, priority and goal elicitation and 'choice-option-decision talks structure to SDM', option talks were a key part of Berger-Hoger's intervention. Agenda setting explicitly stating decisions, the option of no treatment, and when a decision might be reviewed were not captured in the effectiveness evidence but, based on their

experience and expertise, the committee considered them to be key aspects of shared decision making.

After appointments

The committee highlighted that interventions to support shared decision making should carry on after appointments because they should be part of a continuing process.

The committee noted that people might be able to record the consultation on their phone or other electronic device and that this might be particularly useful to people who may need extra support to engage in shared decision making (in accordance with barriers identified in RQ1.2).

Appendices

Appendix A – Review protocols

Review protocol for core components of effective shared decision making.

Field	Content
PROSPERO registration number	CRD42020166149
Review title	What are the core components of effective shared decision making.
Review question	What are the core components of effective shared decision making approaches and activities?
Objective	To assess the effectiveness of : • Pre-consultation interventions • Interventions to improve Health literacy • Preference/values elicitation • 3rd person support (health coaching, advocacy, patient champions) • Patient activation • Documentary interventions (clinician prompts, written records) as components of shared decision making in healthcare settings.
Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR)

	• Database of Abstracts of Reviews of Effect (DARE) • Embase (Ovid) • MEDLINE (Ovid) • MEDLINE In-Process (Ovid) • MEDLINE Epub Ahead of Print • PsycINFO (Ovid) Searches are restricted to English language with no date cut-off. The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion. The full search strategies for MEDLINE database will be published in the final review.
Condition or domain being studied	Shared decision making is a collaborative process through which a healthcare professional supports a person to reach a decision about their care, now or in the future (for example, through advance care planning).
Population	Inclusion: • Adults using healthcare services (and their families, carers and advocates) and healthcare providers

	Exclusion: • People under the age of 18 • Unexpected life-threatening emergency needing immediate life-saving care. • Situations in which people lack mental capacity to make their own decisions about healthcare at that time.
Intervention	Interventions to increase effective shared decision making by improving: • Interventions before consultation • Health literacy • Preference/values elicitation • 3rd person support (health coaching, advocacy, patient champions) • Patient activation • Documentary interventions (clinician prompts, written records)
Comparator/Reference standard/Confounding factors	• Head to head trials with other interventions from the list above. • No intervention/normal care • Sham intervention
Types of study to be included	• RCTs • Systematic reviews of RCTs
Other exclusion criteria	• Non-English language papers • Theses, dissertations and conference abstracts • Editorials, opinion pieces and letters

	• Surveys
	• Non-OECD countries (OECD countries are
	  ○ Australia
	  ○ Austria
	  ○ Belgium
	  ○ Canada
	  ○ Chile
	  ○ Czech Republic
	  ○ Denmark
	  ○ Estonia
	  ○ Finland
	  ○ France
	  ○ Germany
	  ○ Greece
	  ○ Hungary
	  ○ Iceland
	  ○ Ireland
	  ○ Israël
	  ○ Italy
	  ○ Japan
	  ○ Korea
	  ○ Latvia
	  ○ Lithuania
	  ○ Luxembourg
	  ○ Mexico
	  ○ Netherlands

	○ New Zealand ○ Norway ○ Poland ○ Portugal ○ Slovak Republic ○ Slovenia ○ Spain ○ Sweden ○ Switzerland ○ Turkey ○ United Kingdom ○ United States) • Papers prior to 1990
Context	This review is for part of a new NICE guideline for shared decision making.
Primary outcomes (critical outcomes)	• engagement in shared decision making by healthcare providers and people who use healthcare services and their families, carers and advocates, measured using an objective observer-based outcome measure (OBOM). OBOMs are instruments used by a third observer to capture the decision-making process during an encounter between a healthcare professional and a patient/family caregiver when facing health treatment or screening decisions.
Secondary outcomes (important outcomes)	• engagement in shared decision making by healthcare providers and people who use healthcare services and their families, carers and advocates, measured using a subjective measure (Patient Reported Outcome Measure). PROMs are instruments that collect information directly from patients. The

	measurement is recorded without amendment or interpretation by a clinician or other observer. • wellbeing and quality of life (including physical health, mental health and social wellbeing) using validated QoL measures. • changes in knowledge, intentions, culture, norms, ability and confidence in relation to undertaking shared decision making among healthcare providers and people who use healthcare services and their families, carers and advocates, as defined by the authors • satisfaction with shared decision making of people who use healthcare services (including perceptions of how satisfied they are from their family members, carers and advocates) using PROMs • unintended consequences (for example, decisional regret) using PROMs
Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. Data will be extracted from the included studies for assessment of study quality and evidence synthesis. Extracted information will include: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control conditions; study methodology; recruitment and study completion rates; outcomes and times of measurement and information for assessment of the risk of bias.

	Study investigators may be contacted for missing data where time and resources allow.
Risk of bias (quality) assessment	Risk of bias for RCTs will be assessed using the Cochrane RoB (2.0) checklist as described in Developing NICE guidelines: the manual.
Strategy for data synthesis	Meta-analyses of interventional data will be conducted with reference to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al. 2019). Fixed- and random-effects models (der Simonian and Laird) will be fitted for all syntheses, with the presented analysis dependent on the degree of heterogeneity in the assembled evidence. Fixed-effects models will be the preferred choice to report, but in situations where the assumption of a shared mean for fixed-effects model is clearly not met, even after appropriate pre-specified subgroup analyses is conducted, random-effects results are presented. Fixed-effects models are deemed to be inappropriate if one or both of the following conditions was met: • Significant between study heterogeneity in methodology, population, intervention or comparator was identified by the reviewer in advance of data analysis. • The presence of significant statistical heterogeneity in the meta-analysis, defined as I2≥50%. Meta-analyses will be performed in Cochrane Review Manager V5.3

Analysis of sub-groups	If there is heterogeneity in the meta-analysis, and where data allow disambiguation, subgroup analysis will explored, particularly with reference to • Age • Gender • Family origin • Care setting • Immediate vs future care		
Type and method of review	☒ Intervention ☐ Diagnostic ☐ Prognostic ☐ Qualitative ☐ Epidemiologic ☐ Service Delivery ☐ Other (please specify)		
Language	English		
Country	England		
Anticipated or actual start date			
Anticipated completion date			
Stage of review at time of this submission	**Review stage**	**Started**	**Completed**

	Preliminary searches	☐	☐
	Piloting of the study selection process	☐	☐
	Formal screening of search results against eligibility criteria	☐	☐
	Data extraction	☐	☐
	Risk of bias (quality) assessment	☐	☐
	Data analysis	☐	☐
Named contact	**5a. Named contact** Guidelines Updates Team **5b Named contact e-mail** GUTprospero@nice.org.uk **5e Organisational affiliation of the review** National Institute for Health and Care Excellence (NICE)		

Review team members	From the Guideline Updates Team: • Mr. Chris Carmona • Mr. Joseph Crutwell • Ms. Amy Finnegan • Mr. Gabriel Rogers
Funding sources/sponsor	This systematic review is being completed by the Guideline Updates Team, which is part of NICE.
Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10120/
Other registration details	None.

Reference/URL for published protocol	None.
Dissemination plans	– NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE. –
Keywords	Shared decision making, patient engagement, patient activation
Details of existing review of same topic by same authors	
Current review status	☒ Ongoing ☐ Completed but not published ☐ Completed and published ☐ Completed, published and being updated

	☐ Discontinued
Additional information	None.
Details of final publication	www.nice.org.uk

Appendix B- Methods

Methods for combining intervention evidence

Meta-analyses of interventional data were conducted with reference to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al. 2011).

Where different studies presented continuous data measuring the same outcome but using different numerical scales (e.g. a 0-10 and a 0-100 visual analogue scale), these outcomes were all converted to the same scale before meta-analysis was conducted on the mean differences. Where outcomes measured the same underlying construct but used different instruments/metrics, data were analysed using standardised mean differences (Hedges' g).

A pooled relative risk was calculated for dichotomous outcomes (using the Mantel–Haenszel method) reporting numbers of people having an event, and a pooled incidence rate ratio was calculated for dichotomous outcomes reporting total numbers of events. Both relative and absolute risks were presented, with absolute risks calculated by applying the relative risk to the risk in the comparator arm of the meta-analysis (calculated as the total number events in the comparator arms of studies in the meta-analysis divided by the total number of participants in the comparator arms of studies in the meta-analysis).

Fixed- and random-effects models (der Simonian and Laird) were fitted for all syntheses, with the presented analysis dependent on the degree of heterogeneity in the assembled evidence. Fixed-effects models were the preferred choice to report, but in situations where the assumption of a shared mean for fixed-effects model were clearly not met, even after appropriate pre-specified subgroup analyses were conducted, random-effects results are presented. Fixed-effects models were deemed to be inappropriate if one or both of the following conditions was met:

- Significant between study heterogeneity in methodology, population, intervention or comparator was identified by the reviewer in advance of data analysis. This decision was made and recorded before any data analysis was undertaken.
- The presence of significant statistical heterogeneity in the meta-analysis, defined as $I^2 \geq 50\%$.

However, in cases where the results from individual pre-specified subgroup analyses are less heterogeneous (with $I^2 < 50\%$) the results from these subgroups will be reported using fixed effects models. This may lead to situations where pooled results are reported from random-effects models and subgroup results are reported from fixed-effects models.

In situations where subgroup analyses were conducted, pooled results and results for the individual subgroups are reported when there was evidence of between group heterogeneity, defined as a statistically significant test for subgroup interactions (at the 95% confidence level). Where no such evidence as identified, only pooled results are presented.

In any meta-analyses where some (but not all) of the data came from studies at high risk of bias, a sensitivity analysis was conducted, excluding those studies from the analysis. Results from both the full and restricted meta-analyses are reported. Similarly, in any meta-analyses where some (but not all) of the data came from indirect studies, a sensitivity analysis was conducted, excluding those studies from the analysis.

Meta-analyses were performed in Cochrane Review Manager V5.3, with the exception of incidence rate ratio analyses which were carried out in R version 3.3.4.

Minimal clinically important differences (MIDs)

No MIDs were identified for this review, and thus the committee agreed to use the default MIDs as outlined below.

For continuous outcomes expressed as a mean difference where no other MID was available, an MID of 0.5 of the median standard deviations of the comparison group arms was used (Norman et al. 2003). For continuous outcomes expressed as a standardised mean difference where no other MID was available, an MID of 0.5 was used. For relative risks where no other MID was available, a default MID interval for dichotomous outcomes of 0.8 to 1.25 was used.

When decisions were made in situations where MIDs were not available, 'the committee's discussion of the evidence' section of that review makes explicit the committee's view of the expected clinical importance and relevance of the findings. In particular, this includes consideration of whether the whole effect of a treatment (which may be felt across multiple independent outcome domains) would be likely to be clinically meaningful, rather than simply whether each individual sub outcome might be meaningful in isolation.

GRADE for pairwise meta-analyses of interventional evidence

GRADE was used to assess the quality of evidence for the selected outcomes as specified in 'Developing NICE guidelines: the manual (2014)'. Data from all randomised controlled trials was initially rated as high quality and data from observations studies were originally rated as low quality. The quality of the evidence for each outcome was downgraded or not from this initial point, based on the criteria given in **Table 38**.

Table 38: Rationale for downgrading quality of evidence for intervention studies

GRADE criteria	Reasons for downgrading quality
Risk of bias	Not serious: If less than 33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias, the overall outcome was not downgraded. Serious: If greater than 33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias, the outcome was downgraded one level. Very serious: If greater than 33.3% of the weight in a meta-analysis came from studies at high risk of bias, the outcome was downgraded two levels. Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between studies at high and low risk of bias.
Indirectness	Not serious: If less than 33.3% of the weight in a meta-analysis came from partially indirect or indirect studies, the overall outcome was not downgraded. Serious: If greater than 33.3% of the weight in a meta-analysis came from partially indirect or indirect studies, the outcome was downgraded one level. Very serious: If greater than 33.3% of the weight in a meta-analysis came from indirect studies, the outcome was downgraded two levels. Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between direct and indirect studies.
Inconsistency	Concerns about inconsistency of effects across studies, occurring when there is unexplained variability in the treatment effect demonstrated across studies (heterogeneity), after appropriate pre-specified subgroup analyses have been conducted. This was assessed using the I^2 statistic. N/A: Inconsistency was marked as not applicable if data on the outcome was only available from one study. Not serious: If the I^2 was less than 33.3%, the outcome was not downgraded.

GRADE criteria	Reasons for downgrading quality
	Serious: If the I^2 was between 33.3% and 66.7%, the outcome was downgraded one level. Very serious: If the I^2 was greater than 66.7%, the outcome was downgraded two levels. Outcomes meeting the criteria for downgrading above were not downgraded if there was evidence the effect size was not meaningfully different between studies with the smallest and largest effect sizes.
Imprecision	If an MID other than the line of no effect was defined for the outcome, the outcome was downgraded once if the 95% confidence interval for the effect size crossed one line of the MID, and twice if it crosses both lines of the MID. If the line of no effect was defined as an MID for the outcome, it was downgraded once if the 95% confidence interval for the effect size crossed the line of no effect (i.e. the outcome was not statistically significant), and twice if the sample size of the study was sufficiently small that it is not plausible any realistic effect size could have been detected. Outcomes meeting the criteria for downgrading above were not downgraded if the confidence interval was sufficiently narrow that the upper and lower bounds would correspond to clinically equivalent scenarios.

The quality of evidence for each outcome was upgraded if any of the following three conditions were met:

- Data from non-randomised studies showing an effect size sufficiently large that it cannot be explained by confounding alone.
- Data showing a dose-response gradient.
- Data where all plausible residual confounding is likely to increase our confidence in the effect estimate.

Publication bias

Publication bias was assessed in two ways. First, if evidence of conducted but unpublished studies was identified during the review (e.g. conference abstracts, trial protocols or trial records without accompanying published data), available information on these unpublished studies was reported as part of the review. Secondly, where 10 or more studies were included as part of a single meta-analysis, a funnel plot was produced to graphically assess the potential for publication bias.

Interpretation of effect

Interpretation of effect in the summary of clinical studies tables is classified in to one of four categories:

- Situations where the data are only consistent, at a 95% confidence level, with an effect in one direction (i.e. one that is 'statistically significant'), and the magnitude of that effect is most likely to meet or exceed the MID (i.e. the point estimate is not in the zone of equivalence). In such cases, we state that the evidence showed that there is an **effect**.
- Situations where the data are only consistent, at a 95% confidence level, with an effect in one direction (i.e. one that is 'statistically significant'), but the magnitude of that effect is most likely to be **less than the MID** (i.e. the point estimate is in the zone of equivalence). In such cases, we state that the evidence could not demonstrate a meaningful difference.
- Situations where the confidence limits are smaller than the MIDs in both directions. In such cases, we state that the evidence demonstrates that there is **no meaningful difference**.
- In all other cases, we state that the evidence **could not differentiate** between the comparators.

For outcomes without a defined MID or where the MID is set as the line of no effect (for example, in the case of mortality), interpretation of effect is divided into 2 groups as follows:

- We state that the evidence showed that there is an effect if the 95% CI does not cross the line of no effect.
- The evidence could not differentiate between comparators if the 95% CI crosses the line of no effect.

Appendix C – Literature search strategies

Databases	Date searched	Version/files	No. retrieved
Cochrane Central Register of Controlled Trials (CENTRAL)	13/01/2020	Issue 1 of 12, January 2020	2957
Cochrane Database of Systematic Reviews (CDSR)	13/01/2020	Issue 1 of 12, January 2020	125
Database of Abstracts of Reviews of Effect (DARE)	13/01/2020	n/a	227
Embase (Ovid)	15/01/2020	1974 to 2020 January 13	3737
MEDLINE (Ovid)	13/01/2020	1946 to January 10, 2020	4123
MEDLINE In-Process (Ovid)	13/01/2020	1946 to January 10, 2020	338
MEDLINE Epub Ahead of Print[a]	13/01/2020	January 10, 2020	101
PsycINFO (Ovid)	13/01/2020	1806 to January Week 1 2020	2090

Search strategies

Database: Medline
Strategy used: 3 decision making/ (92345) 2 decision support systems, clinical/ (7644) 3 decision support techniques/ (19728) 4 ("shared decision making" or SDM).ti,ab. (6415) 5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 74eports74i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 74eport?or* or conflict* or collab* or aid*)).ti. (29688) 6 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 74eports74i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 74eport?or* or conflict* or collab* or aid*)).ab. /freq=2 (37674) 7 or/1-6 (140515) 8 Health Literacy/ or Patient Education as Topic/ or Consumer Health Information/ (90914) 9 ((health* or medical* or patient* or consumer*) adj3 (information* or advice* or literac* or literat* or reading* or 74eports74ing* or educat*)).tw. (235156) 10 Choice Behavior/ or patient preference/ (38861)

[a] Please search for both development and re-run searches

11 ((patient* or user* or person* or people* or consumer*) adj3 (prefer* or elicit* or choice* or choos* or select* or option*)).tw. (193740)
12 exp directive 75eports75ing/ or mentoring/ (5447)
13 ((health* or medical* or patient*) adj3 (coach* or coaches* or trainer* or advis?r* or mentor* or counsel*)).tw. (21672)
14 (75eports75* adj3 (interview* or advice* or coach* or champion*)).tw. (3516)
15 (teach-back or "teach back").tw. (146)
16 Patient Participation/ or Patient Advocacy/ (47722)
17 ((patient* or user* or person* or people* or consumer*) adj3 (activat* or empower* or engag* or 75eports* or participat* or 75eports75* or support* or spokesperson* or champion* or ally* or allies* or patron* or proponent*)).tw. (155376)
18 Reminder system/ or "Appointments and Schedules"/ (11724)
19 ((physician* or doctor* or nurse* or surgeon* or consultant* or practition* or referral* or ((medical* or health) adj3 (staff* or secretar*))) adj3 (correspond* or letter* or writ* or messag* or mail* or post or postal or remind*)).tw. (8142)
20 ((clinical* or clinician* or physician* or doctor* or nurse* or practition*) adj3 (prompt* or question* or cue or cues)).tw. (27538)
21 ((interven* or inform*) adj3 (before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*)).tw. (158)
22 ((interven* or inform*) adj3 (previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*")).tw. (37)
23 Pamphlets/ or diary as topic/ or Checklist/ or Video Recording/ or Tape Recording/ or Telephone/ or Cell Phone/ or Smartphone/ or Computers, Handheld/ or Computers/ or Office Visits/ (120336)
24 ((previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*") adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")).tw. (91)
25 ((before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*) adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")).tw. (261)
26 or/8-25 (852364)
27 7 and 26 (32202)
28 animals/ not humans/ (4630271)
29 27 not 28 (31580)
30 limit 29 to ed=19900101-20201231 (29673)
31 (MEDLINE or pubmed).tw. (152919)
32 systematic review.tw. (111139)
33 systematic review.pt. (119269)
34 meta-analysis.pt. (109635)
35 intervention$.ti. (118399)
36 or/31-35 (358636)
37 30 and 36 (1948)
38 randomized controlled trial.pt. (498272)
39 randomi?ed.mp. (774004)
40 placebo.mp. (190948)
41 or/38-40 (824953)
42 30 and 41 (2671)

43 37 or 42 (4123)

Database: MIP
Strategy used: 3 decision making/ (0) 2 decision support systems, clinical/ (0) 3 decision support techniques/ (0) 4 (“shared decision making” or SDM).ti,ab. (1665) 5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 76eports76i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 76eport?or* or conflict* or collab* or aid*)).ti. (4864) 6 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 76eports76i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 76eport?or* or conflict* or collab* or aid*)).ab. /freq=2 (7250) 7 or/1-6 (10151) 8 Health Literacy/ or Patient Education as Topic/ or Consumer Health Information/ (0) 9 ((health* or medical* or patient* or consumer*) adj3 (information* or advice* or literac* or literat* or reading* or 76eports76ing* or educat*)).tw. (34402) 10 Choice Behavior/ or patient preference/ (0) 11 ((patient* or user* or person* or people* or consumer*) adj3 (prefer* or elicit* or choice* or choos* or select* or option*)).tw. (27600) 12 exp directive 76eports76ing/ or mentoring/ (0) 13 ((health* or medical* or patient*) adj3 (coach* or coaches* or trainer* or advis?r* or mentor* or counsel*)).tw. (3614) 14 (76eports76* adj3 (interview* or advice* or coach* or champion*)).tw. (641) 15 (teach-back or “teach back”).tw. (44) 16 Patient Participation/ or Patient Advocacy/ (0) 17 ((patient* or user* or person* or people* or consumer*) adj3 (activat* or empower* or engag* or 76eports* or participat* or 76eports76* or support* or spokesperson* or champion* or ally* or allies* or patron* or proponent*)).tw. (22795) 18 Reminder system/ or “Appointments and Schedules”/ (0) 19 ((physician* or doctor* or nurse* or surgeon* or consultant* or practition* or referral* or ((medical* or health) adj3 (staff* or secretar*))) adj3 (correspond* or letter* or writ* or messag* or mail* or post or postal or remind*)).tw. (935) 20 ((clinical* or clinician* or physician* or doctor* or nurse* or practition*) adj3 (prompt* or question* or cue or cues)).tw. (3498) 21 ((interven* or inform*) adj3 (before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*)).tw. (23) 22 ((interven* or inform*) adj3 (previsit* or “pre visit*” or preconsult* or “pre consult*” or preappoint* or “pre appoint*”)).tw. (9) 23 Pamphlets/ or diary as topic/ or Checklist/ or Video Recording/ or Tape Recording/ or Telephone/ or Cell Phone/ or Smartphone/ or Computers, Handheld/ or Computers/ or Office Visits/ (0) 24 ((previsit* or “pre visit*” or preconsult* or “pre consult*” or preappoint* or “pre appoint*”) adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or “check list*” or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or “smart patient” or “how to be prepared”)).tw. (10)

25 ((before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*) adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")).tw. (34)
26 or/8-25 (87290)
27 7 and 26 (2057)
28 animals/ not humans/ (0)
29 27 not 28 (2057)
30 limit 29 to dt=19900101-20201231 (2057)
31 (MEDLINE or pubmed).tw. (32643)
32 systematic review.tw. (26654)
33 systematic review.pt. (601)
34 meta-analysis.pt. (42)
35 intervention$.ti. (19697)
36 or/31-35 (62574)
37 30 and 36 (198)
38 randomized controlled trial.pt. (276)
39 randomi?ed.mp. (69011)
40 placebo.mp. (17011)
41 or/38-40 (75082)
42 30 and 41 (190)
43 37 or 42 (338)

Database: MEP

Strategy used:

3 decision making/ (0)
2 decision support systems, clinical/ (0)
3 decision support techniques/ (0)
4 ("shared decision making" or SDM).ti,ab. (371)
5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 77eports77i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 77eport?or* or conflict* or collab* or aid*)).ti. (925)
6 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 77eports77i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 77eport?or* or conflict* or collab* or aid*)).ab. /freq=2 (1627)
7 or/1-6 (2070)
8 Health Literacy/ or Patient Education as Topic/ or Consumer Health Information/ (0)
9 ((health* or medical* or patient* or consumer*) adj3 (information* or advice* or literac* or literat* or reading* or 77eports77ing* or educat*)).tw. (6241)
10 Choice Behavior/ or patient preference/ (0)
11 ((patient* or user* or person* or people* or consumer*) adj3 (prefer* or elicit* or choice* or choos* or select* or option*)).tw. (4338)
12 exp directive 77eports77ing/ or mentoring/ (0)
13 ((health* or medical* or patient*) adj3 (coach* or coaches* or trainer* or advis?r* or mentor* or counsel*)).tw. (663)
14 (77eports77* adj3 (interview* or advice* or coach* or champion*)).tw. (146)

15 (teach-back or “teach back”).tw. (9)
16 Patient Participation/ or Patient Advocacy/ (0)
17 ((patient* or user* or person* or people* or consumer*) adj3 (activat* or empower* or engag* or 78eports* or participat* or 78eports78* or support* or spokesperson* or champion* or ally* or allies* or patron* or proponent*)).tw. (4177)
18 Reminder system/ or “Appointments and Schedules”/ (0)
19 ((physician* or doctor* or nurse* or surgeon* or consultant* or practition* or referral* or ((medical* or health) adj3 (staff* or secretar*))) adj3 (correspond* or letter* or writ* or messag* or mail* or post or postal or remind*)).tw. (175)
20 ((clinical* or clinician* or physician* or doctor* or nurse* or practition*) adj3 (prompt* or question* or cue or cues)).tw. (583)
21 ((interven* or inform*) adj3 (before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*)).tw. (6)
22 ((interven* or inform*) adj3 (previsit* or “pre visit*” or preconsult* or “pre consult*” or preappoint* or “pre appoint*”)).tw. (2)
23 Pamphlets/ or diary as topic/ or Checklist/ or Video Recording/ or Tape Recording/ or Telephone/ or Cell Phone/ or Smartphone/ or Computers, Handheld/ or Computers/ or Office Visits/ (0)
24 ((previsit* or “pre visit*” or preconsult* or “pre consult*” or preappoint* or “pre appoint*”) adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or “check list*” or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or “smart patient” or “how to be prepared”)).tw. (4)
25 ((before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*) adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or “check list*” or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or “smart patient” or “how to be prepared”)).tw. (7)
26 or/8-25 (15223)
27 7 and 26 (494)
28 animals/ not humans/ (0)
29 27 not 28 (494)
30 limit 29 to dt=19900101-20201231 (494)
31 (MEDLINE or pubmed).tw. (6705)
32 systematic review.tw. (6510)
33 systematic review.pt. (23)
34 meta-analysis.pt. (24)
35 intervention$.ti. (3963)
36 or/31-35 (13269)
37 30 and 36 (62)
38 randomized controlled trial.pt. (1)
39 randomi?ed.mp. (12961)
40 placebo.mp. (2998)
41 or/38-40 (13945)
42 30 and 41 (57)
43 37 or 42 (101)

Database: Embase

Strategy used:
3 shared decision making/ (5791)
2 decision support system/ (21641)
3 clinical decision support system/ (2751)
4 ("shared decision making" or SDM).ti,ab. (11621)
5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 79eports79i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 79eport?or* or conflict* or collab* or aid*)).ti. (43314)
6 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 79eports79i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 79eport?or* or conflict* or collab* or aid*)).ab. /freq=2 (62000)
7 or/1-6 (103857)
8 health literacy/ or patient education/ or consumer health information/ (123900)
9 ((health* or medical* or patient* or consumer*) adj3 (information* or advice* or literac* or literat* or reading* or 79eports79ing* or educat*)).tw. (372918)
10 decision making/ or patient preference/ (235471)
11 ((patient* or user* or person* or people* or consumer*) adj3 (prefer* or elicit* or choice* or choos* or select* or option*)).tw. (352939)
12 exp directive 79eports79ing/ or mentoring/ (3613)
13 ((health* or medical* or patient*) adj3 (coach* or coaches* or trainer* or advis?r* or mentor* or counsel*)).tw. (40678)
14 (79eports79* adj3 (interview* or advice* or coach* or champion*)).tw. (6373)
15 (teach-back or "teach back").tw. (407)
16 patient participation/ or patient advocacy/ (47245)
17 ((patient* or user* or person* or people* or consumer*) adj3 (activat* or empower* or engag* or 79eports* or participat* or 79eports79* or support* or spokesperson* or champion* or ally* or allies* or patron* or proponent*)).tw. (279841)
18 reminder system/ or hospital management/ (46169)
19 ((physician* or doctor* or nurse* or surgeon* or consultant* or practition* or referral* or ((medical* or health) adj3 (staff* or secretar*))) adj3 (correspond* or letter* or writ* or messag* or mail* or post or postal or remind*)).tw. (13377)
20 ((clinical* or clinician* or physician* or doctor* or nurse* or practition*) adj3 (prompt* or question* or cue or cues)).tw. (44845)
21 ((interven* or inform*) adj3 (before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*)).tw. (322)
22 ((interven* or inform*) adj3 (previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*")).tw. (79)
23 publication/ or checklist/ or literature/ or videorecording/ or recording/ or audio recording/ or telephone/ or mobile phone/ or smartphone/ or personal digital assistant/ (415810)
24 ((previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*") adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")).tw. (195)
25 ((before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*) adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")).tw. (544)
26 or/8-25 (1757464)
27 7 and 26 (58001)

28 nonhuman/ not human/ (4537667)
29 27 not 28 (56626)
30 limit 29 to dc=19900101-20201231 (55084)
31 (MEDLINE or pubmed).tw. (242928)
32 exp systematic review/ or systematic review.tw. (277792)
33 meta-analysis/ (179037)
34 intervention$.ti. (190842)
35 or/31-34 (621098)
36 30 and 35 (3855)
37 random:.tw. (1492982)
38 placebo:.mp. (446830)
39 double-blind:.tw. (205367)
40 or/37-39 (1745289)
41 30 and 40 (5355)
42 36 or 41 (8266)
43 limit 42 to 80eports language (8109)
44 limit 43 to (conference abstract or conference paper or "conference review") (2663)
45 43 not 44 (5446)
46 limit 45 to medline (1709)
47 45 not 46 (3737)

Database: Cochrane – CENTRAL/CDSR

Strategy used:
#1 MeSH descriptor: [Decision Making] this term only 2164
#2 MeSH descriptor: [Decision Support Systems, Clinical] this term only 350
#3 MeSH descriptor: [Decision Support Techniques] this term only 779
#4 ("shared decision making" or SDM):ti,ab1204
#5 (decision* or decide* or deciding* or decisive* or choice* or goal* or judgment* or judgement*) NEAR/1 (share* or sharing* or inform* or making* or make* or support* or behaviour* or behavior* or conflict* or collab* or aid*):ti,ab 13545
#6 {or #1-#5} 14850
#7 MeSH descriptor: [Health Literacy] this term only 336
#8 MeSH descriptor: [Patient Education as Topic] this term only 8484
#9 MeSH descriptor: [Consumer Health Information] this term only 140
#10 (health* or medical* or patient* or consumer*) near/3 (information* or advice* or literac* or literat* or reading* or 80eports80ing* or educat*):ti,ab 27443
#11 MeSH descriptor: [Choice Behavior] this term only 1333
#12 MeSH descriptor: [Patient Preference] this term only 713
#13 ((patient* or user* or person* or people* or consumer*) near/3 (prefer* or elicit* or choice* or choos* or select* or option*)):ti,ab 34263
#14 MeSH descriptor: [Directive Counseling] explode all trees 1138
#15 MeSH descriptor: [Mentoring] explode all trees 114
#16 ((health* or medical* or patient*) near/3 (coach* or coaches* or trainer* or advisor* or adviser* or mentor* or counsel*)):ti,ab 4240
#17 (80eports80* near/3 (interview* or advice* or coach* or champion*)):ti,ab 3323
#18 (teach-back or "teach back"):ti,ab 89
#19 MeSH descriptor: [Patient Participation] this term only 1276
#20 MeSH descriptor: [Patient Advocacy] this term only 77

#21 ((patient* or user* or person* or people* or consumer*) near/3 (activat* or empower* or engag* or 81eports* or participat* or 81eports81* or support* or spokesperson* or champion* or ally* or allies* or patron* or proponent*)):ti,ab 33264
#22 MeSH descriptor: [Reminder Systems] this term only 893
#23 MeSH descriptor: [Appointments and Schedules] this term only 434
#24 ((physician* or doctor* or nurse* or surgeon* or consultant* or practition* or referral* or ((medical* or health) near/3 (staff* or secretar*))) near/3 (correspond* or letter* or writ* or messag* or mail* or post or postal or remind*)):ti,ab 1451
#25 ((clinical* or clinician* or physician* or doctor* or nurse* or practition*) near/3 (prompt* or question* or cue or cues)):ti,ab 3953
#26 ((interven* or inform*) near/3 (before* or prior* or ahead* or advance*) near/3 (consult* or appointment* or visit* or waiting room*)):ti,ab 166
#27 ((interven* or inform*) near/3 (previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*")):ti,ab 46
#28 MeSH descriptor: [Pamphlets] this term only 866
#29 MeSH descriptor: [Diary as Topic] this term only 6
#30 MeSH descriptor: [Checklist] this term only 254
#31 MeSH descriptor: [Video Recording] this term only 1335
#32 MeSH descriptor: [Tape Recording] this term only 219
#33 MeSH descriptor: [Telephone] this term only 2009
#34 MeSH descriptor: [Cell Phone] this term only 635
#35 MeSH descriptor: [Smartphone] this term only 292
#36 MeSH descriptor: [Computers, Handheld] this term only 255
#37 MeSH descriptor: [Computers] this term only 529
#38 MeSH descriptor: [Office Visits] this term only 441
#39 ((previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*") near/3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")):ti,ab 43
#40 ((before* or prior* or ahead* or advance*) near/3 (consult* or appointment* or visit* or waiting room*) near/3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")):ti,ab 183
#41 {or #7-#40} 111163
#42 #6 and #41 4970
#43 "clinicaltrials.gov":so 150519
#44 "www.who.int":so 126722
#45 (clinicaltrials or trialsearch):so 277406
#46 "conference":pt169256
#47 {or #43-#46} 446664
#48 #42 not #47 with Publication Year from 1990 to 2020, in Trials 2957
#49 #42 not #47 with Cochrane Library publication date Between Jan 1990 and Jan 2020, in Cochrane Reviews 125

Database: DARE
Strategy used:

1	MeSH DESCRIPTOR decision making	359
2	MeSH DESCRIPTOR decision support systems, clinical	101
3	MeSH DESCRIPTOR decision support techniques	1352
4	(("shared decision making" or SDM))	44
5	(((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj1 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)))	3368
6	#1 OR #2 OR #3 OR #4 OR #5	3369
7	MeSH DESCRIPTOR health literacy	15
8	MeSH DESCRIPTOR patient education as topic	814
9	MeSH DESCRIPTOR consumer health information	19
10	((health* or medical* or patient* or consumer*) adj3 (information* or advice* or literac* or literat* or reading* or readabilit* or educat*))	3642
11	MeSH DESCRIPTOR choice behavior	38
12	MeSH DESCRIPTOR patient preference	58
13	((patient* or user* or person* or people* or consumer*) adj3 (prefer* or elicit* or choice* or choos* or select* or option*))	2718
14	MeSH DESCRIPTOR directive counseling	52
15	MeSH DESCRIPTOR mentoring	0
16	((health* or medical* or patient*) adj3 (coach* or coaches* or trainer* or advis?r* or mentor* or counsel*))	932
17	(motivat* adj3 (interview* or advice* or coach* or champion*))	127
18	(teach-back or "teach back")	0
19	MeSH DESCRIPTOR patient participation	132
20	MeSH DESCRIPTOR patient advocacy	9
21	((patient* or user* or person* or people* or consumer*) adj3 (activat* or empower* or engag* or involv* or participat* or advocat* or support* or spokesperson* or champion* or ally* or allies* or patron* or proponent*))	1511
22	MeSH DESCRIPTOR reminder systems	99
23	MeSH DESCRIPTOR appointments and schedules	49
24	((physician* or doctor* or nurse* or surgeon* or consultant* or practition* or referral* or ((medical* or health) adj3 (staff* or secretar*))) adj3 (correspond* or letter* or writ* or messag* or mail* or post or postal or remind*))	82
25	((clinical* or clinician* or physician* or doctor* or nurse* or practition*) adj3 (prompt* or question* or cue or cues))	412
26	((interven* or inform*) adj3 (before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*))	4
27	((interven* or inform*) adj3 (previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*"))	2
28	MeSH DESCRIPTOR pamphlets	21
29	MeSH DESCRIPTOR medical records	71
30	MeSH DESCRIPTOR checklist	22
31	MeSH DESCRIPTOR video recording	34
32	MeSH DESCRIPTOR tape recording	5
33	MeSH DESCRIPTOR telephone	153
34	MeSH DESCRIPTOR cell phones	48
35	MeSH DESCRIPTOR smartphone	0
36	MeSH DESCRIPTOR computers, handheld	13
37	MeSH DESCRIPTOR computers	38
38	MeSH DESCRIPTOR office visits	76
39	((previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*") adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared"))	2

40	((before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*) adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared"))	2
41	#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40	8836
42	(#6 and #41) IN DARE FROM 1990 TO 2020	227

Database: PsycInfo

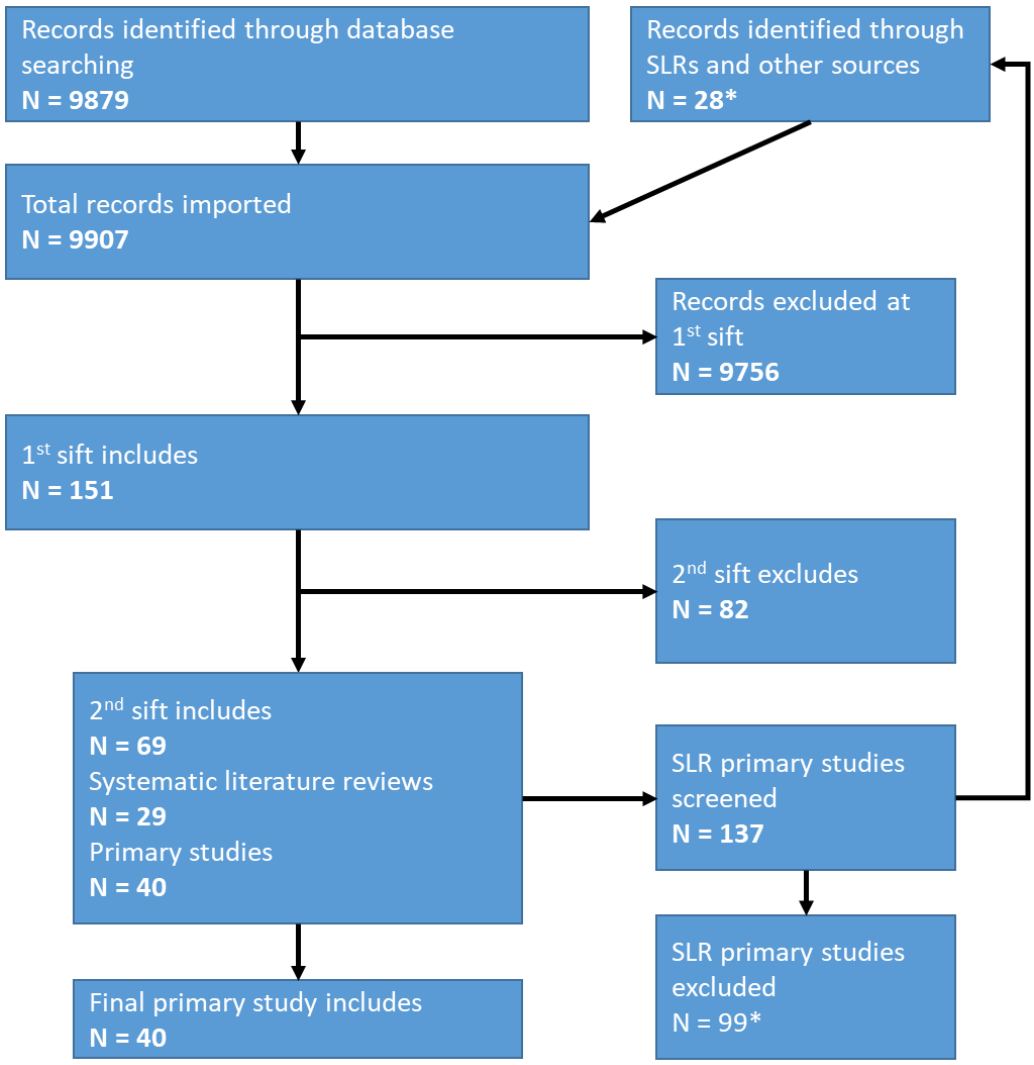
Strategy used:

3 exp Decision Making/ (117070)
2 exp Decision Support Systems/ (3212)
3 ("shared decision making" or SDM).ti,ab. (2614)
4 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 83eports83i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 83eport?or* or conflict* or collab* or aid*)).ti. (26379)
5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or 83eports83i*) adj1 (share* or sharing* or inform* or making* or make* or support* or 83eport?or* or conflict* or collab* or aid*)).ab. /freq=2 (34684)
6 or/1-5 (130855)
7 exp Health Literacy/ or exp Client Education/ or exp Health Information/ (8634)
8 ((health* or medical* or patient* or consumer*) adj3 (information* or advice* or literac* or literat* or reading* or 83eports83ing* or educat*)).tw. (79681)
9 exp Choice Behavior/ or exp Client Attitudes/ (65635)
10 ((patient* or user* or person* or people* or consumer*) adj3 (prefer* or elicit* or choice* or choos* or select* or option*)).tw. (41240)
11 exp Counseling/ or exp Mentor/ (82270)
12 ((health* or medical* or patient*) adj3 (coach* or coaches* or trainer* or advis?r* or mentor* or counsel*)).tw. (9166)
13 (83eports83* adj3 (interview* or advice* or coach* or champion*)).tw. (4398)
14 (teach-back or "teach back").tw. (74)
15 exp Client Participation/ or exp Advocacy/ (6797)
16 ((patient* or user* or person* or people* or consumer*) adj3 (activat* or empower* or engag* or 83eports* or participat* or 83eports83* or support* or spokesperson* or champion* or ally* or allies* or patron* or proponent*)).tw. (70100)
17 ((physician* or doctor* or nurse* or surgeon* or consultant* or practition* or referral* or ((medical* or health) adj3 (staff* or secretar*))) adj3 (correspond* or letter* or writ* or messag* or mail* or post or postal or remind*)).tw. (2813)
18 ((clinical* or clinician* or physician* or doctor* or nurse* or practition*) adj3 (prompt* or question* or cue or cues)).tw. (7832)
19 ((interven* or inform*) adj3 (before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*)).tw. (61)
20 ((interven* or inform*) adj3 (previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*")).tw. (16)

21 exp Journal Writing/ or exp "Checklist (Testing)"/ or exp Videotapes/ or exp Audiovisual Communications Media/ or exp Tape Recorders/ or exp Telephone Systems/ or exp Mobile Phones/ or exp Smartphones/ or exp Computers/ (74067)
22 ((previsit* or "pre visit*" or preconsult* or "pre consult*" or preappoint* or "pre appoint*") adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")).tw. (38)
23 ((before* or prior* or ahead* or advance*) adj3 (consult* or appointment* or visit* or waiting room*) adj3 (pamphlet* or leaflet* or diary* or diaries or booklet* or guidebook* or guide or handbook* or sheet* or checklist* or "check list*" or agenda* or question* or card or cards or helpcard* or video* or tape* or audiotape* or DVD or DVDs or CD or CDs or film* or telephone* or phone* or smartphone* or computer* or laptop* or "smart patient" or "how to be prepared")).tw. (101)
24 or/7-23 (405425)
25 6 and 24 (59168)
26 animals/ not (animals/ and humans/) (7211)
27 25 not 26 (59120)
28 (199* or 200* or 201* or 202*).up. (3759718)
29 27 and 28 (53364)
30 (MEDLINE or pubmed).tw. (21678)
31 systematic review.tw. (26090)
32 systematic review.pt. (0)
33 meta-analysis.pt. (0)
34 intervention$.ti. (68587)
35 or/30-34 (103332)
36 29 and 35 (1286)
37 randomized controlled trial.pt. (0)
38 randomi?ed.mp. (80865)
39 placebo.mp. (39666)
40 or/37-39 (105527)
41 29 and 40 (1048)
42 36 or 41 (2165)
43 limit 42 to 84eports (2090)

1 Appendix D – Clinical evidence study selection

2



3

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

Appendix F – GRADE tables

Pre-consultation intervention

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Brown 2004 – Decisional conflict: DCS – post-consultation											
1	RCT	60	+/- 1.50	MD 1.20 (-0.83, 3.23)	-	-	Serious [1]	Not serious	NA[4]	Serious [5]	Low
Brown 2004 – Satisfaction: Patient satisfaction – post-consultation											
1	RCT	60	+/- 1.10	MD -0.10 (-1.12, 0.92)	-	-	Serious [1]	Not serious	NA[4]	Serious [5]	Low
Brown 2004 – Depression (Beck depression Inventory) - 6 months											
1	RCT	60	+/- 0.70	MD 1.90 (0.21, 3.59)	-	-	Serious [1]	Not serious	NA[4]	Serious [5]	Low
Brown 2004 – Anxiety – 6 months											

1	RCT	60	+/- 4.70	MD -1.30 (-7.10, 4.50)	-	-	Serious [1]	Not serious	NA[4]	Serious [5]	Low
Dillon 2017 (Arm 1) – OPTION 5 – ASK vs Usual Care											
1	Cluster RCT	20	+/- 3.02	MD 1.90 (-3.40, 7.20)	-	-	Serious [1]	Not serious	NA[4]	Very serious [6]	Very low
Nayak 2019 – CARE: empathy											
1	RCT	79	+/- 2.85	MD -1.40 (-4.47, 1.67)	-	-	Very serious [2]	Not serious	NA[4]	Serious [5]	Very low
Nayak 2019 – self-efficacy: PEPPI-5											
1	RCT	79	+/- 1.95	MD 0.40 (-1.46, 2.26)	-	-	Very serious [2]	Not serious	NA[4]	Serious [5]	Very low
Nayak 2019 – PROM SDM: PDMS											
1	RCT	79	+/- 13.55	MD 1.00 (-10.07, 12.07)	-	-	Very serious [2]	Not serious	NA[4]	Not serious	Low
Landrey 2013 – PROM SDM: CPS (preferred active role in SDM)											
1	RCT	283	0.80 , 1.25	RR 0.98 (0.91, 1.05)	93.2 per 100	91.2 per 100 (85.2, 97.6)	Very serious [2]	Not serious	NA[4]	Not serious	Low
Shepherd 2011 - OBOM SDM: OPTION											

1	RCT	36	+/- 1.84	MD 4.70 (2.30, 7.10)	-	-	Not serious	Serious [3]	NA[4]	Not serious	Moderate
Shepherd 2011 - communication about evidence and patient preferences: ACEPP											
1	RCT	36	+/- 4.90	MD 11.50 (5.10, 17.90)	-	-	Not serious	Serious [3]	NA[4]	Not serious	Moderate
Timmers 2018 – Actual Knowledge (self-developed questionnaire)											
1	Cluster RCT	213	+/- 3.40	MD 9.00 (7.06, 10.94)	-	-	Very serious [2]	Not serious	NA[3]	Not serious	Low
Timmers 2018 – Perceived knowledge (self-developed questionnaire)											
1	Cluster RCT	213	+/- 2.05	MD 3.50 (1.92, 5.08)	-	-	Very serious [2]	Not serious	NA[3]	Serious [5]	Very low
Timmers 2018 – Satisfaction with information (self-developed questionnaire)											
1	Cluster RCT	213	+/- 1.25	MD 1.70 (1.05, 2.35)	-	-	Very serious [2]	Not serious	NA[3]	Serious [5]	Very low
Timmers 2018 – Satisfaction with knowledge (self-developed questionnaire)											
1	Cluster RCT	213	+/- 1.25	MD 1.40 (0.69, 2.11)	-	-	Very serious [2]	Not serious	NA[3]	Serious [5]	Very low

1. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
2. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
3. >33.3% of studies partially direct
4. NA
5. 95% confidence intervals cross one end of the defined MIDs
6. 95% confidence intervals cross both ends of the defined MIDs

Interventions for improving Health literacy

No outcomes presented enough data for GRADE analysis.

Preference/Value Elicitation

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Denig 2014 – Diabetes empowerment scale (setting and achieving goals)											
1	Cluster RCT	315	+/- 0.20	MD 0.04 (-0.06, 0.13)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Denig 2014 – Diabetes empowerment scale (readiness to change)											

1	Cluster RCT	315	+/- 0.19	MD -0.02 (-0.10, 0.07)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Denig 2014 – Diabetes empowerment scale (psychosocial management)											
1	Cluster RCT	312	+/- 0.19	MD -0.00 (-0.09, 0.08)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Denig 2014 – PEQ5d											
1	Cluster RCT	313	+/- 7.40	MD -0.73 (-4.18, 2.72)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Denig 2014 – EQ5d-NL											
1	Cluster RCT	308	+/- 0.06	MD -0.01 (-0.04, 0.02)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Granados-Santiago 2019 – QoL: EuroQoL 5D – 3 months											
1	RCT	42	+/- 10.29	MD -8.28 (-23.24, 6.68)	-	-	Not serious	Not serious	NA[3]	Serious[4]	Moderate
Granados-Santiago 2019 – Knowledge: COPD-Q – 3 months											

1	RCT	42	+/- 0.81	MD 3.88 (3.17, 4.59)	-	-	Not serious	Not serious	NA[3]	Not serious	High
Granados-Santiago 2019 – Anxiety/Depression (Hospital Anxiety and Depression Scale (HADS) – 3 months											
1	RCT	42	+/- 0.36	MD -0.13 (-0.44, 0.18)	-	-	Not serious	Not serious	NA[3]	Serious[4]	Moderate
Henselmans 2019 – PDA, no training vs no PDA, no training – OPTION-12											
1	RCT	99	+/- 7.20	MD 0.38 (-5.06, 5.82)	-	-	Serious[2]	Not serious	NA[3]	Not serious	Moderate
Henselmans 2019 – PDA, no training vs no PDA, no training – 4 SDM											
1	RCT	99	+/- 2.68	MD 1.09 (-1.00, 3.18)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
Henselmans 2019 – PDA, no training vs no PDA, no training											
1	RCT	99	+/- 5.07	MD 2.31 (-1.66, 6.28)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low

Henselmans 2019 – PDA, no training vs no PDA, no training – satisfaction: patient satisfaction											
1	RCT	99	+/- 7.84	MD -2.73 (-9.31, 3.85)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
Henselmans 2019 – PDA, no training vs no PDA, no training – oncologist satisfaction											
1	RCT	99	+/- 5.41	MD 2.25 (-2.25, 6.75)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
Henselmans 2019 – PDA, no training vs no PDA, no training – Decisional conflict: patient DC											
1	RCT	99	+/- 4.04	MD 2.34 (-1.32, 6.00)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
Henselmans 2019 – PDA, no training vs no PDA, no training – patient QoL – 3 month											
1	RCT	99	+/- 9.60	MD 2.40 (-5.09, 9.89)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
Henselmans 2019 – Training, PDA vs Training, No PDA – OPTION-12											
1	RCT	95	+/- 7.09	MD 0.34	-	-	Serious[2]	Not serious	NA[3]	Not serious	Moderate

				(-5.09, 5.77)							
Henselmans 2019 – Training, PDA vs Training, No PDA – 4 SDM											
1	RCT	95	+/- 2.44	MD 0.87 (-0.97, 2.71)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
Henselmans 2019 – Training, PDA vs Training, No PDA – patient reported SDM											
1	RCT	95	+/- 3.50	MD 0.92 (-1.98, 3.82)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
Henselmans 2019 – Training, PDA vs Training, No PDA – satisfaction: patient satisfaction											
1	RCT	95	+/- 9.23	MD 0.05 (-7.55, 7.65)	-	-	Serious[2]	Not serious	NA[3]	Not serious	Moderate
Henselmans 2019 – Training, PDA vs Training, No PDA – oncologist satisfaction											
1	RCT	95	+/- 6.20	MD -2.49 (-8.02, 3.04)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
Henselmans 2019 – Training, PDA vs Training, No PDA – Decisional conflict: patient DC											

1	RCT	95	+/- 4.07	MD -0.30 (-3.79, 3.19)	-	-	Serious[2]	Not serious	NA[3]	Not serious	Moderate
Henselmans 2019 – Training, PDA vs Training, No PDA – patient QoL – 3 month											
1	RCT	95	+/- 10.40	MD 0.90 (-7.15, 8.95)	-	-	Serious[2]	Not serious	NA[3]	Not serious	Moderate
Joosten 2008 – Patient Health alliance questionnaire – 3 months											
1	RCT	103	+/- 2.80	MD -0.50 (-2.49, 1.49)	-	-	Very serious[1]	Not serious	NA[3]	Not serious	Low
Joosten 2008 – Clinician Health alliance questionnaire – 3 months											
1	RCT	95	+/- 2.70	MD 1.60 (-0.35, 3.55)	-	-	Very serious[1]	Not serious	NA[3]	Serious[4]	Very low
Joosten 2008 – Health alliance questionnaire difference score – 3 months											
1	RCT	88	+/- 3.65	MD -3.30 (-6.02, -0.58)	-	-	Very serious[1]	Not serious	NA[3]	Serious[4]	Very low

Krones 2008 – Shared decision making (patient participation scale) (PROM, continuous)											
1	Cluster RCT	1132	+/- 2.25	MD 1.72 (1.22, 2.22)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Van Roosmalen 2004 – Decision uncertainty: DCS – uncertainty subscale											
1	RCT	80	+/- 0.50	MD -0.20 (-0.62, 0.22)	-	-	Very serious [1]	Not serious	NA[3]	Serious[4]	Very low
Van Roosmalen 2004 – General health											
1	RCT	88	+/- 0.65	MD -0.30 (-0.99, 0.39)	-	-	Very serious [1]	Not serious	NA[3]	Serious[4]	Very low
Van Roosmalen 2004 – Anxiety (Spielberger State-Trait Anxiety Inventory state anxiety subscale)											
1	RCT	86	+/- 0.50	SMD -0.18 (-0.60, 0.25)	-	-	Very serious [1]	Not serious	NA[3]	Serious[4]	Very low
Van Roosmalen 2004 – Depression (Center for Epidemiologic Studies Depression Scale)											
1	RCT	86	+/- 3.65	MD -2.00 (-5.13, 1.13)	-	-	Very serious [1]	Not serious	NA[3]	Serious[4]	Very low

Van Roosmalen 2004 – Shared decision making (PROM, continuous)											
1	RCT	78	+/- 0.50	SMD 0.30 (-0.14, 0.75)	-	-	Very serious [1]	Not serious	NA[3]	Serious[4]	Very low
Wilson 2010 – Patient-perceived roles in treatment decision-making											
1	RCT	408	+/- 0.45	MD 0.60 (0.45, 0.75)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low

1. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
2. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
3. NA
4. 95% confidence intervals cross one end of the defined MIDs

Patient activation

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Cheng 2019 – Empowerment level (Diabetes empowerment scale short form)1 week											

1	RCT	209	+/- 0.28	MD 0.16 (0.01, 0.31)	-	-	Not serious	Not serious	NA[3]	Serious [4]	Mod erate
Cheng 2019 – Empowerment level (Diabetes empowerment scale short form) - 3 months											
1	RCT	201	+/- 0.28	MD 0.18 (0.02, 0.33)	-	-	Not serious	Not serious	NA[3]	Serious [4]	Mod erate
Cheng 2019 – Diabetes related distress (diabetes distress scale) – 1 week											
1	RCT	209	+/- 0.26	MD -0.13 (-0.27, 0.01)	-	-	Not serious	Not serious	NA[3]	Serious [4]	Mod erate
Cheng 2019 – Diabetes related distress (diabetes distress scale) – 3 months											
1	RCT	201	+/- 0.31	MD -0.18 (-0.35, -0.01)	-	-	Not serious	Not serious	NA[3]	Serious [4]	Mod erate
Cheng 2019 – Quality of life (audit diabetes dependent quality of life) – 1 week											
1	RCT	209	+/- 7.99	MD 1.62 (-2.72, 5.95)	-	-	Not serious	Not serious	NA[3]	Not serious	High
Cheng 2019 – Quality of life (audit diabetes dependent quality of life) – 3 months											
1	RCT	201	+/- 5.17	MD 4.15 (1.29, 7.01)	-	-	Not serious	Not serious	NA[3]	Serious [4]	Mod erate
Deen 2012 PA vs doctor visit – Patient activation											
1	RCT	142	+/- 2.83	MD 0.51 (-1.43, 2.45)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Deen 2012 PA vs doctor visit – Decision self-efficacy											

1	RCT	35	+/- 9.64	MD 2.13 (-9.13, 13.39)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Deen 2012 PDA vs doctor visit - Patient activation											
1	RCT	138	+/- 2.83	MD -0.38 (-2.21, 1.45)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Deen 2012 PDA vs doctor visit - Decision self-efficacy											
1	RCT	36	+/- 9.64	MD 4.83 (-6.94, 16.60)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Deen 2012 PA and PDA vs doctor visit – Patient activation											
1	RCT	137	+/- 2.83	MD 0.23 (-1.63, 2.09)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Deen 2012 PA and PDA vs doctor visit – Decision self-efficacy											
1	RCT	32	+/- 9.64	MD 6.40 (-5.85, 18.65)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Deen 2012 PA vs PDA – Patient activation											
1	RCT	142	+/- 2.64	MD 0.89 (-0.99, 2.77)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Deen 2012 PA vs PDA – Decision self-efficacy											

1	RCT	41	+/- 7.70	MD -2.70 (-11.35, 5.95)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Deen 2012 PA vs PA and PDA – Patient activation											
1	RCT	141	+/- 2.73	MD 0.28 (-1.64, 2.20)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Deen 2012 PA vs PA and PDA – Decision self-efficacy											
1	RCT	37	+/- 7.78	MD -4.27 (-13.55, 5.01)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Deen 2012 PA and PDA vs PDA – Patient activation											
1	RCT	137	+/- 2.64	MD 0.61 (-1.19, 2.41)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Deen 2012 PA and PDA vs PDA – Decision self-efficacy											
1	RCT	38	+/- 7.70	MD 1.57 (-8.33, 11.47)	-	-	Very serious [1]	Not serious	NA[3]	Very Serious [5]	Very low
Dillon 2017 – OPTION 5 – Opencomm vs usual care											
1	Cluster RCT	20	+/- 3.52	MD 4.05 (-2.11, 10.22)	-	-	Serious [2]	Not serious	NA[3]	Serious [4]	Low
Hamann 2011 – Shared decision making (PROM, continuous)											
1	RCT	61	+/- 0.50	SMD -0.18 (-0.68, 0.32)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low

Hamann 2011 – Satisfaction with treatment											
1	RCT	61	+/- 0.50	SMD -0.32 (-0.83, 0.19)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Hamann 2011 – Decision self-efficacy											
1	RCT	61	+/- 0.50	SMD 0.04 (-0.46, 0.55)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Hamann 2020 - PROM SDM: SDM-q-9 Perceived involvement in DM											
1	Cluster RCT	322	+/- 17.17	MD 16.50?(9.00, 24.00)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Hamann 2020 - Patient measure of therapeutic relationship: Helping alliance scale (HAS-P)											
1	Cluster RCT	322	+/- 1.56	MD 1.07?(0.39, 1.75)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low

Hamann 2020 - Clinician measure of therapeutic relationship: Helping alliance scale (HAS-C)											
1	Cluster RCT	322	+/- 1.19	MD -0.42?(-0.94, 0.10)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Hamann 2020 - Patient satisfaction with treatment (ZUF8)											
1	Cluster RCT	322	+/- 3.09	MD 3.04?(1.69, 4.39)	-	-	Very serious [1]	Not serious	NA[3]	Serious [4]	Very low
Hamann 2020 - Camberwell assessment of need self-report questionnaire (unmet need)											
1	Cluster RCT	322	+/- 2.56	MD -0.79?(-1.91, 0.33)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Hamann 2020 - wellbeing (WHO-5)											
1	Cluster RCT	322	+/- 32.68	MD 3.96?(-10.32, 18.24)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low
Hamann 2020 - Quality of life: EUROHIS-QOL											
1	Cluster RCT	322	+/- 7.00	MD 1.59?(-1.47, 4.65)	-	-	Very serious [1]	Not serious	NA[3]	Not serious	Low

1. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
2. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
3. NA
4. 95% confidence intervals cross one end of the defined MIDs
5. 95% confidence intervals cross both ends of the defined MIDs

Third person support

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Aljumah 2015 – Beliefs about medicine (patients beliefs about medicine questionnaire) – 6 months									
1		220	+/- 2.21	MD -2.76?(-3.83, -1.69)	Serious [1]	Not serious	NA[3]	Serious[4]	Low
Aljumah 2015 – Treatment satisfaction (Treatment Satisfaction questionnaire for medication (TSQM 1,4) – 6 months									
1		220	+/- 6.70	MD 5.82?(2.61, 9.03)	Serious [1]	Not serious	NA[3]	Serious[4]	Low
Aljumah 2015 – Depression (Montgomery-Asberg scale) – 6 months									
1		220	+/- 6.27	MD -0.21?(-3.45, 3.03)	Serious [1]	Not serious	NA[3]	Not serious	Moderate
Aljumah 2015 – Quality of life: EQ-5D – 6 months									
1		220	+/- 0.19	MD 0.02?(-0.08, 0.12)	Serious [1]	Not serious	NA[3]	Not serious	Moderate
Collinsworth 2018 – Patient activation (PAM)									
1		100	+/- 0.48	MD -0.17?(-0.54, 0.20)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Collinsworth 2018 – COPD assessment test score – 6 months									
1		100	+/- 3.89	MD -4.89?(-8.44, -1.34)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low

Dobke 2008 – Decisional conflict: DCS									
1		24	+/- 1.85	MD 1.60?(-1.46, 4.66)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Dobke 2008 – SDM satisfaction (satisfaction with decision making scale)									
1		24	+/- 9.45	MD 7.80?(-4.42, 20.02)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Doherty 2018 – QoL: SF-36 Physical component – 2 years									
1		30	+/- 2.13	MD -21.00?(-23.33, -18.67)	Very serious [2]	Not serious	NA[3]	Not serious	Low
Doherty 2018 – QoL: SF-36 mental component – 2 years									
1		30	+/- 0.82	MD -1.40?(-2.27, -0.53)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Hacking 2013 - Decision self-efficacy post-intervention									
1		90	+/- 8.70	MD 6.10 (0.13, 12.07)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Hacking 2013 - Decision self-efficacy 6 months (DSE scale)									
1		90	+/- 8.30	MD 6.30 (0.47, 12.13)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Hacking 2013 - Decisional conflict post-intervention									

1		101	+/- 0.32	MD -0.16 (-0.40, 0.08)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Hacking 2013 - Decisional conflict 6 months (DCS scale)									
1		101	+/- 0.32	MD -0.23 (-0.46, -0.00)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Hacking 2013 - Decision regret 6 months									
1		102	+/- 8.00	MD -6.30 (-12.20, -0.40)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Ishii 2017 – Satisfaction: CSJ-8 – discharge									
1		517	+/- 7.40	MD 3.58?(0.86, 6.30)	Very serious [2]	Not serious	NA[3]	Not serious	Low
Ishii 2017 – Global assessment of functioning – discharge									
1		517	+/- 4.63	MD -1.10?(-3.19, 0.99)	Very serious [2]	Not serious	NA[3]	Not serious	Low
Rahn 2018 – MAPPIN'SDM (physician consultation) – patient									
1		59	+/- 0.20	MD 0.30?(0.04, 0.56)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Rahn 2018 – MAPPIN'SDM (physician consultation) – physician									
1		55	+/- 0.25	MD 0.30?(0.06, 0.54)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Rahn 2018 – Decisional conflict (DCS) – patient									

1		59	+/- 0.30	MD 0.30?(0.03, 0.57)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Rahn 2018 – Decisional conflict: DCS – physician									
1		55	+/- 0.35	MD 0.40?(0.09, 0.71)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Rahn 2018 – PROM SDM: CPS (subscale – trust)									
1		54	+/- 4.60	MD -1.60?(-7.26, 4.06)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Shepherd 2018 - Decision self-efficacy post third consultation									
1		66	+/- 7.70	MD 9.47¬(3.15, 15.79)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Shepherd 2018 - Decisional conflict 3 months									
1		69	+/- 0.27	MD -0.22¬(-0.47, 0.03)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Shepherd 2018 - Decisional regret 3 months									
1		68	+/- 11.43	MD -9.71¬(-18.67, -0.75)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Shepherd 2018 - preparation for decision making									
1		72	+/- 15.98	MD 29.56¬(17.15, 41.97)	Very serious [2]	Not serious	NA[3]	Not serious	Low
Shepherd 2018 - Anxiety (HADS-A) 3 months									

1		68	+/- 2.23	MD -0.33¬(-2.41, 1.75)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Shepherd 2018 - Depression (HADS-D) 3 months									
1		68	+/- 1.91	MD -0.33¬(-2.02, 1.36)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Swoboda 2017 – Depression: PHQ-8 – 16 weeks									
1		53	+/- 2.90	MD 0.37?(-2.64, 3.38)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Swoboda 2017 – Diabetes self-efficacy – 16 weeks									
1		53	+/- 1.10	MD 0.92?(-0.29, 2.13)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Swoboda 2017 – Diabetes empowerment – 16 weeks									
1		53	+/- 0.52	MD 0.53?(-0.04, 1.10)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Swoboda 2017 – Diabetes distress – 16 weeks									
1		53	+/- 0.32	MD -0.16?(-0.54, 0.22)	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low

1. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
2. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
3. NA
4. 95% confidence intervals cross one end of the defined MIDs

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Aljumah 2015 – Beliefs about medicine (patients beliefs about medicine questionnaire) – 6 months	RCT										
1		220	+/- 2.21	MD -2.76 (-3.83, -1.69)	-	-	Serious[1]	Not serious	NA[3]	Serious[4]	Low
Aljumah 2015 – Treatment satisfaction (Treatment Satisfaction questionnaire for medication (TSQM 1,4) – 6 months											
1	RCT	220	+/- 6.70	MD 5.82 (2.61, 9.03)	-	-	Serious[1]	Not serious	NA[3]	Serious[4]	Low
Aljumah 2015 – Depression (Montgomery-Asberg scale) – 6 months											
1	RCT	220	+/- 6.27	MD -0.21 (-3.45, 3.03)	-	-	Serious[1]	Not serious	NA[3]	Not serious	Moderate
Aljumah 2015 – Quality of life: EQ-5D – 6 months											

1	RCT	220	+/-0.19	MD 0.02 (-0.08, 0.12)	-	-	Serious[1]	Not serious	NA[3]	Not serious	Moderate
Collinsworth 2018 – Patient activation (PAM)											
1	RCT	100	+/-0.48	MD -0.17 (-0.54, 0.20)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Collinsworth 2018 – COPD assessment test score – 6 months											
1	RCT	100	+/-3.89	MD -4.89 (-8.44, -1.34)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Dobke 2008 – Decisional conflict: DCS											
1	RCT	30	+/-2.13	MD -21.00 (-23.33, -18.67)	-	-	Very serious[2]	Not serious	NA[3]	Not serious	Low
Dobke 2008 – SDM satisfaction (satisfaction with decision making scale)											
1	RCT	30	+/-0.82	MD -1.40 (-2.27, -0.53)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Doherty 2018 – QoL: SF-36 Physical component – 2 years											

1	RCT	517	+/-7.40	MD 3.58 (0.86, 6.30)	-	-	Very serious[2]	Not serious	NA[3]	Not serious	Low
Doherty 2018 – QoL: SF-36 mental component – 2 years											
1	RCT	517	+/-4.63	MD -1.10 (-3.19, 0.99)	-	-	Very serious[2]	Not serious	NA[3]	Not serious	Low
Ishii 2017 – Satisfaction: CSJ-8 – discharge											
1	RCT	24	+/-1.85	MD 1.60 (-1.46, 4.66)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Ishii 2017 – Global assessment of functioning – discharge											
1	RCT	24	+/-9.45	MD 7.80 (-4.42, 20.02)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Swoboda 2017 – Depression: PHQ-8 – 16 weeks											
1	RCT	53	+/-2.90	MD 0.37 (-2.64, 3.38)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Swoboda 2017 – Diabetes self-efficacy – 16 weeks											
1	RCT	53	+/-1.10	MD 0.92 (-0.29, 2.13)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low

Swoboda 2017 – Diabetes empowerment – 16 weeks											
1	RCT	53	+/- 0.52	MD 0.53 (-0.04, 1.10)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Swoboda 2017 – Diabetes distress – 16 weeks											
1	RCT	53	+/- 0.32	MD -0.16 (-0.54, 0.22)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low

1. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
2. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
3. NA
4. 95% confidence intervals cross one end of the defined MIDs

Documentary intervention

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Kravitz 2018 – Shared decision making (PROM, continuous) consumer assessment of healthcare providers and systems survey– 12 months											

1	RCT	215	+/- 17.48	MD 9.40 (0.05, 18.75)	-	-	Very serious[1]	Not serious	NA[3]	Serious[4]	Very low
Kravitz 2018- patient satisfaction with care											
1	RCT	170	+/- 11.91	MD 6.19 (-0.98, 13.36)	-	-	Very serious[1]	Not serious	NA[3]	Serious[4]	Very low
Kravitz 2018 – Health-related quality of life (physical)											
1	RCT	170	+/- 3.14	MD 1.64 (-0.25, 3.53)	-	-	Very serious[1]	Not serious	NA[3]	Serious[4]	Very low
Kravitz 2018 – Health-related quality of life (mental)											
1	RCT	170	+/- 4.52	MD 2.45 (0.11, 4.79)	-	-	Very serious[1]	Not serious	NA[3]	Serious[4]	Very low
Metz 2019 – Health-related quality of life											
1	Cluster RCT	186	+/- 0.47	MD -0.05 (-0.32, 0.22)	-	-	Very serious[1]	Not serious	NA[3]	Not serious	Low
Metz 2019 – Alliance											

1	Cluster RCT	186	+/- 0.44	MD -0.03 (-0.29, 0.23)	-	-	Very serious[1]	Not serious	NA[3]	Not serious	Low
Metz 2019 – Decisional conflict											
1	Cluster RCT	186	+/- 8.26	MD -0.15 (-5.31, 5.01)	-	-	Very serious[1]	Not serious	NA[3]	Not serious	Low
Metz 2019 – Shared decision making (PROM, continuous) – SDM-Q-9 (patient) – 2 months											
1	Cluster RCT	175	+/- 12.82	MD 7.56 (0.48, 14.64)	-	-	Serious[2]	Not serious	NA[3]	Serious[4]	Low
O'Leary 2016 – Concordance between experienced role and preferred role in SDM											
1	Cluster RCT	236	0.80, 1.25	RR 0.99 (0.91, 1.08)	89.3 per 100	88.6 per 100 (81.0, 96.9)	Very serious[1]	Not serious	NA[3]	Not serious	Low
O'Leary 2016 – Patient activation											
1	Cluster RCT	236	+/- 6.87	MD 0.69	-	-	Very serious[1]	Not serious	NA[3]	Not serious	Low

				(-2.82, 4.20)							
O'Leary 2016 – Satisfaction (overall)											
1	Cluster RCT	236	0.80, 1.25	RR 1.14 (0.76, 1.70)	27.0 per 100	30.7 per 100 (20.6, 45.9)	Very serious[1]	Not serious	NA[3]	Very serious[5]	Very low

1. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
2. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
3. NA
4. 95% confidence intervals cross one end of the defined MIDs
5. 95% confidence intervals cross both ends of the defined MIDs

Multiple components – Patient activation + Pre-consultation intervention

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Dillon 2017 – OPTION 5 – OpenComm + ASK vs Usual care											
1	Cluster RCT	20	+/- 2.89	MD -2.29 (-7.35, 2.78)	-	-	Serious[1]	Not serious	NA[2]	Serious[3]	Low

1. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias

2. NA
3. 95% confidence intervals cross one end of the defined MIDs

Multiple components – Patient activation + Documentary intervention

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Ledford 2018 – change in Patient activation (PAM) – 32 weeks											
1	RCT	205	+/- 7.36	MD -4.35 (-8.24, -0.46)	-	-	Serious[1]	Not serious	NA[2]	Serious[3]	Low

1. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
2. NA
3. 95% confidence intervals cross one end of the defined MIDs

Multiple components – Preference/value elicitation + Patient activation

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Wilkes 2013 – overall PSA SDM (patient self-report)											

1	Cluster RCT	581	+/- 3.20	MD 0.87 (-0.17, 1.91)	-	-	Very serious[1]	Not serious	NA[2]	Not serious	Low
Wilkes 2013 – overall PSA SDM (physician self-report)											
1	Cluster RCT	120	+/- 0.86	MD -0.10 (-0.77, 0.57)	-	-	Very serious[1]	Not serious	NA[2]	Not serious	Low

1. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
2. NA

Multiple components – Third person support and patient activation

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Alegria 2018 – Shared decision making (OBOM, continuous) – targeting patients – OPTION 12											
1	RCT	312	+/- 6.89	MD 0.36 (-2.70, 3.42)	-	-	Serious[1]	Not serious	NA[3]	Not serious	Moderate
Alegria 2018 – Shared decision making (PROM, continuous) – targeting patients – SDM-Q-9 (patient)											

1	RCT	312	+/- 9.58	MD 1.45 (-2.80, 5.70)	-	-	Very Serious [2]	Not serious	NA[3]	Not serious	Low
Alegria 2018 – Shared decision making (OBOM, continuous) – int targeting professionals – OPTION 12											
1	RCT	74	+/- 4.65	MD 4.52 (0.27, 8.77)	-	-	Serious [1]	Not serious	NA[3]	Serious[4]	Low
Alegria 2018 – Shared decision making (PROM, continuous) –targeting professionals - SDM-Q-9 (professional)											
1	RCT	74	+/- 4.63	MD -0.86 (-5.09, 3.37)	-	-	Very serious [2]	Not serious	NA[3]	Serious[4]	Very low
Alegria 2018 – Shared decision making (OBOM, continuous) – targeting both – OPTION 12											
1	RCT	312	+/- 13.47	MD 2.52 (-3.46, 8.50)	-	-	Serious [1]	Not serious	NA[3]	Not serious	Moderate
Alegria 2018 – Shared decision making (PROM, continuous) – targeting both – SDM-q-9 (patient)											
1	RCT	312	+/- 20.36	MD 4.78 (-4.26, 13.82)	-	-	Very serious [2]	Not serious	NA[3]	Not serious	Low

1. >33.3% of the weight in a meta-analysis came from studies at moderate risk of bias

2. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
3. NA
4. 95% confidence intervals cross one end of the defined MIDs

Multiple components – Third person support and preference/value elicitation

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Berger-Hoger 2019 – OBOM SDM: MAPPIN-Q											
1	Cluster RCT	64	+/- 0.63	MD 1.88 (1.26, 2.50)	-	-	Serious[1]	Not serious	NA[3]	Not serious	Moderate
Berger-Hoger 2019 – Decisional conflict (DCS) (patient)											
1	Cluster RCT	65	+/- 9.07	MD -0.03 (-7.79, 7.73)	-	-	Serious[1]	Not serious	NA[3]	Not serious	Moderate
Berger-Hoger 2019 – Decisional conflict (DCS) (physician)											
1	Cluster RCT	66	+/- 18.36	MD -1.74 (-16.80, 13.32)	-	-	Serious[1]	Not serious	NA[3]	Not serious	Moderate

Berger-Hoger 2019 – Knowledge: Patient informed choice (%)											
1	Cluster RCT	64	+/- 35.46	MD 47.66 (12.64, 82.68)	-	-	Serious[1]	Not serious	NA[3]	Serious[4]	Low
Berger-Hoger 2019 – Duration of consultation (minutes)											
1	Cluster RCT	64	+/- 7.61	MD 33.80 (19.16, 48.44)	-	-	Serious[1]	Not serious	NA[3]	Not serious	Moderate
Causarano 2015 – Decision self-efficacy											
1	RCT	39	+/- 4.90	MD 0.60 (-6.53, 7.73)	-	-	Very serious[2]	Not serious	NA[3]	Very serious[5]	Very low
Causarano 2015 – Other: Satisfaction with information provided											
1	RCT	39	+/- 7.50	MD 1.50 (-7.22, 10.22)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Causarano 2015 – PROM SDM: Decision making – M-PICS											
1	RCT	39	+/- 0.50	SMD -0.44 (-1.08, 0.19)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Causarano 2015 – Decisional conflict: DCS											

1	RCT	39	+/- 8.00	MD -13.40 (-25.61, -1.19)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Mcbride 2016 – Decision self-efficacy – 12 weeks											
1	RCT	56	+/- 7.92	MD 5.66 (-2.12, 13.44)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Mcbride 2016 – Decisional conflict: DCS – 12 weeks											
1	RCT	50	+/- 7.56	MD 5.19 (-3.21, 13.59)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Mcbride 2016 – Decisional regret – 12 weeks											
1	RCT	47	+/- 8.50	MD 2.00 (-6.17, 10.17)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Mcbride 2016 – HR-QoL – 12 weeks											
1	RCT	52	+/- 11.39	MD 5.52 (-6.14, 17.18)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Myers 2011 – Decisional conflict: DCS											
1	RCT	288	+/- 0.24	MD -0.03 (-0.13, 0.07)	-	-	Very serious[2]	Not serious	NA[3]	Not serious	Low

Myers 2011 – Knowledge: Patient knowledge of prostate cancer screening											
1	RCT	288	+/- 0.95	MD 0.70 (0.24, 1.16)	-	-	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Raue 2019 – Patient satisfaction with decision											
1	RCT	202	+/- 0.17	MD -0.04 (-0.12, 0.04)	-	-	Very serious[2]	Not serious	NA[3]	Not serious	Low
Raue 2019 – Depression (continuous) HAM-D											
1	RCT	202	+/- 0.45	MD 0.90 (0.65, 1.15)	-	-	Very serious[2]	Not serious	NA[3]	Not serious	Low
Sheridan 2012 – PROM SDM: number with preferred participation in decision-making (unadjusted)											
1	RCT	89	0.80 , 1.25	RR 0.93 (0.72, 1.20)	76.5 per 100	71.1 per 100 (55.1, 91.6)	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Sheridan 2012 – Knowledge: number having key knowledge about screening (self-made questionnaire)											
1	RCT	128	0.80 , 1.25	RR 3.62 (1.85, 7.07)	12.9 per 100	46.6 per 100	Very serious[2]	Not serious	NA[3]	Not serious	Low

						(23.8, 90.9)					
Sheridan 2012 – Men reporting shared decision											
1	RCT	89	0.80 , 1.25	RR 0.96 (0.76, 1.23)	76.5 per 100	73.7 per 100 (57.8, 94.0)	Very serious[2]	Not serious	NA[3]	Serious[4]	Very low
Sheridan 2012 – Men agreeing a screening test is a decision											
1	RCT	128	0.80 , 1.25	RR 2.79 (1.74, 4.47)	22.9 per 100	63.8 per 100 (39.8, 102.3)	Very serious[2]	Not serious	NA[3]	Not serious	Low
Yamaguchi 2017 – Shared decision making (OBOM, continuous) – targeting both – SDM-18											
1	RCT	37	+/- 0.66	MD 2.24 (1.40, 3.08)	-	-	Serious[1]	Not serious	NA[3]	Not serious	Moderate
Yamaguchi 2017 – Shared decision making (PROM, continuous) – SDM-q-9											
1	RCT	53	+/- 5.41	MD 6.50 (-1.58, 14.58)	-	-	Serious[1]	Not serious	NA[3]	Serious[4]	Low
Yamaguchi 2017 – Satisfaction with consultation											

1	RCT	53	+/- 2.38	MD 1.74 (-0.73, 4.21)	-	-	Serious[1]	Not serious	NA[3]	Serious[4]	Low
Yamaguchi 2017 – Patient-physician communication (IPC Interpersonal Processes of Care Survey) – 6 months											
1	RCT	53	+/- 2.27	MD 3.63 (1.10, 6.16)	-	-	Serious[1]	Not serious	NA[3]	Serious[4]	Low
Yamaguchi 2017 – Health-related quality of life (mental)											
1	RCT	53	+/- 2.53	MD 1.00 (-1.71, 3.71)	-	-	Serious[1]	Not serious	NA[3]	Serious[4]	Low
Yamaguchi 2017 – Health-related quality of life (physical)											
1	RCT	53	+/- 2.49	MD 0.96 (-2.21, 4.13)	-	-	Serious[1]	Not serious	NA[3]	Serious[4]	Low

1. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
2. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
3. NA
4. 95% confidence intervals cross one end of the defined MIDs
5. 95% confidence intervals cross both ends of the defined MIDs

Multiple components – Third person support + preference/value elicitation and patient activation

No. of studies	Study design	Sample size	MIDs	Effect size (95% CI)	Absolute risk: control	Absolute risk: intervention (95% CI)	Risk of bias	Indirectness	Inconsistency	Imprecision	Quality
Walczak 2017 – Other: Patient communication self-efficacy (PEPPI)											
1	RCT	79	+/- 1.75	MD 1.16 (-0.27, 2.59)	-	-	Very serious[1]	Not serious	NA[2]	Serious[3]	Very low
Walczak 2017 – QoL: Patient QoL (FACT-G)											
1	RCT	79	+/- 9.40	MD -6.89 (-14.65, 0.87)	-	-	Very serious[1]	Not serious	NA[2]	Serious[3]	Very low

1. >33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias
2. >33.3% of the weight in a meta-analysis came from studies at high risk of bias
3. NA
4. 95% confidence intervals cross one end of the defined MIDs
5. 95% confidence intervals cross both ends of the defined MIDs

Appendix G – Excluded studies

Study	Code [Reason]
Agarwal, N, Funahashi, R, Taylor, T et al. (2020) Patient Education and Engagement Through Multimedia: a Prospective Pilot Study on Health Literacy in Patients with Cerebral Aneurysms. World neurosurgery	- No SDM outcomes *Does not measure SDM knowledge or other SDM outcomes and debatable wther it is and SDM outcome at all.*
Ahmad, Muayyad, Abu Tabar, Nazih, Othman, Elham H et al. (2020) Shared Decision-Making Measures: A Systematic Review. Quality management in health care 29(2): 54-66	- Not an SDM intervention *SLR not related to SDM*
Allen, Larry A, McIlvennan, Colleen K, Thompson, Jocelyn S et al. (2018) Effectiveness of an Intervention Supporting Shared Decision Making for Destination Therapy Left Ventricular Assist Device: The DECIDE-LVAD Randomized Clinical Trial. JAMA internal medicine 178(4): 520-529	- Clinician training only
Almario, CV, Chey, WD, Khanna, D et al. (2016) Impact of National Institutes of Health Gastrointestinal PROMIS Measures in Clinical Practice: results of a Multicenter Controlled Trial. American journal of gastroenterology 111(11): 1546-1556	- Not a relevant study design
Berry, Donna L, Hong, Fangxin, Blonquist, Traci M et al. (2018) Decision Support with the Personal Patient Profile-Prostate: A Multicenter Randomized Trial. The Journal of urology 199(1): 89-97	- Included in PDA study *Berry 2013 study considers same intervention and included in that SLR*
Brabers, Anne E M, van Dijk, Liset, Groenewegen, Peter P et al. (2016) Does a strategy to promote shared decision-making reduce medical practice variation in the choice of either single or double embryo transfer after in vitro fertilisation? A secondary analysis of a randomised controlled trial. BMJ open 6(5): e010894	- No SDM outcomes
Bradley, Katharine A, Bobb, Jennifer F, Ludman, Evette J et al. (2018) Alcohol-Related Nurse Care Management in Primary Care: A Randomized Clinical Trial. JAMA internal medicine 178(5): 613-621	- No SDM outcomes

Study	Code [Reason]
Bradley, Katharine A, Ludman, Evette Joy, Chavez, Laura J et al. (2017) Patient-centered primary care for adults at high risk for AUDs: the Choosing Healthier Drinking Options In primary CarE (CHOICE) trial. Addiction science & clinical practice 12(1): 15	- No SDM outcomes
Brandel, Michael G, Reid, Christopher M, Parmeshwar, Nisha et al. (2017) Efficacy of a Procedure-Specific Education Module on Informed Consent in Plastic Surgery. Annals of plastic surgery 78(5suppl4): 225-s228	- Data not reported in an extractable format *not enough data*
Brenner AT, Hoffman R, McWilliams A et al. (2016) Colorectal Cancer Screening in Vulnerable Patients: Promoting Informed and Shared Decisions. American journal of preventive medicine 51(4): 454-462	- No SDM outcomes
Buhse, Susanne, Kuniss, Nadine, Liethmann, Kathrin et al. (2018) Informed shared decision-making programme for patients with type 2 diabetes in primary care: cluster randomised controlled trial. BMJ open 8(12): e024004	- No SDM outcomes
Buhse, Susanne, Muhlhauser, Ingrid, Heller, Tabitha et al. (2015) Informed shared decision-making programme on the prevention of myocardial infarction in type 2 diabetes: a randomised controlled trial. BMJ open 5(11): e009116	- Newer study data available
Cheng, Li, Sit, Janet W. H, Choi, Kai-chow et al. (2018) Effectiveness of a patient-centred, empowerment-based intervention programme among patients with poorly controlled type 2 diabetes: A randomised controlled trial. International Journal of Nursing Studies 79: 43-51	- Secondary analysis of included study *cheng 2019*
Consoli, S.M., Duclos, M., Grimaldi, A. et al. (2020) OPADIA Study: Is a Patient Questionnaire Useful for Enhancing Physician-Patient Shared Decision Making on Physical Activity Micro-objectives in Diabetes?. Advances in Therapy 37(5): 2317-2336	- Duplicate reference *In 1.1*
Couet, Nicolas, Labrecque, Michel, Robitaille, Hubert et al. (2015) The impact of DECISION+2 on patient intention to engage in shared decision making: secondary analysis of a multicentre clustered randomized trial. Health	- Clinician training only

Study	Code [Reason]
expectations : an international journal of public participation in health care and health policy 18(6): 2629-37	
Demmel, R, Rist, F, Hagen, J et al. (2003) Secondary prevention beyond screening and brief advice. Suchtmedizin in forschung und praxis 5(1): 33-36	- Data not reported in an extractable format *german*
Frosch, Dominick L; Kaplan, Robert M; Felitti, Vincent J (2003) A randomized controlled trial comparing internet and video to facilitate patient education for men considering the prostate specific antigen test. Journal of general internal medicine 18(10): 781-7	- Not an SDM intervention *A 2003 intervention considering internet use will not be applicable to a modern day setting.*
Goossens, B., Sevenants, A., Declercq, A. et al. (2019) Improving shared decision-making in advance care planning: Implementation of a cluster randomized staff intervention in dementia care. Patient Education and Counseling	- Clinician training only
Hamann, Johannes, Parchmann, Anna, Sassenberg, Nina et al. (2017) Training patients with schizophrenia to share decisions with their psychiatrists: a randomized-controlled trial. Social psychiatry and psychiatric epidemiology 52(2): 175-182	- No SDM outcomes
Harter, Martin, Dirmaier, Jorg, Dwinger, Sarah et al. (2016) Effectiveness of Telephone-Based Health Coaching for Patients with Chronic Conditions: A Randomised Controlled Trial. PloS one 11(9): e0161269	- No SDM outcomes
Joosten, E A G, de Jong, C A J, de Weert-van Oene, G H et al. (2009) Shared decision-making reduces drug use and psychiatric severity in substance-dependent patients. Psychotherapy and psychosomatics 78(4): 245-53	- No SDM outcomes - Data not reported in an extractable format
Joosten, Evelien A G, De Jong, Cor A J, de Weert-van Oene, Gerdien H et al. (2011) Shared decision-making: increases autonomy in substance-dependent patients. Substance use & misuse 46(8): 1037-8	- No SDM outcomes
Jorgensen, Rikke, Munk-Jorgensen, Povl, Lysaker, Paul H et al. (2014) Overcoming recruitment barriers revealed high readiness to participate and low dropout rate among people	- No SDM outcomes

Study	Code [Reason]
with schizophrenia in a randomized controlled trial testing the effect of a Guided Self-Determination intervention. BMC psychiatry 14: 28	- Not an SDM intervention
Kasper, Jurgen, Liethmann, Katrin, Heesen, Christoph et al. (2017) Training doctors briefly and in situ to involve their patients in making medical decisions-Preliminary testing of a newly developed module. Health expectations : an international journal of public participation in health care and health policy 20(6): 1254-1263	- Not a relevant study design
Kennedy, Anne, Bower, Peter, Reeves, David et al. (2013) Implementation of self management support for long term conditions in routine primary care settings: cluster randomised controlled trial. BMJ (Clinical research ed.) 346: f2882	- No SDM outcomes
Kim, Gyuri, Bae, Ji Cheol, Yi, Byoung Kee et al. (2017) An information and communication technology-based centralized clinical trial to determine the efficacy and safety of insulin dose adjustment education based on a smartphone personal health record application: a randomized controlled trial. BMC medical informatics and decision making 17(1): 109	- Protocol
Koelewijn-van Loon, Marije S, van der Weijden, Trudy, Ronda, Gaby et al. (2010) Improving lifestyle and risk perception through patient involvement in nurse-led cardiovascular risk management: a cluster-randomized controlled trial in primary care. Preventive medicine 50(12): 35-44	- No SDM outcomes
Koelewijn-van Loon, Marije S, van der Weijden, Trudy, van Steenkiste, Ben et al. (2009) Involving patients in cardiovascular risk management with nurse-led clinics: a cluster randomized controlled trial. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne 181(12): e267-74	- No SDM outcomes
Koerner, Mirjam, Wirtz, Markus, Michaelis, Martina et al. (2014) A multicentre cluster-randomized controlled study to evaluate a train-the-trainer programme for implementing internal and external participation in medical rehabilitation. Clinical rehabilitation 28(1): 20-35	- Clinician training only - Not an SDM intervention *Intervention not relevant to this question, 2.1 only.*

Study	Code [Reason]
Korner, M; Ehrhardt, H; Steger, A-K (2011) [Development of an interprofessional train-the-trainer programme to implement shared decision-making in medical rehabilitation clinics]. Die Rehabilitation 50(5): 331-9	- Not a relevant study design
Korner, Mirjam, Ehrhardt, Heike, Steger, Anne-Kathrin et al. (2012) Interprofessional SDM train-the-trainer program "Fit for SDM": provider satisfaction and impact on participation. Patient education and counseling 89(1): 122-8	- Clinician training only
Kunneman, M., Branda, M.E., Hargraves, I.G. et al. (2020) Assessment of Shared Decision-making for Stroke Prevention in Patients with Atrial Fibrillation: A Randomized Clinical Trial. JAMA Internal Medicine	- Not an SDM intervention *PDA, not for this RQ*
Legare, France, Guerrier, Mireille, Nadeau, Catherine et al. (2013) Impact of DECISION + 2 on patient and physician assessment of shared decision making implementation in the context of antibiotics use for acute respiratory infections. Implementation science : IS 8: 144	- Clinician training only
Lenert, L A and Cher, D J (1999) Use of meta-analytic results to facilitate shared decision making. Journal of the American Medical Informatics Association : JAMIA 6(5): 412-9	- Not a relevant study design *Not an RCT just uses dat from them.*
Lizarondo, L., Pham, C., Aromataris, E. et al. (2016) Strategies for implementing shared decision making in elective surgery by healthcare practitioners: A systematic review protocol. JBI Database of Systematic Reviews and Implementation Reports 14(12): 100-108	- Protocol
Longo, Mirella F, Cohen, David R, Hood, Kerenza et al. (2006) Involving patients in primary care consultations: assessing preferences using discrete choice experiments. The British journal of general practice : the journal of the Royal College of General Practitioners 56(522): 35-42	- No SDM outcomes
Ludman, E, Von Korff, M, Katon, W et al. (2000) The design, implementation, and acceptance of a primary care-based intervention to prevent depression relapse. International journal of psychiatry in medicine 30(3): 229-45	- No SDM outcomes

Study	Code [Reason]
Malm, U, Ivarsson, B, Allebeck, P et al. (2003) Integrated care in schizophrenia: a 2-year randomized controlled study of two community-based treatment programs. Acta psychiatrica Scandinavica 107(6): 415-23	- No SDM outcomes
Maslin, A M, Baum, M, Walker, J S et al. (1998) Using an interactive video disk in breast cancer patient support. Nursing times 94(44): 52-5	- No SDM outcomes *no useable SDM outcomes reportes*
McIlvennan, Colleen K, Matlock, Daniel D, Thompson, Jocelyn S et al. (2018) Caregivers of Patients Considering a Destination Therapy Left Ventricular Assist Device and a Shared Decision-Making Intervention: The DECIDE-LVAD Trial. JACC. Heart failure 6(11): 904-913	- Clinician training only - decision aid only
Mertz, Kevin, Shah, Romil F, Eppler, Sara L et al. (2020) A Simple Goal Elicitation Tool Improves Shared Decision Making in Outpatient Orthopedic Surgery: A Randomized Controlled Trial. Medical decision making : an international journal of the Society for Medical Decision Making: 272989x20943520	- Duplicate reference *included in 1.1*
Metz, M J, Veerbeek, M A, Elfeddali, I et al. (2019) [Shared decision making in mental health care; evaluation of the added value for patients and clinicians]. Tijdschrift voor psychiatrie 61(7): 487-497	- Study not in English
Metz, Margot J, Franx, Gerdien C, Veerbeek, Marjolein A et al. (2015) Shared Decision Making in mental health care using Routine Outcome Monitoring as a source of information: a cluster randomised controlled trial. BMC psychiatry 15: 313	- Protocol
Metz, Margot, Elfeddali, Iman, Veerbeek, Marjolein et al. (2018) Effectiveness of a multi-facetted blended eHealth intervention during intake supporting patients and clinicians in Shared Decision Making: A cluster randomised controlled trial in a specialist mental health outpatient setting. PloS one 13(6): e0199795	- Secondary analysis of included study
Miller, Michael J, Allison, Jeroan J, Cobaugh, Daniel J et al. (2014) A group-randomized trial of shared decision making for non-steroidal anti-inflammatory drug risk awareness: primary results and lessons learned. Journal of evaluation in clinical practice 20(5): 638-48	- No SDM outcomes

Study	Code [Reason]
Peek, Monica E; Drum, Melinda; Cooper, Lisa A (2014) The Association of Patient Chronic Disease Burden and Self-Management Requirements With Shared Decision Making in Primary Care Visits. Health services research and managerial epidemiology 1	- Secondary analysis of included study
Pel-Littel, Ruth E, van Weert, Julia C M, Minkman, Mirella M et al. (2020) The development of the evidence-based SDMMCC intervention to improve shared decision making in geriatric outpatients: the DICO study. BMC medical informatics and decision making 20(1): 35	- Not a relevant study design *Not a primary controlled study*
Probst, M.A., Lin, M.P., Sze, J.J. et al. (2020) Shared Decision Making for Syncope in the Emergency Department: A Randomized Controlled Feasibility Trial. Academic Emergency Medicine	- Duplicate reference *Moved to 1.1*
Probst, Marc A, Tschatscher, Craig F, Lohse, Christine M et al. (2018) Factors Associated With Patient Involvement in Emergency Care Decisions: A Secondary Analysis of the Chest Pain Choice Multicenter Randomized Trial. Academic emergency medicine : official journal of the Society for Academic Emergency Medicine 25(10): 1107-1117	- decision aid only
Sanders, Ariette R J, Bensing, Jozien M, Magnee, Tessa et al. (2018) The effectiveness of shared decision-making followed by positive reinforcement on physical disability in the long-term follow-up of patients with nonspecific low back pain in primary care: a clustered randomised controlled trial. BMC family practice 19(1): 102	- Clinician training only - decision aid only
Sassen, Barbara, Kok, Gerjo, Schepers, Jan et al. (2014) Supporting health care professionals to improve the processes of shared decision making and self-management in a web-based intervention: randomized controlled trial. Journal of medical Internet research 16(10): e211	- Not an SDM intervention
Schroy, Paul C 3rd, Duhovic, Emir, Chen, Clara A et al. (2016) Risk Stratification and Shared Decision Making for Colorectal Cancer Screening: A Randomized Controlled Trial. Medical decision making : an international	- Included in PDA study

Study	Code [Reason]
journal of the Society for Medical Decision Making 36(4): 526-35	
Seal, K.H., Borsari, B., Tighe, J. et al. (2019) Optimizing pain treatment interventions (OPTI): A pilot randomized controlled trial of collaborative care to improve chronic pain management and opioid safety-Rationale, methods, and lessons learned. Contemporary Clinical Trials 77: 76-85	- No SDM outcomes
Sepucha, Karen, Bedair, Hany, Yu, Liyang et al. (2019) Decision Support Strategies for Hip and Knee Osteoarthritis: Less Is More: A Randomized Comparative Effectiveness Trial (DECIDE-OA Study). The Journal of bone and joint surgery. American volume 101(18): 1645-1653	- No SDM outcomes *No follow up data*
Sferra, Shelby R, Cheng, Joyce S, Boynton, Zachary et al. (2020) Aiding shared decision making in lung cancer screening: two decision tools. Journal of public health (Oxford, England)	- Duplicate reference *Already in 1.1*
Siebenhofer, Andrea, Ulrich, Lisa R, Mergenthal, Karola et al. (2012) Primary care management for optimized antithrombotic treatment [PICANT]: study protocol for a cluster-randomized controlled trial. Implementation science : IS 7: 79	- Protocol
Siebenhofer, Andrea, Ulrich, Lisa-Rebekka, Mergenthal, Karola et al. (2019) Primary care management for patients receiving long-term antithrombotic treatment: A cluster-randomized controlled trial. PloS one 14(1): e0209366	- Not an SDM intervention
Singer, Susanne, Danker, Helge, Meixensberger, Jurgen et al. (2019) Structured multi-disciplinary psychosocial care for cancer patients and the perceived quality of care from the patient perspective: a cluster-randomized trial. Journal of cancer research and clinical oncology 145(11): 2845-2854	- Not an SDM intervention
Stamm, Andrew W, Banerji, John S, Wolff, Erika M et al. (2017) A decision aid versus shared decision making for prostate cancer screening: results of a randomized, controlled trial. The Canadian journal of urology 24(4): 8910-8917	- Data not reported in an extractable format

Study	Code [Reason]
Stegmann, M.E., Brandenbarg, D., Berendsen, A.J. et al. (2020) Prioritisation of treatment goals among older patients with non-curable cancer: The OPTion randomised controlled trial in Dutch primary care. British Journal of General Practice 70(696): e450-e456	- Not an SDM intervention *Decision aid - covered by 1.3b*
Tannenbaum, Cara, Martin, Philippe, Tamblyn, Robyn et al. (2014) Reduction of inappropriate benzodiazepine prescriptions among older adults through direct patient education: the EMPOWER cluster randomized trial. JAMA internal medicine 174(6): 890-8	- No SDM outcomes
Tay, Djin L, Ellington, Lee, Towsley, Gail L et al. (2020) Evaluation of a Collaborative Advance Care Planning Intervention among Older Adult Home Health Patients and Their Caregivers. Journal of palliative medicine	- Not a relevant study design *pre post not an RCT*
Tilburgs, B., Koopmans, R., Vernooij-Dassen, M. et al. (2019) Educating Dutch General Practitioners in Dementia Advance Care Planning: A Cluster Randomized Controlled Trial. Journal of the American Medical Directors Association	- Not an SDM intervention
van der Krieke, Lian, Emerencia, Ando C, Boonstra, Nynke et al. (2013) A web-based tool to support shared decision making for people with a psychotic disorder: randomized controlled trial and process evaluation. Journal of medical Internet research 15(10): e216	- decision aid only
Veroff, David R; Ochoa-Arvelo, Tamara; Venator, Benjamin (2013) A randomized study of telephonic care support in populations at risk for musculoskeletal preference-sensitive surgeries. BMC medical informatics and decision making 13: 21	- No SDM outcomes
Veroff, David; Marr, Amy; Wennberg, David E (2013) Enhanced support for shared decision making reduced costs of care for patients with preference-sensitive conditions. Health affairs (Project Hope) 32(2): 285-93	- No SDM outcomes
Vitger, T., Austin, S.F., Petersen, L. et al. (2019) The Momentum trial: The efficacy of using a smartphone application to promote patient activation and support shared decision making in people with a diagnosis of schizophrenia in	- Protocol

Study	Code [Reason]
outpatient treatment settings: A randomized controlled single-blind trial. BMC Psychiatry 19(1): 185	
Von Korff, Michael, Katon, Wayne, Rutter, Carolyn et al. (2003) Effect on disability outcomes of a depression relapse prevention program. Psychosomatic medicine 65(6): 938-43	- Not an SDM intervention
Woltmann, Emily M, Wilkniss, Sandra M, Teachout, Alexandra et al. (2011) Trial of an electronic decision support system to facilitate shared decision making in community mental health. Psychiatric services (Washington, D.C.) 62(1): 54-60	- No SDM outcomes
Yen, R.W., Durand, M.-A., Harris, C. et al. (2020) Text-only and picture conversation aids both supported shared decision making for breast cancer surgery: Analysis from a cluster randomized trial. Patient Education and Counseling	- Duplicate reference *in 1.1*
Yun, Y.H., Lee, M.K., Park, S. et al. (2011) Use of a decision aid to help caregivers discuss terminal disease status with a family member with cancer: A randomized controlled tria. Journal of Clinical Oncology 29(36): 4811-4819	- Data not reported in an extractable format
Zeng-Treitler, Qing, Gibson, Bryan, Hill, Brent et al. (2016) The effect of simulated narratives that leverage EMR data on shared decision-making: a pilot study. BMC research notes 9: 359	- Not an SDM intervention *Comparison between 2 almost identical interventions in crossover trial with very little baseline data*

Appendix H – References to included studies

Primary studies identified through searches

Alegria, Margarita, Nakash, Ora, Johnson, Kirsten et al. (2018) 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 75(4): 325-335

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

Berger-Hoger, Birte, Liethmann, Katrin, Muhlhauser, Ingrid et al. (2019) 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 93: 141-152

Brown, Rhonda F, Butow, Phyllis N, Sharrock, Merin Anne et al. (2004) 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 7(4): 303-16

Causarano, Natalie, Platt, Jennica, Baxter, Nancy N et al. (2015) 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 23(5): 1365-75

Cheng, Li, Sit, Janet W H, Choi, Kai-Chow et al. (2019) 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: 103407

Collinsworth, Ashley W, Brown, Rachel M, James, Cameron S et al. (2018) The impact of patient education and shared decision making on hospital readmissions for COPD. International journal of chronic obstructive pulmonary disease 13: 1325-1332

Deen, Darwin, Lu, Wei Hsin, Weintraub, Miranda Ritterman et al. (2012) The impact of different modalities for activating patients in a community health center setting. Patient education and counseling 89(1): 178-83

Dillon, Ellis C, Stults, Cheryl D, Wilson, Caroline et al. (2017) An evaluation of two interventions to enhance patient-physician communication using the observer OPTION5 measure of shared decision making. Patient education and counseling 100(10): 1910-1917

Dobke, M.K., Bhavsar, D., Gosman, A. et al. (2008) Pilot trial of telemedicine as a decision aid for patients with chronic wounds. Telemedicine and e-Health 14(3): 245-249

Doherty, Michael, Jenkins, Wendy, Richardson, Helen et al. (2018) 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) 392(10156): 1403-1412

Granados-Santiago, M., Valenza, M.C., Lopez-Lopez, L. et al. (2019) Shared decision-making and patient engagement program during acute exacerbation of COPD hospitalization: A randomized control trial. Patient Education and Counseling

Hacking, Belinda, Wallace, Louise, Scott, Sarah et al. (2013) 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 22(5): 1017-1024

Henselmans, I., van Laarhoven, H.W.M., van Maarschalkerweerd, P. et al. (2019) 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

Hamann, J., Holzhuter, F., Blakaj, S. et al. (2020) Implementing shared decision-making on acute psychiatric wards: A cluster-randomized trial with inpatients suffering from schizophrenia (SDM-PLUS). Epidemiology and Psychiatric Sciences: e137

Ishii, Mio, Okumura, Yasuyuki, Sugiyama, Naoya et al. (2017) Feasibility and efficacy of shared decision making for first-admission schizophrenia: a randomized clinical trial. BMC psychiatry 17(1): 52

Kravitz, Richard L, Schmid, Christopher H, Marois, Maria et al. (2018) Effect of Mobile Device-Supported Single-Patient Multi-crossover Trials on Treatment of Chronic Musculoskeletal Pain: A Randomized Clinical Trial. JAMA internal medicine 178(10): 1368-1377

Landrey, Alison R, Matlock, Daniel D, Andrews, Laura et al. (2013) Shared decision making in prostate-specific antigen testing: the effect of a mailed patient flyer prior to an annual exam. Journal of primary care & community health 4(1): 67-74

Ledford, Christy J W, Womack, Jasmyne J, Rider, Heather A et al. (2018) 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 45(3): 323-330

McBride, E, Hacking, B, O'Carroll, R et al. (2016) Increasing patient involvement in the diabetic foot pathway: a pilot randomized controlled trial. Diabetic medicine : a journal of the British Diabetic Association 33(11): 1483-1492

Metz, Margot J, Veerbeek, Marjolein A, Twisk, Jos W R et al. (2019) Shared decision-making in mental health care using routine outcome monitoring: results of a cluster randomised-controlled trial. Social psychiatry and psychiatric epidemiology 54(2): 209-219

Muscat, Danielle M, Morony, Suzanne, Trevena, Lyndal et al. (2019) Skills for Shared Decision-Making: Evaluation of a Health Literacy Program for Consumers with Lower Literacy Levels. Health literacy research and practice 3(3suppl): 58-s74

Myers, Ronald E, Daskalakis, Constantine, Kunkel, Elisabeth J S et al. (2011) Mediated decision support in prostate cancer screening: a randomized controlled trial of decision counseling. Patient education and counseling 83(2): 240-6

Nayak, J.G., Scalzo, N., Chu, A. et al. (2019) The development and comparative effectiveness of a patient-centered prostate biopsy report: a prospective, randomized study. Prostate Cancer and Prostatic Diseases

O'Leary, Kevin J, Killarney, Audrey, Hansen, Luke O et al. (2016) Effect of patient-centred bedside rounds on hospitalised patients' decision control, activation and satisfaction with care. BMJ quality & safety 25(12): 921-928

Rahn, A. C, Kopke, S, Backhus, I et al. (2018) 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 78: 26-36

Raue, P.J., Schulberg, H.C., Bruce, M.L. et al. (2019) Effectiveness of Shared Decision-Making for Elderly Depressed Minority Primary Care Patients. American Journal of Geriatric Psychiatry 27(8): 883-893

Shepherd, Heather L., Barratt, Alexandra, Trevena, Lyndal J. et al. (2011) 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 84(3): 379-385

Shepherd, S.C., Hacking, B., Wallace, L.M. et al. (2019) Randomised controlled trial of a repeated consultation support intervention for patients with colorectal cancer. Psycho-Oncology 28(4): 702-709

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

Swoboda, Christine M; Miller, Carla K; Wills, Celia E (2017) 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 100(7): 1367-1373

Timmers, Thomas, Janssen, Loes, Pronk, Yvette et al. (2018) 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 6(12): e10742

van Roosmalen, M S, Stalmeier, P F M, Verhoef, L C G et al. (2004) 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 22(16): 3293-301

Walczak, Adam, Butow, Phyllis N, Tattersall, Martin H N et al. (2017) 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 67: 31-40

Wilkes, Michael S, Day, Frank C, Srinivasan, Malathi et al. (2013) Pairing physician education with patient activation to improve shared decisions in prostate cancer screening: a cluster randomized controlled trial. Annals of family medicine 11(4): 324-34

Yamaguchi, Sosei, Taneda, Ayano, Matsunaga, Asami et al. (2017) Efficacy of a Peer-Led, Recovery-Oriented Shared Decision-Making System: A Pilot Randomized Controlled Trial. Psychiatric services (Washington, D.C.) 68(12): 1307-1311

Primary studies identified from other sources

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

Hamann, Johannes, Mendel, Rosmarie, Meier, Anna et al. (2011) "How to speak to your psychiatrist": shared decision-making training for inpatients with schizophrenia. Psychiatric services (Washington, D.C.) 62(10): 1218-21

Joosten E, de Weert G, Sensky T et al. (2008) Effect of shared decision-making on therapeutic alliance in addiction health care. Patient preference and adherence 2: 277-285

Krones, Tanja, Keller, Heidemarie, Sonnichsen, Andreas et al. (2008) Absolute cardiovascular disease risk and shared decision making in primary care: a randomized controlled trial. Annals of family medicine 6(3): 218-27

Wilson, Sandra R, Strub, Peg, Buist, A Sonia et al. (2010) Shared treatment decision making improves adherence and outcomes in poorly controlled asthma. American journal of respiratory and critical care medicine 181(6): 566-77

Systematic reviews identified through searches

Austin, C Adrian, Mohottige, Dinushika, Sudore, Rebecca L et al. (2015) Tools to Promote Shared Decision Making in Serious Illness: A Systematic Review. JAMA internal medicine 175(7): 1213-21

Baptista, Sofia, Teles Sampaio, Elvira, Heleno, Bruno et al. (2018) Web-based versus usual care and other formats of decision aids to support prostate cancer screening decisions: Systematic review and meta-analysis. Journal of Medical Internet Research 20(6)

Bomhof-Roordink, H., Gartner, F.R., Stiggelbout, A.M. et al. (2019) Key components of shared decision making models: A systematic review. BMJ Open 9(12): e031763

Boss, Emily F, Mehta, Nishchay, Nagarajan, Neeraja et al. (2016) Shared Decision Making and Choice for Elective Surgical Care: A Systematic Review. Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery 154(3): 405-20

Coxeter, Peter, Del Mar, Chris B, McGregor, Leanne et al. (2015) Interventions to facilitate shared decision making to address antibiotic use for acute respiratory infections in primary care. The Cochrane database of systematic reviews: cd010907

Currie, A, Askari, A, Nachiappan, S et al. (2015) A systematic review of patient preference elicitation methods in the treatment of colorectal cancer. Colorectal disease : the official journal of the Association of Coloproctology of Great Britain and Ireland 17(1): 17-25

Duncan Edward, Best Catherine, Hagen Suzanne (2010) Shared decision making interventions for people with mental health conditions. Cochrane Database of Systematic Reviews: Reviews issue1

Friedrichs, Anke, Spies, Maren, Harter, Martin et al. (2016) Patient Preferences and Shared Decision Making in the Treatment of Substance Use Disorders: A Systematic Review of the Literature. PloS one 11(1): e0145817

Greenwood, D.A.; Young, H.M.; Quinn, C.C. (2014) Telehealth remote monitoring systematic review: Structured self-monitoring of blood glucose and impact on A1C. Journal of Diabetes Science and Technology 8(2): 378-389

Hauser, Katarina, Koerfer, Armin, Kuhr, Kathrin et al. (2015) Outcome-Relevant Effects of Shared Decision Making. Deutsches Arzteblatt international 112(40): 665-71

Johnson, Rachel A, Huntley, Alyson, Hughes, Rachael A et al. (2018) Interventions to support shared decision making for hypertension: A systematic review of controlled studies. Health expectations : an international journal of public participation in health care and health policy 21(6): 1191-1207

Joosten, E A G, DeFuentes-Merillas, L, de Weert, G H et al. (2008) Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. Psychotherapy and psychosomatics 77(4): 219-26

Kashaf, Michael Saheb and McGill, Elizabeth (2015) Does Shared Decision Making in Cancer Treatment Improve Quality of Life? A Systematic Literature Review. Medical decision making : an international journal of the Society for Medical Decision Making 35(8): 1037-48

Kew, Kayleigh M, Malik, Poonam, Aniruddhan, Krishnan et al. (2017) Shared decision-making for people with asthma. The Cochrane database of systematic reviews 10: cd012330

Kryworuchko, Jennifer, Hill, Elina, Murray, Mary Ann et al. (2013) Interventions for shared decision-making about life support in the intensive care unit: a systematic review. Worldviews on evidence-based nursing 10(1): 3-16

Land, Victoria; Parry, Ruth; Seymour, Jane (2017) Communication practices that encourage and constrain shared decision making in health-care encounters: Systematic review of conversation analytic research. Health expectations : an international journal of public participation in health care and health policy 20(6): 1228-1247

Lee, S.J., O'leary, M.C., Umble, K.E. et al. (2018) Eliciting vulnerable patients' preferences regarding colorectal cancer screening: A systematic review. Patient Preference and Adherence 12: 2267-2282

Legare, France, Adekpedjou, Rheda, Stacey, Dawn et al. (2018) Interventions for increasing the use of shared decision making by healthcare professionals. The Cochrane database of systematic reviews 7: cd006732

Legare, France, Turcotte, Stephane, Stacey, Dawn et al. (2012) Patients' perceptions of sharing in decisions: a systematic review of interventions to enhance shared decision making in routine clinical practice. The patient 5(1): 1-19

Martinez-Gonzalez, N.A., Neuner-Jehle, S., Plate, A. et al. (2018) The effects of shared decision-making compared to usual care for prostate cancer screening decisions: A systematic review and meta-analysis. BMC Cancer 18(1): 1015

Martinez-Gonzalez, Nahara Anani, Plate, Andreas, Senn, Oliver et al. (2018) Shared decision-making for prostate cancer screening and treatment: a systematic review of randomised controlled trials. Swiss medical weekly 148: w14584

Rose, Alice; Rosewilliam, Sheeba; Soundy, Andrew (2017) Shared decision making within goal setting in rehabilitation settings: A systematic review. Patient education and counseling 100(1): 65-75

Simmons, L.A., Wolever, R.Q., Bechard, E.M. et al. (2014) Patient engagement as a risk factor in personalized health care: A systematic review of the literature on chronic disease. Genome Medicine 6(2): 16

Singh Ospina, N., Phillips, K.A., Rodriguez-Gutierrez, R. et al. (2019) Eliciting the Patient's Agenda-Secondary Analysis of Recorded Clinical Encounters. Journal of General Internal Medicine 34(1): 36-40

Stacey D, Kryworuchko J, Bennett C, Murray MA, Mullan S, Légaré F. Decision coaching to prepare patients for making health decisions: a systematic review of decision coaching in trials of patient decision AIDS. Med Decis Making. 2012;32(3):E22-E33. doi:10.1177/0272989X12443311

Tousignant-Laflamme, Y., Christopher, S., Clewley, D. et al. (2017) Does shared decision making results in better health related outcomes for individuals with painful musculoskeletal disorders? A systematic review. Journal of Manual and Manipulative Therapy 25(3): 144-150

Wofford, James L; Smith, Edward D; Miller, David P (2005) The multimedia computer for office-based patient education: a systematic review. Patient education and counseling 59(2): 148-57

Zandstra, D, Busser, J A S, Aarts, J W M et al. (2017) Interventions to support shared decision-making for women with heavy menstrual bleeding: A systematic review. European journal of obstetrics, gynecology, and reproductive biology 211: 156-163

Appendix I – "Core components of SDM" discussion paper

Introduction

We agreed there are two elements to this:

1. Core components that need to happen for a process to be defined as SDM
2. Interventions that might support the delivery of the core components

The ultimate delivery of SDM happens within and around consultations, and involves clinicians and patients having different conversations. A pathway approach can help identify where the core components might be delivered and where interventions may have their impact. Put simply there is what happens before a consultation (preparation), what happens within a consultation and what happens after a consultation (which may bridge to a second or further consultations) (see table 1).

Nonetheless, whilst largely delivered at the patient/clinician interface, decision making is both distributed (in time, place and person) and supported or hindered by wider factors. Hence, we also need to consider different levels, for example using the Ferlie and Shortell multi-level framework (individual – clinician and patient; group/team; organisational; system/wider environment – see table 2). In that model, the system level would be covered within Q2.1, so we would focus on the other levels within Q1.3. Alternatively we could see all levels above the individual as systems elements and focus 1.3 on those components and interventions directly impacting upon the consultation.

Core components that need to happen

1. Patient and clinician need to establish a collaborative relationship
2. Patients (and clinicians) clarify that there are choices to be made (choice talk/team talk)
3. Patients (and clinicians) explore what the available options are, and discuss the risks, benefits and consequences of the available options (option talk).
4. Patients (and clinicians explore what matters to the patient – their preferences and values (preference elicitation)
5. Patients weigh up the options in light of their informed preferences and their understanding of the risks, benefits and consequences of the options.
6. A shared decision is arrived at that is informed and consistent with patient preferences and values, and this decision is used to construct an agreed plan about what to do next (decision talk)

Whilst it would be desirable if we could turn each of the above into a single effectiveness question, this would be challenging since interventions tend to target more than one (often several) of the above (see table 3). For example patient decision aids enhance attitudes, clarify the need for choice, present options, support implicit or explicit values elicitation, and support weighing up of options.

The interventions we are interested in are those that enable effective SDM – getting it right.

Interventions that might support delivery

Note that a number of these may already be covered within Question 1.1 and 2.1, but it is probably more important to ensure we haven't missed any than to be over-concerned about which question they help answer.

Patient questions and prompts

Patient activation

Patient decision aids

Interventions to improve health literacy

Undergraduate education/training

Clinician skills training (different career stages starting at undergraduate level)

Clinician reminders/prompts (including computer based)

Risk communication skills

Risk presentation methods/tools

Preference/values elicitation

Coaching/patient advocates

Patient/clinician champions

A formal record of what was discussed and agreed

The following list is probably more relevant to Q2.1 and systems approaches

Clinical team engagement and leadership

Measurement/indicators (especially those that support direct patient care)

Incentives

QI methods (including PDSA)

Pathway mapping (key decision points)

Board development/leadership

Contracts

National policy alignment

Professional bodies

Richard Thomson

Louisa Polak

Sian Phipps

Appendix J – Research recommendations

Research question	How do the same shared decision making interventions differ in effectiveness between different patient populations and different care settings?
Population	Healthcare service users and practitioners
Intervention	Shared decision making interventions

Research question	How do the same shared decision making interventions differ in effectiveness between different patient populations and different care settings?
Comparators	Same SDM intervention in a different setting
Outcome measures	Acceptability of SDM: This could be measured by • Objective measure of adoption of SDM (eg. OPTION) • Participant recorded measure of adoption of SDM (eg. SDM-q-9) • Decisional regret • Decision conflict • Satisfaction with shared decision making process for both healthcare users and providers
Study designs	Randomised controlled trials Systematic review of randomised controlled trials
Subgroups of interest	NA

Potential criterion	Explanation
Importance to patients, service users or the population	Patients have specific preferences and values that need to be tailored for in SDM, knowing which interventions work best for which demographics will offer a good starting point for this process.
Relevance to NICE guidance	High priority: Tailoring is a key part of the SDM process and many different demographics will be using SDM. This applies across all populations and settings.
Current evidence base	Currently very few high quality studies directly comparing different SDM interventions.
Equality	Certain minority demographics will not be adequately represented in the current evidence base due to low number of high quality studies and low number of studies in specific settings/populations.
Feasibility	This would require multiple studies in multiple subgroups or settings, but is key to the better implementation of SDM.

Research question	How do SDM skills and techniques need to be modified for remote discussions?
Population	Any adult engaging in SDM remotely
Intervention	SDM interventions in a remote setting (eg. Virtual or over telephone)
Comparators	SDM interventions in other remote or non-remote settings
Outcome measures	Measurement of use of SDM: This could be measured by • Objective measure of adoption of SDM (eg. OPTION) • Participant recorded measure of adoption of SDM (eg. SDM-q-9)
Study designs	Randomised controlled trials Systematic review of randomised controlled trials
Subgroups of interest	NA

Potential criterion	Explanation
Importance to patients, service users or the population	There is an increased use of remote discussions, which would provide potential barriers to SDM practices. This includes new methods such as virtual video consultations as well as more established ones such as telephone consultations.

Potential criterion	Explanation
Relevance to NICE guidance	High priority: As technology progresses this question will become more and more relevant
Current evidence base	Currently very few high-quality studies looking at remote discussions and SDM
Equality	Remote discussions risk alienating certain groups who are less familiar with this type of discussion and thus a study of the effects of SDM in these remote discussions and in these groups is vital.
Feasibility	As remote discussions become more commonplace this should not be too difficult to study in the same way you would SDM in a face-to-face discussion. The principles of SDM remain the same.