

Shared decision making

[A] Evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement

NICE guideline

Evidence review A

December 2020

Draft for Committee

*These evidence reviews were developed
by the NICE Guideline Updates Team*

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1 Effectiveness of approaches and activities to increase 2 engagement in shared decision making and the 3 barriers and facilitators to engagement

4 Review questions

5 1.1 What are the most effective approaches and activities to support the following
6 groups to engage with shared decision making:

7 (a) people using healthcare services, and their families, carers and advocates?

8 (b) healthcare providers?
9

10 1.2: What are the barriers to, and facilitators for, engagement with shared decision
11 making by:

12 (a) People using healthcare services, and their families, carers and advocates?

13 (b) Healthcare providers?

14 Introduction

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

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

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

1 The aim of this review is to explore the most effective approaches and activities to
 2 support the engagement with shared decision making by both people using
 3 healthcare services (including their families, carers and advocates) and healthcare
 4 practitioners and to identify barriers and facilitators to that engagement.

5 PICO table

6 **Table 1: PICO table for identifying most effective approaches and activities to**
 7 **support engagement with shared decision making**

| Type of review | Effectiveness review |
|---------------------|--|
| Population | RQ1.1a: Adults (aged 18 years and over) using healthcare services (and their families, carers and advocates if they choose to involve them). RQ1.1b: Healthcare providers Exclusions: <ul style="list-style-type: none"> • 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 engagement with SDM in healthcare services |
| Comparators | <ul style="list-style-type: none"> • Each other • No intervention • Sham intervention • Different intensity of same intervention |
| Outcomes | <ul style="list-style-type: none"> • engagement in shared decision making by healthcare providers and people who use healthcare services and their families, carers and advocates • 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 • |
| Study types | <ul style="list-style-type: none"> • RCTs and SR of RCTs. • If less than 5 good quality RCTs are available, then comparative observational studies will be considered. • Quantitative elements of mixed methods studies that meet the above criteria |

1 **SPIDER table**

2 **Table 2: SPIDER table for barriers and facilitators to shared decision making**

| Type of review | Qualitative evidence synthesis |
|-------------------------------|---|
| Sample | RQ1.2a: Adults (aged 18 years and over) using healthcare services (and their families, carers and advocates if they choose to involve them). RQ1.2b: Healthcare providers Exclusions: <ul style="list-style-type: none"> • 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. |
| Phenomenon of Interest | Engagement in shared decision making in healthcare services |
| Design | <ul style="list-style-type: none"> • Qualitative studies • Syntheses of qualitative studies • Qualitative elements of mixed methods studies |
| Evaluation | <ul style="list-style-type: none"> • Perceived barriers and facilitators to SDM • engagement in shared decision making by healthcare providers and people who use healthcare services and their families, carers and advocates • unintended consequences |
| Research type | Qualitative and mixed methods |
| Search date | 1990 |
| Exclusion criteria | <ul style="list-style-type: none"> • Surveys (all types) • Non-English language papers • Theses, dissertations and conference abstracts • Editorials, opinion pieces and letters |

3

4 **Methods and process**

5 This evidence review addresses two separate but related review questions. The first
 6 is answered by using a systematic review of the quantitative evidence and the
 7 second by a review of the qualitative evidence. Since the reviews address different
 8 facets of the same question they are both presented in a single review. Both reviews
 9 were considered together by the guideline committee and the recommendations were
 10 based on their discussion of both reviews together.

1 **Methods and process - Quantitative review**

2 This evidence review is an update of an existing Cochrane systematic review (Légaré
3 2018). Searches from this review were updated and new included studies added to
4 the analyses, which are presented below.

5 This evidence review update was developed using the methods and process
6 described in [Developing NICE guidelines: the manual](#). Methods specific to this review
7 question are described in the review protocol in appendix A

8 For further details of the methods used see appendix B.

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

10 Declarations of interest were recorded according to [NICE's 2018 conflicts of interest](#)
11 [policy](#).

12 **Methods and process – Qualitative review**

13 This evidence review was developed using the methods and process described in
14 [Developing NICE guidelines: the manual](#). Methods specific to this review question
15 are described in the review protocol in appendix A

16 Studies were uploaded to Nvivo version 11 software¹ and coded based on the data
17 presented in the primary studies. Once coding was complete, the codes were
18 examined and aggregated iteratively into groups of common meaning until this was
19 no longer meaningful. These top level aggregations of codes formed the themes that
20 were presented in this review. For further details of the methods used see appendix
21 B.

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

23 Declarations of interest were recorded according to [NICE's 2018 conflicts of interest](#)
24 [policy](#).

25 **Collected evidence**

26 References for all included studies can be found in appendix K.

27 **Included studies - Quantitative**

28 Database searches from both the original Cochrane search (up to August 2019) and
29 the rerun search (up to August 18th 2020) identified 7,251 articles for title and
30 abstract screening. 7,093 articles were excluded at this stage, leaving 158 articles for
31 full text screening. Of these, 136 were excluded due to: inappropriate study design,
32 no intervention designed to increase the uptake of shared decision making and
33 having no outcomes of interest. Therefore, 22 studies were included, of which all
34 were randomised controlled trials.

35 4 studies reported insufficient outcome data and thus were excluded from the meta-
36 analysis (Dillon 2017, Geiger 2017, Shirk 2017, Woltmann 2011).

37 For references from the previous Cochrane review please see their reference list
38 ([Legare 2018](#)).

¹ NVivo qualitative data analysis software; QSR International Pty Ltd. Version 11,
2015.

1 Included studies - Qualitative

2 Database searches from both the original search (5th June 2019) and rerun searches
 3 (18th August 2020) using a validated qualitative filter identified 9,978 articles for title
 4 and abstract screening. 9,893 articles were excluded at this stage, leaving 72 articles
 5 for full text screening. 8 of these articles were excluded due to not reporting any of
 6 the factors of interest specified in the protocol or being an incorrect study type. This
 7 left 64 included articles in the review. 5 of these were identified from reruns.

8 Of these 64, 60 were primary qualitative studies, whilst 4 were systematic reviews.
 9 These systematic reviews were not included in the overall review and instead
 10 checked for relevant references.

11 A flow of included studies for quantitative and qualitative reviews can be found in
 12 appendix D

13 Excluded studies

14 Details of all studies excluded at full text, with reasons for exclusion, are given in
 15 appendix I.

16 Summary of quantitative studies included in the evidence review

17 Of the 21 included quantitative studies, 4 presented data for interventions targeting
 18 practitioners (Metz 2018, Metz 2019, Harris 2009, Henselmans 2019), 10 data for
 19 interventions targeting patients (Berger-Hoger 2019, Consoli 2018, Doll 2019,
 20 Kunneman 2020, Mertz 2020, Oddone 2018, Probst 2020, Raue 2019, Shirk 2017,
 21 Yen 2020), and 6 data for interventions targeting both patients and practitioners
 22 (Dillon 2017, Geiger 2017, Goossens 2020, Kravitz 2018, Woltmann 2011,
 23 Yamaguchi 2017). 1 Study contained all 3 intervention targets (patient, practitioner,
 24 both) and presented stratified data for these. (Alegria 2018).

25 All but one study (Dillon 2017) observed the effect of a shared decision making
 26 intervention compared to usual care.

27 Further study characteristics are presented in Table 3.

28 Table 3: Summary of characteristics of included quantitative studies

| Author | Country | N | Intervention | Setting |
|-----------------------|---------|--|--|-------------------------------|
| Alegria 2018 | USA | 312 patients, 74 clinicians | DECIDE-PC: 3 areas of patient- centered communication in promoting SDM, Control | Behavioural health clinics |
| Berger- Hoger 2019 | Germany | 64 patients, 84 healthcare professionals | Decision coaching (involving decision aid and nurse-led coaching), Standard care | Medical centres |

| | | | | |
|------------------|-------------|---|--|---|
| Consoli 2020 | France | 256 patients, 80 health professionals | OPTIMA-PA Questionnaire Standard CARE | General practices |
| Dillon, 2017 | USA | 40 patients and clinicians | Open Communication, AskShareKnow, Open Communication and AskShareKnow, usual care. | Primary care clinics |
| Doll, 2019 | USA | 203 | Decision aid, usual care | Hospital |
| Geiger, 2017 | Germany | 144 | doktormitSDM (manual and video), control | Hospitals |
| Goosens 2020 | Belgium | 311 staff | We Decide Optimized | Nursing homes |
| Harris 2009 | UK | 169 patients, 56 healthcare professionals | Medication management training, Waiting list controls. | Community mental health (NHS) |
| Henselmans, 2019 | Netherlands | 31 | Training Control | Medical oncology departments in hospitals |
| Kravitz, 2018 | USA | 215 | Trial supported by mobile health app, Control | Primary care, Family medicine clinic, Veteran affairs, Air force base |
| Kunneman 2020 | USA | 922 | Anti-coagulation choice SDM tool Standard care | Emergency and inpatient hospital departments |
| Mertz 2020 | USA | 105 | Goal elicitation worksheet Control | Orthopaedic surgery clinic |
| Metz, 2019 | Netherlands | 186 | Shared decision making using Routine Outcome Monitoring (SDMR), Control | Multi-center (specialist mental health care organisations) |

| | | | | |
|-----------------|-------------|-------------------------------|---|--|
| Metz, 2018 | Netherlands | 200 | Shared Decision Making Digital Intake (SDM-DI), Intake as Usual | Multi-center (specialist mental health care organisations) |
| Oddone, 2018 | USA | 417 | Health risk assessment and health coaching, Health risk assessment | Primary care clinics |
| Probst 2020 | USA | 51 | Syncope Decision Aid Control | Academic emergency department |
| Raue, 2019 | USA | 202 physicians and patients | Shared decision making, Usual care | Mental Health center |
| Shirk, 2017 | USA | 130 | Software-based preference assessment in addition to the brochure, Education with a brochure about prostate cancer treatment. | Medical centers |
| Woltmann, 2011 | USA | 80 patients, 19 case managers | Electronic decision support systems, Control | Community mental health |
| Yamaguchi, 2017 | Japan | 43 | Shared decision making system, Treatment as usual | Outpatient sites |
| Yen 2020 | USA | 311 | Text only conversation aid Text and picture conversation aid Usual care | Cancer centres |

1

2 See appendix E for full evidence tables.

3 Summary of qualitative studies included in the evidence review

4 Of the 60 included qualitative studies, there were two examples of papers presenting
 5 the same patient population (Schoenfeld 2016, 2018b and 2019) and (Peek 2009,

- 1 2013). In this textual summary these 5 studies will be counted as 2 to prevent
 2 duplication of themes.
- 3 The number of participants ranged from 8 to 198 across all studies.
- 4 The most common study location was the USA (24), followed by the UK (12),
 5 Netherlands (6), Canada (5), Germany (3), Australia (3), France (1), Indonesia (1),
 6 Taiwan (1), and a study that took place across both the Netherlands and Italy.
- 7 The means of data collection in the studies comprised of semi-structured interviews
 8 (35), Focus groups (19), Observation (2), Unstructured interviews (2), work groups
 9 (2), and questionnaires (1). Some studies undertook multiple methods of data
 10 collection.
- 11 Twenty studies analysed data from patient populations, 21 studies analysed data
 12 from healthcare professionals, and 15 studies analysed data from both populations.
- 13 There were a variety of different settings, including emergency medicine, mental
 14 health departments, Primary care and other hospitals settings. Some studies
 15 examined effects of SDM in specific subpopulations, including US veterans, African-
 16 American communities, LGBT communities, women, and the elderly.
- 17 Further study characteristics are presented in Table 4.

18 **Table 4: Summary of characteristics of included studies**

| Author | Country | N | Type of analysis | Setting | Providers /Patients /Both |
|--------------|---------|-----------------------------------|--|--|---------------------------|
| Barker 2018 | Canada | 25 (16 medics, 9 nurses) | Semi-structured interviews | Hospital birthing unit/mother baby unit | Providers |
| Belcher 2006 | USA | 51 | Semi-structured interviews | Senior medical centres | Patients |
| Bouma 2014 | USA | 15 | Semi-structured interviews | Medical centre | Providers |
| Bi 2019 | USA | 50 (40 interview, 10 focus group) | Semi-structured interviews, Focus groups | Community wellness settings | Patients |
| Bradley 2018 | UK | 46 Pa 55 Pr | Questionnaire | Mental health and learning disability organisation | Both |

| | | | | | |
|--------------------|-------------|------------------|---|----------------------------------|-----------|
| Chong 2013 | Australia | 31 | Semi-structured interviews | Mental health settings | Providers |
| Claramita 2011 | Indonesia | 393 | Interviews and questionnaire survey. | Teaching hospital | Both |
| Cohen 2003 | UK | 19 | Semi-structured interviews | General practice | Patients |
| De Snoo-Trimp 2015 | Netherlands | 12 | Interviews and focus groups | University hospital | Patients |
| Eliacin 2015 | USA | 54 | Semi-structured interviews | Veterans medical center | Patients |
| Elwyn 1999 | UK | 39 | Focus groups | General practice | Providers |
| Fraenkel 2007 | USA | 26 | Semi-structured interviews | Medical centre | Patients |
| Frerichs 2016 | Germany | 25 | Focus groups and semi-structured interviews | | Providers |
| Fuller 2017 | USA | 53 | Semi-structured interviews | Medical home initiative | Patients |
| Giacco 2018 | UK | 38 | Focus groups and interviews | Hospital | Patients |
| Gruss 2019 | USA | 17 (6 Pr, 11 Pa) | Observation/s semi-structured interviews | Breast cancer clinic | Both |
| Hahlweg 2017 | Germany | 54 | Observation | University cancer centre | Both |
| Hajjzadeh 2015 | USA | 11 Pa 5 Pr | Semi-structured interviews | Hospital | Both |
| Hamann 2016 | Germany | 16 Pa 17 Pr | Focus group | Hospital setting | Both |
| Hirpara 2016 | Canada | 20 | Semi-structured interviews | Gastrointestinal oncology clinic | Patients |
| Hofstede 2013 | Netherlands | 64 | Focus groups and semi- | Medical centre work or home | Both |

| | | | | | |
|-----------------|-------------------|-------------|---|---------------------------------------|-----------|
| | | | structured interviews | | |
| Jansen 2019 | Australia | 30 | Semi-structured interviews | Primary care | Patients |
| Kamara 2018 | USA | 13 | Observation | Hospitals | Both |
| Ladin 2017 | USA | 31 | Semi-structured interviews | Dialysis clinics | Patients |
| Legare 2013 | Canada | 8 | Interviews, questionnaire and focus group | Home care programs | Providers |
| Lin 2020 | Taiwan | 20 | Semi-structured interviews | Psychiatric halfway houses | Patients |
| Lowenstein 2019 | USA | 30 Pa 12 Pr | Semi-structured interviews | Urban academic primary care | Both |
| Lown 2009 | USA | 44 Pa 41 Pr | Collaborative work groups | Primary care | Both |
| Maffei 2012 | USA | 101 | Semi-structured interviews | Medical centre | Patients |
| Mahone 2011b | USA | 44 | Focus group | Mental health clinics | Both |
| Mahone 2011a | USA | 8 | Work groups and focus groups | Mental health clinics | Providers |
| Mariani 2017 | Netherlands/Italy | 19 | Focus group | Nursing homes | Providers |
| McCarter 2016 | USA | 30 | Semi-structured interviews | Oncology inpatient/outpatient nursing | Providers |
| Molenaar 2018 | Netherlands | 11 | Focus groups | Multiple | Both |
| Moreau 2012 | France | 25 | Focus groups | Multiple | Patients |
| Muscat 2016 | Australia | 26 | Semi-structured interviews | Low literacy adults | Patients |
| Naik 2005 | USA | 41 Pa 11 Pr | Focus groups | Multiple | Both |

| | | | | | |
|-----------------------|-------------|--------------------------|---|----------------------------------|-----------|
| Patel 2014 | USA | 15 | Semi-structured interviews | Health centres | Providers |
| Peek 2009 | USA | 51 | Focus groups + Semi-structured interviews | Medical centres | Patients |
| Peek 2013 | USA | 51 | Semi-structured interviews | Medical centres | Patients |
| Roodbein 2020 | Holland | 17 (11 medics, 6 nurses) | Semi-structured interview | 4 hospitals | Providers |
| Rose 2019 | UK | 9 | Semi-structured interviews | Intermediate care rehabilitation | Patients |
| Rosenberg-Yunger 2018 | Canada | 16 | Semi-structured interviews | Pharmacy | Providers |
| Savelberg 2019 | Netherlands | 27 | Semi-structured interviews | Breast cancer teams | Providers |
| Schoenfeld 2018a | USA | 29 | Semi-structured interviews | Emergency medicine | Patients |
| Schoenfeld 2018b | USA | 15 | Semi-structured interviews | Emergency medicine | Providers |
| Schoenfeld 2019 | USA | 15 | Semi-structured interviews | Emergency medicine | Providers |
| Schoenfeld 2016 | USA | 15 | Semi-structured interviews | Emergency medicine | Providers |
| Seale 2006 | UK | 21 | Semi-structured interviews | Mental health care trusts | Providers |
| Shepherd 2014 | UK | 26 | Semi-structured interviews | Mental health trusts | Providers |
| Siegel 2015 | USA | 106 | Semi-structured interviews | Gastroenterology | Providers |

| | | | | | |
|----------------------------|-------------|-----|--|----------------------------------|---------------|
| Stevenso n 2003 | UK | 11 | Focus groups | Primary care GPs | Provider s |
| Towle 2006 | Canada | 198 | Unstructured interviews and observations | Family practice | Provider s |
| Upton 2011 | UK | 20 | Semi- structured interviews | Post- qualification nurses | Provider s |
| van Veenend aal 2018 | Netherlands | 51 | Focus Groups, Semi structured interviews , Written feedback | Multiple | Both |
| Walter 2004 | UK | 40 | Focus groups, semi- structured interviews, | Primary care | Patients |
| Watson 2008 | UK | 54 | Focus groups | Primary care | Provider s |
| Wiener 2018 | USA | 95 | Focus groups, semi- structured interviews | Veterans medical center | Both |
| Zeuner 2015 | USA | 20 | Semi- structured interviews | Multiple | Provider s |
| Ziebland 2015 | UK | 32 | Unstructured interviews | Cancer | Patients |

Pa: Patients
 Pr: Practitioners

1
 2

1 **Summary of findings table - Quantitative**

2 **Table 5: Interventions targeting patients compared to no intervention/usual**
3 **care**

| Name | Sample size | Final Effect Estimate | Quality | Interpretation of effect |
|---|-------------|------------------------------|-----------------|--------------------------------------|
| Main analysis: Shared decision making (OBOM, continuous) | 1945 | SMD 0.54 (0.26, 0.82) | Very low | Effect (Favours intervention) |
| Subgroup analysis: Shared decision making (OBOM, continuous) - parallel | 1765 | SMD 0.32 (0.07, 0.57) | Very low | Less than MID (Favours intervention) |
| Subgroup analysis: Shared decision making (OBOM, continuous) - cluster | 180 | SMD 0.99 (0.43, 1.55) | Very low | Effect (Favours intervention) |
| Shared decision making (PROM, continuous) | 2211 | SMD 0.30(0.17, 0.43) | Very low | No meaningful difference |
| Shared decision making (PROM, continuous) - NRCT | 303 | MD 0.30 (-4.05, 4.65) | Low | No meaningful difference |
| Shared decision making (PROM, categorical) | 1911 | RR 0.99 (0.93, 1.06) | Very low | No meaningful difference |
| Knowledge | 615 | SMD 0.37 (0.21, 0.53) | Very low | No meaningful difference |
| Knowledge (categorical) | 312 | RR 1.33 (1.07, 1.66) | Very low | Effect (Favours intervention) |
| Satisfaction | 309 | SMD -0.05 (-0.27, 0.17) | Low | No meaningful difference |
| Decisional conflict | 1403 | SMD 0.37 (0.21, 0.53) | Very low | No meaningful difference |
| Decision regret | 212 | MD -1.50 (-5.91, 2.91) | Low | No meaningful difference |
| Patient-physician communication (number of topics raised by patients) | 100 | MD 0.60 (-0.30, 1.50) | Very low | Could not differentiate |
| Patient-physician communication (patient raised discussion) | 157 | RR 1.83 (1.29, 2.59) | Low | Effect (Favours intervention) |
| Patient-physician communication (patient participation in discussion) | 157 | RR 1.53 (1.20, 1.96) | Very low | Effect (Favours intervention) |
| Decision self-efficacy | 274 | SMD 0.16 (-0.08, 0.40) | Low | No meaningful difference |
| Empowerment | 342 | MD 0.09 (0.02, 0.16) | Low | No meaningful difference |
| Empowerment (categorical) | 262 | RR 1.25 (1.11, 1.40) | Very low | Less than MID (Favours intervention) |

| | | | | |
|---|------------|---------------------------------------|------------|--------------------------------------|
| Adherence | 598 | RR 0.97 (0.91, 1.03) | Low | No meaningful difference |
| Health-related quality of life (physical) | 116 | MD 0.00 (-3.64, 3.64) | Low | No meaningful difference |
| Health-related quality of life (mental) | 116 | MD 1.00 (-2.64, 4.64) | Low | No meaningful difference |
| Anxiety | 419 | SMD 0.02 (-0.33, 0.37) | Very low | No meaningful difference |
| Anxiety (categorical) | 127 | RR 1.40 (0.51, 3.80) | Very low | Could not differentiate |
| Depression (categorical) | 127 | RR 4.54 (1.36, 15.18) | Low | Effect (Favours intervention) |
| Consultation length | 1054 | SMD 0.07 (-0.14, 0.28) | Moderate | No meaningful difference |
| Cost | 105 | MD 405.30 (227.41, 583.19) | Low | Effect (Favours intervention) |
| Depression (Continuous) | 202 | MD 0.90 (0.65, 1.15) | Low | Effect (Favours intervention) |

1

2 **Table 6: Interventions targeting healthcare professionals compared with no**
3 **intervention/usual care**

| Name | Sample size | Final Effect Estimate | Quality | Interpretation of effect |
|---|-------------|----------------------------------|-----------------|--------------------------------------|
| Main analysis: Shared decision making (OBOM, continuous) | 584 | SMD 0.78 (0.36, 1.21) | Very low | Effect (Favours intervention) |
| Shared decision making (OBOM, continuous) - CBAs | 21 | MD -1.28 (-11.43, 8.87) | Very low | Could not differentiate |
| Main analysis: Shared decision making (PROM, continuous) | 6021 | SMD 0.05 (-0.10, 0.20) | Very low | No meaningful difference |
| Shared decision making (PROM, categorical) | 6303 | RR 1.05 (0.87, 1.27) | Very low | Could not differentiate |
| Knowledge | 969 | SMD 0.26 (-0.16, 0.69) | Very low | Could not differentiate |
| Knowledge (categorical) | 80 | RR 0.69 (0.37, 1.29) | Very low | Could not differentiate |
| Satisfaction with consultation | 479 | MD 0.00 (-0.45, 0.45) | Low | No meaningful difference |
| Satisfaction with information | 1492 | RR 1.03 (0.97, 1.10) | Moderate | No meaningful difference |
| Satisfaction with decision making process | 1488 | RR 0.97 (0.92, 1.02) | Moderate | No meaningful difference |
| Satisfaction with discussion | 1483 | RR 0.99 (0.92, 1.07) | Moderate | No meaningful difference |

| | | | | |
|--|------------|---------------------------------|---------------------|--|
| Decision regret | 326 | MD 4.80 (1.19, 8.41) | Low | Less than MID (Favours intervention) |
| Self-efficacy | 4475 | MD -0.70 (-2.06, 0.66) | Low | No meaningful difference |
| Adherence | 827 | MD -0.60 (-1.64, 0.44) | Low | No meaningful difference |
| General health | 4056 | MD 0.50 (-1.09, 2.09) | Low | No meaningful difference |
| Psychological well-being | 4052 | MD 0.00 (-1.39, 1.39) | Low | No meaningful difference |
| Health-related quality of life (physical) | 359 | MD 1.20 (-0.38, 2.78) | Mod erate | No meaningful difference |
| Health-related quality of life (mental) | 359 | MD 2.70 (0.71, 4.69) | Mod erate | No meaningful difference |
| Health-related quality of life | 4635 | SMD -0.00 (-0.06, 0.06) | Low | No meaningful difference |
| Anxiety | 3003 | RR 1.00 (0.81, 1.22) | Mod erate | No meaningful difference |
| Consultation length | 175 | MD 2.70 (1.12, 4.28) | Very low | Effect (Favours intervention) |
| Consultation length (10-20 min) | 479 | RR 0.93 (0.79, 1.09) | Very low | Could not differentiate |
| Safety | 154 | MD 0.00 (-0.22, 0.22) | Mod erate | No meaningful difference |
| Alliance | 309 | SMD 0.06 (-0.17, 0.28) | Low | No meaningful difference |
| patient - physician communication (doctor responding to emotions) | 31 | MD 0.40 (-0.20, 1.00) | Mod erate | Could not differentiate |
| patient-physician communication (information provision) | 31 | MD 0.90 (0.44, 1.36) | High | Effect (Favours intervention) |
| Satisfaction (Physician) | 31 | MD -4.00 (-8.78, 0.78) | High | Could not differentiate |
| Decisional conflict | 186 | MD -0.15 (-5.31, 5.01) | Mod erate | No meaningful difference |

1 **Table 7: Interventions targeting both patients and healthcare professionals**
2 **compared with no intervention/usual care**

| Name | Sample size | Final Effect Estimate | Quality | Interpretation of effect |
|---|-------------|--------------------------|----------|-------------------------------|
| Shared decision making (OBOM, continuous) | 1680 | SMD 1.03 (0.43, 1.63) | Very low | Effect (Favours intervention) |
| Shared decision making (PROM, continuous) | 2059 | SMD 0.15 (0.04, 0.26) | Very low | No meaningful difference |
| Main analysis: Shared decision making (PROM, categorical) | 166 | RR 0.97 (0.59, 1.59) | Very low | Could not differentiate |

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| Subgroup analysis: Shared decision making (PROM, categorical) - parallel | 97 | RR 1.23 (0.84, 1.80) | Very low | Could not differentiate |
| Subgroup analysis: Shared decision making (PROM, categorical) - cluster | 169 | RR 0.75 (0.48, 1.17) | Very low | Could not differentiate |
| Knowledge | 1004 | SMD 0.41 (0.28, 0.53) | Low | Less than MID (favours intervention) |
| Knowledge (categorical) | 1260 | RR 2.24 (1.18, 4.26) | Very low | Effect (Favours intervention) |
| Satisfaction with care | 532 | SMD 0.43 (-0.11, 0.97) | Very low | Could not differentiate |
| Satisfaction with decision | 424 | MD 3.60 (0.76, 6.44) | Low | No meaningful difference |
| Satisfaction with consultation | 446 | SMD 0.05 (-0.15, 0.26) | Very low | No meaningful difference |
| Decisional conflict | 1065 | SMD -0.35 (-0.71, 0.01) | Very low | Could not differentiate |
| Confidence in decision | 414 | MD 0.50 (-2.95, 3.95) | Low | No meaningful difference |
| Decision regret | 369 | MD 2.00 (-1.18, 5.18) | Low | No meaningful difference |
| Patient-physician communication (patient-centered communication) | 318 | SMD 0.43 (-0.07, 0.94) | Very low | Could not differentiate |
| Match between preferred and actual level of participation in decision making | 185 | RR 0.96 (0.80, 1.15) | Low | Effect (Favours control) |
| Adherence | 489 | SMD 0.60 (0.36, 0.83) | Very low | Effect (Favours intervention) |
| Adherence (categorical) | 145 | RR 1.01 (0.81, 1.25) | Very low | Could not differentiate |
| Health-related quality of life | 265 | MD 0.06 (-0.12, 0.25) | Low | No meaningful difference |
| Health-related quality of life (physical) | 298 | SMD 0.20 (-0.03, 0.43) | Low | No meaningful difference |
| Health-related quality of life (mental) | 298 | SMD 0.21 | Low | No meaningful difference |

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| | | (-0.01, 0.44) | | |
| Anxiety | 419 | MD -0.50 (-1.32, 0.32) | Low | No meaningful difference |
| Depression | 418 | MD -0.60 (-1.42, 0.22) | Very low | Could not differentiate |
| Consultation length | 536 | MD 1.30 (1.24, 1.36) | Mod erat e | No meaningful difference |
| Safety | 898 | RR 0.00 (-0.00, 0.00) | Mod erat e | No meaningful difference |

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2 **Table 8: Interventions targeting patients compared to other interventions**

| Name | Sample size | Final Effect Estimate | Quality | Interpretation of effect |
|--|-------------|------------------------------|-----------------|--------------------------------------|
| Shared decision making (OBOM, continuous) | 271 | SMD 0.88 (0.39, 1.37) | Very low | Effect (Favours intervention) |
| Shared decision making (PROM, continuous) | 1906 | SMD 0.03 (-0.18, 0.24) | Very low | No meaningful difference |
| Shared decision making (PROM, continuous) comp1 - NRCT | 97 | MD -8.00 (-22.87, 6.87) | Very low | Could not differentiate |
| Shared decision making (PROM, continuous) comp2 - NRCT | 110 | MD -7.00 (-20.90, 6.90) | Very low | Could not differentiate |
| Shared decision making (PROM, continuous) comp3 - NRCT | 99 | MD 1.00 (-12.12, 14.12) | Low | No meaningful difference |
| Shared decision making (PROM, categorical) | 2272 | RR 1.07 (0.97, 1.19) | Low | No meaningful difference |
| Knowledge | 596 | MD 8.60 (3.82, 13.38) | Low | No meaningful difference |
| Knowledge (categorical) | 706 | RR 1.41 (0.83, 2.38) | Very low | Could not differentiate |
| Satisfaction with decision | 596 | MD 0.80 (-1.11, 2.71) | Low | No meaningful difference |
| Satisfaction with treatment | 267 | SMD -0.09 (-0.33, 0.15) | Low | No meaningful difference |
| Satisfaction with consultation | 207 | MD -0.02 (-0.06, 0.02) | Very low | Could not differentiate |
| Satisfaction with information provided | 39 | MD 1.50 (-7.22, 10.22) | Very low | Could not differentiate |
| Decisional conflict | 1088 | SMD -0.20 (-0.48, 0.08) | Very low | No meaningful difference |

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| Decision uncertainty | 80 | MD -0.20 (-0.62, 0.22) | Very low | Could not differentiate |
| Decision self-efficacy | 100 | SMD -0.02 (-0.41, 0.37) | Low | No meaningful difference |
| Match between preferred and actual level of participation in decision making | 1206 | RR 0.81 (0.74, 0.89) | Very low | Less than MID (Favours control) |
| Match between preferred option and decision made | 363 | RR 0.60 (0.14, 2.59) | Very low | Could not differentiate |
| Adherence | 100 | MD 0.10 (-0.75, 0.95) | Low | No meaningful difference |
| Adherence (categorical) | 301 | RR 1.02 (0.84, 1.24) | Low | No meaningful difference |
| General health | 88 | MD -0.30 (-0.99, 0.39) | Very low | Could not differentiate |
| Anxiety | 682 | SMD -0.11 (-0.27, 0.05) | Low | No meaningful difference |
| Depression | 86 | MD -2.00 (-5.13, 1.13) | Very low | Could not differentiate |
| Consultation length | 39 | MD -7.00 (-13.68, -0.32) | Very low | Effect (Favours control) |

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2 **Table 9: Interventions targeting practitioners compared to other interventions**

| Name | Sample size | Final Effect Estimate | Quality | Interpretation of effect |
|---|-------------|----------------------------|----------|--------------------------|
| Shared decision making (OBOM, continuous) | 20 | MD -4.00 (-15.14, 7.14) | Very low | Could not differentiate |
| Main analysis: Shared decision making (PROM, continuous) | 1459 | MD 0.24 (-0.10, 0.58) | Very low | Could not differentiate |
| Subgroup analysis: Shared decision making (PROM, continuous) - parallel | 1132 | MD 1.72 (1.22, 2.22) | Low | No meaningful difference |
| Subgroup analysis: Shared decision making (PROM, continuous) - cluster | 327 | SMD 0.05 (-0.17, 0.27) | Moderate | No meaningful difference |
| Health status (mental) | 295 | MD 2.64 (0.08, 5.20) | Moderate | No meaningful difference |
| Health status (physical) | 295 | MD 0.57 (-2.33, 3.47) | Moderate | No meaningful difference |
| Anxiety | 843 | SMD 0.14 (0.00, 0.28) | Moderate | No meaningful difference |

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1 **Table 10: Interventions targeting patients and practitioners compared to other**
 2 **interventions.**

| Name | Sample size | Final Effect Estimate | Quality | Interpretation of effect |
|--|-------------|----------------------------|----------|--------------------------|
| Shared decision making (OBOM, continuous) | 20 | MD -4.70 (-18.47, 9.07) | Very low | Could not differentiate |
| Shared decision making (OBOM; categorical) | 134 | RR 0.49 (0.12, 1.95) | Very low | Could not differentiate |
| Shared decision making (PROM, continuous) | 150 | MD 0.00 (-4.25, 4.25) | Low | No meaningful difference |
| Decisional conflict | 286 | MD -0.03 (-0.13, 0.07) | Low | No meaningful difference |

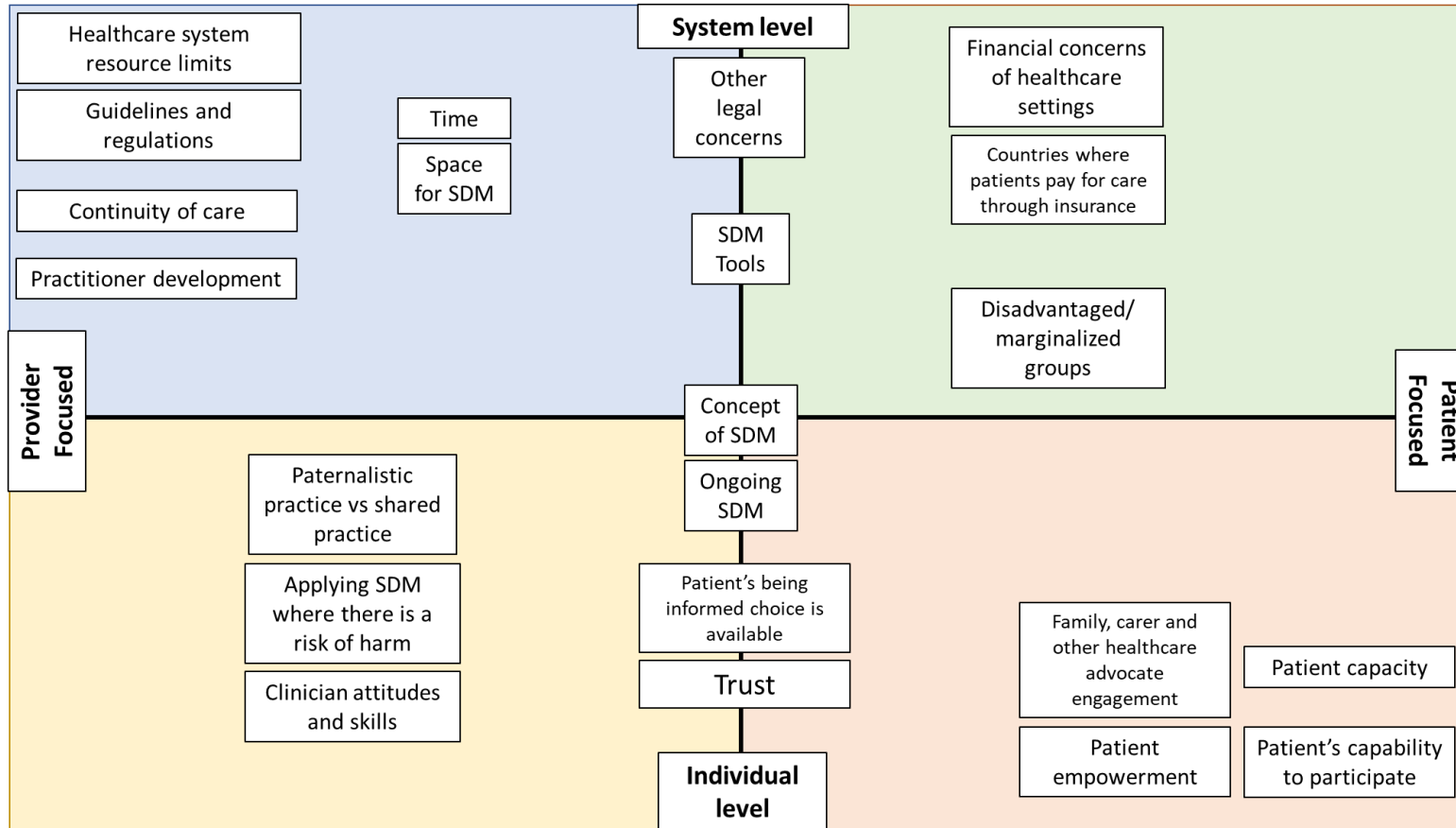
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2 **Qualitative theme summary**

3 Figure 1 is a summary of the themes identified in this evidence review. Full
4 description of the themes and their relationship to shared decision making can be
5 seen in Table 11: Summary of qualitative findings. This figure is not intended to be
6 interpreted as any kind of logic model or conceptual framework, and is instead an
7 explanatory visualisation of the themes to that the committee agreed was a helpful to
8 their decision-making.

1 **Figure 1: visual summary of theme type and name**



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1 Summary of findings table – Qualitative

2 **Table 11: Summary of qualitative findings**

| Themes | illustrative quotes | Studies (bold denotes high methodological concerns) | CERQual concerns | CERQual explanation |
|--|--|---|--|--|
| <p>Patient empowerment</p> <p>Some practitioners believed that SDM was made difficult due to a lack of health literacy in the patient (“information asymmetry”), and that the practitioner thus makes medical decisions alone due to lack of patient input. Patients could also willingly refuse to participate in SDM, citing their own lack of medical literacy. Patients may also not be aware that SDM is not occurring as they have not been educated in how to recognise SDM. Education level and age factors were cited as a common cause of this barrier.</p> <p>Greater patient knowledge could be achieved both by self-driven education prior to initial appointments, and further facilitated by the practitioner and wider health team continuously throughout the healthcare process. Factors that increased patient knowledge included ongoing</p> | <p><i>The doctor did not instruct me to get an X-ray again, so I probably should have asked him about the X-ray - but he did not instruct me, so I felt I couldn't ask him that question. The doctor knows more than I do. I think he did the right thing.</i> (Patient – Claramita 2011)</p> <p><i>“I think that sometimes when you feel like their education is limited, their education background is limited, sometimes I feel like if we lay all the options out there sometimes it confuses them and they are not really making a good decision in the end.”</i> (Practitioner – Zeuner 2014)</p> <p><i>“You just have to be your own person—strong enough to question the treatment that you get. Go buy you a medicine book that's number 1, buy that book. If they give you some medicine and you don't want</i></p> | <p>41</p> <p>Belcher 2006 Chong 2013 Claramita 2011 Cohen 2003 De Snoo-Trimpp 2015 Elwyn 1999 Fraenkel 2007 Frerichs 2016 Fuller 2017 Giacco 2018 Grus 2019 Hahlweg 2017 Hajizadeh 2014 Hamann 2016 Hirpara 2015 Hofstede 2013 Jansen 2019 Kamara 2018 Ladin 2017 Lin 2019 Lown 2008 Maffei 2012 Mahone 2011a Mahone 2011b McCarter 2016 Molenaar 2018</p> | <p>ML: Minor C: Minor A: None R: None</p> <p>Overall: Moderate Confidence</p> | <p>Minor concerns about coherence: Many sub-themes under one banner – may be difficult to make a single recommendation. A lot of different facets to patient knowledge.</p> <p>Four studies with high methodological concerns.</p> |

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| <p>experience with the disease (particularly if the patient had a negative experience such as side effects or an incorrect diagnosis) as well as information retention from appointments through activities such as list-making of concerns/recording appointments.</p> <p>Many emphasised that health literacy wasn't the only type of patient knowledge that facilitated SDM, and instead larger concepts such as understanding choice and uncertainty in medicine, being familiar with their medical history, and understanding their own preferences, were key for making the patient an active participant in their own healthcare.</p> <p>Whilst educational resources for increasing patient knowledge are available, patients highlighted that they had difficulty identifying accurate information, particularly on the internet. A lack of resources for certain languages and low literacy patients was also highlighted. A key facilitator may be directing patients to reliable evidence-based sources, as well as producing resources in different languages and in literacy appropriate styles.</p> | <p><i>to question, then go home and look it up. That way you'll have the guts enough to call the doctor and say, 'Hey, I don't think this is right for me' or whatever"</i> (Patient – Peek 2009)</p> <p><i>"If it seems like they have had a pretty good level of understanding, they read up or they seem educated on the situation, it's easier to discuss options with them."</i> (Medical Oncology, Female, 6–10 years in practice) - Zeuner 2014</p> | <p>Moreau 2012 Muscat 2016 Naik 2005 Patel 2014 Peek 2009 Rose 2019 Roodbeen 2020 Rosenberg-Yunger 2018 Schoenfeld 2018a Schoenfeld 2019 Stevenson 2003 van Veenendaal 2018 Wiener 2018 Zeuner 2014 Ziebland 2014</p> | | |
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| <p>Patient’s capability to participate Practitioners, and some patients, highlighted that there was a lack of desire in a number of patients to put themselves in a SDM situation. Potential reasons for this included preconceived notions about how practice should occur, anxiety from the patient, lack of confidence in expressing own preferences, and not wanting to contradicting the professional, who they viewed as the arbiter of a final decision. There were multiple mentions of being a “Good Patient”, “Doing as I’m told”, and not wanting to be “someone causing trouble”. There were also cases where patients believed they were participating in SDM, when they were simply being informed of processes without taking an active role.</p> <p>Behaviours that show patient willingness were thought to include expressing treatment preferences, suggesting treatment options, taking the time necessary to deliberate about treatment decisions, and asking for explanations required to make informed decisions. The notion that medical care was something the patient was ‘paying for’ rather than something being given was thought to be a facilitator of patient</p> | <p><i>“If I say [a different treatment preference] to the doctor, maybe the doctor wouldn’t be happy, because of his profession, he might think more or less that I’m telling him his job. So I don’t think I would say it to him. I think he might feel that I’m insulting him.”</i> (Patient, aged 78, Cohen 2003).</p> <p><i>“Sometimes I just tell them, “This is your body. I can’t make these decisions for you.” With just the medical stuff too, like the patients with diabetes who are like, “I’ll do whatever I want and you just increase my medication.” It’s like, “No. This is your body. You are doing this to your body.” But sometimes I really don’t know how to give them that power, have them create that power. I really don’t know how to do that.”</i> (Primary care physician - Patel 2014)</p> <p><i>“A patient has to be involved. It’s their body and ultimately they are the ones who are going to be carrying out whatever decisions been made because they’re the ones living with it day to day.”</i> (Patient - Fraenkel 2007)</p> | <p>38 Barker 2018 Belcher 2006 Bouma 2014 Chong 2013 Cohen 2003 Eliacin 2015 Elwyn 1999 Fraenkel 2007 Frerichs 2016 Fuller 2017 Grus 2019 Hahlweg 2017 Hajizadeh 2014 Hamann 2016 Hofstede 2013 Jansen 2019 Ladin 2017 Lowenstein 2019 Lown 2008 Maffei 2012 Mahone 2011a Mahone 2011b McCarter 2016 Molenaar 2018 Moreau 2012 Muscat 2016 Patel 2014 Peek 2009 Rose 2019 Rosenberg-Yunger 2018 Schoenfeld 2018a Schoenfeld 2019 Stevenson 2003</p> | <p>ML: Minor C: Minor A: No concerns R: No concerns</p> <p>Overall: Moderate confidence</p> | <p>Minor concerns about coherence: Many sub-themes under one banner – may be difficult to make a single recommendation.</p> <p>Five studies with methodological concerns.</p> |
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| <p>willingness to engage in SDM, as they felt they were entitled to a service. Willingness may also be facilitated by discussions with family and community outside of appointment.</p> <p>Practitioners stated that for SDM to take place, a patient must be willing to listen to what the doctor has to say and adhere to therapies that have been agreed on in the SDM process. However, decision making in their view should not be imposed on patients who are anxious and not ready to consider choices.</p> <p>Patient willingness to participate in SDM beyond just “being friendly” was said to facilitate a more open discussion and a healthcare partnership, as opposed to a more traditional paternalistic model of care. If a patient actively asked for involvement, physicians were found to alter their behaviour and engage with the patient in a decision-making process that was more collaborative.</p> <p>Practitioners stated patients generally preferred to be actively involved in the consultation. Both patients and practitioners agree that it was both a patient’s right and responsibility to be involved in their own decision making,</p> | <p><i>“We want the brave (patient), the one taking responsibility, the active one”.</i> (Practitioner - Hamaan 2016)</p> | <p>Towle 2006 van Veenendaal 2018 Wiener 2018 Zeuner 2014 Ziebland 2014</p> | | |
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| <p>and to develop a perception of agency/autonomy around their own healthcare, and acknowledge that the practitioner is a partner in this process, not just a physician.</p> | | | | |
| <p>Paternalistic practice versus shared practice</p> <p>Some practitioners continue in a paternalistic style as this is their or their institutions established method of practice. One argument was that some situations, such as urgent or dangerous medical problems, or settings in mental health, required more paternalistic style of decision making due to urgency or lack of patient input (or if there aren't many options). Another reason cited was a lack of evidence that SDM made a difference. Both practitioners and patients are used to this model of care. It was thought that practitioner's personal values might be linked to their tendency towards paternalistic care.</p> <p>Practitioners felt that some patients did not have enough information to participate in the decision and giving them too much information overwhelming. This inequality</p> | <p><i>"[I worry that] sometimes maybe it may be viewed as incompetency rather than the correct thing to say to a patient."</i> (Internal Medicine, Female, 3-5 years in practice - Zeuner 2014)</p> <p><i>"You know what I believe, why people have so much problem getting involved with their care is because they've had so many people for so many years answering that care for them. It's like you've been making this decision for me for so long, why start now making my own decisions, when sometimes in certain situations they make the decision for you anyway?"</i> (Patient - Mahone 2011b)</p> <p><i>"So also it's about the nature of having a relationship where consumers don't feel talked down to, where it's not punitive and you're not behaving in a parental role but you're trying to work with them on an equal – as equal as you can – relationship . . . So again, it is not an easy thing to actually articulate and not necessarily easy to teach but if</i></p> | <p>39</p> <p>Barker 2018 Bouma 2014 Chong 2013 Cohen 2003 Eliacin 2015 Elwyn 1999 Fraenkel 2007 Frerichs 2016 Fuller 2017 Grus 2019 Hirpara 2015 Hofstede 2013 Jansen 2019 Ladin 2017 Lin 2019 Lowenstein 2019 Lown 2008 Mahone 2011a Mahone 2011b McCarter 2016 Molenaar 2018 Moreau 2012 Muscat 2016 Patel 2014 Peek 2009 Rose 2019 Rosenberg-Yunger 2018</p> | <p>ML: Minor C: Minor A: No concerns R: No concerns Overall: Moderate Confidence</p> | <p>Minor concerns about coherence: Many sub-themes under one banner – may be difficult to make a single recommendation. Three studies with methodological concerns.</p> |

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| <p>in interaction was cited by patients as causing difficulties in consultation.</p> <p>From the patient perspective, they discussed feeling like they were in a situation where the practitioner's word was final, and there was no room for SDM. There was a sentiment that physicians should be doing the opposite and facilitating patient participation by allowing themselves to be open to questions and challenges from the patient. Some patients overcame this barrier by challenging these practices.</p> <p>There were mentions of clinicians presenting data in a way that pushes a patient towards a certain outcome especially if they preferred a specific treatment. This created a situation where the patient is persuaded into a certain treatment option, as opposed to going with their own preferences, including if that preference was for no treatment.</p> <p>Some providers were reported as showing an interest in consumer perspectives, saying that SDM improved outcomes and quality of care. It was also stated that when the decision is shared the practitioner feels more</p> | <p><i>you're really going to have genuine partnership and not tokenistic attempts you have to shift your whole orientation towards how you work with people and how you see yourself."</i> (Mental health nurse - Chong 2013)</p> <p><i>"From the beginning, she [Practitioner] let me talk. She didn't baby me. She told me my mistakes too. But she didn't fixate just on alcohol. Yes, alcohol can be a problem depending on how you react to it. She said that. To over-use alcohol is wrong. She made that clear. [However], she realized that wasn't my only problem. . . . We have worked on the problems that I've brought to her. I feel comfortable enough with her that I can open up. I can open up to her about my drinking if I feel like it's too much."</i> (Patient - Eliacin 2015)</p> | <p>Savelberg 2019 Schoenfeld 2018a Schoenfeld 2019 Seale 2006 Shepherd 2014 Siegel 2015 Stevenson 2003 Towle 2006 van Veenendaal 2018 Wiener 2018 Zeuner 2014 Ziebland 2014</p> | | |
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| <p>protected from negative outcomes. Patients saw practitioners as a guide to the SDM process, with the patient stepping in to stand up for themselves. It is a power balance, but some clinicians felt in disagreements decision should be deferred to patient preferences to maintain shared relationship. Some settings this applies more than others, such as maternity where bodily autonomy is seen as discussed at length.</p> | | | | |
| <p>Time</p> <p>Time pressure/constraints a consistently cited barrier. Practitioners state that they are already pressured to finish appointments as quickly as possible and SDM is an added burden on top of this. This feeling is also present in patients, who may defer decision-making responsibility due to concerns about doctor's busy schedule. This lack of time may lead to doctors not engaging with patients or taking time to explain concepts required for SDM to take place and reduces the time available for patients to make a decision, resulting in a communication breakdown.</p> | <p>“Every day for three hours we have to open a clinic for more than 30 patients. It is important to finish consultations as quick as we can.” (Practitioner – Claramita 2011)</p> <p>“I know the doctor is very busy, he still has long of queue of patients after my turn. So, I did not want to bother him with too many questions.” (Patient – Claramita 2011)</p> <p>“I would also swear when only taking once the time, then [...] “Then things just run” (Two practitioners – Frerichs 2016)</p> <p>“ ‘What do you want to do?’ And she said, ‘I don’t know’. And this was a</p> | <p>32</p> <p>Belcher 2006 Bouma 2014 Chong 2013 Claramita 2011 Elwyn 1999 Fraenkel 2007 Frerichs 2016 Hahlweg 2017 Hajizadeh 2014 Hofstede 2013 Ladin 2017 Legare 2013 Lown 2008 Mariani 2017 Molenaar 2018 Moreau 2012 Muscat 2016 Patel 2014 Peek 2009 Roodbeen 2020</p> | <p>ML: Minor C: No concerns A: No concerns R: No concerns Overall: High confidence</p> | <p>Two studies with methodological concerns</p> |

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| <p>Patients felt them having time to make a decision was a right, and they shouldn't be rushed. It was highlighted that decisions could take place over several sessions, reducing SDMs time burden on a single session. Practitioners highlighted that taking time initially could lead to easier conversations and appointments in the future due to patient empowerment and a better patient/practitioner relationship developing.</p> <p>All of these aspects point to time pressure being a higher-level barrier to shared decision making, potentially a cause of other barriers identified in this review.</p> | <p>beautiful case to say alright, here are your options... And then she got up and she said to me, 'Do you know I now have a totally clear picture in my head of what my choices are and now I have to go and sit down with [Name] and have this talk'. And to me that conversation took us 25 minutes, it was worth every minute because she went away feeling very empowered and I didn't make any decision for her. (Practitioner – Towle 2006)</p> | <p>Rosenberg-Yunger 2018 Schoenfeld 2018a Schoenfeld 2019 Seale 2006 Siegel 2015 Stevenson 2003 Towle 2006 Upton 2011 Walter 2004 Watson 2008 Wiener 2018 Zeuner 2014</p> | | |
| <p>Clinician attitudes and skills</p> <p>Good communication and interpersonal skills were seen as vital for patient engagement. These allowed practitioners to elicit patient preferences by exploring their thoughts, feelings and fears around care. They also aided in providing relevant information on disease, test results and diagnoses risks and benefits and adjusting information to patients needs, ensuring it is explained clearly in easy to understand</p> | <p>Listening to each other, quite a normal basic-rule for communication. If the patient constantly interrupts me he will not find out what I am about to tell him and then the conversation will take another course. The whole issue starts with simple rules for communication.” (Psychiatrist – Hamaan 2016)</p> <p>GP16: I was putting my stuff on the table and she was putting her stuff on the table. But I didn't really explore her ideas, concerns, expectations. (GP – Stevenson 2003)</p> | <p>31</p> <p>Barker 2018 Belcher 2006 Chong 2013 Eliacin 2015 Elwyn 1999 Fraenkel 2007 Frerichs 2016 Grus 2019 Hofstede 2013 Kamara 2018 Ladin 2017 Lowenstein 2019 Lown 2008 Mahone 2011b</p> | <p>ML: Minor C: No concerns A: No concerns R: No concerns Overall: High confidence</p> | <p>One study with methodological concerns</p> |

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| <p>language. Respondents also felt interpersonal skills helped practitioners aware of the patients social context and potential cultural differences (particularly in mental health). Fully explain test results and diagnoses. Providers inquired about their personal lives and expressed interests in them make use of common interests. This facilitates patient involvement by making patient feel more at ease, as well as showing care and empathy for the patient.</p> <p>Both participants and patients discussed the importance of being heard and having mutual respect to help foster a strong relationship, recognizing that patients and providers are “at the same level,” and respecting each other’s input in a two-way conversation.</p> <p>Patients also commented on practitioners holding patients accountable for their own care, which shows respect and concern for the patient’s wellbeing. This involved eliciting questions regarding whether the patient understood the care they were being given, whether this aligns with their preferences, and whether they understand what their responsibility is as a patient. It was noted that just because consensus is reached doesn’t</p> | <p>“I like her because she actually does care about me being her patient instead of just a number, next, next one in line. The other ones just see how fast they can get me out of their office. . . . She’s really curious and she’s suggesting things that will help me instead of just running me through the mill.” (Patient – Eliacin 2015)</p> <p>“[I]t is something that I talk to people, or counsel people, about and if they have a strong volition, not to have a particular side-effect, or are wary, whether I think that’s a real, whether I think there’s proper evidence for that or not, you try and work with people I think.” (Practitioner – Shepherd 2014)</p> | <p>Mariani 2017 McCarter 2016 Molenaar 2018 Moreau 2012 Patel 2014 Peek 2009 Peek 2013 Roodbeen 2020 Rose 2019 Savelberg 2019 Schoenfeld 2018a Schoenfeld 2019 Seale 2006 Shepherd 2014 Stevenson 2003 van Veenendaal 2018 Wiener 2018</p> | | |
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| <p>mean patient preferences have been elicited.</p> <p>Poor physician communication style is cited as a barrier to SDM this included, providing sparse or incomplete information, a lack of explanation about care trajectory. Not effectively eliciting input from the patient, rushed discussion, brief rushed discussion and using language that is too technical and for the patient patient. These can lead to patients being confused and worried about their care. Training around communication skills was thought to be a potential solution to this barrier.</p> | | | | |
| <p>Trust</p> <p>Trust makes patients feel more comfortable in engaging in SDM. This trust goes beyond primary practitioner to include all members of the MDT healthcare team, it helps the patient feel like they are being listened to and allows them to speak more openly will give practitioners better idea of their true concerns and preferences. This tends to be more common in primary care, as in other care settings they may have briefer contacts with multiple professionals, instead of visiting one professional who really knows the patient. However,</p> | <p><i>“My doctor advised me to wait, and only told me about the disadvantages why I shouldn’t have a surgery. In the end I needed a surgery, but the only thing I could think of were all the disadvantages of having a surgery” (Patient – Hofstede 2013)”</i></p> <p><i>‘You should really know the patient to respond better to the factors playing a role in deciding whether or not the patient needs a surgery. Who knows the patient nowadays?’ (GP - Hofstede 2013)</i></p> <p><i>“[It helps] having an open and candid dialogue and relationship so that pretty</i></p> | <p>22</p> <p>Belcher 2006 Eliacin 2015 Fraenkel 2007 Fuller 2017 Giacco 2018 Hamann 2016 Hirpara 2015 Hofstede 2013 Ladin 2017 Lown 2008 Maffei 2012 Mahone 2011b Molenaar 2018 Moreau 2012 Peek 2009 Peek 2013</p> | <p>ML: Minor C: Minor A: No concerns R: No concerns</p> <p>Overall: Moderate Confidence</p> | <p>Minor concerns for coherence, difficult to quantify specific aspects of this relationship leading to broad theme.</p> <p>Two studies with methodological concerns.</p> |

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| <p>increasing patient numbers is making this harder even for GPs. A good patient practitioner relationship was defined as one built on trust, respect and empathy, this relationship increases with repeat visits and can act as an increasingly strong facilitator of SDM and can be boosted by positive outcomes for the patient.</p> <p>If there is a low level of trust patient participation is reduced. Low level of trust also results in poor communication between patient and practitioner and can lead to misunderstandings. The relationship may be influenced by the multidisciplinary care patients receive. Trust can actually have the opposite effect, whereby if a patient feels the practitioner has their best interests in mind and understands their preferences or trust the practitioner’s medical knowledge over their own preferences, they will defer decision making to them. Impoliteness and lack of trust in doctors was a part of this barrier, potentially due to the patients’ culture and beliefs around medicine and practitioners or past experiences.</p> | <p><i>much anything can be discussed...If you have the trust, then you find that you are...more willing to put those things out on the table.” (Patient – Lown 2008)</i></p> <p><i>“It could have gone so bad with a strong personality like mine; I usually want to call all the shots. But I really trusted him, and he was patient and he talked me through it ... So we ultimately decided together that insulin would be the best thing ... and I think that [physician encounter] was one of the best experiences of my life and I respect that he was a good doctor.” (Patient – Peek 2013)</i></p> | <p>Schoenfeld 2018a Schoenfeld 2019 Seale 2006 Stevenson 2003 Towle 2006 Ziebland 2014</p> | | |
| <p>Applying SDM where there is a high risk of harm.</p> <p>Both patients and practitioners showed an apprehension to engaging in shared</p> | <p><i>“But this complex therapy and that often something can go wrong, they [patients]are not told about.” (Practitioner - Frerichs 2016)</i></p> | <p>18 Barker 2018 Belcher 2006 De Snoo-Trimp 2015 Frerichs 2016 Hajizadeh 2014 Ladin 2017</p> | <p>ML: Moderate C: No concerns</p> | <p>Four studies with methodological concerns.</p> |

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| <p>decision making practices when the results of the decision were seen to be severe in nature (poor prognosis, large risk of severe side effects). This was due to a combination of fear of making an incorrect decision in a high stakes environment, and fear that if a decision is not made quickly there would be severe health consequences (such as in dialysis.) This fear was observed as being more prominent in people from low socio-economic backgrounds and of ethnic minorities. These fears of bad outcomes were difficult for patients to bring into an SDM space. Practitioners sometimes feared that discussion of side effects would lessen patients desire to take treatment, however some did acknowledge this isn't always the case.</p> <p>Negative consequences from this lack of SDM can be something such as a missed diagnosis or a bad outcome, which could lead to a traumatic event occurring that has not been discussed with the patient.</p> <p>Facilitators for overcoming this barrier included patient/practitioner experience and a high level of patient/practitioner trust.</p> | <p><i>"Lots of doctors tend to not say anything about side effects because they think that their patients might not take the medication" (Mental health service user" – Moreau 2012)</i></p> <p><i>"(I didn't use SDM earlier in my career because) I didn't like trust myself, my clinical instincts, and even the patient's instincts on things...and you're afraid of the medical-legal implications."</i></p> <p><i>'[Interviewer: What is it that the doctors don't feel comfortable with?] 'Missing something, getting sued, I think bad outcomes and all the trimmings'" (Practitioner - Schoenfeld 2019)</i></p> | <p>Lown 2008 Maffei 2012 Mahone 2011a Mahone 2011b Moreau 2012 Peek 2009 Schoenfeld 2018a Schoenfeld 2019 Seale 2006 Shepherd 2014 Towle 2006 Wiener 2018 Ziebland 2014</p> | <p>A: No concerns R: No concerns Overall: Moderate confidence</p> | |
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| <p>Continuity of care</p> <p>As a patient accesses many different practitioners across a multi-disciplinary team, they can encounter contradicting recommendations which may impede the SDM process. This occurs due to different teams operating in ‘silos’, using different models that prevent convergence. Other poor communication practices highlighted included disconnect between inpatient and outpatient prescribing practices, people making decisions without a patient’s full medical history or treatment plan, and new SDM processes not being adopted due to poor communication of aims across teams.</p> <p>Some professions, such as nurses and pharmacists, felt their voice wasn’t heard strongly enough in SDM environments, and their role was undefined with no collaboration.</p> <p>Practitioners emphasised the importance of having the whole multidisciplinary team involved in the SDM process and aligned on their messaging to the patient, possibly through team meetings and sharing medical data. Patients suggested this</p> | <p>“... you’ve got multiple doctors or multiple specialists involved who have vying opinions in relation to what’s occurring ... what can happen is it can lead to medications being changed quite rapidly ... which in a patient’s mind creates this lack of confidence ...” (Clinical psychologist – Chong 2013)</p> <p>“Currently there is much, much work in silos. We have nursing services that are the concern of nurses. There are the social workers who have psychosocial concerns. The same holds true for rehabilitation workers, but in all this, there is nothing that brings all these people together.” (Practitioner - Legare 2013)</p> <p>“If my PT sends a letter to the GP, she does not get an answer. There was also a lack of communication between the medical professionals I visited. It is annoying if you visit a medical professional and there has been no communication at all with the medical professional you have visited previously”. (Patient – Hofstede 2013)</p> | <p>18</p> <p>Belcher 2006 Chong 2013 Giacco 2018 Hahlweg 2017 Hofstede 2013 Legare 2013 Mahone 2011b Mariani 2017 McCarter 2016 Molenaar 2018 Peek 2009 Rosenberg-Yunger 2018 Schoenfeld 2018a Schoenfeld 2019 Seale 2006 Shepherd 2014 van Veenendaal 2018 Ziebland 2014</p> | <p>ML: Minor C: Minor A: No concerns R: No concerns</p> <p>Overall: Moderate confidence</p> | <p>Minor concerns on coherence, many different concerns with multidisciplinary team under one theme.</p> <p>One study with methodological concerns.</p> |
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| <p>information being exchanged made the decision making easier.</p> <p>Organisational culture created barriers to SDM in other ways, including poor logistics/implementation of SDM, practitioners untrained in SDM, and high staff turnover.</p> | | | | |
| <p>Disadvantaged/Marginalised groups</p> <p>The wider social and cultural environment around patients was thought to have a large and varied effect on the practice of SDM.</p> <p>A difference in cultural background posed difficulties for some patients in their efforts to connect and communicate with their providers, the most commonly cited being language barrier and ethnicity.</p> <p>Patients from ethnic minorities perceived less practitioner trust in them and thus themselves had less trust in the practitioners, and language barrier makes SDM more difficult due to difficulty of communication, specifically due to a lack of tools for certain diseases in different languages as highlighted by practitioners. A potential</p> | <p><i>'The cultural background definitely plays a role in how patients make decisions ... For example, one case comes to mind. Recently I had a patient from Bangladesh, a female who preferred to have her husband make decisions on her behalf, so we used an interpreter just to document those preferences and then we took that into consideration and abided by that request'. (Doctor, Male, 30)</i></p> <p><i>The [doctor] came into the room speaking in a very condescending manner—as if we were children. My mother, my brother, my sister and my dad were all in the room ... It was his tone of voice, and it was his mannerisms. As if he didn't want to be there ... And I'm sure that if [we] had been of a different race, [the doctor] probably would have been different."</i> (Patient – Peek 2013)</p> | <p>17 Barker 2018 Bi 2019 Bouma 2014 Chong 2013 Eliacin 2015 Hajizadeh 2014 Hirpara 2015 Hofstede 2013 Kamara 2018 Mariani 2017 Molenaar 2018 Patel 2014 Peek 2009 Peek 2013 Rosenberg-Yunger 2018 Schoenfeld 2019 Towle 2006</p> | <p>ML: Minor C: Minor A: No concerns R: No concerns Overall: Moderate Confidence</p> | <p>Moderate concerns for coherence, many different cultural factors under one banner – may be difficult to make a single recommendation.</p> <p>Two studies with methodological concerns.</p> |

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| <p>solution to this problem was inviting racially or language matched staff from the surrounding community to dispel concerns.</p> <p>Other cultural barriers included gender, sexuality, and socioeconomic status. This points to how individual characteristics might challenge the process of SDM.</p> | | | | |
| <p>Family, carer and other healthcare advocate engagement</p> <p>There was a sense among people who accompanied patients in the healthcare setting that they were being excluded from the shared decision making space. Practitioners stated they felt challenged or untrusted by family members/carers/advocates who held different views to their own, and managing a three-way or larger conversation could be more difficult.</p> <p>However, other practitioners acknowledged that engaging family members and carers in the patients' health process was a key facilitator to SDM, as it can help if patients are having difficulty expressing their thoughts, and including the carer can make them feel backed up, as well as having</p> | <p><i>"I was given the impression that my input was not welcomed and possibly resented as interference which I fail to understand as being a carer I need to know and understand what the overall picture and future is the aims" (Family member + Carer of patient – Bradley 2017)</i></p> <p><i>'I was thinking about this earlier actually and especially if a patient is too unwell to engage, then their carers probably have a far better idea of what they'd like than I do. So having a conversation with the carer, if the patient wants them to be involved, could help'– (Practitioner - Giacco 2018)</i></p> | <p>15 Belcher 2006 Bradley 2017 Chong 2013 Frerichs 2016 Giacco 2018 Hofstede 2013 Lown 2008 Mariani 2017 Molenaar 2018 Naik 2005 Patel 2014 Rose 2019 Schoenfeld 2018a Schoenfeld 2019 Ziebland 2014</p> | <p>ML: Minor C: No concerns A: No concerns R: No concerns Overall: High confidence</p> | <p>One study with methodological concerns.</p> |

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| <p>another person to remember information from the visit. Practitioners stated this benefit depended on the disposition of the family member/carer, and how prepared they were themselves to engage in an SDM process.</p> | | | | |
| <p>Practitioner development</p> <p>Continued practitioner development was seen as a facilitator, particularly by practitioner’s themselves, this was particularly the case around becoming more adept at patient engagement.</p> <p>Regarding specific development prior to becoming a professional, it was highlighted that communication skills were not always learned during training. Most practitioners agreed they would benefit from training in this area in particular, and that increased experience practicing these techniques facilitated more SDM.</p> <p>Patients highlight that practitioners sometimes lacked knowledge of the disease area and treatment options, frequently only mentioning one when there are multiple. The former has resulted in incorrect diagnosis, these are barriers to SDM as whatever options</p> | <p><i>“Yeah, I mean. I think any sort of training in communication and helping with choices and that sort of thing is probably helpful. ‘Cause as much as you do in psychiatry, in psychiatry you learn how to ask questions, I don’t know if you really learn how to negotiate that much ...”</i> (Practitioner – Giacco 2018)</p> <p><i>“I went to the PT and GP and they said: “Nowadays doctors do not perform sciatica surgeries anymore, you will just have to wait, because your body will recover your herniated disc itself” [The sciatica guideline recommends that the patient and professional together decide on surgical or prolonged conservative treatment after considering the harms and benefits of each treatment option] (Patient – Hofstede 2013)</i></p> | <p>15</p> <p>Chong 2013 Claramita 2011 Giacco 2018 Hofstede 2013 Mahone 2011a Mahone 2011b McCarter 2016 Molenaar 2018 Peek 2009 Rosenberg-Yunger 2018 Schoenfeld 2019 Seale 2006 Upton 2011 van Veenendaal 2018 Wiener 2018</p> | <p>ML: Minor C: No concerns A: No concerns R: No concerns</p> <p>Overall: High confidence</p> | <p>Two studies with methodological concerns.</p> |

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| <p>now given are inaccurate and the patient cannot make an informed decision. This lack of training was mentioned at both a physician and nurse level.</p> | | | | |
| <p>Patient capacity</p> <p>Concerns around mental health highlighted some different barriers to SDM. Lack of cognitive capacity was often reported as a barrier as cognitive problems affected the patient’s insight and communication and thus made it difficult to operate in an SDM space. However, patients expressed the sentiment that people should not be disregarded as being able to participate in SDM just because of a mental health condition, and that ability to engage varied.</p> <p>In psychiatry and mental health settings specifically, there was also the issue of the social stigma around mental health, which lead to some patients having a negative attitude to SDM due to not acknowledging the existence of the condition. Psychiatrists believed that patients only had limited interest in their treatment, yet patients reported experiences of powerlessness in mental health settings.</p> | <p><i>“In case of an emergency, I don’t think twice about it, I let them do what they have to do. The only thing I want is to stop the pain”</i> (Patient - Moreau 2012)</p> <p><i>“... the biggest problem is that for the people we deal with, the nature of their illness is that they are often paranoid and they have a lot of ideas about medication but they don’t necessarily fit with your ideas. And obviously they don’t believe they have an illness, some of them.”</i> (Hospital pharmacist – Chong 2013)</p> <p><i>“[SDM is] so basic to human dignity - to have a say in your own choices in your own life. You know, it’s not brain science.”</i> (Patient - Mahone 2011b)</p> <p><i>“So, I think, at that stage you, well I attempt to, discuss the issues with the patient but, to be perfectly honest, if it’s clear that they’re insightful, or that they’re not going to agree, and you get that, not only with the one-to-one conversation that you have, but also being aware of how they’re being, from the time they’re admitted to the unit. I</i></p> | <p>11</p> <p>Chong 2013 Hamann 2016 Mahone 2011a Mahone 2011b Mariani 2017 Molenaar 2018 Moreau 2012 Patel 2014 Schoenfeld 2019 Seale 2006 Shepherd 2014</p> | <p>ML: Minor C: No concerns A: No concerns R: Moderate</p> <p>Overall: Moderate confidence</p> | <p>Moderate concerns for relevancy, as patients who lack mental capacity to make decisions are excluded from our review but reduced mental capacity as a barrier still retains some relevance in more minor cases.</p> <p>Two studies with methodological concerns</p> |

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| <p>This mental health condition concern also spread to when patients felt unfit to make a decision due to a state of intense pain or stress, such as in childbirth, anxiety, or severe cancers.</p> | <p><i>don't think there is much point, at that moment in time, to get into a conflict.</i>" (Practitioner – Shepherd 2014)</p> | | | |
| <p>Ongoing SDM</p> <p>Both patients and practitioners emphasised that SDM was not a one-off activity, but an ongoing process that should start as early as possible. A decision may take several appointments, and that decision could change over time, and the patient should only make the decision when they felt ready to. This means SDM should still be available even in times I may not seem like a normal SDM space, such as a mental health crisis.</p> <p>Barriers regarding ongoing SDM include not appropriately planning for follow up on a patient's decision, and previous decision states being lost due to changing of practitioner.</p> | <p><i>'I do agree with the earlier, the better because I think once they can have a conversation where it's more of a conversation and a dialogue then they know what is happening, and how it will go on'</i> (Practitioner – Giacco 2018)</p> <p><i>I've...[made] a decision that my doctor absolutely hated. And, I think, the best thing he did was actually expressed that. He said, "Today you are saying no. Can we agree to talk about it tomorrow?" And I said, "Well, we can agree to talk about it an hour from now, two hours from now, a day from now, but it's not going to change my mind". Well, surprisingly, I changed my mind.</i>" (Patient – Lown 2008)</p> | <p>12</p> <p>Barker 2018 Elwyn 1999 Giacco 2018 Lown 2008 Mahone 2011b Patel 2014 Savelberg 2019 Schoenfeld 2018a Schoenfeld 2019 Seale 2006 Shepherd 2014 Towle 2006 Watson 2008</p> | <p>ML: Minor C: No concerns A: No concerns R: No concerns Overall: High confidence</p> | <p>1 study with methodological concerns.</p> |
| <p>SDM tools</p> <p>Practitioners highlighted access to certain tools facilitated SDM, such as care plans, patient decision aids and other forms of patient information. Lack of such tools was perceived as a barrier.</p> | <p><i>"(numbers) make you more comfortable having the conversation... with some degree of knowledge associated it with as opposed to a gestalt for what we think it is"</i> (Practitioner - Schoenfeld 2019)</p> <p><i>"I make use of a lot of diagrams and</i></p> | <p>12</p> <p>Chong 2013 Hofstede 2013 Legare 2013 Lin 2018 Mahone 2011b Mariani 2017 Molenaar 2018</p> | <p>ML: Minor C: No concerns A: No concerns R: Moderate</p> | <p>Two studies with methodological concerns</p> <p>Moderate concerns for relevancy as only one UK</p> |

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| <p>Access to computer based information was cited as a facilitator, including online resources for patients outside of the healthcare setting, and access to computerised medical records and decision aids for practitioners. Conflicting information or lack of any information can be a barrier.</p> | <p><i>pictures - I find that that sticks"</i> (Practitioner – Rosenberg-Yunger 2018)</p> | <p>Roodbeen 2020 Rosenberg-Yunger 2018 Schoenfeld 2019 Upton 2011 Van Veenendaal 2018</p> | <p>Overall: Moderate confidence</p> | <p>study (Upton 2011). Provision of SDM tools can also vary depending on country study is conducted in.</p> |
| <p>Healthcare system resource limits</p> <p>Many practitioners cited the limited resources within healthcare settings as a barrier, with larger patient numbers, longer waiting lists and larger staff workloads meaning people must be moved through healthcare settings quickly. Practitioners highlighted that SDM is rarely the path of least resistance, and in these high pressure scenarios SDM may not be performed.</p> <p>More specific issues around staff resource included high staff turnover, high staff stress and fatigue, and less time for staff communication, meaning communication between professionals will occur less.</p> <p>Accessibility to the practitioner themselves was also mentioned, including being available for telephone</p> | <p><i>"The neurologists in this region have an enormous waiting list. Sometimes that influences your way to get things done, for example you refer the patient early in the process, so that at least the appointment has already been made"</i> (GP – Hofstede 2013)</p> <p><i>"Every time the staff changes and has to learn to use the record, there really is a waste of time. But it is difficult to solve the problem of staff stability."</i> (Practitioner – Legare 2013)</p> <p><i>"Administration would say 'Oh yes.' Oh sure they're supportive of it [practice of SDM] but I mean, in mouth, but then I don't think we always have the bodies to, you know, to execute."</i> (Nurse - McCarter 2016)</p> | <p>10 Barker 2018 Bouma 2014 Hofstede 2013 Legare 2013 Mariani 2017 McCarter 2016 Schoenfeld 2019 Shepherd 2014 Stevenson 2003 Towle 2006</p> | <p>ML: Minor C: Minor A: No concerns R: Minor Overall: Moderate Confidence</p> | <p>Minor concerns about coherence, many different types of resource limits under one theme.</p> <p>Minor concerns on relevancy, two UK studies quite small (Shepherd, Stevenson)</p> <p>One study with methodological concerns.</p> |

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| <p>consultations. This was countered by practitioners, who stated that their energy is a finite resource, and too large workload for staff could be a barrier to SDM practices.</p> | | | | |
| <p>Space for SDM</p> <p>Lack of a designated space within which to practice SDM was a barrier identified particularly in hospital settings, where many conversations took place with patients in hallways and wards with a lack of privacy, interruptions, and lots of background noise, which led to stress and an unwillingness to talk candidly. The dynamics and policies of a ward setting also made it an unsuitable space for SDM practices. The best space for practicing SDM was thought to be in a private, quiet space, where the patient is comfortable and able to sit.</p> | <p><i>“I think in terms of things that you can control, location is obviously important in the middle of a busy ward where all the TVs are blurring next to you. Finding a more private space is probably better”</i> (Practitioner Giacco 2018)</p> <p><i>“Having a real conversation in the hallway, it’s not private...can’t sit down...”</i> (Practitioner – Schonefeld 2019)</p> | <p>8</p> <p>Chong 2013 Giacco 2018 Mariani 2017 Rose 2019 Rosenberg-Yunger 2018 Schoenfeld 2018a Schoenfeld 2019 Siegel 2015</p> | <p>ML: No concerns C: No concerns A: No concerns R: No concerns</p> <p>Overall: High confidence</p> | |
| <p>Patients being informed that choice is available.</p> <p>Some healthcare events led to the patient feeling they were in a situation where a shared decision could not be made. This included life threatening cancer diagnosis requiring surgery and</p> | <p><i>‘... they told me if I didn’t have it [dialysis], I’d be dead by morning time... And they told me I did, that I was gonna be dead by morning and everything. So I agreed’</i> (<65-year-old woman – Ladin 2017)</p> | <p>7</p> <p>Fraenkel 2007 Hirpara 2015 Jansen 2019 Ladin 2017 Mahone 2011b Schoenfeld 2018a Ziebland 2014</p> | <p>ML: No concerns C: No concerns A: No concerns R: Moderate</p> | <p>Moderate concerns for relevancy, only 1 UK study (Ziebland 2014), however, Patients being informed of choice could be transferable across countries.</p> |

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| <p>dialysis, where the severity of the condition affected the patients perceived lack of choice.</p> <p>For medication, patients often perceived this was 'needed' but did not have a sense that there were different options to consider. Lifestyle changes were seen as an addition as opposed to an alternative.</p> <p>Presenting the patient with a choice, even if that choice is variation within a specific treatment, or the choice is to do nothing, was seen as a facilitator for SDM.</p> | <p><i>"I: Did they [the doctors] give you the option [of refusing chemotherapy]?"</i></p> <p><i>R: No, well actually it is a question that didn't come up, you know."</i> (Patient – Ziebland 2014)</p> | | <p>Overall: Moderate confidence</p> | <p>One study with methodological concerns.</p> |
| <p>Countries where patients pay for care through insurance</p> <p>Whilst not applicable to the UK setting, financial pressures on patient limiting choice was cited as a common barrier in these results.</p> <p>If the patient was not paying for care they felt like they had less right to participate in healthcare decisions, whereas when people felt they were spending money on a service. However, where healthcare was not covered financially by insurers, there was less SDM possible, due to the cost barrier for certain treatments</p> | <p><i>"We felt like we were helpless in the decision making. One, because he was in a situation where we weren't paying any medical because of where he was, so they made you feel like you didn't have any say in the decision."</i> (Patient – Fraenkel 2007)</p> | <p>7 Belcher 2006 Fraenkel 2007 Hofstede 2013 McCarter 2016 Peek 2013 Siegel 2015 Zeuner 2015</p> | <p>ML: No concerns C: No concerns A: Minor R: Serious Overall: Very low confidence</p> | <p>Minor concerns about adequacy, only 7 studies</p> <p>Serious concerns about relevance, healthcare system in UK differs greatly from settings that describe this theme.</p> |

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| <p>Guidelines and regulations</p> <p>Practitioners presented both positive and negative views concerning treatment guidelines and other organisational regulations.</p> <p>Some said too many national regulations, making it difficult to balance limitations imposed by them with provision of patient care, and that sometimes guidelines limited options for the service used. Some said that more regulations would facilitate the implementation of quality improvement projects.</p> | <p><i>"I am pro-guidelines. I feel like people still need their autonomy, but you also still need to make sure that there's a standard of care and that there's expectations met when patients come to the Emergency Department."</i> (Practitioner – Schoenfeld 2019)</p> | <p>5</p> <p>Mariani 2017 Schoenfeld 2019 Shepherd 2014 Towle 2006 van Veenendaal 2018</p> | <p>ML: No concerns C: No concerns A: Minor R: Serious</p> <p>Overall: Low confidence</p> | <p>Minor concerns about adequacy, only 5 studies.</p> <p>Serious concerns about relevancy: Contribution of the 1 UK based study (Shepherd 2014) minor and guidelines regulations very country specific.</p> |
| <p>Financial concerns of healthcare settings</p> <p>Practitioners stated that SDM was sometimes not possible due to the risk of not matching reimbursement in high cost environments such as surgery, this was also the case for taking time to engage in multidisciplinary deliberation. This lack of funding was stated to hinder implementation of quality improvement projects in general.</p> | <p><i>Our primary care trust is telling us to take people off combined inhalers... (and) that we are to take them off certain branded inhalers. We've had to overhaul absolutely everybody and put them back on to single inhalers, and to use metered dose inhalers."</i> – Upton 2011</p> <p><i>"I think that the cost is, I mean I think it's a disadvantage for the patient because they are going to pick the cheapest even if it's not the option that has the best risk benefit ratio to them."</i> (Oncologist 6-10 years practice - Zeuner 2014)</p> | <p>4</p> <p>Hofstede 2013 Mariani 2017 Upton 2011 Van Veenendal 2018</p> | <p>ML: No concerns C: No concerns A: Moderate R: Moderate</p> <p>Overall: Moderate confidence</p> | <p>Moderate concerns for adequacy, only four studies.</p> <p>Serious concerns for relevancy, only 1 UK study (Upton). Other studies from other EU countries.</p> |

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| <p>Another barrier was quality assurance/quality outcome frameworks not being set up in a way that encourages SDM, with practitioners stating they prioritised increasing efficiency rather than focusing on patient care.</p> | | | | |
| <p>Concept of SDM</p> <p>Some professionals mentioned that the concept of what SDM itself entailed was not clear, this was seen as a barrier as then professionals were not sure if they were actually meeting all the conditions for practising SDM. This is then thought to spread to lack of clear institutional SDM policy and lack of clear criteria for referrals in areas such as surgery.</p> | <p><i>“Which conditions do you have to meet before you can say this is decision that has been taken jointly? That is not clear to me.”</i> (Practitioner – Hofstede 2013)</p> | <p>3 Barker 2018 Hofstede 2013 van Veenendaal 2018</p> | <p>ML: No concerns C: No concerns A: Serious concerns R: Serious concerns Overall: Very Low confidence</p> | <p>Serious concerns for Adequacy: Only three studies Serious concerns for Relevancy: No UK studies, 2 from Netherlands and one from Canada.</p> |
| <p>Other legal concerns.</p> <p>Some practitioners highlighted that local laws prevented some practitioners from practicing SDM, and some feared SDM could increase risk of legal liability.</p> | <p><i>“As a nurse practitioner in the state of Pennsylvania, I know that I’m unable to initiate chemotherapy. I can continue therapy and I can adjust dosing based on toxicity but initiating a new regimen, I am unable to do in my level or scope of practice.”</i> – (Nurse practitioner – McCarter 2016)</p> | <p>2 McCarter 2016 Siegel 2015</p> | <p>ML: No concerns C: No concerns A: Serious R: Serious Overall: Very Low confidence</p> | <p>Serious concerns for adequacy: only two studies Serious concerns for relevancy. No UK studies.</p> |

1 Quality assessment of studies included in the evidence review

2 Individual RCTs and cluster RCTs were quality assessed using the Cochrane Risk of
3 Bias Tool v2.0. Each individual study was classified into one of the following three
4 groups:

- 5 • Low risk of bias – The true effect size for the study is likely to be close to the
6 estimated effect size.
- 7 • Moderate risk of bias – There is a possibility the true effect size for the study is
8 substantially different to the estimated effect size.
- 9 • High risk of bias – It is likely the true effect size for the study is substantially
10 different to the estimated effect size.

11 Each individual study was also classified into one of three groups for directness,
12 based on if there were concerns about the population, intervention, comparator
13 and/or outcomes in the study and how directly these variables could address the
14 specified review question. Studies were rated as follows:

- 15 • Direct – No important deviations from the protocol in population, intervention,
16 comparator and/or outcomes.
- 17 • Partially indirect – Important deviations from the protocol in one of the population,
18 intervention, comparator and/or outcomes.
- 19 • Indirect – Important deviations from the protocol in at least two of the following
20 areas: population, intervention, comparator and/or outcomes

21 Qualitative studies were critically appraised using the CASP qualitative study
22 checklist.

23 Individual qualitative studies were quality assessed using the CASP qualitative
24 checklist and classified into one of the following three groups:

- 25 • Low risk of bias – The findings and themes identified in the study are likely to
26 accurately capture the true picture.
- 27 • Moderate risk of bias – There is a possibility the findings and themes identified in
28 the study are not a complete representation of the true picture.
- 29 • High risk of bias – It is likely the findings and themes identified in the study are
30 not a complete representation of the true picture

31 Each individual qualitative study was also classified into one of three groups for
32 relevance, based on if there were concerns about the perspective, population,
33 phenomenon of interest and/or setting in the included studies and how directly these
34 variables could address the specified review question. Studies were rated as follows:

- 35 • Highly relevant – No important deviations from the protocol in perspective,
36 population, phenomenon of interest and/or setting.
- 37 • Relevant – Important deviations from the protocol in one of the perspective,
38 population, phenomenon of interest and/or setting.
- 39 • Partially relevant – Important deviations from the protocol in at least two of the
40 perspective, population, phenomenon of interest and/or setting.

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- 1 See appendix E for appraisal of individual studies.
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1 Recommendations supported by this evidence review

2 This evidence review supports recommendations 1.1.1 to 1.1.9 and the research
3 recommendation on organisational engagement in shared decision making. Other
4 evidence supporting these recommendations can be found in the evidence reviews
5 on normalising shared decision making (review 2.1).

6 The committee's discussion of the evidence

7 The outcomes that matter most

8 The committee agreed that the most important quantitative primary outcome was
9 'use of SDM'. Use of SDM was mostly measured in terms of observer-based
10 outcome measures (OBOMs) and participant-recorded outcome measures (PROMs).
11 The relative importance of OBOMs and PROMs was not discussed at length by the
12 committee due to the lack of effectiveness of the interventions whichever measure of
13 'use of SDM' was reported. The committee was unsure that the identified studies
14 were measuring the same construct. Since different studies used different SDM
15 outcome measures focused on different aspects of decisions they were likely to get
16 very different results. Some measures were more similar, such as OPTION and
17 MAPPIN'SDM, both based on a set of 12 and 15 indicators respectively on good
18 SDM practice by observers. Some differed greatly, especially in PROM measures,
19 where some measured SDM specifically (SDM-Q-9), some measured "patient
20 activation" (PAM) and some measured different facets of SDM within that (eg.
21 COMRADE measures "Risk communication" and "treatment decision-making", SDM-
22 Q-9 is 9 questions on a strongly agree to strongly disagree 5-point scale mainly
23 based on shared decision-making behaviours).

24 The Cochrane review presented many different kinds of studies and outcome
25 measures in the meta-analyses. The committee agreed that this required an
26 assumption that SDM was a transferable concept that could be applied across
27 healthcare disciplines in similar ways. This assumption was challenged by the
28 committee, who agreed that SDM has a range of generalisable elements, but that
29 there is also context variation. It argued that SDM is a complex intervention and must
30 be tailored to the specific clinical situation, individuals and environment. This creates
31 a difficulty in undertaking meta-analysis on SDM outcomes as it suggests that they
32 will be heterogenous because of the differential impact of interventions in different
33 contexts. This heterogeneity of exact intervention contents specifically meant it was
34 difficult for the committee to interpret any meaning from the standardised mean
35 difference outcomes in the review.

36 The committee stated that as the primary outcome of 'use of SDM' was not shown to
37 be achieved, the secondary outcomes would not help inform the results of this review
38 and therefore on the basis of the quantitative review, the committee were not able to
39 recommend any interventions to increase engagement in SDM as effective.

40 Based on the lack of robust quantitative evidence of the effectiveness of
41 interventions, and the committee's lack of confidence in the quantitative data, the
42 qualitative data was used as a guide for creating recommendations. A number of
43 barriers and facilitators to the use of SDM were represented strongly in the qualitative
44 data, and the committee agreed that these were an accurate representation of their
45 expert understanding of the main issues with SDM.

1 As a result the committee was confident to make a recommendation on the basis of
2 the qualitative data where that data was reflected in multiple studies and was
3 assessed as being of high or moderate quality.

4 **The quality of the evidence**

5 Most of the quantitative evidence was rated as very low quality, partially due to the
6 high risk of bias across all studies, and partially due to high levels of inconsistency
7 and imprecision. Standard risk of bias analyses often downgrades studies looking at
8 SDM as, even with objective outcomes, it is not always possible to be entirely blinded
9 to the intervention being received. However, high heterogeneity, large confidence
10 intervals and a lack of effect size seen in point estimates in primary outcomes
11 suggest even taking risk of bias into account wouldn't help elicit clearer results.

12 The committee agreed that due to the low quality of the evidence in the primary
13 outcome (use of SDM), it was not possible to make recommendations based on this.
14 There were some secondary outcomes for which SDM interventions showed
15 effectiveness, but these were either of low quality or of individual studies, and the
16 committee could not be sure if effectiveness in the secondary outcomes was linked to
17 the primary outcome of use of SDM. It agreed that it might be beneficial to have
18 some sort of theoretical framework to provide an explanation for how these
19 secondary outcomes can inform the primary outcome, but that there were no
20 universal frameworks. It agreed that using validated behaviour change models and
21 frameworks might be a good way to understand the processes of SDM better, for
22 example, the COM-B model².

23 The committee commented on the high degree of heterogeneity in the SDM
24 outcomes, both in terms of study type and the observational tools. Even when
25 stratified by continuous, categorical/dichotomous outcomes the committee felt it was
26 hard to elicit a meaning from the meta-analysed data due to the great differences
27 between both the type of tools used to capture SDM and the patient populations
28 involved. They also stated that it was not always clear in the evidence whether
29 outcomes were measuring patient or practitioner measures, despite these being split
30 into different populations, and this made it more difficult to draw conclusions from the
31 evidence.

32 For the qualitative evidence, themes identified as salient across individual research
33 papers were grouped and analysed in descriptive themes based on their direct
34 content. The committee discussed the descriptive themes and reflected on them as a
35 group, using their combined expertise and experience to make the themes more
36 interpretive and therefore more useful for formulating recommendations, alongside
37 considering the quality of the evidence as judged by CERQual.

38 In terms of the themes produced from the qualitative review, the committee agreed
39 that only themes that scored high or moderate quality on the CERQual scale should
40 be included were the findings in which the committee could have the most
41 confidence.

42 Four themes scored high on the CERQual scale. With eleven scored as moderate,
43 one scored low, and three scored very low. Themes with larger numbers of studies
44 had issues around coherence, as the studies diverged on the finer points of each
45 theme and made the theme less clear. Almost all themes had minor/no

² Michie, S., van Stralen, M. M., & West, R. (2011). The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation Science*, 6, [42]. <https://doi.org/10.1186/1748-5908-6-42>

1 methodological limitations concerns, with the themes with larger study numbers
2 having a majority low risk of bias studies. Some themes were marked down for
3 relevancy, due to a lack of UK studies, if there were no UK studies or the theme was
4 thought to be setting specific, with almost no contribution from UK studies, then this
5 was considered as 'serious relevancy concerns'. Themes with low or very low
6 numbers of studies were scored down for adequacy (4 studies equals moderate
7 concerns, 2 studies equals serious concerns), relative to the number seen in the
8 larger themes.

9 The committee discussed the way the themes had been organised and noted that
10 other methods may have also been appropriate. It noted that some of the themes
11 overlapped, for example 'Paternalistic practice vs shared decision making'
12 overlapped with 'Patient empowerment', 'Patient's capability to participate', and
13 'Clinicians attitudes and skills. It also highlighted that 'Applying SDM where there is a
14 high risk of harm' is hard to identify as a coherent theme from the excerpts in the
15 qualitative data.

16 The committee commented on the lack of facilitators found in the qualitative evidence
17 but acknowledged that it is within the scope of the committee's deliberations to
18 recommend facilitators to overcome the barriers identified in this review.

19 The committee was aware that it was tasked both with trying to encourage
20 engagement in SDM and with identifying effective components of SDM themselves,
21 and that these two aspects were different but overlapping. The committee showed
22 interest in putting together a specific recommendation on tools and resources that
23 can be used to facilitate core components of SDM in review question 1.3 [Evidence
24 review B].

25 The committee's recommendations suggest ways to improve the adoption of SDM,
26 as opposed to stringent requirements for its practice. Due to the limited quality of the
27 evidence identified the committee used its expertise and experience but were only
28 able to make a 'consider' recommendation

29 **Benefits and harms**

30 The committee understood that NICE have already agreed that SDM is a process
31 that should be undertaken as part of their social value judgements, and that their role
32 as a committee was not to recommend whether or not SDM should happen, but
33 rather to focus on how to make it happen. For this review, therefore, the committee
34 looked at the most effective way to encourage use of SDM in healthcare situations.

35 The committee agreed that an SDM guideline will aid in the implementation of SDM
36 for those who are not sure of the best way to practice it and to support organisations
37 and individuals who are trying to engage in SDM but need additional support. This
38 includes informing both people who use healthcare services and people and
39 organisations who provide healthcare services of the common barriers and
40 facilitators to SDM to help them identify what may be influencing their own capability,
41 opportunity and motivation to practice this process.

42 The committee discussed at some length whether SDM required more time and that
43 allowing a larger amount of time for SDM may increase consultation length and cost.
44 Although it did not see any quantitative evidence to reflect this, it did note that the
45 qualitative evidence highlighted 'lack of time' as a barrier to using SDM. Overall, it
46 agreed that any additional time needed could potentially be offset by fostering a
47 better patient-practitioner relationship in early sessions, leading to shorter ones in the
48 future, although they also acknowledged that many healthcare professionals only see
49 people short term. They highlighted issues around practitioners questioning what the

1 evidence is for more time being needed, and that more research is needed into what
2 interventions reduce time commitment.

3 The committee noted from the qualitative evidence and their own experience that
4 what practitioners and patients want from the process of SDM can be different.
5 Patients prefer trust, empathy, being listened to, expressing what is important to
6 them and understanding the process of decision making, whereas practitioners
7 prioritise explaining options and focusing on ensuring joint decisions are made. The
8 perceived structure of SDM can also vary, patients see it as a process whereas
9 practitioners see it more as a decision point. The committee discussed whether this
10 could be linked to the fact that patients can often see multiple practitioners and are
11 the only ones aware of their whole SDM timeline. They agreed that some of the
12 facilitators from the qualitative evidence, such as 'Continuity of, and access to, care'
13 could be part of a solution to this perception of a disconnected process. This involves
14 not just the sharing of information between services that is important, but also
15 between consultants in different health institutions.

16 The committee discussed the differences between 'what a person knows' and 'how a
17 person acts' in an SDM setting, and how these apply to both healthcare service users
18 and practitioners.

19 When discussing patient empowerment, specifically the information the patient has
20 access to and knowledge of, the committee agreed information availability has
21 changed: people look in physical media less and are more likely to search online. It
22 noted that patient literacy has evolved as technology has developed, but the amount
23 of misinformation has too. It also noted that older adults are less likely to access
24 online services, and older people are also more likely to have chronic health
25 conditions such as arthritis where they are likely to be involved in ongoing decision
26 making about their future care. Online access would also vary by other factors such
27 as social class, ethnicity and those with disabilities affecting cognition or
28 communication. It stated that the key aspect was providing access to information at
29 the right time, in the right way, for the right people. They wanted to acknowledge that
30 healthcare practitioners have a role in empowering and supporting patients with
31 lower health literacy to try and address this power imbalance and that there are
32 interventions to support practitioners in identifying people with health literacy issues.
33 patient decision aids can also be designed to address health literacy with these
34 people. There were also tools mentioned that help with information retention and the
35 committee wished to add that this could include letters written to patients as well as
36 list-making and recording. Clinicians have a role to help patients explore their
37 preferences and elicit values, and both clinicians and the system have a role to
38 signpost valid and reliable information sources, ensuring access to relevant data and
39 information at the right time in the right place. Including family and carers in this
40 process is often particularly helpful in this respect, despite SDM being distributed
41 across these additional members posing a challenge for clinicians. The distribution of
42 SDM across multiple encounters provides time to think about the information
43 provided and discuss the person's potential choices. Equally, ongoing SDM provides
44 capacity for repeat consultation and time to think about this information and the
45 person's potential choices.

46 The committee agreed it is important to consider the locus of control when discussing
47 patient's capability to participate, trust, and continuity of care. It thought there may be
48 situations where further discussion is ethical, such as when the patient's initial
49 decision appears not to align with the patient's informed preferences. In these cases,
50 the practitioner can seek to ensure these differences are highlighted, redressing the
51 balance. Both practitioners and patients should be aware of their own biases and be

1 aware of how 'nudging' can affect SDM. Misinformation is also an issue for both
2 patients and practitioners, and it should be ensured that both parties have access to
3 a good quality information before decisions are made, and a record of decisions from
4 previous appointments, which should be communicated as the service user transfers
5 through different practitioners in the healthcare system.

6 Patient's capability to participate in SDM is affected by a patient's previous
7 experience in a healthcare environment, and by the practitioner's previous
8 experience with patients. Patient engagement in SDM may be affected by their
9 concerns of being labelled as an "awkward or a "good" patient, as well as other
10 factors such as age. Some health service users are considered to "willingly refuse"
11 SDM. The committee highlighted that asking "What would you do doctor?" or similar
12 questions is sometimes mistakenly interpreted as not wanting to take part in decision
13 making, or taken as a cue to engage in more paternalistic care. However, the
14 committee discussed how if these perceptions are challenged by other people in the
15 decision process, treatment can progress in a more positive manner, and this is why
16 trust is vital.

17 The committee felt that the point about healthcare being seen as something that is
18 'paid for' may differ contextually in the UK due to payment being through taxation, but
19 this still applied to facets of UK healthcare such as dentistry and prescriptions.

20 Continuation of paternalistic practice identified by the qualitative review was also a
21 concern of the committee, who state this is linked with different parties having
22 different perceptions of what SDM is, and the more paternalistic preferences
23 sometimes being enforced by more senior practitioners, who may consider it a failure
24 of the junior doctor if they do not persuade the patient to do the 'right' thing.

25 Regarding SDM use in situations with high risk of harm, the committee highlighted
26 the relationship of high stakes situations to the absence of medically acceptable
27 options, and that healthcare service users should be aware that there is an option to
28 do nothing even in these situations, even when the clinician considers it a dangerous
29 option. They also showed concern as to whether there was a large enough evidence
30 base to be sure that negative consequences are a result of a lack of SDM.

31 The committee acknowledged that practitioner training can address many of the
32 barriers highlighted in this review and should cover not just generic communication
33 skills but also skills specific to SDM and patient engagement. They were aware that
34 communication skills are taught during training but commented that this tended to
35 focus on the part of the consultation that didn't involve decision-making. The
36 committee noted that making recommendations about professional training was
37 outside of the remit of this guideline but were hopeful that pre-registration and
38 continuing professional development training would incorporate up to date ideas
39 about SDM.

40 The committee agreed that continuity of, and access to, care was an important area
41 in aiding SDM but highlighted the lack of evidence in the review regarding electronic
42 medical records and communication through different contexts through these (eg.
43 SystemOne) and stated this would have helped inform their recommendations.

44 The committee agreed that guidelines limit options but are a key component of
45 medical knowledge people expect clinicians to have. They discussed whether this
46 may or may not act as a barrier or facilitator to SDM depending, for example, on how
47 they are framed and how they are used, and that the SDM process incorporates
48 discussion of a menu of options that is always going to be limited. Doctors have the
49 power to decide what options to offer a patient, while the patient has the power to say

1 no to what is offered. They stated that this theme didn't just cover guidelines but also
2 other system-based constraints such as referral management systems that have
3 become very widespread in recent years in the UK.

4 In terms of financial system concerns, whilst the NHS is a taxation system, the
5 committee acknowledged this theme can be relevant to the UK setting through QOF
6 in primary care, referral management systems, cancer pathways, time limits and
7 other factors.

8 Regarding the theme "other legal concerns", the committee discussed how one
9 possible area for recommendations relates to supporting practitioners in situations
10 where the agreed management plan leads to a bad outcome, provided that plan was
11 built on a documented SDM process. This support would be really helpful in reducing
12 'defensive medicine' (doctor-driven over-investigation and over-treatment) though the
13 committee also highlighted that the literature on this theme will not have caught up
14 with the change in law since the Montgomery ruling.

15 Some identified themes from the qualitative review were not included in the
16 recommendations as the committee felt that, even though they were very important
17 issues, were driven by wider social and cultural factors that a NICE guideline could
18 not address, including SDM in disadvantaged/marginalised groups and healthcare
19 system resource limits. SDM tools will be addressed in evidence review 1.3 and are
20 thus not addressed in this review.

21 The committee did still comment on SDM in disadvantaged/marginalised groups,
22 discussing whether language barriers and ethnicity are more severe barriers when
23 services do not have sufficient time or fail to provide well-trained interpreters and
24 advocates or when there was unconscious bias. The committee desired more
25 evidence on work with translators specifically in SDM and more evidence about the
26 way expectations about doctor-patient interactions vary between different cultures.

27 The committee acknowledged that they are not considering decision-making in
28 situations where the service user is deemed to lack capacity. In practice this
29 definition of capacity is nuanced and transient. They stated that capacity should still
30 be decision-specific and vary from situation to situation.

31
32 The committee felt some themes weren't captured in this review that could be
33 important for SDM. For example, practitioners believing that they are already
34 practising SDM does not come out explicitly in the literature review but is touched
35 upon by the 'concept of SDM' theme. The difficulty of measuring SDM was also
36 mentioned, as tension exists between validated and reliable measures for research
37 and measuring the quality improvement in practice. 'Competing demands and
38 priorities' were also mentioned such as other key performance indicators that take
39 the focus away from SDM.

40

1 Appendices

2 Appendix A – Review protocols

3 Review protocol for assessing the most effective approaches to support 4 people using healthcare services, and their families carers and 5 advocates, to engage in shared decision making.

6

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| Prospero registration number | CRD42019147209 |
| Review title | Assessing the most effective approaches to support people using healthcare services, and their families carers and advocates, to engage in shared decision making. |
| Review question | What are the most effective approaches and activities to support the following groups to engage with shared decision making: (a) people using healthcare services, and their families, carers and advocates? (b) healthcare providers |
| Objective | To update the Legare et al (2018) Cochrane review “Interventions for increasing the use of shared decision making by healthcare professionals” including both patient facing and practitioner facing interventions. |
| Searches | <p>The following databases will be searched:</p> <ul style="list-style-type: none"> • 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) • Emcare • Clinicaltrials.gov • WHO trials <p>Searches will be restricted by:</p> <ul style="list-style-type: none"> • Studies published from July 2017 to present day • Studies reported in English |

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| | <ul style="list-style-type: none"> • Study design RCT and SR filters applied • Animal studies will be excluded • Conference abstracts/proceedings will be excluded <p>The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion.</p> <p>The full search strategies for MEDLINE database will be published in the final review.</p> |
| Condition or domain being studied | <p>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).</p> |
| Population | <p>Inclusion:</p> <ul style="list-style-type: none"> • Adults (aged 18 years and over) using healthcare services (and their families, carers and advocates if they choose to involve them). • Healthcare providers <p>Exclusion:</p> <ul style="list-style-type: none"> • 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/Exposure/Test | <p>Studies will be included if they evaluated an intervention designed to increase the adoption of SDM by healthcare professionals. For the adoption of SDM by healthcare professionals to occur, the content of the intervention will need to, at a minimum, help patients recognize there is a decision to be made and express their preference. It may also include:</p> <ul style="list-style-type: none"> • Establishing a context in which patients' views about treatment options are valued and deemed necessary; • Transferring evidence-based information; • Making explicit the component of uncertainty in the clinical decision-making process; • Ensuring patients understand this information; |

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| | <ul style="list-style-type: none"> Eliciting patients' preferences, ideas, concerns and expectations; Establishing or reviewing the patients' preferences for role in decision-making; Agreeing upon an action plan and completing arrangements for follow-up. <p>Studies that evaluate patient-mediated interventions (e.g. use of patient decision aids by patients in preparation for consultation with healthcare professionals) will be considered if they include an assessment of the direct healthcare professional-related outcome of interest that is, adoption by the healthcare professional of SDM.</p> |
| Comparator/Reference standard/Confounding factors | <ul style="list-style-type: none"> Each other No intervention Sham intervention Different intensity |
| Types of study to be included | <p>We will include:</p> <p>randomised controlled trials (RCTs)</p> <p>well-designed quasi-experimental studies (quasi-RCTs)</p> <p>controlled clinical trials (CCTs)</p> <p>controlled before and after studies (CBAs) and interrupted time series analyses (ITS). For ITS, there needs to be a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention.</p> <p>In the event that an unmanageable volume of literature is recovered then we will prioritise studies in the order they are listed above.</p> |
| Other exclusion criteria | <ul style="list-style-type: none"> Non-English language papers Theses, dissertations and conference abstracts Editorials, opinion pieces and letters |
| Context | <p>This review is for part of a new NICE guideline for shared decision making.</p> |
| Primary outcomes (critical outcomes) | <p>Objective measure of the adoption of SDM, defined in an inclusive manner as:</p> <ul style="list-style-type: none"> a joint process between healthcare professionals and patients to make decisions; |

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| | <ul style="list-style-type: none"> • the use of decision support interventions including decision aids; • the fostering by healthcare professionals of active participation of patients in the decision making process. <p>For example (not exhaustive), the primary outcome of interest could be assessed with the OPTION scale, the Decision Support Assessment Tool (DSAT), or with any other validated scale that measure involvement of patient in the decision making process.</p> |
| <p>Secondary outcomes (important outcomes)</p> | <p>If and only if the primary outcome of interest is met then:</p> <p><i>Secondary outcomes (over the duration of the study)</i></p> <ul style="list-style-type: none"> • Objective measure of patient health outcomes (e.g. health related quality of life etc.); • Measures of patient process outcomes which may include economic outcomes (e.g. length of hospital stay, adherence to medication, satisfaction, etc.); • Measures of health practitioners' knowledge, attitudes, satisfaction with SDM; • Other measures of patient outcomes (e.g., have less regret on the decision made, be less likely to blame the health practitioner for bad outcomes, have less decisional conflict, etc.); • Measures or practitioner process outcomes (e.g. prescription patterns, adherence to clinical practice guidelines, etc.); • Subjective measures of adoption of SDM by healthcare professionals (e.g., self-administered questionnaire to healthcare professionals, patients, patients' relatives, etc.). |
| <p>Data extraction (selection and coding)</p> | <p>All references identified by the searches and from other sources will be uploaded into EPPI reviewer 5 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.</p> <p>The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form will be used to extract data from studies (see Developing NICE guidelines: the manual section 6.4). Study</p> |

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| | <p>investigators may be contacted for missing data where time and resources allow.</p> <p>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.</p> |
| Risk of bias (quality) assessment | <p>Risk of bias for RCTs will be assessed using the Cochrane RoB (2.0) checklist as described in Developing NICE guidelines: the manual. Other studies will be assessed using the appropriate checklist from the NICE manual.</p> |
| Strategy for data synthesis | <p>Meta-analyses of primary and secondary outcome data will be conducted for all comparators that are reported by more than one study with reference to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al. 2011).</p> <p>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:</p> <ul style="list-style-type: none"> • 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 <p>Meta-analyses will be performed in Cochrane Review Manager V5.3</p> |
| Analysis of sub-groups | <ul style="list-style-type: none"> • If there is heterogeneity in the meta-analysis, and where data allow disambiguation, subgroup analysis by demographic groupings will be explored: <ul style="list-style-type: none"> • Age • Gender • Family origin |
| Type and method of review | <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Intervention <input type="checkbox"/> Diagnostic <input type="checkbox"/> Prognostic <input type="checkbox"/> Qualitative <input type="checkbox"/> Epidemiologic |

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| | <input type="checkbox"/> Service Delivery <input type="checkbox"/> Other (please specify) |
| Language | English |
| Country | England |

1

1 Review protocol for identifying barriers and facilitators to SDM.

2

| Field | Content |
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| PROSPERO registration number | 147209 |
| Review question | <p>What are the barriers to, and facilitators for, engagement with shared decision making by:</p> <p style="padding-left: 40px;">a) people using healthcare services, and their families, carers and advocates</p> <p style="padding-left: 40px;">b) healthcare providers.</p> |
| Objective | <p>To identify key barriers and facilitators for engagement in shared decision making by</p> <p style="padding-left: 40px;">a) people using healthcare services, and their families, carers and advocates</p> <p style="padding-left: 40px;">b) healthcare providers.</p> |
| Searches | <p>The following databases will be searched:</p> <ul style="list-style-type: none"> • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE • Psychinfo <p>Searches will be restricted by:</p> |

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| | <ul style="list-style-type: none"> • 1990 • English language • Human studies <p>The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion.</p> <p>The full search strategies for MEDLINE database will be published in the final review.</p> |
| Condition or domain being studied | <p>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).</p> |
| Population | <p>Inclusion:</p> <ul style="list-style-type: none"> • Adults (aged 18 years and over) using healthcare services (and their families, carers and advocates if they choose to involve them). • Healthcare providers <p>Exclusion:</p> <ul style="list-style-type: none"> • 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/Exposure/Test | <p>Shared decision making in healthcare services</p> |

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| Comparator/Reference standard/Confounding factors | N/A |
| Types of study to be included | <ul style="list-style-type: none"> • Qualitative studies • Syntheses of qualitative studies • Qualitative elements of mixed methods studies |
| Other exclusion criteria | <ul style="list-style-type: none"> • Non-English language papers • Theses, dissertations and conference abstracts • Editorials, opinion pieces and letters • Surveys |
| Context | This review is for part of a new NICE guideline for shared decision making. |
| Primary outcomes (critical outcomes) | <ul style="list-style-type: none"> • Perceived barriers and facilitators to SDM |
| Secondary outcomes (important outcomes) | N/A |
| Data extraction (selection and coding) | <p>All references identified by the searches and from other sources will be uploaded into EPPI reviewer 5 and de-duplicated. The references will undergo a first sift for relevance based on title and abstract. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.</p> <p>The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form will be used to extract data from</p> |

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| | <p>studies (see Developing NICE guidelines: the manual section 6.4). . Study investigators may be contacted for missing data where time and resources allow.</p> |
| <p>Risk of bias (quality) assessment</p> | <p>Individual qualitative studies will be quality assessed using the CASP qualitative checklist and classified into one of the following three groups:</p> <ul style="list-style-type: none"> • Low risk of bias – The findings and themes identified in the study are likely to accurately capture the true picture. • Moderate risk of bias – There is a possibility the findings and themes identified in the study are not a complete representation of the true picture. • High risk of bias – It is likely the findings and themes identified in the study are not a complete representation of the true picture |
| <p>Strategy for data synthesis</p> | <p>Where multiple qualitative studies are identified for a single question, information from the studies will be combined using a thematic synthesis. By examining the findings of each included study, descriptive themes will be independently identified and coded in NVivo v.11. Once all of the included studies have been examined and coded, the resulting themes and sub-themes will be evaluated to examine their relevance to the review question, the importance given to each theme, and the extent to which each theme recurs across the different studies. The qualitative synthesis will use these ‘descriptive themes’ to develop ‘analytical themes’, which will be interpreted by the reviewer in light of the overarching review questions.</p> <p>CERQual will be used to assess the confidence we have in the summary findings of each of the identified themes. Evidence from all qualitative study designs (interviews, focus groups etc.) is initially rated as high confidence and the confidence in the evidence for each theme will be downgraded from this initial point.</p> |

| | |
|---------------------------|--|
| Analysis of sub-groups | Differences within codes will be explored to see if there are potential explanatory factors that may explain outliers. |
| Type and method of review | <input type="checkbox"/> Intervention <input type="checkbox"/> Diagnostic <input type="checkbox"/> Prognostic <input checked="" type="checkbox"/> Qualitative <input type="checkbox"/> Epidemiologic <input type="checkbox"/> Service Delivery <input type="checkbox"/> Other (please specify) |
| Language | English |
| Country | England |

1

1 Appendix B- Methods

2 Methods for combining intervention evidence

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

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

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

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

- 24 • Significant between study heterogeneity in methodology, population, intervention or
25 comparator was identified by the reviewer in advance of data analysis. This decision was
26 made and recorded before any data analysis was undertaken.
- 27 • The presence of significant statistical heterogeneity in the meta-analysis, defined as
28 $I^2 \geq 50\%$.

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

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

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

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

44

1 Minimal clinically important differences (MIDs)

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

4 For continuous outcomes expressed as a mean difference where no other MID was
 5 available, an MID of 0.5 of the median standard deviations of the comparison group arms
 6 was used (Norman et al. 2003). For continuous outcomes expressed as a standardised
 7 mean difference where no other MID was available, an MID of 0.5 was used. For relative
 8 risks where no other MID was available, a default MID interval for dichotomous outcomes of
 9 0.8 to 1.25 was used.

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

16 GRADE for pairwise meta-analyses of interventional 17 evidence

18 GRADE was used to assess the quality of evidence for the selected outcomes as specified in
 19 ‘Developing NICE guidelines: the manual (2014)’. Data from all randomised controlled trials
 20 was initially rated as high quality and data from observations studies were originally rated as
 21 low quality. The quality of the evidence for each outcome was downgraded or not from this
 22 initial point, based on the criteria given in Table 12.

23 **Table 12: Rationale for downgrading quality of evidence for intervention studies**

| GRADE criteria | Reasons for downgrading quality |
|----------------|---|
| Risk of bias | <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> |
| Indirectness | <p>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.</p> <p>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.</p> <p>Very serious: If greater than 33.3% of the weight in a meta-analysis came from indirect studies, the outcome was downgraded two levels.</p> <p>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.</p> |
| Inconsistency | <p>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 I² statistic.</p> |

| GRADE criteria | Reasons for downgrading quality |
|----------------|---|
| | <p>N/A: Inconsistency was marked as not applicable if data on the outcome was only available from one study.</p> <p>Not serious: If the I^2 was less than 33.3%, the outcome was not downgraded.</p> <p>Serious: If the I^2 was between 33.3% and 66.7%, the outcome was downgraded one level.</p> <p>Very serious: If the I^2 was greater than 66.7%, the outcome was downgraded two levels.</p> <p>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.</p> |
| Imprecision | <p>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.</p> <p>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.</p> <p>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.</p> |

- 1 The quality of evidence for each outcome was upgraded if any of the following three
2 conditions were met:
- 3 • Data from non-randomised studies showing an effect size sufficiently large that it cannot
4 be explained by confounding alone.
 - 5 • Data showing a dose-response gradient.
 - 6 • Data where all plausible residual confounding is likely to increase our confidence in the
7 effect estimate.

8 Publication bias

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

15 Evidence statements

16 Evidence statements for pairwise intervention data are classified in to one of four categories:

- 17 • Situations where the data are only consistent, at a 95% confidence level, with an effect in
18 one direction (i.e. one that is 'statistically significant'), and the magnitude of that effect is
19 most likely to meet or exceed the MID (i.e. the point estimate is not in the zone of
20 equivalence). In such cases, we state that the evidence showed that there is an effect.
- 21 • Situations where the data are only consistent, at a 95% confidence level, with an effect in
22 one direction (i.e. one that is 'statistically significant'), but the magnitude of that effect is
23 most likely to be less than the MID (i.e. the point estimate is in the zone of equivalence).
24 In such cases, we state that the evidence could not demonstrate a meaningful difference.
- 25 • Situations where the confidence limits are smaller than the MIDs in both directions. In
26 such cases, we state that the evidence demonstrates that there is no meaningful
27 difference.

- 1 • In all other cases, we state that the evidence could not differentiate between the
2 comparators.
- 3 For outcomes without a defined MID or where the MID is set as the line of no effect (for
4 example, in the case of mortality), evidence statements are divided into 2 groups as follows:
- 5 • We state that the evidence showed that there is an effect if the 95% CI does not cross the
6 line of no effect.
- 7 • The evidence could not differentiate between comparators if the 95% CI crosses the line
8 of no effect.

9 Qualitative evidence

10 Quality assessment

- 11 Individual qualitative studies were quality assessed using the CASP qualitative checklist.
12 Each individual study was classified into one of the following three groups:
- 13 • Low risk of bias – The findings and themes identified in the study are likely to accurately
14 capture the true picture.
- 15 • Moderate risk of bias – There is a possibility the findings and themes identified in the
16 study are not a complete representation of the true picture.
- 17 • High risk of bias – It is likely the findings and themes identified in the study are not a
18 complete representation of the true picture
- 19 Each individual study was also classified into one of three groups for relevance, based on if
20 there were concerns about the perspective, population, phenomenon of interest and/or
21 setting in the included studies and how directly these variables could address the specified
22 review question. Studies were rated as follows:
- 23 • Highly relevant – No important deviations from the protocol in perspective, population,
24 phenomenon of interest and/or setting.
- 25 • Relevant – Important deviations from the protocol in one of the perspective, population,
26 phenomenon of interest and/or setting.
- 27 • Partially relevant – Important deviations from the protocol in at least two of the
28 perspective, population, phenomenon of interest and/or setting.

29 Methods for combining qualitative evidence

- 30 Where multiple qualitative studies were identified for a single question, information from the
31 studies was combined using a thematic synthesis. By examining the findings of each
32 included study, descriptive themes were independently identified and coded. Once all of the
33 included studies had been examined and coded, the resulting themes and sub-themes were
34 evaluated to examine their relevance to the review question, the importance given to each
35 theme, and the extent to which each theme recurred across the different studies. The
36 qualitative synthesis then proceeded by using these 'descriptive themes' to develop
37 'analytical themes', which were interpreted by the reviewer in light of the overarching review
38 questions.

39 CERQual for qualitative studies

- 40 CERQual was used to assess the confidence we have in the summary findings of each of the
41 identified themes. Evidence from all qualitative study designs (interviews, focus groups etc.)
42 was initially rated as high confidence and the confidence in the evidence for each theme was
43 then downgraded from this initial point as detailed in **Table 13** below.

1 **Table 13 Rationale for downgrading confidence in evidence for qualitative questions**

| CERQual criteria | Reasons for downgrading confidence |
|----------------------------|---|
| Methodological limitations | Not serious: If the theme was identified in studies at low risk of bias, the outcome was not downgraded Serious: If the theme was identified only in studies at moderate or high risk of bias, the outcome was downgraded one level. Very serious: If the theme was identified only in studies at high risk of bias, the outcome was downgraded two levels. |
| Relevance | High: If the theme was identified in highly relevant studies, the outcome was not downgraded Moderate: If the theme was identified only in relevant and partially relevant studies, the outcome was downgraded one level. Low: If the theme was identified only in partially relevant studies, the outcome was downgraded two levels. |
| Coherence | Coherence was addressed based on two factors: Between study – does the theme consistently emerge from all relevant studies Theoretical – does the theme provide a convincing theoretical explanation for the patterns found in the data The outcome was downgraded once if there were concerns about one of these elements of coherence, and twice if there were concerns about both elements. |
| Adequacy of data | The outcome was downgraded if there was insufficient data to develop an understanding of the phenomenon of interest, either due to insufficient studies, participants or observations. |

2 **Publication bias**

3 If evidence of conducted but unpublished studies was identified during the review (e.g.
 4 conference abstracts or protocols without accompanying published results), available
 5 information on these unpublished studies was reported as part of the review.

6

7

1 Appendix C – Literature search strategies

2

3 Search strategies - Quantitative

4

| Database: Ovid MEDLINE(R) <1946 to July 31, 2019> |
|---|
| Strategy used: |
| 1 (shared decision or sharing decision or informed decision or informed choice or decision aid).ti,ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti. (10406) |
| 2 exp Clinical Decision-Making/ or exp Decision Making/ or exp Decision Support Systems, Clinical/ or (decision making or decision support or choice behaviour).ti,ab. or ((decision* or choice*) and (making* or support* or behaviour*)).ti. (268473) |
| 3 exp Patient Participation/ or (patient participation or consumer participation or patient involvement or consumer involvement).ti,ab. or ((patient* or consumer*) and (involvement* or involving* or participation* or participating*)).ti. (32441) |
| 4 exp Physician-Patient Relations/ or exp Nurse-Patient Relations/ or (exp Nurses/ or exp Physicians/ or (nurse* or physician* or clinician* or doctor* or general practitioners or gps or health care professionals or healthcare professionals or health care providers or healthcare providers or resident*)).ti. (482109) |
| 5 exp Patients/ or (patient* or consumer* or people*).ti. (1664581) |
| 6 4 and 5 (65213) |
| 7 1 or (2 and 3) or (2 and 6) or (3 and 6) (22733) |
| 8 limit 7 to ed=20170615-20191231 (4082) |
| 9 (MEDLINE or pubmed).tw. (143702) |
| 10 systematic review.tw. (102679) |
| 11 systematic review.pt. (110007) |
| 12 meta-analysis.pt. (103357) |
| 13 intervention\$.ti. (113685) |
| 14 or/9-13 (339850) |
| 15 randomized controlled trial.pt. (486224) |
| 16 randomi?ed.mp. (750991) |
| 17 placebo.mp. (186835) |
| 18 or/15-17 (801179) |
| 19 Controlled Before-After Studies/ (409) |

- 20 (Control* adj Before adj After adj Stud*).tw. (198)
- 21 Interrupted Time Series Analysis/ (622)
- 22 "Interrupted Time Series Analys*".tw. (813)
- 23 Comparative Study.pt. (1836230)
- 24 (comparat* adj stud*).tw. (86818)
- 25 (follow up adj (study or studies)).tw. (43527)
- 26 or/19-25 (1911765)
- 27 14 or 18 or 26 (2759971)
- 28 8 and 27 (881)
- 29 animals/ not humans/ (4571743)
- 30 28 not 29 (880)
- 31 limit 30 to english language (865)
- 32 limit 31 to (letter or historical article or comment or editorial or news or case reports) (12)
- 33 31 not 32 (853)

1

Database: Medline in process

Strategy used:

- 1 (shared decision or sharing decision or informed decision or informed choice or decision aid).ti,ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti. (2268)
- 2 exp Clinical Decision-Making/ or exp Decision Making/ or exp Decision Support Systems, Clinical/ or (decision making or decision support or choice behaviour).ti,ab. or ((decision* or choice*) and (making* or support* or behaviour*)).ti. (19648)
- 3 exp Patient Participation/ or (patient participation or consumer participation or patient involvement or consumer involvement).ti,ab. or ((patient* or consumer*) and (involvement* or involving* or participation* or participating*)).ti. (1431)
- 4 exp Physician-Patient Relations/ or exp Nurse-Patient Relations/ or (exp Nurses/ or exp Physicians/ or (nurse* or physician* or clinician* or doctor* or general practitioners or gps or health care professionals or healthcare professionals or health care providers or healthcare providers or resident*)).ti. (28108)
- 5 exp Patients/ or (patient* or consumer* or people*).ti. (187812)
- 6 4 and 5 (3677)
- 7 1 or (2 and 3) or (2 and 6) or (3 and 6) (2559)
- 8 limit 7 to dt=20170615-20191231 (1782)

9 (MEDLINE or pubmed).tw. (30617)
10 systematic review.tw. (25134)
11 systematic review.pt. (305)
12 meta-analysis.pt. (37)
13 intervention\$.ti. (18965)
14 or/9-13 (59563)
15 randomized controlled trial.pt. (276)
16 randomi?ed.mp. (67617)
17 placebo.mp. (16513)
18 or/15-17 (73536)
19 Controlled Before-After Studies/ (0)
20 (Control* adj Before adj After adj Stud*).tw. (21)
21 Interrupted Time Series Analysis/ (0)
22 "Interrupted Time Series Analys*".tw. (207)
23 Comparative Study.pt. (45)
24 (comparat* adj stud*).tw. (11247)
25 (follow up adj (study or studies)).tw. (3155)
26 or/19-25 (14658)
27 14 or 18 or 26 (132715)
28 8 and 27 (335)
29 animals/ not humans/ (0)
30 28 not 29 (335)
31 limit 30 to english language (333)
32 limit 31 to (letter or historical article or comment or editorial or news or case reports) (4)
33 31 not 32 (329)

1

2

Database: Medline ePub ahead

Strategy used:

- 1 (shared decision or sharing decision or informed decision or informed choice or decision aid).ti,ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti. (480)
- 2 exp Clinical Decision-Making/ or exp Decision Making/ or exp Decision Support Systems, Clinical/ or (decision making or decision support or choice behaviour).ti,ab. or ((decision* or choice*) and (making* or support* or behaviour*)).ti. (3992)
- 3 exp Patient Participation/ or (patient participation or consumer participation or patient involvement or consumer involvement).ti,ab. or ((patient* or consumer*) and (involvement* or involving* or participation* or participating*)).ti. (288)
- 4 exp Physician-Patient Relations/ or exp Nurse-Patient Relations/ or (exp Nurses/ or exp Physicians/ or (nurse* or physician* or clinician* or doctor* or general practitioners or gps or health care professionals or healthcare professionals or health care providers or healthcare providers or resident*)).ti. (4333)
- 5 exp Patients/ or (patient* or consumer* or people*).ti. (30240)
- 6 4 and 5 (634)
- 7 1 or (2 and 3) or (2 and 6) or (3 and 6) (555)
- 8 limit 7 to dt=20170615-20191231 (450)
- 9 (MEDLINE or pubmed).tw. (6406)
- 10 systematic review.tw. (5993)
- 11 systematic review.pt. (18)
- 12 meta-analysis.pt. (7)
- 13 intervention\$.ti. (3792)
- 14 or/9-13 (12564)
- 15 randomized controlled trial.pt. (1)
- 16 randomi?ed.mp. (12573)
- 17 placebo.mp. (3012)
- 18 or/15-17 (13617)
- 19 Controlled Before-After Studies/ (0)
- 20 (Control* adj Before adj After adj Stud*).tw. (6)
- 21 Interrupted Time Series Analysis/ (0)
- 22 "Interrupted Time Series Analys*".tw. (62)
- 23 Comparative Study.pt. (0)
- 24 (comparat* adj stud*).tw. (1322)
- 25 (follow up adj (study or studies)).tw. (625)
- 26 or/19-25 (2012)

- 27 14 or 18 or 26 (24960)
- 28 8 and 27 (82)
- 29 animals/ not humans/ (0)
- 30 28 not 29 (82)
- 31 limit 30 to english language (81)
- 32 limit 31 to (letter or historical article or comment or editorial or news or case reports) (0)
- 33 31 not 32 (81)

1

Database: Embase

Strategy used:

- 1 (shared decision or sharing decision or informed decision or informed choice or decision aid).ti,ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti. (17848)
- 2 exp clinical decision making/ or exp decision making/ or exp decision support system/ or exp ethical decision making/ or exp family decision making/ or exp medical decision making/ or exp patient decision making/ or (decision making or decision support or choice behaviour).ti,ab. or ((decision* or choice*) and (making* or support* or behaviour*)).ti. (423186)
- 3 exp patient participation/ or (patient participation or consumer participation or patient involvement or consumer involvement).ti,ab. or ((patient* or consumer*) and (involvement* or involving* or participation* or participating*)).ti. (39338)
- 4 exp doctor patient relation/ or exp nurse patient relationship/ or ((exp nurse/ or exp physician/ or (nurse* or physician* or clinician* or doctor* or general practitioners or gps or health care professionals or healthcare professionals or health care providers or healthcare providers or resident*)).ti. and (exp patient/ or (patient* or consumer* or people*).ti.)) (458829)
- 5 1 or (2 and 3) or (2 and 4) or (3 and 4) (56708)
- 6 limit 5 to dc=20170615-20191231 (10371)
- 7 (MEDLINE or pubmed).tw. (227959)
- 8 exp systematic review/ or systematic review.tw. (257820)
- 9 meta-analysis/ (168139)
- 10 intervention\$.ti. (183455)
- 11 or/7-10 (588799)
- 12 random:.tw. (1439489)
- 13 placebo:.mp. (437818)
- 14 double-blind:.tw. (200707)
- 15 or/12-14 (1688776)

- 16 Clinical study/ (154399)
- 17 Case control study/ (143690)
- 18 Family study/ (26055)
- 19 Longitudinal study/ (128546)
- 20 Retrospective study/ (805012)
- 21 comparative study/ (812982)
- 22 Prospective study/ (539439)
- 23 Randomized controlled trials/ (165481)
- 24 22 not 23 (533855)
- 25 Epidemiology/ (204475)
- 26 (Control* adj Before adj After adj Stud*).tw. (249)
- 27 "Interrupted Time Series Analys*".tw. (1369)
- 28 comparative study/ (812982)
- 29 (comparat* adj stud*).tw. (114197)
- 30 (follow up adj (study or studies)).tw. (60572)
- 31 or/25-30 (1131447)
- 32 11 or 15 or 31 (3108707)
- 33 6 and 32 (2145)
- 34 nonhuman/ not human/ (4448093)
- 35 33 not 34 (2133)
- 36 limit 35 to (conference abstract or conference paper or "conference review") (700)
- 37 35 not 36 (1433)
- 38 limit 37 to English language (1417)

1

Database: Ovid Emcare <1995 to 2019 week 30>

Strategy used:

- 1 (shared decision or sharing decision or informed decision or informed choice or decision aid).ti,ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti. (7709)
- 2 exp clinical decision making/ or exp decision making/ or exp decision support system/ or exp ethical decision making/ or exp family decision making/ or exp medical decision making/ or exp patient decision making/ or (decision making or decision support or choice behaviour).ti,ab. or ((decision* or choice*) and (making* or support* or behaviour*)).ti. (167095)

- 3 exp patient participation/ or (patient participation or consumer participation or patient involvement or consumer involvement).ti,ab. or ((patient* or consumer*) and (involvement* or involving* or participation* or participating*)).ti. (12289)
- 4 exp doctor patient relation/ or exp nurse patient relationship/ or ((exp nurse/ or exp physician/ or (nurse* or physician* or clinician* or doctor* or general practitioners or gps or health care professionals or healthcare professionals or health care providers or healthcare providers or resident*)).ti. and (exp patient/ or (patient* or consumer* or people*).ti.)) (165212)
- 5 1 or (2 and 3) or (2 and 4) or (3 and 4) (23658)
- 6 limit 5 to dc=20170615-20191231 (3231)
- 7 (MEDLINE or pubmed).tw. (82461)
- 8 exp systematic review/ or systematic review.tw. (102408)
- 9 meta-analysis/ (52550)
- 10 intervention\$.ti. (77329)
- 11 or/7-10 (222597)
- 12 random:.tw. (404598)
- 13 placebo:.mp. (106709)
- 14 double-blind:.tw. (46179)
- 15 or/12-14 (459561)
- 16 Clinical study/ (45058)
- 17 Case control study/ (31763)
- 18 Family study/ (8710)
- 19 Longitudinal study/ (50943)
- 20 Retrospective study/ (182666)
- 21 comparative study/ (110424)
- 22 Prospective study/ (151042)
- 23 Randomized controlled trials/ (59914)
- 24 22 not 23 (149174)
- 25 Epidemiology/ (38635)
- 26 (Control* adj Before adj After adj Stud*).tw. (128)
- 27 "Interrupted Time Series Analys*".tw. (610)
- 28 comparative study/ (110424)
- 29 (comparat* adj stud*).tw. (18945)
- 30 (follow up adj (study or studies)).tw. (14509)

- 31 or/25-30 (167999)
- 32 11 or 15 or 31 (754330)
- 33 6 and 32 (706)
- 34 nonhuman/ not human/ (374331)
- 35 33 not 34 (704)
- 36 limit 35 to (conference abstract or conference paper or "conference review") (5)
- 37 35 not 36 (699)
- 38 limit 37 to English language (695)

1

Database: PsycINFO <1806 to July Week 5 2019>

Strategy used:

- 1 (shared decision or sharing decision or informed decision or informed choice or decision aid).ti,ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti. (4633)
- 2 exp Clinical Decision-Making/ or exp Decision Making/ or exp Decision Support Systems, Clinical/ or (decision making or decision support or choice behaviour).ti,ab. or ((decision* or choice*) and (making* or support* or behaviour*)).ti. (148667)
- 3 exp Patient Participation/ or (patient participation or consumer participation or patient involvement or consumer involvement).ti,ab. or ((patient* or consumer*) and (involvement* or involving* or participation* or participating*)).ti. (4610)
- 4 exp Physician-Patient Relations/ or exp Nurse-Patient Relations/ or (exp Nurses/ or exp Physicians/ or (nurse* or physician* or clinician* or doctor* or general practitioners or gps or health care professionals or healthcare professionals or health care providers or healthcare providers or resident*)).ti. (101646)
- 5 exp Patients/ or (patient* or consumer* or people*).ti. (279266)
- 6 4 and 5 (18594)
- 7 1 or (2 and 3) or (2 and 6) or (3 and 6) (6929)
- 8 (20170615* or 20170616* or 20170617* or 20170618* or 20170619* or 2017062* or 2017063* or 201707* or 201708* or 201709* or 20171* or 2018* or 2019*).up. (358561)
- 9 7 and 8 (1018)
- 10 (MEDLINE or pubmed).tw. (20576)
- 11 systematic review.tw. (24421)
- 12 systematic review.pt. (0)
- 13 meta-analysis.pt. (0)

14 intervention\$.ti. (66665)
 15 or/10-14 (99554)
 16 randomized controlled trial.pt. (0)
 17 randomi?ed.mp. (78213)
 18 placebo.mp. (39122)
 19 or/16-18 (102652)
 20 (Control* adj Before adj After adj Stud*).tw. (16)
 21 "Interrupted Time Series Analys*".tw. (266)
 22 (comparat* adj stud*).tw. (14668)
 23 (follow up adj (study or studies)).tw. (12624)
 24 or/20-23 (27533)
 25 15 or 19 or 24 (212131)
 26 9 and 25 (155)
 27 animals/ not humans/ (7179)
 28 26 not 27 (155)
 29 limit 28 to english language (128)
 30 limit 29 to conference proceedings (0)
 31 29 not 30 (128)

1
 2

| Database: Cochrane | |
|--------------------|---|
| Strategy used: | |
| #1 | ((shar* or inform*) near/3 (decision* or aid* or deciding* or choice*)):ti,ab,kw 4146 |
| #2 | ((decision* or choice*) near/3 (making* or support* or behaviour*)):ti,ab,kw 15476 |
| #3 | ((patient* or consumer*) near/3 (involvement* or involving* or participation* or participating*)):ti,ab,kw11831 |
| #4 | ((nurse* or physician* or clinician* or doctor* or general practitioner* or gps or health care professional* or healthcare professional* or health care provider* or healthcare provider* or resident*) near/3 (patient* or consumer* or people*)):ti,ab,kw 73855 |

| | | |
|----|---|--------|
| #5 | #1 or (#2 and #3) or (#2 and #4) or (#3 and #4) with Cochrane Library publication date Between Jun 2017 and Aug 2019 | 4428 |
| #6 | "conference":pt or (clinicaltrials or trialsearch):so | 418379 |
| #7 | #5 not #6 | 2097 |

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| |
|-----------------------|
| Database: DARE |
| Strategy used: |

| Line | Search | Hits |
|------|---|-------|
| 1 | ((shared decision or sharing decision or informed decision or informed choice or decision aid)) OR (((share* or sharing* or informed*) and (decision* or deciding* or choice*)):TI | 131 |
| 2 | MeSH DESCRIPTOR Clinical Decision-Making EXPLODE ALL TREES | 3 |
| 3 | MeSH DESCRIPTOR Decision Making EXPLODE ALL TREES | 447 |
| 4 | MeSH DESCRIPTOR Decision Support Systems, Clinical EXPLODE ALL TREES | 101 |
| 5 | ((decision making or decision support or choice behaviour)) | 2814 |
| 6 | #2 OR #3 OR #4 OR #5 | 2886 |
| 7 | ((((decision* or choice*) and (making* or support* or behaviour*)):TI | 213 |
| 8 | #6 OR #7 | 2889 |
| 9 | MeSH DESCRIPTOR Patient Participation EXPLODE ALL TREES | 132 |
| 10 | ((patient participation or consumer participation or patient involvement or consumer involvement)) OR (((patient* or consumer*) and (involvement* or involving* or participation* or participating*)):TI | 265 |
| 11 | #9 OR #10 | 265 |
| 12 | MeSH DESCRIPTOR Physician-Patient Relations EXPLODE ALL TREES | 112 |
| 13 | MeSH DESCRIPTOR Nurse-Patient Relations EXPLODE ALL TREES | 39 |
| 14 | MeSH DESCRIPTOR NURSES EXPLODE ALL TREES | 181 |
| 15 | MeSH DESCRIPTOR physicians EXPLODE ALL TREES | 202 |
| 16 | ((nurse* or physician* or clinician* or doctor* or general practitioners or gps or health care professionals or healthcare professionals or health care providers or healthcare providers or resident*)):TI | 742 |
| 17 | #12 OR #13 OR #14 OR #15 OR #16 | 1024 |
| 18 | MeSH DESCRIPTOR patients EXPLODE ALL TREES | 390 |
| 19 | ((patient* or consumer* or people*)):TI | 12110 |
| 20 | #18 OR #19 | 12348 |
| 21 | #17 AND #20 | 276 |
| 22 | #8 AND #11 | 64 |
| 23 | #8 AND #21 | 21 |
| 24 | #11 AND #21 | 12 |
| 25 | #1 OR #22 OR #23 OR #24 | 189 |
| 26 | (#25) IN DARE WHERE LPD FROM 15/06/2017 TO 02/08/2019 | 0 |
| 27 | (#25) IN DARE FROM 2017 TO 2019 | 0 |

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|--------------------------------------|
| Database: Clinical trials.gov |
| Strategy used: |

| |
|---|
| <p>"informed choice" OR "decision making" OR "decision support" OR "informed decision" OR "decision aid" OR "sharing decision" OR "shared decision"</p> <p>Limited by 'first posted' date: 08/04/2017-08/02/2019</p> |
| <p>Database: WHO trials</p> |
| <p>Strategy used:</p> <p>"informed choice" OR "decision making" OR "decision support" OR "informed decision" OR "decision aid" OR "sharing decision" OR "shared decision"</p> <p>Limited by 'registration date': 04/08/2017 - current</p> |

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3 Search strategies - Qualitative

| |
|--|
| <p>Database: Medline</p> |
| <p>Strategy used:</p> <ol style="list-style-type: none"> 1 Decision Making/ (88880) 2 Clinical Decision-Making/ (5860) 3 Decision Support Systems, Clinical/ (7213) 4 Decision Support Techniques/ (18838) 5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj3 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).tw. (213168) 6 Informed Consent/ (35271) 7 (inform* adj3 (treatment* or consult* or exchange* or consent* or decision* or choice* or plan*)).tw. (72049) 8 or/1-7 (349099) 9 *Patient Participation/ or *Physician-Patient Relations/ or *nurse-patient relations/ (63115) 10 (decision* or decide* or deciding* or choice* or goal* or judg?ment*).tw. (843758) 11 9 and 10 (9615) 12 *"Patient Acceptance of Health Care"/ (24971) 13 *Patient Preference/ (4465) 14 *Patient care planning/ (13542) |

- 15 ((patient* or consumer* or client* or people* or person* or autonom* or individual* or female* or male* or wom?n* or man* or men*) adj (center* or centre* or prefer* or participat* or involv* or empower* or sensitive* or generat*)).ti. (12116)
- 16 ((care or medicine* or treat* or inform*) adj (personali?e* or tailor* or individual* or participat*)).ti. (302)
- 17 *professional-family relations/ or *professional-patient relations/ (17199)
- 18 *Patients/ (12893)
- 19 *patient-centered care/ (11115)
- 20 ("international patient decision aid standard*" or IPDAS).tw. (86)
- 21 or/11-20 (97750)
- 22 8 and 21 (15346)
- 23 ("shared decision making" or SDM).ti,ab. (5711)
- 24 "decision making".ti. (19905)
- 25 "decision making".ab. /freq=2 (19445)
- 26 or/23-25 (34801)
- 27 22 or 26 (45433)
- 28 animals/ not (animals/ and humans/) (4553169)
- 29 27 not 28 (44065)
- 30 limit 29 to english language (41578)
- 31 limit 30 to ed=19900101-20191231 (39248)
- 32 limit 31 to (letter or historical article or comment or editorial or news or case reports) (3510)
- 33 31 not 32 (35738)
- 34 (qualitative or themes).tw. (192303)
- 35 33 and 34 (4756)

Database: Medline in process

Strategy used:

- 1 Decision Making/ (0)
- 2 Clinical Decision-Making/ (0)
- 3 Decision Support Systems, Clinical/ (0)
- 4 Decision Support Techniques/ (0)
- 5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment* or structur*) adj3 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).tw. (39100)

- 6 Informed Consent/ (0)
- 7 (inform* adj3 (treatment* or consult* or exchange* or consent* or decision* or choice* or plan*)).tw. (11233)
- 8 or/1-7 (46257)
- 9 *Patient Participation/ or *Physician-Patient Relations/ or *nurse-patient relations/ (0)
- 10 (decision* or decide* or deciding* or choice* or goal* or judgment*).tw. (130408)
- 11 9 and 10 (0)
- 12 *"Patient Acceptance of Health Care"/ (0)
- 13 *Patient Preference/ (0)
- 14 *Patient care planning/ (0)
- 15 ((patient* or consumer* or client* or people* or person* or autonom* or individual* or female* or male* or woman* or man* or men*) adj (center* or centre* or prefer* or participat* or involv* or empower* or sensitive* or generat*)).ti. (2063)
- 16 ((care or medicine* or treat* or inform*) adj (personalize* or tailor* or individual* or participat*)).ti. (41)
- 17 *professional-family relations/ or *professional-patient relations/ (0)
- 18 *Patients/ (0)
- 19 *patient-centered care/ (0)
- 20 ("international patient decision aid standard*" or IPDAS).tw. (19)
- 21 or/11-20 (2123)
- 22 8 and 21 (344)
- 23 ("shared decision making" or SDM).ti,ab. (1542)
- 24 "decision making".ti. (3259)
- 25 "decision making".ab. /freq=2 (3529)
- 26 or/23-25 (6308)
- 27 22 or 26 (6522)
- 28 animals/ not (animals/ and humans/) (0)
- 29 27 not 28 (6522)
- 30 limit 29 to english language (6436)
- 31 limit 30 to dt=19900101-20191231 (6411)
- 32 limit 31 to (letter or historical article or comment or editorial or news or case reports) (258)
- 33 31 not 32 (6153)
- 34 (qualitative or themes).tw. (35247)
- 35 33 and 34 (694)

Database: Medline ePub ahead

Strategy used:

- 1 Decision Making/ (0)
- 2 Clinical Decision-Making/ (0)
- 3 Decision Support Systems, Clinical/ (0)
- 4 Decision Support Techniques/ (0)
- 5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judgment* or structur*) adj3 (share* or sharing* or inform* or making* or make* or support* or behavior* or conflict* or collab* or aid*)).tw. (7808)
- 6 Informed Consent/ (0)
- 7 (inform* adj3 (treatment* or consult* or exchange* or consent* or decision* or choice* or plan*)).tw. (2526)
- 8 or/1-7 (9061)
- 9 *Patient Participation/ or *Physician-Patient Relations/ or *nurse-patient relations/ (0)
- 10 (decision* or decide* or deciding* or choice* or goal* or judgment*).tw. (24162)
- 11 9 and 10 (0)
- 12 *"Patient Acceptance of Health Care"/ (0)
- 13 *Patient Preference/ (0)
- 14 *Patient care planning/ (0)
- 15 ((patient* or consumer* or client* or people* or person* or autonom* or individual* or female* or male* or woman* or man* or men*) adj (center* or centre* or prefer* or participat* or involv* or empower* or sensitive* or generat*)).ti. (400)
- 16 ((care or medicine* or treat* or inform*) adj (personalize* or tailor* or individual* or participat*)).ti. (10)
- 17 *professional-family relations/ or *professional-patient relations/ (0)
- 18 *Patients/ (0)
- 19 *patient-centered care/ (0)
- 20 ("international patient decision aid standard*" or IPDAS).tw. (4)
- 21 or/11-20 (414)
- 22 8 and 21 (70)
- 23 ("shared decision making" or SDM).ti,ab. (312)
- 24 "decision making".ti. (649)
- 25 "decision making".ab. /freq=2 (815)
- 26 or/23-25 (1348)
- 27 22 or 26 (1390)
- 28 animals/ not (animals/ and humans/) (0)

- 29 27 not 28 (1390)
- 30 limit 29 to english language (1381)
- 31 limit 30 to dt=19900101-20191231 (1381)
- 32 limit 31 to (letter or historical article or comment or editorial or news or case reports) (16)
- 33 31 not 32 (1365)
- 34 (qualitative or themes).tw. (7585)
- 35 33 and 34 (183)

Database: Embase

Strategy used:

- 1 decision making/ (209004)
- 2 medical decision making/ or clinical decision making/ (122575)
- 3 decision support system/ (20504)
- 4 clinical decision support system/ (2267)
- 5 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judgment* or structur*) adj3 (share* or sharing* or inform* or making* or make* or support* or behavior* or conflict* or collab* or aid*)).tw. (332280)
- 6 informed consent/ (100582)
- 7 (inform* adj3 (treatment* or consult* or exchange* or consent* or decision* or choice* or plan*)).tw. (146509)
- 8 or/1-7 (689932)
- 9 *patient participation/ or *doctor patient relation/ or *nurse patient relationship/ (58948)
- 10 (decision* or decide* or deciding* or choice* or goal* or judgment*).tw. (1367014)
- 11 9 and 10 (7267)
- 12 *patient attitude/ (20008)
- 13 *patient preference/ (4050)
- 14 *patient care planning/ or *advance care planning/ or *health care planning/ (43500)
- 15 ((patient* or consumer* or client* or people* or person* or autonom* or individual* or female* or male* or woman* or man* or men*) adj (center* or centre* or prefer* or participat* or involv* or empower* or sensitive* or generat*)).ti. (18108)
- 16 ((care or medicine* or treat* or inform*) adj (personalize* or tailor* or individual* or participat*)).ti. (464)
- 17 *professional-patient relationship/ or *human relation/ (33747)
- 18 *patient/ (377981)
- 19 *patient care/ (63605)

- 20 ("international patient decision aid standard*" or IPDAS).tw. (166)
- 21 or/11-20 (556572)
- 22 8 and 21 (38084)
- 23 ("shared decision making" or SDM).ti,ab. (10224)
- 24 "decision making".ti. (29136)
- 25 "decision making".ab. /freq=2 (31627)
- 26 or/23-25 (54765)
- 27 22 or 26 (87002)
- 28 nonhuman/ not human/ (4390213)
- 29 27 not 28 (85505)
- 30 limit 29 to english language (81831)
- 31 (199* or 200* or 201*).dc. (26272732)
- 32 30 and 31 (78803)
- 33 32 not (conference abstract or conference paper or conference proceeding or "conference review" or letter or editorial).pt. (49990)
- 34 (qualitative or qualitative study).tw. (250420)
- 35 33 and 34 (4755)
- 36 limit 35 to medline (2167)
- 37 35 not 36 (2588)

Database: PsycInfo

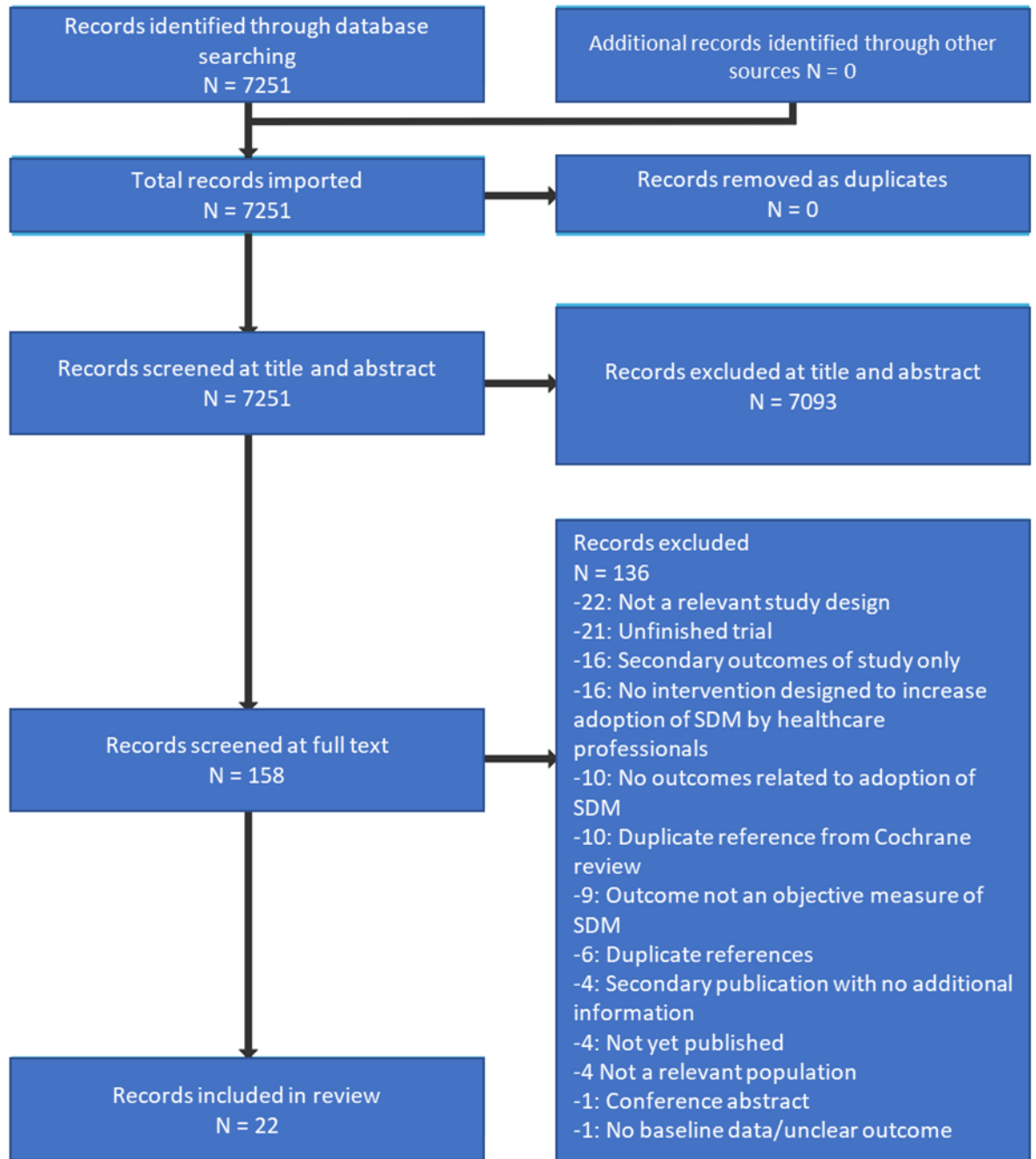
Strategy used:

- 1 exp Decision Making/ (113573)
- 2 exp Decision Support Systems/ (3089)
- 3 ((decision* or decide* or deciding* or decisive* or choice* or goal* or judg?ment*) adj3 (share* or sharing* or inform* or making* or make* or support* or behavi?or* or conflict* or collab* or aid*)).tw. (156850)
- 4 exp Informed Consent/ (4133)
- 5 (inform* adj3 (treatment* or consult* or exchange* or consent* or decision* or choice* or plan*)).tw. (30973)
- 6 or/1-5 (218677)
- 7 *Patient Participation/ or *Physician-Patient Relations/ or *nurse-patient relations/ (1555)
- 8 (decision* or decide* or deciding* or choice* or goal* or judg?ment*).tw. (567693)
- 9 7 and 8 (583)

- 10 *Client Participation/ (1555)
- 11 *Client Attitudes/ (12876)
- 12 *Client Characteristics/ or *Treatment Planning/ (16209)
- 13 ((patient* or consumer* or client* or people* or person* or autonom* or individual*) adj (center* or centre* or prefer* or participat* or involv* or empower* or sensitive* or generat*)).ti. (6129)
- 14 ((care or medicine* or treat* or inform*) adj (personali?e* or tailor* or individual* or participat*)).ti. (191)
- 15 *PATIENTS/ (6484)
- 16 *client centered therapy/ (2676)
- 17 ("international patient decision aid standard*" or IPDAS).tw. (28)
- 18 or/9-17 (43051)
- 19 6 and 18 (4647)
- 20 ("shared decision making" or SDM).ti,ab. (2431)
- 21 "decision making".ti. (21054)
- 22 "decision making".ab. /freq=2 (21937)
- 23 or/20-22 (33900)
- 24 19 or 23 (37331)
- 25 animals/ not (animals/ and humans/) (7174)
- 26 24 not 25 (37300)
- 27 limit 26 to english language (35655)
- 28 (199* or 200* or 201*).up. (3660999)
- 29 27 and 28 (32281)
- 30 limit 29 to conference proceedings (13)
- 31 29 not 30 (32268)
- 32 (qualitative or themes).tw. (207257)
- 33 31 and 32 (3944)

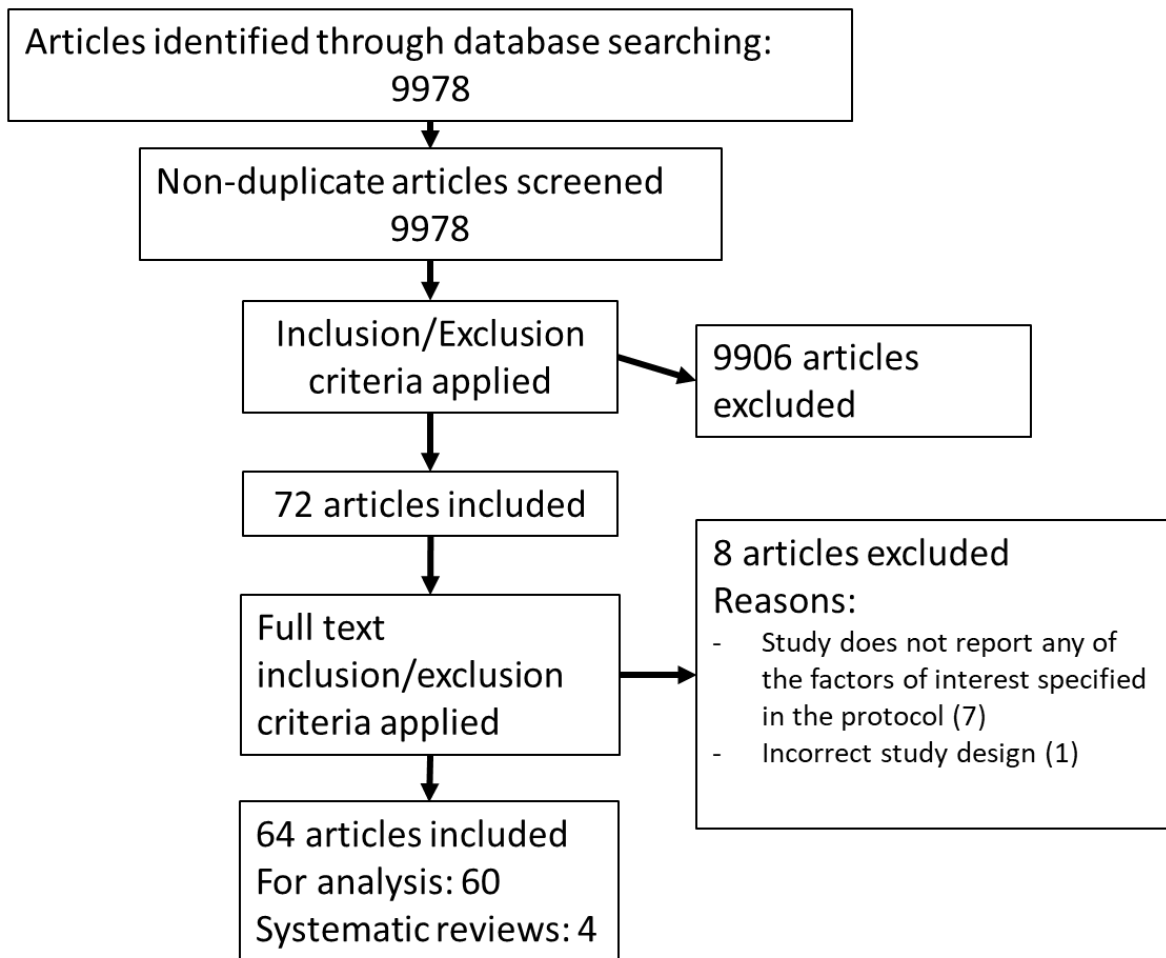
1 Appendix D – Clinical evidence study selection

2 Quantitative review



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1 Qualitative review



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1 Appendix E – Clinical evidence tables

2 Quantitative

Alegria, 2018

3

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

4

5 Study details

| | |
|------------------------------|---|
| Study type | Randomised controlled trial (RCT) Describes as: 'cross-level 2x2 RCT with clinicians at level 2 and patients nested within clinicians at level 1 to assess the effectiveness of patient and clinician interventions' |
| 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 Aged 18 to 80 years Criteria 2 English, Spanish or Mandarin speaking Criteria 3 No previous exposure to DECIDE-PA intervention |
| Exclusion criteria | Criteria 1 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) |

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| Condition specific characteristics | Clinician's specialty Psychiatrist, psychologist, social worker, nurse or other. |
| Outcome measures | 9 item shared decision making questionnaire (SDM-Q-9) OPTION Perceptions of Care Survey (POC) Global Evaluation of Care Scale Working Alliance Inventory Kim Alliance Scale Communication subscale |

1 **Study arms**

| | |
|--|---|
| | <p>DECIDE-PC (N = 197)</p> <p>3 areas of patient-centered 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.</p> <p>Usual care (N = 189)</p> <p>Patients continued usual treatment, completed 3 assessments and had a recorded clinical session.</p> |
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| <p>Domain 1: Bias arising from the randomisation process</p> <p>1. 1. Was the allocation sequence random?</p> |
|--|

Yes

1. 2. Was the allocation sequence concealed until participants were enrolled and assigned to interventions?

Yes

1.3 Did baseline differences between intervention groups suggest a problem with the randomisation process?

No

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)

2.1. Were participants aware of their assigned intervention during the trial?

Yes

(Clinicians aware, unclear if patients were aware.)

2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?

No

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?

Not applicable

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?

Not applicable

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?

Not applicable

2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?

Yes

(ITT used.)

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?

Not applicable

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low

Domain 3. Bias due to missing outcome data

3.1 Were data for this outcome available for all, or nearly all, participants randomised?

Yes

3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?

Not applicable

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?

Not applicable

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?

Not applicable

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?

Not applicable

Risk-of-bias judgement for missing outcome data

Low

Domain 4. Bias in measurement of the outcome

4.1 Was the method of measuring the outcome inappropriate?

No

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?

No

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?

No

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

Not applicable

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

Not applicable

Risk-of-bias judgement for measurement of the outcome

Low

Domain 5. Bias in selection of the reported result

5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ?

Yes

5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk-of-bias judgement for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

Low

Overall Directness

Directly applicable

1

Berger-Hoger, 2019

2

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

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5 Study details

| | |
|-----------------------|-------------------------------------|
| 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 | Criteria 1 Aged 18 years or older Criteria 2 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 | 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). History of cancer (except breast cancer) Intervention: 3/32, control: 1/28 |
| Outcome measures | Decisional Conflict (DC) Multifocal APProach to the sharing' IN Shared decision making "(MAPPIN-Q) |

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2 **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 tumor board.

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1a. Bias arising from the randomisation process

1a. 1. Was the allocation sequence random?

Yes

1a. 2. Is it likely that the allocation sequence was subverted?

No

1a. 3. Were there baseline imbalances that suggest a problem with the randomisation process?

No

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

1b. 1. Were all the individual participants identified before randomisation of clusters (and if the trial specifically recruited patients were they all recruited before randomisation of clusters)?

No

1b. 2. If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention?

Yes

1b. 3. Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

No

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).

2.1a Were participants aware that they were in a trial?

No information

2.1b If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?

No

2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?

Yes

(Patients were recruited by the participating physicians.)

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?

Probably no

2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Not applicable

2.5a Were any clusters analysed in a group different from the one to which they were assigned?

No

2.5b Were any participants analysed in a group different from the one to which their original cluster was randomised?

No

2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?

Not applicable

Risk of bias judgement for deviations from intended interventions

Some concerns

3. Bias due to missing outcome data

3.1a Were outcome data available for all, or nearly all, clusters randomised?

Yes

3.1b Were outcome data available for all, or nearly all, participants within clusters?

No

(Only some information available at patient level, all outcomes available at cluster level.)

3.2 If N/PN/NI to 3.1a or 3.1b: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Yes

3.3 If N/PN/NI to 3.1a or 3.1b: Is there evidence that results were robust to the presence of missing outcome data?

Yes

Risk of bias judgement for missing outcome data

Some concerns

4. Bias in measurement of the outcome

4.1a Were outcome assessors aware that a trial was taking place?

Yes

4.1b If Y/PY/NI to 4.1: Were outcome assessors aware of the intervention received by study participants?

Probably yes

4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

Probably yes

Risk of bias judgement for measurement of the outcome

Some concerns

(For objective measures)

5. Bias in selection of the reported result

5.1 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.2 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk of bias for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

Some concerns
 Overall Directness
 Directly applicable

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Consoli, 2020

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Bibliographic Reference Consoli, S.M.; Duclos, M.; Grimaldi, A.; Penfornis, A.; Bineau, S.; Sabin, B.; Pouriel, M.; Freund, E.; Dejager, S.; OPADIA Study: Is a Patient Questionnaire Useful for Enhancing Physician-Patient Shared Decision Making on Physical Activity Micro-objectives in Diabetes?; *Advances in Therapy*; 2020; vol. 37 (no. 5); 2317-2336

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5 **Study details**

| | |
|------------------------------|---|
| Study type | Randomised controlled trial (RCT) <small>OPADIA was a multicentre, national, prospective, comparative, randomised study</small> |
| Study location | Paris, France |
| Study setting | 80 GPs who validated their participation practiced in all French metropolitan regions except Corsica, mainly in Ile-de-France (21.3%), Grand-Est (16.3%), Hauts-de-France (16.3%) and Nouvelle-Aquitaine (12.5%). They practiced mainly in towns (92.5%), in medical or medical group offices (43.8% and 56.3%, respectively). None of the GPs practiced in a clinic or health centre, or for a mutual insurance company. |
| Study dates | July 2017 to August 2018 |
| Duration of follow-up | 3 months |

| | |
|---------------------------|---|
| Sources of funding | Sponsorship for this study the journals rapid service fee and open access fee were funded by MSD France. |
| Inclusion criteria | Criteria 1 GPs at participating centres |
| Sample size | 256 patients 80 GPs |
| Loss to follow-up | Intervention: 1 Control: 4 |
| % Female | Intervention: 36.6% Control: 32.8% |
| Mean age (SD) | Int: 64.1 (11.6) Ctrl: 63.2 (10.6) |
| Outcome measures | <p>Outcome 1 proportion of inclusion visits ending with at least one SMART-PA micro-objective being set up.</p> <p>Outcome 2 IPAQ-SF - seven open-ended questions about an individual's PA during daily life over the past 7 days</p> <p>Outcome 3 SEPCG-27 27-item version of the preliminary 88-item questionnaire (SEPCQ-88) [8]. Three factors were identified as valid subscales covering core aspects of a physician's self-efficacy in patient-centredness: (1) exploring the patient's perspective, (2) sharing information and power and (3) dealing with communicative challenges. The scoring format is a five-point Likert scale with "0" (to a very low degree) and "4" (to a very high degree) as endpoints.</p> <p>Outcome 4 ENTRED Two simple-choice questions derived from the original ENTRED self-questionnaire [9] were used in our study: (1) In your relationship with your doctor, would you say generally that: (a) the physician decides and you follow his/her prescriptions; (b) the physician and you both decide together; (c) the physician gives you his/ her advice and you decide by yourself? (2) Would you say that you can easily discuss your concerns with your doctor? (a) absolutely; (b) mostly yes; (c) not always; (d) not at all.</p> <p>Outcome 5 GIRERD validated self-questionnaire composed of six questions with yes/no answers: (1) Do you sometimes forget to take your medicine? (2) Have you ever run out of your medicine? (3) Do you sometimes take your medicine late? (4) Do you sometimes decide not to take your medicine because some days you feel that your treatment does more harm</p> |

than good? (5) Do you think that you have too many pills to take? (6) When you feel better, do you sometimes stop taking your medicine? Scores of 0 and 1 are respectively assigned to each “no” and “yes” answer. An overall score of 0 is considered as indicating good compliance, an overall score of 1 or 2 as indicating minor noncompliance and an overall score C 3 as indicating noncompliance/poor compliance.

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2 **Study arms**

OPTIMA-PA questionnaire (N = 134)

one of the five modules constituting the OPTIMA questionnaire [6]. This module consists of 14 items: 11 items each describing a specific type of PA—for which the patients indicated on a five-point Likert scale how “easy” they would find the PA to do, how “useful” they considered this activity to be for controlling their T2DM and the frequency at which they thought they would be able to do this activity — and three items related to a PA that the patient considered as realistically feasible. For these last three items, the patients were asked to indicate the activity name, the time during which they could do this activity and the frequency at which they could do it. Responses for these last three items were used by the GPs during the inclusion visit as a basis for discussions with their patient about PA objectives.

Standard care (N = 122)

Patient follow-up according to GPs usual care

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| Section | Question | Answer |
|--|---|--|
| 1a. Bias arising from the randomisation process | Risk of bias judgement for the randomisation process | Some concerns <i>(Baseline imbalances due to randomisation and no clarity on how randomisation is performed.)</i> |
| 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 | High <i>(Participants recruited by GPs after randomisation and GPs</i> |

| Section | Question | Answer |
|--|---|--|
| | participants in relation to timing of randomisation | <i>seemed aware of their group, and exclusion reasoning could be "not selected by GP"))</i> |
| 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 <i>(Participant recorded outcomes and unblinded participants.)</i> |
| 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 <i>(GPs randomised before individual patient recruitment so will have known which arm they were in, and baseline characteristics in outcomes were imbalanced. Also unblinded participants recording outcomes.)</i> |
| | Overall Directness | Direct |

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Dillon, 2017

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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

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Study details

| | |
|------------------------------|--|
| Study type | Cluster randomised controlled trial |
| Study location | Northern California |
| Study setting | Four primary care clinics |
| Study dates | Not reported |
| Duration of follow-up | Not reported |
| Sources of funding | Patient-Centered Outcomes Research Institute (PCORI) |
| Inclusion criteria | None reported |
| Exclusion criteria | None reported |
| Sample size | N=40 |
| % Female | 65% |
| Mean age (SD) | Mean = 51.4 years to 60.4 years in groups |

| Outcome measures | OPTION |
|------------------|--------|
|------------------|--------|

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2 **Study arms**

| | |
|--|--|
| | <p>Open Communication (N = 10)</p> <p>Physician coaching and patient activation: 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.</p> <p>AskShareKnow (ASK) (N = 10)</p> <p>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?</p> <p>Open Communication and ASK combined (N = 10) Usual care (N = 10)</p> <p>No additional training, although some PCPs may have had prior training in SDM.</p> |
|--|--|

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4

1a. Bias arising from the randomisation process

1a. 1. Was the allocation sequence random?

No information

(No information on sequence generation)

1a. 2. Is it likely that the allocation sequence was subverted?

No information

1a. 3. Were there baseline imbalances that suggest a problem with the randomisation process?

No

Risk of bias judgement for the randomisation process

High

1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation

1b. 1. Were all the individual participants identified before randomisation of clusters (and if the trial specifically recruited patients were they all recruited before randomisation of clusters)?

No information

1b. 2. If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention?

Probably no

1b. 3. Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

No

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).

2.1a Were participants aware that they were in a trial?

Yes

(Consent to participate given.)

2.1b If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?

No information

2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?

No

(PCP were aware of allocation, but ratings were done by 2 members of research team who were blinded to allocation.)

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?

Not applicable

2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Not applicable

2.5a Were any clusters analysed in a group different from the one to which they were assigned?

No

2.5b Were any participants analysed in a group different from the one to which their original cluster was randomised?

No

2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?

Not applicable

Risk of bias judgement for deviations from intended interventions

Low

3. Bias due to missing outcome data

3.1a Were outcome data available for all, or nearly all, clusters randomised?

Yes

3.1b Were outcome data available for all, or nearly all, participants within clusters?

Yes

3.2 If N/PN/NI to 3.1a or 3.1b: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Not applicable

3.3 If N/PN/NI to 3.1a or 3.1b: Is there evidence that results were robust to the presence of missing outcome data?

Not applicable

Risk of bias judgement for missing outcome data

Low

4. Bias in measurement of the outcome

4.1a Were outcome assessors aware that a trial was taking place?

Yes

4.1b If Y/PY/NI to 4.1: Were outcome assessors aware of the intervention received by study participants?

No

4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

Not applicable

Risk of bias judgement for measurement of the outcome

Some concerns

5. Bias in selection of the reported result

5.1 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.2 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk of bias for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

Some concerns

Overall Directness

Directly applicable

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Doll, 2019

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Bibliographic Reference Doll, Jacob A.; Jones, W. Schuyler; Lokhnygina, Yuliya; Culpepper, Sara; Parks, Robin L.; Calhoun, Christy; Au, David H.; Patel, Manesh R.; PREPARED Study: A Study of Shared Decision-Making for Coronary Artery Disease; Circulation. Cardiovascular quality and outcomes; 2019; vol. 12 (no. 2); e005244

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Study details

| | |
|------------------------------|--|
| Study type | Cluster randomised controlled trial Physician-level cluster randomisation |
| Study location | North Carolina, USA |
| Study setting | Duke University Hospital |
| Study dates | November 2014 - March 2016 |
| Duration of follow-up | 3 months |
| Sources of funding | Gilead Sciences, Inc, |
| Inclusion criteria | Criteria 1 Patients referred to the catheterization laboratory for diagnostic coronary angiography with a reasonable expectation of coronary artery disease, defined as chronic stable angina, chest pain with a positive functional study, unstable angina, or non-ST segment elevation myocardial infarction. |
| Exclusion criteria | Criteria 1 Unable to provide informed consent. Criteria 2 Critical illness Cannot read or speak english |

| | |
|---|--|
| | Criteria 4 When a delay in angiography to administer the decision aid could lead to adverse clinical outcome. |
| Sample size | N = 203 |
| Split between study groups | Educational intervention = 103 Usual care = 100 |
| Loss to follow-up | N = 4 |
| % Female | 38% |
| Mean age (SD) | 63.6 (55.1 - 70.8) |
| Condition specific characteristics | CAD presentation CAD presentation: atypical or no symptoms (20.7%), stable angina (30%), unstable angina (37.9%), NSTEMI (11.3%). |
| Outcome measures | Decisional Conflict (DC) patient treatment preferences Control Preferences Scale (CPS) |

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2 **Study arms**

| | |
|--|--|
| | Decision Aid (N = 103) The decision aid included text, images, and videos to describe (1) the significance of Coronary Artery Disease (CAD); (2) the treatment options for CAD; and (3) the benefits and risks of medical therapy, percutaneous coronary intervention, and CABG, including descriptions of potential benefits, numerical probabilities, and graphical representation of procedural risks |
|--|--|

Usual care (N = 100)

Patients in the initial (usual care) phase of the study responded to a questionnaire, including assessments of knowledge, treatment preferences, and attitudes, desire for SDM and decision quality.

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1a. Bias arising from the randomisation process

1a. 1. Was the allocation sequence random?

No information

(Only randomisation reported and: "Cardiologists randomized to receive preferences were given a sealed envelope that contained preference information, the Control Preferences Scale, and the SAQ-7.")

1a. 2. Is it likely that the allocation sequence was subverted?

Yes

1a. 3. Were there baseline imbalances that suggest a problem with the randomisation process?

No

Risk of bias judgement for the randomisation process

High

1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation

1b. 1. Were all the individual participants identified before randomisation of clusters (and if the trial specifically recruited patients were they all recruited before randomisation of clusters)?

No

1b. 2. If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention?

Yes

1b. 3. Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

No

Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation

High

2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).

2.1a Were participants aware that they were in a trial?

No information

2.1b If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?

Yes

2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?

Yes

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?

No

2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Not applicable

2.5a Were any clusters analysed in a group different from the one to which they were assigned?

No

2.5b Were any participants analysed in a group different from the one to which their original cluster was randomised?

No

2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?

Not applicable

Risk of bias judgement for deviations from intended interventions

Some concerns

3. Bias due to missing outcome data

3.1a Were outcome data available for all, or nearly all, clusters randomised?

Yes

3.1b Were outcome data available for all, or nearly all, participants within clusters?

Yes

3.2 If N/PN/NI to 3.1a or 3.1b: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Not applicable

3.3 If N/PN/NI to 3.1a or 3.1b: Is there evidence that results were robust to the presence of missing outcome data?

Not applicable

Risk of bias judgement for missing outcome data

Some concerns

4. Bias in measurement of the outcome

4.1a Were outcome assessors aware that a trial was taking place?

Yes

4.1b If Y/PY/NI to 4.1: Were outcome assessors aware of the intervention received by study participants?

Yes

4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

Yes

Risk of bias judgement for measurement of the outcome

Some concerns

5. Bias in selection of the reported result

5.1 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.2 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk of bias for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

Some concerns

Overall Directness

Directly applicable

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Geiger, 2017

Bibliographic Reference Geiger, Friedemann; Liethmann, Katrin; Reitz, Daniela; Galalae, Razvan; Kasper, Jurgen; Efficacy of the doktormitSDM training module in supporting shared decision making - Results from a multicenter double-blind randomized controlled trial; Patient education and counseling; 2017; vol. 100 (no. 12); 2331-2338

Study details

| | |
|------------------------------|--|
| Study type | Randomised controlled trial (RCT) |
| Study location | Germany |
| Study setting | 6 hospitals across Germany. Units comprised of: stroke unit, multiple sclerosis outpatient ward, stem cell transplantation unit, clinics of dentistry, radiation oncology, surgery, neurosurgery, and three clinics of gynecology. |
| Study dates | 2011 - 2014 |
| Duration of follow-up | 3 months |
| Sources of funding | Tumor Center Kiel, Germany. |
| Inclusion criteria | Criteria 1 |

| | |
|---|--|
| | Participants were included from different medical specialties in six hospitals across Germany. |
| Exclusion criteria | None reported |
| Sample size | N= 144 |
| Split between study groups | Number of patients in each arm: N = 76 Number of doctors in each arm: N = 19 |
| Loss to follow-up | N = 0 |
| % Female | Intervention: 70% Control: 54% |
| Mean age (SD) | Intervention: 48.5 (15.6) Control: 44.8 (17.1) |
| Condition specific characteristics | Years of experience Mean (SD): Intervention: 8.6 (7), Control: 7.8 (6.5) |
| Outcome measures | SDMmass |

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2 **Study arms**

| | |
|--|---|
| | <p>doktormitSDM (N = 76)</p> <p>doktormitSDM aims to stimulate efforts to involve patients in the decision making process. It includes 1) a manual which comprehensively explain the idea of SDM according to the 15 SDM skills addressed by MAPPIN'SDM (Multifocal Approach to the 'Sharing' in SDM'). 2) A video tutorial showing a neurologist discussing a decision about immunotherapy with a patient. 3) Face-to-face feedback: feedback based on a MAPPIN'SDM assessment of their own consultation video.</p> |
|--|---|

Control (N = 76)

Did not receive doktormitSDM until after consultation 2.

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Domain 1: Bias arising from the randomisation process

1. 1. Was the allocation sequence random?

Yes

1. 2. Was the allocation sequence concealed until participants were enrolled and assigned to interventions?

Yes

1.3 Did baseline differences between intervention groups suggest a problem with the randomisation process?

No

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)

2.1. Were participants aware of their assigned intervention during the trial?

No

2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?

No

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?

Not applicable

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?

Not applicable

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?

Not applicable

2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?

Yes

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?

Not applicable

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low

Domain 3. Bias due to missing outcome data

3.1 Were data for this outcome available for all, or nearly all, participants randomised?

Yes

3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?

Not applicable

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?

Not applicable

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?

Not applicable

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?

Not applicable

Risk-of-bias judgement for missing outcome data

Low

Domain 4. Bias in measurement of the outcome

4.1 Was the method of measuring the outcome inappropriate?

No

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?

No

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?

No

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

Not applicable

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

Not applicable

Risk-of-bias judgement for measurement of the outcome

Low

Domain 5. Bias in selection of the reported result

5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ?

Yes

5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk-of-bias judgement for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

Low

Overall Directness

Directly applicable

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Goossens, 2020

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Bibliographic Reference Goossens, B.; Sevenants, A.; Declercq, A.; Van Audenhove, C.; Improving shared decision-making in advance care planning: Implementation of a cluster randomized staff intervention in dementia care; Patient Education and Counseling; 2020; vol. 103 (no. 4); 839-847

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Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

1 **Study details**

| | |
|------------------------------|---|
| Study type | Cluster randomised controlled trial Cluster RCT |
| Study location | Belgium |
| Study setting | Nursing homes |
| Study dates | NR |
| Duration of follow-up | 6 months |
| Sources of funding | This study is part of the Flemish Initiative for Networks for Dementia Research (VIND), a collaboration between KU Leuven and the University of Antwerp. The Flemish government agency for Innovation by Science and Technology supported the study with a grant [SBO IWT nr. 135043]. The King Baudouin Foundation supported the information campaign of the study [Malou Malou Fund np. ZKD0097]. The IWT and the King Baudouin Foundation exerted no influence on the design, execution, analysis and interpretation of the data. |
| Inclusion criteria | <p>Criteria 1 The ward unit must be focused on persons with dementia, or at least have a mixed population.</p> <p>Criteria 2 A minimum of 4 to a maximum of 6 ward staff members can participate.</p> <p>Criteria 3 At least one of these members must stem from either middle or executive management. This person must be directly involved with the participating ward (e.g. work there or coordinate tasks) and delegate all information and assessment requirements to the other members. These other participants can be either care or non-care professionals as long as they interact with the residents and their families on a regular basis. Enlisting wards enroll in both the training as well as the research module. The nursing home has not participated in 'We DECide', and will not participate in other ACP research for the duration of the training.</p> |
| Exclusion criteria | <p>Criteria 1 NR</p> |
| Sample size | 311 |
| Loss to follow-up | Int: 6 - High turnover of participants |

| | |
|------------------|---|
| | Ctrl: 7 - High turnover of participants |
| % Female | Int: 87,5% |
| | Ctrl: 87.4% |
| Mean age (SD) | Staff: |
| | Ctrl: 40.12 (11.68) |
| | Int: 42.06 (10.60) |
| Outcome measures | Outcome 1 |
| | IFC-SDM |
| | OPTION OPTION-12 |

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2 **Study arms**

We DECiDE optimized (N = 34)

Provides three steps to SDM: creating insight into the availability of multiple options (Choice Talk), providing information on these options (Option Talk) and discussing preferences while working towards a decision (Decision Talk). The intervention consisted of 2 workshops of 4 hours each, in which 3 modules were introduced, and was followed by implementation support. The two workshops were separated by one month. The modules were: (1) theoretical information on ACP and SDM, (2) role play exercises and (3) reviewing the internal ACP policy. A homework assignment between sessions let the participants practice the three-talk model during daily conversations with residents with dementia and their family members.

Control (N = 31)

No training

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| 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 <i>(Some missing recordings and reasons not clarified between the two arms. However, reasons for not recording conversations were 1) not receiving informed consent from the resident with dementia or family members, (2) absence of opportunity to discuss ACP due to no new admissions or crises, and (3) difficulties with recording the conversation. It was felt these reasons were not clearly linked to intervention and thus paper was scored low.)</i> |
| 4. Bias in measurement of the outcome | Risk of bias judgement for measurement of the outcome | Low |

| Section | Question | Answer |
|---|---|---------------------|
| 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 | Low |
| | Overall Directness | Directly applicable |

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Harris, 2009

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Bibliographic Reference Harris, Neil; Lovell, Karina; Day, Jennifer; Roberts, Christopher; An evaluation of a medication management training programme for community mental health professionals; service user level outcomes: A cluster randomised controlled trial; International Journal of Nursing Studies; 2009; vol. 46 (no. 5); 645-652

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5 Study details

| | |
|-----------------------|---|
| Study type | Cluster randomised controlled trial |
| Study location | UK |
| Study setting | community mental health professionals from NHS trusts |
| Study dates | NR |

| | |
|------------------------------|--|
| Duration of follow-up | 9 months |
| Sources of funding | North West Regional Training Fellowship |
| Inclusion criteria | Patients with various diagnosis (depression, anxiety and personality disorders). schizophrenia |
| Sample size | CHMP N = 56 Patient N = 169 |
| Loss to follow-up | Intervention = 16 patients Control = 30 patients |
| % Female | CHMP Intervention: 61% CHMP Control: 68% Patient intervention: 49% Patient control: 37% |
| Mean age (SD) | CHMP Intervention: 39 (+/- 7) CHMP Control: 40 (+/- 6) Patient intervention: 44 (+/- 13.8) Patient control: 41.4 (+/- 13.5) |

| | |
|---|--|
| Condition specific characteristics | Years of experience Intervention: 11 (7), Control 12 (6) |
| Outcome measures | Outcome 1 Global psychopathology KGV Outcome 2 Social functioning scale (SFS) Outcome 3 Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS) Outcome 4 Drug attitude inventory (DAI) (The Californian Psychopharmacology Alliance Scale (CALPAS) |

1

2 **Study arms**

| | |
|--|---|
| | <p>Medication management training (N = 88)</p> <p>10-day programme to enable CMHPs to learn evidence-based clinical skills which enhanced the safe and effective management of long-term antipsychotic medication</p> <p>Waiting list controls (N = 81)</p> |
|--|---|

3

4

1a. Bias arising from the randomisation process

1a. 1. Was the allocation sequence random?

No information

1a. 2. Is it likely that the allocation sequence was subverted?

Probably no

(Double randomised)

1a. 3. Were there baseline imbalances that suggest a problem with the randomisation process?

No

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

1b. 1. Were all the individual participants identified before randomisation of clusters (and if the trial specifically recruited patients were they all recruited before randomisation of clusters)?

Yes

1b. 2. If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention?

Not applicable

1b. 3. Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

No

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).

2.1a Were participants aware that they were in a trial?

Yes

2.1b If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?

Yes

(CMHP Yes Patients no)*

2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?

No

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?

Probably no

2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Not applicable

2.5a Were any clusters analysed in a group different from the one to which they were assigned?

No

2.5b Were any participants analysed in a group different from the one to which their original cluster was randomised?

No

2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?

Not applicable

Risk of bias judgement for deviations from intended interventions

Low

3. Bias due to missing outcome data

3.1a Were outcome data available for all, or nearly all, clusters randomised?

No

3.1b Were outcome data available for all, or nearly all, participants within clusters?

No

3.2 If N/PN/NI to 3.1a or 3.1b: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Probably Yes

(same number of clusters, happened to have different no. of patients. Reasons similar)

3.3 If N/PN/NI to 3.1a or 3.1b: Is there evidence that results were robust to the presence of missing outcome data?

Probably Yes

(It was recognised that some service users would withdraw or be lost to follow-up. Additional CMHPs were recruited, along with their study caseloads, to offset potential attrition and produce viable educational cohort sizes. (Unsure.))

Risk of bias judgement for missing outcome data

Some concerns

(Large amount of missing data and not clear analysis is robust enough to account for this.)

4. Bias in measurement of the outcome

4.1a Were outcome assessors aware that a trial was taking place?

Yes

4.1b If Y/PY/NI to 4.1: Were outcome assessors aware of the intervention received by study participants?

Yes

(it was reported that a number of service users preferred to complete the questionnaire with their CMHP, an unbiased response, therefore, cannot be assumed.)

4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

Yes

(it was reported that a number of service users preferred to complete the questionnaire with their CMHP, an unbiased response, therefore, cannot be assumed.)

Risk of bias judgement for measurement of the outcome

High

(Blinding of outcome assessment undermined by reports of service users completing assessments with CMHP)

5. Bias in selection of the reported result

5.1 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.2 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk of bias for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

High

Overall Directness

Directly applicable

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3

Henselmans, 2019

4

Bibliographic Reference

Henselmans, Inge; van Laarhoven, Hanneke W. M.; de Haes, Hanneke C. J. M.; Tokat, Meltem; Engelhardt, Ellen G.; van Maarschalkerweerd, Pomme E. A.; Kunneman, Marleen; Ottevanger, Petronella B.; Dohmen, Serge E.; Creemers, Geert-Jan; Sommeijer, Dirkje W.; de Vos, Filip Y. F. L.; Smets, Ellen M. A.; Training for Medical Oncologists on Shared Decision-Making About Palliative Chemotherapy: A Randomized Controlled Trial; *The oncologist*; 2019; vol. 24 (no. 2); 259-265

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Study details

| | |
|------------------------------|--|
| Study type | Randomised controlled trial (RCT) |
| Study location | Netherlands |
| Study setting | Medical oncology departments of three academic and three non-academic hospitals. |
| Study dates | Nov 2015 - Aug 2016 |
| Duration of follow-up | 4 months |

| | |
|---------------------------|--|
| Sources of funding | Dutch Cancer Society |
| Inclusion criteria | Oncologists and oncologists-in-training |
| Exclusion criteria | None reported |
| Sample size | N=31 |
| Loss to follow-up | None reported. |
| % Female | 74% |
| Mean age (SD) | 40.6 years (9.0) |
| Outcome measures | OPTION 4SDM Patient Satisfaction Questionnaire |

1

2 **Study arms**

| | |
|--|--|
| | <p>Training (N = 15)</p> <p>Standardized patient assessments (SPA) at baseline (T0) and in a second SPA after a period of 4 months (T1, after training). Oncologists filled out a questionnaire after each SPA. The training was based on a recent model of SDM [2] with four stages: (a) setting the SDM agenda, (b) informing about the options and pros/cons, (c) exploring patients' values and support preference construction, and (d) making or referring a decision in agreement. The training was provided in small groups (n53–6) by an experienced trainer (medical psychologist) in two sessions of 3.5 hours each with approximately 2 weeks in between.</p> |
|--|--|

Control (N = 16)
Continue standard practice

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2

1a. Bias arising from the randomisation process

1a. 1. Was the allocation sequence random?

Yes

1a. 2. Is it likely that the allocation sequence was subverted?

No

(Oncologists could not be blinded for their allocation.)

1a. 3. Were there baseline imbalances that suggest a problem with the randomisation process?

No

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

1b. 1. Were all the individual participants identified before randomisation of clusters (and if the trial specifically recruited patients were they all recruited before randomisation of clusters)?

No

(Oncologists were not blinded to intervention allocation.)

1b. 2. If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention?

No

1b. 3. Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

No

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).

2.1a Were participants aware that they were in a trial?

Yes

2.1b If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?

Yes

(Oncologists aware, patients unaware.)

2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?

No

(Two blind raters rated the video-recorded consultations.)

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?

Not applicable

2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Not applicable

2.5a Were any clusters analysed in a group different from the one to which they were assigned?

No

2.5b Were any participants analysed in a group different from the one to which their original cluster was randomised?

No

2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?

Not applicable

Risk of bias judgement for deviations from intended interventions

Some concerns

3. Bias due to missing outcome data

3.1a Were outcome data available for all, or nearly all, clusters randomised?

Yes

3.1b Were outcome data available for all, or nearly all, participants within clusters?

Yes

3.2 If N/PN/NI to 3.1a or 3.1b: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Not applicable

3.3 If N/PN/NI to 3.1a or 3.1b: Is there evidence that results were robust to the presence of missing outcome data?

Not applicable

Risk of bias judgement for missing outcome data

Low

4. Bias in measurement of the outcome

4.1a Were outcome assessors aware that a trial was taking place?

Yes

4.1b If Y/PY/NI to 4.1: Were outcome assessors aware of the intervention received by study participants?

No

4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

No

Risk of bias judgement for measurement of the outcome

Some concerns

5. Bias in selection of the reported result

5.1 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.2 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk of bias for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

Low

Overall Directness

Directly applicable

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Kravitz, 2018

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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

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Study details

| | |
|------------------------------|--|
| Study type | Randomised controlled trial (RCT) |
| 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 | <p>Criteria 1 18-75 years old</p> <p>Criteria 2 musculoskeletal pain for at least 6 weeks at the time of screening</p> <p>Criteria 3 has smartphone or tablet with a data plan Can read and speak english</p> <p>Criteria 4 score of 4 or higher out of 10 on at least 1 item of 3 item pain, enjoyment and general activity questionnaire.</p> |
| Exclusion criteria | <p>Criteria 1 Cancer treatment within the past 5 years</p> <p>Criteria 2 Life expectancy less than 2 years Psychological disorder (eg. dementia, memory loss, psychosis serious psychiatric condition Drug/alcohol abuse Evidence of drug or alcohol abuse.</p> |

| | |
|---|--|
| Sample size | 215 |
| Loss to follow-up | Intervention N = 4 Control N = 6 |
| % Female | 47% |
| Mean age (SD) | 55.5 years (+/- 11.1) |
| Condition specific characteristics | Clinician's specialty 21 general internists, 21 family physicians, 2 veteran affairs pain speciality physicians practicing in close association with primary care, 1 nurse practitioner, 2 physician assistants, 1 clinical pharmacist. |
| Outcome measures | Outcome 1 Pain interference, pain intensity Outcome 2 Global physical health, Global mental health, analgesic adherence Patient Satisfaction Questionnaire with pain information, with medical care, with pain medication. PROMIS 6 month PROMIS interference scale Medication related shared decision making only calculated in patients who reported discussing medications with their clinician in the past 12 months. Trust in clinician |

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2 **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.

3

Domain 1: Bias arising from the randomisation process

1. 1. *Was the allocation sequence random?*

Yes

1. 2. *Was the allocation sequence concealed until participants were enrolled and assigned to interventions?*

Yes

1.3 *Did baseline differences between intervention groups suggest a problem with the randomisation process?*

No

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)

2.1. *Were participants aware of their assigned intervention during the trial?*

Yes

2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?

Yes

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?

No/Probably no

(n of 1 trial conduct would be very similar in normal practice.)

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?

Not applicable

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?

Not applicable

2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?

Yes

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?

Not applicable

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low

(Unblinded but unlikely to occur differently in normal clinical practice.)

Domain 3. Bias due to missing outcome data

3.1 Were data for this outcome available for all, or nearly all, participants randomised?

No

3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?

Yes

(Model that accounts for missingness when the probability of missingness depends on the values of previous outcomes (gaussian models))

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?

Not applicable

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?

Not applicable

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?

Not applicable

Risk-of-bias judgement for missing outcome data

Low

(Analysis accounts for missingness of data)

Domain 4. Bias in measurement of the outcome

4.1 Was the method of measuring the outcome inappropriate?

Yes

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?

No

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?

Yes

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

Yes

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

No information

(Unclear whether measure patient recorded or third party recorded. Assume RoB)

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

5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ?

No

(One PROMIS analysis not prespecified but not key outcome for this review)

5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

(consistent timepoints)

5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data?

No information

Risk-of-bias judgement for selection of the reported result

Low

(for SDM outcome reporting, no concerns)

Overall bias and Directness

Risk of bias judgement

High

(not enough info about outcome to determine objectivity)

Overall Directness

Directly applicable

1

Kunneman, 2020

2

Bibliographic Reference

Kunneman, M.; Branda, M.E.; Hargraves, I.G.; Sivly, A.L.; Lee, A.T.; Gorr, H.; Burnett, B.; Suzuki, T.; Jackson, E.A.; Hess, E.; Linzer, M.; Brand-Mccarthy, S.R.; Brito, J.P.; Noseworthy, P.A.; Montori, V.M.; Assessment of Shared Decision-making for Stroke Prevention in Patients with Atrial Fibrillation: A Randomized Clinical Trial; JAMA Internal Medicine; 2020

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Study details

| | |
|-----------------------|---|
| Study location | Minnesota; Mississippi; Alabama, USA |
| Study setting | Emergency and inpatient hospital departments and outpatient safety-net, primary care, and cardiology clinics at US academic medical centers |
| Study dates | January 30, 2017 to June 27, 2019 |

| | |
|------------------------------|---|
| Duration of follow-up | Post-appointment and recordings |
| Sources of funding | NR |
| Inclusion criteria | <p>Criteria 1 Clinicians: All clinicians at the participating sites who regularly had conversations about anticoagulant treatment with patients with AF were eligible for participation.</p> <p>Criteria 2 Diagnosis of nonvalvular AF</p> <p>Criteria 3 High risk of experiencing a thromboembolic event</p> <p>Can read and speak english and understand informed consent document</p> <p>Aged 18 years or over</p> |
| Sample size | 922 |
| Loss to follow-up | <p>I: 12 with reasons</p> <p>C: 8 with reasons</p> |
| % Female | 39.4% |
| Mean age (SD) | 71 (11) |
| Outcome measures | <p>Outcome 1 Quality of SDM (Overall)</p> <p>Outcome 2 Subscale: communication (Consumer Assessment of Healthcare Providers and Systems Clinician and Group Survey) Each item was coded as yes (definitely or somewhat) or no.</p> <p>Decisional Conflict (DC) score range, 0-100, with higher scores indicating greater decisional conflict</p> <p>OPTION OPTION-12</p> |

Patient Satisfaction Questionnaire

Participants indicated, on a 7-point Likert scale (with higher scores indicating stronger recommendation), the extent to which they would recommend the approach used in the encounter to other patients and clinicians.

Clinician satisfaction

Clinicians indicated, on a 5-point Likert scale (with higher scores indicating greater satisfaction), the extent to which they were satisfied with their conversation with the patient. Each question was converted to a binary response of strongly recommend (6-7 points) or completely satisfied (4-5 points), respectively

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2 **Study arms**

Anticoagulation choice shared decision making tool (N = 463)

This tool is a freely available online conversation aid that is designed for use within the encounter.^{19,20} The tool calculates the patient's risk of stroke using the CHA₂DS₂-VASc score²¹ and provides the patient's individualized risk of experiencing stroke at 1 year or 5 years, with and without anticoagulant treatment, using natural frequency expressions (eg, "out of 100 people like you") and 100-person pictographs that illustrate the proportion of people experiencing non disabling strokes, disabling or fatal strokes, or no such events. The tool then supports the comparison of available anticoagulant treatment options (ie, warfarin and DOAC medications) across patient-important issues, such as how to use the medications, the need for periodic monitoring, the reversibility of anticoagulant treatment, the estimated out-of-pocket costs, and the association of lifestyle or medical factors with the risk of bleeding (using the HAS-BLED [hypertension, abnormal kidney or liver function, stroke, bleeding, labile international normalized ratio, elderly age (>65 years), and drug or alcohol use] estimator; score range, 0-9, with higher scores indicating higher risk²²). The tool offers a patient report and tailored text that can be copied into the clinical note to document the conversation and the decision.

Standard care (N = 459)

clinical encounters were conducted according to the clinicians' usual approach

3

| Section | Question | Answer |
|--|--|----------------|
| Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention) | 2.1. Were participants aware of their assigned intervention during the trial? | Yes |
| | 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? | Yes |
| | 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? | No/Probably no |
| | 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? | Not applicable |
| | 2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome? | Not applicable |
| | 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? | Yes |
| | 2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? | Not applicable |
| | Risk of bias for deviations from the intended interventions (effect of assignment to intervention) | Low |
| Domain 3. Bias due to missing outcome data | 3.1 Were data for this outcome available for all, or nearly all, participants randomised? | No |
| | 3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data? | Probably no |

| Section | Question | Answer |
|--|--|--|
| | 3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value? | Probably no |
| | 3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups? | Not applicable |
| | 3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? | Not applicable |
| | Risk-of-bias judgement for missing outcome data | Low |
| Domain 4. Bias in measurement of the outcome | 4.1 Was the method of measuring the outcome inappropriate? | No |
| | 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ? | Probably no |
| | 4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ? | Yes |
| | 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? | Probably no |
| | 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? | Probably no |
| | Risk-of-bias judgement for measurement of the outcome | Low <i>(Low in objective/some concerns or high in subjective)</i> |

| Section | Question | Answer |
|--|---|---------------------|
| Domain 5. Bias in selection of the reported result | 5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ? | Yes |
| | 5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? | No/Probably no |
| | 5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data? | No/Probably no |
| | Risk-of-bias judgement for selection of the reported result | Low |
| Overall bias and Directness | Risk of bias judgement | Low |
| | Overall Directness | Directly applicable |

1

Mertz, 2020

2

Bibliographic Reference Mertz, K.; Shah, R.F.; Eppler, S.L.; Yao, J.; Safran, M.; Palanca, A.; Hu, S.S.; Gardner, M.; Amanatullah, D.F.; Kamal, R.N.; 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; 2020; 272989x20943520

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5 Study details

| | |
|-------------------|-----------------------------------|
| Study type | Randomised controlled trial (RCT) |
|-------------------|-----------------------------------|

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

| | |
|------------------------------|--|
| Study location | California, USA |
| Study setting | multispecialty orthopedic surgery clinic |
| Study dates | July 2018 to November 2018 |
| Duration of follow-up | same day |
| Sources of funding | Financial support for this study was provided in part by a grant from the National Institutes of Health (Mentored Patient-Oriented Research Career Development Award [K23AR073307]). |
| Inclusion criteria | Can read and speak english and can provide informed consent Aged 18 years or over |
| Sample size | 105 |
| Loss to follow-up | None (some incomplete questionnaires [4 control, 5 intervention.]) |
| % Female | Control: 53.1% Intervention: 53.5% |
| Mean age (SD) | Control: 51.76 (19.85) Intervention: 54.11 (17.40) |
| Outcome measures | Outcome 1 PROM SDM: Perceived involvement in care scale (PICS) |

1

2 Study arms

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Goal elicitation worksheet (N = 46)

The goal elicitation tool asked the patient to list 3 goals for their consultation that day. + Demographics questionnaire

Control (N = 50)

Demographics questionnaire only

1

| Section | Question | Answer |
|--|--|----------------|
| Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention) | 2.1. Were participants aware of their assigned intervention during the trial? | Yes |
| | 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? | Yes |
| | 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? | No/Probably no |
| | 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? | Not applicable |
| | 2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome? | Not applicable |
| | 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? | Yes |
| | 2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? | Not applicable |

| Section | Question | Answer |
|--|--|--------|
| | Risk of bias for deviations from the intended interventions (effect of assignment to intervention) | Low |
| Domain 3. Bias due to missing outcome data | 3.1 Were data for this outcome available for all, or nearly all, participants randomised? | No |
| | 3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data? | No |
| | 3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value? | Yes |
| | 3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups? | No |
| | 3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? | No |
| | Risk-of-bias judgement for missing outcome data | Low |
| Domain 4. Bias in measurement of the outcome | 4.1 Was the method of measuring the outcome inappropriate? | No |
| | 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ? | No |
| | 4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ? | Yes |
| | 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? | Yes |
| | 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? | Yes |

| Section | Question | Answer |
|--|---|--|
| | Risk-of-bias judgement for measurement of the outcome | High <i>(subjective unblinded outcome)</i> |
| Domain 5. Bias in selection of the reported result | 5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ? | No information |
| | 5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? | No information |
| | 5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data? | No information |
| | Risk-of-bias judgement for selection of the reported result | Some concerns <i>(No mention of protocol)</i> |
| Overall bias and Directness | Risk of bias judgement | High <i>(Subjective unblinded outcome.)</i> |
| | Overall Directness | Directly applicable |

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Metz, 2019

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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

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Study details

| | |
|------------------------------|---|
| Study type | Cluster randomised controlled trial Two-arm match-paired cluster RCT. |
| Study location | Netherlands |
| Study setting | Multi-center: 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 |
| Inclusion criteria | Criteria 1 Teams (in centers) which are participating in the Dutch Breakthrough ROM network (project). |
| Exclusion criteria | Criteria 1 Not able to speak and read Dutch. Criteria 2 No consent given. |

| | |
|---|---|
| Sample size | 186 |
| Split between study groups | Intervention: 94 patients Control: 92 patients |
| Loss to follow-up | Intervention: 13 patients Control: 15 patients |
| % Female | 59% in total study population |
| Mean age (SD) | 47.2 (18.0) |
| Condition specific characteristics | Primary diagnosis Depressive disorder (25.8%), Personality disorder (20.4%), Psychotic disorder (17.2%), Anxiety disorder (14.5%), Bipolar disorder (12.9%), other (9.1%). |
| Outcome measures | Decisional Conflict (DC) Working Alliance Inventory Outcome Questionnaire (OQ-45) Manchester Short Quality of Life Measurement (MANSA-VN-16) |

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2 **Study arms**

| | |
|--|---|
| | <p>Shared decision making using Routine Outcome Monitoring (SDMR) (N = 94)</p> <p>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.</p> |
|--|---|

Control (N = 92)

No further information provided.

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1a. Bias arising from the randomisation process

1a. 1. Was the allocation sequence random?

Yes

1a. 2. Is it likely that the allocation sequence was subverted?

No

1a. 3. Were there baseline imbalances that suggest a problem with the randomisation process?

No

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

1b. 1. Were all the individual participants identified before randomisation of clusters (and if the trial specifically recruited patients were they all recruited before randomisation of clusters)?

No

1b. 2. If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention?

Yes

(Blinding of the clinicians and patients was not possible.)

1b. 3. Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

No

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).

2.1a Were participants aware that they were in a trial?

Yes

2.1b If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?

Yes

2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?

Yes

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?

No information

2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Not applicable

2.5a Were any clusters analysed in a group different from the one to which they were assigned?

No

2.5b Were any participants analysed in a group different from the one to which their original cluster was randomised?

No
2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?

Not applicable

Risk of bias judgement for deviations from intended interventions

Some concerns

3. Bias due to missing outcome data

3.1a Were outcome data available for all, or nearly all, clusters randomised?

Yes

3.1b Were outcome data available for all, or nearly all, participants within clusters?

Yes

3.2 If N/PN/NI to 3.1a or 3.1b: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Not applicable

3.3 If N/PN/NI to 3.1a or 3.1b: Is there evidence that results were robust to the presence of missing outcome data?

Not applicable

Risk of bias judgement for missing outcome data

Low

4. Bias in measurement of the outcome

4.1a Were outcome assessors aware that a trial was taking place?

Yes

4.1b If Y/PY/NI to 4.1: Were outcome assessors aware of the intervention received by study participants?

Yes

4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

Yes

Risk of bias judgement for measurement of the outcome

High

5. Bias in selection of the reported result

5.1 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.2 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk of bias for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

Some concerns

Overall Directness

Directly applicable

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Metz, 2018

Bibliographic Reference Metz, Margot; Elfeddali, Iman; Veerbeek, Marjolein; de Beurs, Edwin; Beekman, Aartjan; van der Feltz-Cornelis, Christina; Effectiveness of a multi-faceted 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; 2018; vol. 13 (no. 6); e0199795

Study details

| | |
|------------------------------|--|
| Study type | Cluster randomised controlled trial Matched-pair cluster RCT |
| Study location | Netherlands |
| Study setting | Four outpatient departments of a specialist mental health care organisation (GGz Breburg). |
| Study dates | Oct 2016 - Aug 2017 |
| Duration of follow-up | 2 months |
| Sources of funding | GGz Brezburg |
| Inclusion criteria | Patients with various diagnosis (depression, anxiety and personality disorders). |

| | |
|---------------------------|---|
| Exclusion criteria | Did not speak or read Dutch Could not complete questionnaires due to cognitive functioning or ongoing crisis. |
| Sample size | N=200 |
| Loss to follow-up | 13% (N= 11 intervention and N=14 control) |
| % Female | 66% |
| Mean age (SD) | 38.3 years (10.2) |
| Outcome measures | 9 item shared decision making questionnaire (SDM-Q-9) Decisional Conflict (DC) Patient Participation Questionnaire (PPQ) Patient-Doctor Relationship Questionnaire-9 |

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2 **Study arms**

| | |
|--|---|
| | <p>Shared Decision Making Digital Intake (SDM-DI) (N = 94)</p> <p>A digital intake approach incorporating a blended eHealth intervention integrated with Routine Outcome Monitoring (ROM), support of peer workers and training of clinicians. Process involved 2 eHealth modules to explore treatment needs, expectations and preferences of patients aiming to support patients in preparing themselves, along with relatives, for the intake consultations.</p> |
| | <p>Intake as Usual (IAU) (N = 106)</p> <p>A single ROM measurement and no eHealth intervention, peer support or training of clinicians.</p> |

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1a. Bias arising from the randomisation process

1a. 1. Was the allocation sequence random?

Yes

(Computer-generated random numbers, per block of 2 intake teams.)

1a. 2. Is it likely that the allocation sequence was subverted?

No

(Blinding of the clinicians and patients was not feasible.)

1a. 3. Were there baseline imbalances that suggest a problem with the randomisation process?

No

Risk of bias judgement for the randomisation process

Some concerns

1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation

1b. 1. Were all the individual participants identified before randomisation of clusters (and if the trial specifically recruited patients were they all recruited before randomisation of clusters)?

Yes

1b. 2. If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention?

Not applicable

1b. 3. Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

No

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).

2.1a Were participants aware that they were in a trial?

No information

2.1b If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?

Yes

2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?

No

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?

Not applicable

2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Not applicable

2.5a Were any clusters analysed in a group different from the one to which they were assigned?

No

2.5b Were any participants analysed in a group different from the one to which their original cluster was randomised?

No

2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?

Not applicable

Risk of bias judgement for deviations from intended interventions

Low

3. Bias due to missing outcome data

3.1a Were outcome data available for all, or nearly all, clusters randomised?

Yes

3.1b Were outcome data available for all, or nearly all, participants within clusters?

Yes

3.2 If N/PN/NI to 3.1a or 3.1b: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Not applicable

3.3 If N/PN/NI to 3.1a or 3.1b: Is there evidence that results were robust to the presence of missing outcome data?

Not applicable

Risk of bias judgement for missing outcome data

Low

4. Bias in measurement of the outcome

4.1a Were outcome assessors aware that a trial was taking place?

Yes

4.1b If Y/PY/NI to 4.1: Were outcome assessors aware of the intervention received by study participants?

No

(The independent research assistants were blinded to the allocation of the condition.)

4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

Not applicable

Risk of bias judgement for measurement of the outcome

Some concerns

5. Bias in selection of the reported result

5.1 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.2 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk of bias for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

Some concerns

Overall Directness

Directly applicable

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Oddone, 2018

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Bibliographic Reference Oddone EZ; Gierisch JM; Sanders LL; Fagerlin A; Sparks J; McCant F; May C; Olsen MK; Damschroder LJ; A Coaching by Telephone Intervention on Engaging Patients to Address Modifiable Cardiovascular Risk Factors: a Randomized Controlled Trial.; Journal of general internal medicine; 2018; vol. 33 (no. 9)

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4 Study details

| | |
|------------------------------|--|
| Study type | Randomised controlled trial (RCT) |
| Study location | North Carolina, USA |
| Study setting | Primary care clinics at 3 Veterans Affairs facilities |
| Study dates | November 2014 - May 2016. |
| Duration of follow-up | 6 months |
| Sources of funding | Department of Veterans Affairs, Health Services Research and Development Service |
| Inclusion criteria | Criteria 1 Current smoker of cigarettes or other tobacco Criteria 2 |

| | |
|---------------------------|---|
| | <p>Current smoker of cigarettes or other tobacco</p> <p>Criteria 3</p> <p>BMI \geq 30, n (%)</p> <p>Criteria 4</p> <p>Physical activity < 150 min per week, n (%)</p> |
| Exclusion criteria | <p>Criteria 1</p> <p>Severely hearing impaired or</p> <p>Criteria 2</p> <p>serious/terminal illness as indicated by referral to hospice or palliative care</p> <p>Cannot read or speak english</p> <p>Psychological disorder (eg. dementia, memory loss, psychosis dementia or other memory loss condition, active diagnosis of psychosis, seirous personality disorder, uncontrolled substance abuse disorder</p> <p>No access to telephone</p> <p>Nursing home resident</p> <p>Criteria 4</p> <p>participating in a prevention program or another VA study within the last 6 months</p> |
| Sample size | 417 |
| Loss to follow-up | Intervention: N = 31 |

| | |
|-------------------------|--|
| | Control: N = 10 |
| % Female | 14.6% |
| Mean age (SD) | 55.8 (+/- 12.2) |
| Outcome measures | Outcome 1 cumulative enrollment in prevention programs by 6-month assessment Outcome 2 Framingham Risk Score (FRS). Patient activation measure (PAM) |

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2 **Study arms**

| | |
|--|---|
| | <p>HEalth risk assessment + health coaching (N = 208)</p> <p>HRA + Two telephone delivered health coaching calls at 1 and 4 weeks to collaboratively set goals to enroll in, and attend structured prevention programs designed to reduce modifiable risk factors.</p> <p>Health risk assessment (N = 209)</p> <p>HRA alone</p> |
|--|---|

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Domain 1: Bias arising from the randomisation process

1. 1. *Was the allocation sequence random?*

Yes

(The randomization scheme was created by a statistician prior to study start and included a block size of four and was stratified by region (Michigan and North Carolina).)

1. 2. *Was the allocation sequence concealed until participants were enrolled and assigned to interventions?*

Yes

(Research assistants were blinded to block size and did not have access to the group assignment until after participants completed their baseline survey and outcome assessments.)

1.3 *Did baseline differences between intervention groups suggest a problem with the randomisation process?*

No

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)

2.1. *Were participants aware of their assigned intervention during the trial?*

Yes

2.2. *Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?*

Yes

2.3. *If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?*

No/Probably no

(Deviations similar to real world setting)

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?

Not applicable

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?

Not applicable

2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?

Yes

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?

Not applicable

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low

Domain 3. Bias due to missing outcome data

3.1 Were data for this outcome available for all, or nearly all, participants randomised?

Yes

3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?

No

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?

Yes

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?

Yes

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?

Yes

(Health coaching via phone call could potentially put some people off of treatment (over invasive?))

Risk-of-bias judgement for missing outcome data

High

(Large discrepancy between intervention and control dropouts and true value of these dropouts not provided.)

Domain 4. Bias in measurement of the outcome

4.1 Was the method of measuring the outcome inappropriate?

No

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?

No

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?

Probably no

(At 6 month limitation listed as outcome assessors not being blinded at 6 mo.)

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

Yes

(Potentially objective PAM but not blinded)

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

No

Risk-of-bias judgement for measurement of the outcome

High

(PROM PAM with lack of blinding? (Ask committee))

Domain 5. Bias in selection of the reported result

5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ?

No information

5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk-of-bias judgement for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

High

(Missing outcome data imbalanced between groups. Lack of blinding on a potentially patient reported outcome PAM.)

Overall Directness

Directly applicable

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Probst, 2020

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Bibliographic Reference Probst, M.A.; Lin, M.P.; Sze, J.J.; Hess, E.P.; Breslin, M.; Frosch, D.L.; Sun, B.C.; Langan, M.-N.; Thiruganasambandamoorthy, V.; Richardson, L.D.; Shared Decision Making for Syncope in the Emergency Department: A Randomized Controlled Feasibility Trial; Academic Emergency Medicine; 2020

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Study details

| | |
|------------------------------|---|
| Study type | Randomised controlled trial (RCT) |
| Study location | USA |
| Study setting | Urban, academic emergency department in a tertiary care medical center |
| Study dates | January 2017 to January 2019 |
| Duration of follow-up | 30 days |
| Sources of funding | Career Development Grant from the National Institutes of Health |
| Inclusion criteria | <p>Criteria 1 Adults (\geq 30 years)</p> <p>Criteria 2 presented with syncope</p> <p>Criteria 3 deemed appropriate for SDM by the treating attending physician</p> |
| Exclusion criteria | <p>Criteria 1 Major communication barrier (e.g., significant visual or auditory impairment, altered mental status)</p> <p>Criteria 2 lack of fixed address and telephone number</p> |

| | |
|--------------------------|---|
| | <p>Cannot read or speak english</p> <p>Criteria 4 serious diagnosis identified in the ED, as determined by the treating clinician</p> <p>Criteria 5 inappropriate for observation care based on their risk profile (e.g., too low risk to be offered observation care or too high risk to be offered direct discharge from ED)</p> <p>Criteria 6 not appropriate for SDM based clinical variables (e.g., dementia, altered mental status, intoxication, other disease process requiring admission)</p> |
| Sample size | 51 |
| Loss to follow-up | 6 |
| % Female | <p>Ctrl: 65%</p> <p>Int: 50%</p> |
| Mean age (SD) | <p>Ctrl: 60 (47.8 - 73)</p> <p>Int: 54.4 (45.3-70)</p> |
| Outcome measures | <p>Outcome 1 subjective numeracy scale</p> <p>Outcome 2 short literacy survey</p> <p>OPTION OPTION-5</p> <p>Control Preferences Scale (CPS)</p> |

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2 **Study arms**

SyncopeDA (N = 25)

a paper-based, personalized, syncope patient decision aid (SynDA). Briefly, the tool uses simple language to explain what syncope is, what potential underlying conditions are still possible, what the patient’s risk of a 30-day serious medical event is, and what the possible disposition options are (i.e., direct discharge with primary care provider follow-up, direct discharge with cardiology followup, or admit to the observation unit). Tool differed depending on risk score.

Control (N = 26)

standard care

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| Section | Question | Answer |
|--|---|----------------|
| Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention) | 2.1. Were participants aware of their assigned intervention during the trial? | Yes |
| | 2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? | Yes |
| | 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? | No/Probably no |
| | 2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups? | Not applicable |
| | 2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome? | Not applicable |
| | 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? | Yes |

| Section | Question | Answer |
|--|--|----------------|
| | 2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? | Not applicable |
| | Risk of bias for deviations from the intended interventions (effect of assignment to intervention) | Low |
| Domain 3. Bias due to missing outcome data | 3.1 Were data for this outcome available for all, or nearly all, participants randomised? | No |
| | 3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data? | No |
| | 3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value? | Probably yes |
| | 3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups? | No |
| | 3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? | No |
| | Risk-of-bias judgement for missing outcome data | Low |
| Domain 4. Bias in measurement of the outcome | 4.1 Was the method of measuring the outcome inappropriate? | No |
| | 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ? | Yes |
| | 4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ? | Yes |
| | 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? | Probably no |

| Section | Question | Answer |
|--|---|---|
| | 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? | Probably no |
| | Risk-of-bias judgement for measurement of the outcome | Low <i>(Low for OPTION outcome, high for others)</i> |
| Domain 5. Bias in selection of the reported result | 5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ? | Yes |
| | 5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain? | No/Probably no |
| | 5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data? | No/Probably no |
| | Risk-of-bias judgement for selection of the reported result | Low |
| Overall bias and Directness | Risk of bias judgement | Low |
| | Overall Directness | Directly applicable |

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Bibliographic Reference Raue, Patrick J.; Schulberg, Herbert C.; Bruce, Martha L.; Banerjee, Samprit; Artis, Amanda; Espejo, Maria; Catalan, Idalia; Romero, Sara; Effectiveness of Shared Decision-Making for Elderly Depressed Minority Primary Care Patients; The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry; 2019; vol. 27 (no. 8); 883-893

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Study details

| | |
|------------------------------|--|
| Study type | Randomised controlled trial (RCT) |
| Study location | New York City, USA |
| Study setting | Mental Health Center |
| 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 Can read and speak english And Spanish |

| | |
|---------------------------|--|
| | Can read and speak Spanish English or Spanish not both |
| 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 Satisfaction with decision making scale Wills CE, Rovner MH: Preliminary validation of the Satisfaction with Decision scale with depressed primary care patients. Health Expect 2003; 6:149–159 |

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2 **Study arms**

| | |
|--|--|
| | SDM (N = 22) 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 = 23) physicians engaged patients in depression treatment decisions as part of routine care |

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4

Domain 1: Bias arising from the randomisation process

1. 1. *Was the allocation sequence random?*

No information

1. 2. *Was the allocation sequence concealed until participants were enrolled and assigned to interventions?*

No information

1.3 *Did baseline differences between intervention groups suggest a problem with the randomisation process?*

No

Risk of bias judgement for the randomisation process

High

(No information on how randomization took place)

Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

2.1. Were participants aware of their assigned intervention during the trial?

Yes

2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?

Yes

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?

No/Probably no

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?

Not applicable

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?

Not applicable

2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?

Yes

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?

Not applicable

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

3.1 Were data for this outcome available for all, or nearly all, participants randomised?

No

3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?

No

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?

Yes

(Lack of SDM in this setting could lead to attrition bias)

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?

No

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?

No

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

4.1 Was the method of measuring the outcome inappropriate?

Yes

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?

No

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?

Yes

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

Yes

(Patient reported outcome measure with RA present?)

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

No

Risk-of-bias judgement for measurement of the outcome

High

(PROM? .For committee)

Domain 5. Bias in selection of the reported result

5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ?

No information

5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk-of-bias judgement for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

High

(Lack of data on randomization, patient reported? outcome.)

Overall Directness

Directly applicable

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Shirk, 2017

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Bibliographic Reference

Shirk, Joseph D.; Crespi, Catherine M.; Saucedo, Josemanuel D.; Lambrechts, Sylvia; Dahan, Ely; Kaplan, Robert; Saigal, Christopher; Does Patient Preference Measurement in Decision Aids Improve Decisional Conflict? A Randomized Trial in Men with Prostate Cancer; The patient; 2017; vol. 10 (no. 6); 785-798

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Study details

| | |
|------------------------------|--|
| Study type | Randomised trial |
| Study location | Los Angeles, USA |
| Study setting | Veterans Affairs (VA) Medical Center urology clinic and UCLA medical centre. |
| Study dates | January 2011 - May 2015. |
| Duration of follow-up | Prior and post clinical-visit |

| | |
|---------------------------|---|
| Sources of funding | National Institutes of Health. |
| Inclusion criteria | Criteria 1 Positive prostate cancer biopsy.. Can read and speak english |
| Exclusion criteria | None reported |
| Sample size | 130 |
| Loss to follow-up | NR |
| % Female | NR |
| Mean age (SD) | Intervention: 63 ears (+/- 7) Control: 64 years (+/- 5) |
| Outcome measures | Outcome 1 Prostate Cancer Knowledge Survey Outcome 2 Service Satisfaction Scale for Cancer Care Decisional Conflict (DC) 11 item SDM questionnaire - SDM-Q-11 patient treatment preferences |

1 **Study arms**

Software-based preference assessment in addition to the brochure. (N = 59)

educational brochure followed by preference assessment using a software program that used discrete-choice experiments to measure preferences for key outcomes

Education with a brochure about prostate cancer treatment. (N = 63)

brochure titled Making the Choice: Deciding What to Do About Early Stage Prostate Cancer provides facts about their disease, treatment choices, and possible results in appropriate language,

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Domain 1: Bias arising from the randomisation process

1. 1. Was the allocation sequence random?

No information

1. 2. Was the allocation sequence concealed until participants were enrolled and assigned to interventions?

No information

1.3 Did baseline differences between intervention groups suggest a problem with the randomisation process?

No

Risk of bias judgement for the randomisation process

Some concerns

(No information available on how patients were randomised.)

Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

2.1. *Were participants aware of their assigned intervention during the trial?*

Yes

2.2. *Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?*

Yes

2.3. *If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?*

No/Probably no

(Subtle interventions, unlikely to be large desire to switch from patients.)

2.4. *If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?*

Not applicable

2.5 *If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?*

Not applicable

2.6 *Was an appropriate analysis used to estimate the effect of assignment to intervention?*

Yes

2.7 *If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?*

Not applicable

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low

Domain 3. Bias due to missing outcome data

3.1 Were data for this outcome available for all, or nearly all, participants randomised?

Yes

3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?

Not applicable

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?

Not applicable

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?

Not applicable

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?

Not applicable

Risk-of-bias judgement for missing outcome data

Low

Domain 4. Bias in measurement of the outcome

4.1 Was the method of measuring the outcome inappropriate?

Yes

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?

No

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?

Yes

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

Yes

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

Yes

(Patient or clinician recorded subjective outcome measure more at risk than objective measures,)

Risk-of-bias judgement for measurement of the outcome

High

(High risk for objective measures.)

Domain 5. Bias in selection of the reported result

5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ?

No information

5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk-of-bias judgement for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

High

(concerns about randomisation. Subjective outcome measures.)

Overall Directness

Directly applicable

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Woltmann, 2011

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Bibliographic Reference Woltmann, Emily; M Wilkniss, Sandra; Teachout, Alexandra; Mchugo, Gregory; E Drake, Robert; Trial of an Electronic Decision Support System to Facilitate Shared Decision Making in Community Mental Health; Psychiatric services (Washington, D.C.); 2011; vol. 62; 54-60

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5 **Study details**

| | |
|-----------------------|---|
| Study type | Cluster randomised controlled trial Case managers from three clinics were randomly assigned to the intervention group or treatment as usual. Clients were assigned to the same group to which their case manager was assigned. |
| Study location | USA |
| Study setting | 3 urban community mental health sites |
| Study dates | September 2008 - January 2009 |

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|---|---|
| Duration of follow-up | 6 months |
| Sources of funding | West Family Foundation, Segal Family Foundation. |
| Inclusion criteria | None reported |
| Exclusion criteria | None reported |
| Sample size | Case managers N= 19 Patients N = 80 |
| Split between study groups | Case managers: EDSS = 10, Control = 9 |
| Loss to follow-up | NR |
| % Female | Case managers: EDSS = 80%, Control = 9% Patients: EDSS = 38%, Control = 30% |
| Mean age (SD) | Case managers: EDSS = 47 (+/- 2), Control = 31 (+/- 7) Patients: EDSS = 47 (+/- 9), Control = 46 (+/- 11) |
| Condition specific characteristics | Years of experience At clinic: EDSS = 7(+/-5), Control = 3(+/-2). In mental health field: EDSS = 12 (+/- 10), Control = (5 +/- 4) |
| Outcome measures | Outcome 1 case manager satisfaction measure asks case managers to rate their satisfaction with each care planning encounter, instead of their overall satisfaction with the care planning process. |

Patient Satisfaction Questionnaire

seven statements rated by the client on a 5- point Likert scale, ranging from 1, strongly disagree, to 5, strongly agree; higher summary scores indicate more satisfaction. Based on the literature regarding what makes clients satisfied with a mental health encounter, the items were designed to assess case manager–client communication, involvement in decision making, being informed about decisions that were made, and having a clear management plan

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2 **Study arms**

Electronic decision support systems (EDSSs) (N = 40)

First, clients indicate their top priorities and ideas for services at a touchscreen-enabled computer kiosk. Second, the information is electronically sent to the clients' case managers, who then complete a similar process. Finally, the two perspectives are merged electronically and presented graphically in a shared decision-making session with the dyad.

Control (N = 40)

Clients who were assigned to receive usual care planning met with their case managers at the time that their six-month care plans were due. Case managers and clients were told to complete their care plans in the way that they normally would. use of a behavioural health electronic medical record designed to aid with billing and to theoretically help case managers create recovery-oriented care plans.

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1a. Bias arising from the randomisation process

1a. 1. Was the allocation sequence random?

No information

1a. 2. Is it likely that the allocation sequence was subverted?

No

1a. 3. Were there baseline imbalances that suggest a problem with the randomisation process?

Yes

(Clients in the intervention and control groups were balanced on all variables except for length of time working with the case manager, which is related to the randomization failure on case manager age.)

Risk of bias judgement for the randomisation process

High

(Clients in the intervention and control groups were balanced on all variables except for length of time working with the case manager, which is related to the randomization failure on case manager age.)

1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation

1b. 1. Were all the individual participants identified before randomisation of clusters (and if the trial specifically recruited patients were they all recruited before randomisation of clusters)?

Yes

1b. 2. If N/PN/NI to 1b.1: Is it likely that selection of individual participants was affected by knowledge of the intervention?

Not applicable

1b. 3. Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

Yes

(Larger amount of experience in EDSS arm than Control arm. Could affect implementation of intervention.)

Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation

High

(Larger amount of experience in EDSS arm than Control arm. Could affect implementation of intervention.)

2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).

2.1a Were participants aware that they were in a trial?

Yes

2.1b If Y/PY/NI to 2.1a: Were participants aware of their assigned intervention during the trial?

Yes

2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?

Yes

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?

Probably no

(Deviations to EDSS likely to be similar in real-world)

2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Not applicable

2.5a Were any clusters analysed in a group different from the one to which they were assigned?

No

2.5b Were any participants analysed in a group different from the one to which their original cluster was randomised?

No

2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?

Not applicable

Risk of bias judgement for deviations from intended interventions

Low

3. Bias due to missing outcome data

3.1a Were outcome data available for all, or nearly all, clusters randomised?

Yes

3.1b Were outcome data available for all, or nearly all, participants within clusters?

Yes

3.2 If N/PN/NI to 3.1a or 3.1b: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Not applicable

3.3 If N/PN/NI to 3.1a or 3.1b: Is there evidence that results were robust to the presence of missing outcome data?

Not applicable

Risk of bias judgement for missing outcome data

Low

4. Bias in measurement of the outcome

4.1a Were outcome assessors aware that a trial was taking place?

Yes

4.1b If Y/PY/NI to 4.1: Were outcome assessors aware of the intervention received by study participants?

Yes

(recorded interviews, will have seen intervention)

4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

Yes

(Subjective outcomes)

Risk of bias judgement for measurement of the outcome

High

(Subjective SDM outcomes with unblinded participants)

5. Bias in selection of the reported result

5.1 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

5.2 Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

Risk of bias for selection of the reported result

Low

Overall bias and Directness

Risk of bias judgement

High

(Subjective unblinded SDM outcome and major concerns around failure of randomisation of clusters.)

Overall Directness

Directly applicable

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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

| | |
|------------------------------|--|
| Study type | Randomised controlled trial (RCT) Pilot RCT |
| 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 | <p>Criteria 1 regularly received medical care from one of the four participating doctors at the two sites,</p> <p>Criteria 2 received services from case managers in either a psychiatric day care or visiting nurse program</p> <p>Criteria 3 age 20 years or older</p> |
| Exclusion criteria | <p>Criteria 1 primary ICD-10 diagnosis of substance abuse, dementia, or neurotic disorder</p> |
| Sample size | N=43 |
| Loss to follow-up | 1.7% (N=1 intervention) |
| % Female | <p>38.5% N=10 intervention</p> <p>44.5% N=12 control</p> |
| Mean age (SD) | <p>39.38 (± 11.60) intervention</p> <p>38.19 (± 9.45) control</p> |
| Outcome measures | <p>Outcome 1 clinical outcomes (weight, symptoms, overall functioning, medication side effects and adherence, service satisfaction)</p> <p>Outcome 2 related outcomes (quality of life, recovery stage).</p> |

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|--|---|
| | <p>decision support centre fidelity scale</p> <p>The scale consisted of 13 items, with scores ranging from 13 to 65. Higher scores indicated closer adherence to the CommonGround approach.</p> <p>SDM-18</p> <p>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.</p> <p>STAR-Clinician</p> <p>STAR-Patient</p> <p>IPC</p> <p>Interpersonal Processes of Care Survey Short Form</p> <p>Patient activation measure (PAM)</p> |
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2 **Study arms**

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

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Domain 1: Bias arising from the randomisation process

1. 1. *Was the allocation sequence random?*

Yes

(random permuted blocks with a block size of four and stratified by site using Stata version 12.)

1. 2. *Was the allocation sequence concealed until participants were enrolled and assigned to interventions?*

No

(A researcher not involved in the interventions, assessments, or data analysis generated random permuted blocks with a block size of four and stratified by site using Stata version 12.)

1.3 *Did baseline differences between intervention groups suggest a problem with the randomisation process?*

No

(A researcher not involved in the interventions, assessments, or data analysis generated random permuted blocks with a block size of four and stratified by site using Stata version 12.)

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)

2.1. *Were participants aware of their assigned intervention during the trial?*

Yes

2.2. *Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?*

Yes

2.3. *If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?*

No/Probably no

(Intervention fairly subdued so not being allocated unlikely to cause large disappointment/regret in patients.)

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?

Not applicable

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?

Not applicable

2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?

Yes

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?

Not applicable

Risk of bias for deviations from the intended interventions (effect of assignment to intervention)

Low

Domain 3. Bias due to missing outcome data

3.1 Were data for this outcome available for all, or nearly all, participants randomised?

Yes

3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?

Not applicable

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?

Not applicable

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?

Not applicable

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?

Not applicable

Risk-of-bias judgement for missing outcome data

Low

Domain 4. Bias in measurement of the outcome

4.1 Was the method of measuring the outcome inappropriate?

No

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?

No

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?

Yes

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?

Yes

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?

Yes

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

5.1 Was the trial analysed in accordance with a pre-specified plan that was finalised before unblinded outcome data were available for analysis ?

No information

5.2 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

No/Probably no

(consistent timepoints and measures listed.)

5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple analyses of the data?

No/Probably no

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

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Yen, 2020

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Bibliographic Reference Yen, R.W.; Durand, M.-A.; Harris, C.; Cohen, S.; Ward, A.; O'Malley, A.J.; Schubbe, D.; Saunders, C.H.; Elwyn, G.; 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; 2020

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Study details

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|------------------------------|--|
| Study type | Cluster randomised controlled trial |
| Study location | USA |
| Study setting | Four cancer centres |
| Study dates | NR |
| Duration of follow-up | Recorded appointments |
| Sources of funding | Research reported in this manuscript is funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (1443 511-32875). The statements presented in this manuscript are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee. The study funder has no role in any aspects of the set up or execution of the study. |
| Inclusion criteria | Criteria 1 Women Criteria 2 confirmed diagnosis of stage I-IIIa breast cancer Criteria 3 Adult |
| Sample size | 311 |

| | |
|--------------------------|-----------------------------------|
| Loss to follow-up | 16 collaborate scores |
| % Female | 100% |
| Mean age (SD) | 60.5 (12.2) |
| Outcome measures | OPTION OPTION-5 CollaboRATE |

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2 **Study arms**

Text only conversation aid (Option grid) (N = 40)

The Option Grid and Picture Option Grid are encounter patient conversation aids developed by several of the study authors. They are designed to support SDM when women are deciding between breast-conserving surgery plus radiation versus mastectomy for treating their breast cancer. Both tools display Frequently Asked Questions to provide evidence-based information on the two surgical options for breast cancer.

Picture enhanced conversation aid (Picture option grid) (N = 144)

Picture Option Grid includes simpler text and images to help support understanding among patients of lower health literacy and lower socioeconomic status.

Usual care (N = 127)

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| Section | Question | Answer |
|--|---|---|
| 1a. Bias arising from the randomisation process | Risk of bias judgement for the randomisation process | Some concerns <i>(Randomisation did not account for cluster number thus some clusters much larger)</i> |
| 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 |
| 4. Bias in measurement of the outcome | Risk of bias judgement for measurement of the outcome | Low |
| 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 <i>(Randomisation not accounting for cluster size.)</i> |
| | Overall Directness | Directly applicable |

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1 Qualitative – study characteristics

2 Barker 2019

3 Characteristics

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|-------------------------------|---|
| Study type | Semi structured interviews |
| Study details | <p>Study location Canada</p> <p>Study setting Hospital birthing unit/mother baby unit</p> <p>Study methods A semi-structured interview guide (Figure 1), adapted from the GUIDE-IT tool and published framework (23,24), was developed and pilot tested with three HCPs. Modifications were made to the interview guide based on the feedback obtained. A female registered nurse (JR) with qualitative research and interview expertise and no relationship with the participants conducted single one-to-one interviews over the phone (n=11) or in person at the workplace (n=14). The 25 interviews ranged from 13 to 68 minutes, and were audio-recorded with consent and transcribed verbatim. Demographic data about each participant was collected and all but one interviewee consented to be audio-recorded. Detailed field notes of this participant's responses were used in the analysis. No further comments or feedback were collected from participants.</p> <p>Study dates September to December 2015</p> <p>Sources of funding This study was supported by the Children's Hospital of Eastern Ontario (CHEO) Research Growth Award All authors have indicated they have no financial relationships relevant to this article to disclose.</p> |
| Inclusion Criteria | <p>Criteria 1 women admitted to the birthing unit (BU) or mother-baby unit (MBU) at the Ottawa Hospital General Campus who were likely to deliver or were in labour with an EPI.</p> |
| Exclusion criteria | None reported |
| Sample characteristics | <p>Sample size 25 HCPs</p> <p>Characteristic 1 parent: 72%</p> |

| | |
|---------------------------------|---|
| | <p>Characteristic 2 Confidence providing counselling for parents of extremely pre-term infants: Range (0=no confidence, 10 = fully confident) * only completed by physicians (16)</p> <p>Gender Female 19 (76%)</p> <p>Profession Current role Neonatologists and fellows 8 (32%) Maternal-Foetal Medicine Specialists and fellows, obstetricians 5 (20%) Residents (Obs and Paediatrics) 3 (12%) Neonatal ICU nurses 5 (20%) Birthing Unit nurses 4 (16%)</p> <p>Years of experience giving care <5-8: (32%) 5-10: 6 (24%) 11-15: 5 (20%) >15: 6 (24%)</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Knowledge: Awareness of SDM, Correct understanding of SDM and how its applied. Misunderstandings/misconceptions of SDM and how it is applied.</p> <p>Theme 2 Skills: Creates a consistent approach and removes HCP bias and judgement from discussion, Parents more prepared and confident; HCP difficulty not persuading parents, parents cannot comprehend info due to its complexity, HCP difficulty knowing what cases truly apply to SDM and how to align the prognostic factors with each family's values.</p> <p>Theme 3 Belief about consequences: HCP belief in positive impacts of SDM for parents; Increased difficulties created by SDM, Uncertainty of using SDM at low GAs (specifically GA 22 weeks)</p> <p>Theme 4 Emotion: HCP positive attitude toward SDM, positive hope parents; False hope experienced parents, stress of decision for parents, parental emotions driving their decision making</p> <p>Theme 5 Environmental context and resources: Time of day (day time); Time of day (night time), increased amount of work, communication challenges (multicultural context)</p> <p>Theme 6 Social/professional role and identity and belief about capabilities: choice should be families to make (align with their beliefs); HCP uncertain of skill and proficiency, HCP belief that SDM prevented use of their knowledge and expertise, parents cannot shift decision making to HCP if they desire</p> <p>Theme 7 Intention: HCP feeling inclined to provide intensive care due to SDM</p> |
| <p>CASP Score</p> | <p>Risk of bias – Moderate</p> <p>Relevance – Partially Relevant</p> |

1 Belcher 2006

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|---------------------------|---|
| Study type | <p>Semi structured interviews One-on-one interviews were conducted to uncover participants' perceptions of medication-related decision making through semi structured, open-ended questions.</p> |
| Study details | <p>Study location USA</p> <p>Study setting 3 senior centres</p> <p>Study methods One-on-one interviews were conducted. Participants were asked for demographic and health data including age, race, gender, education, employment status, number of physicians seen in the past year, number and names of prescription medications, and self-reported medical conditions using a chronic disease questionnaire. The transcripts were analysed with multiple close readings by the authors.^{34–36} Themes were compared within and across interviews according to the constant comparative method of analysis. Codes were later combined and synthesized into broader, recurrent themes. All authors then reviewed the coding scheme; consensus was reached through discussion.</p> <p>Study dates NR</p> <p>Sources of funding This work was supported in part by a grant (P30AG10,469) to Yale University from the National Institute on Aging. Dr. Agostini is the recipient of a Veterans Affairs Health Services Career Development Award and a Merck/American Federation for Aging Research Junior Investigator Award in Geriatric Clinical Pharmacology. Dr. Fried is the recipient of National Institute on Aging Mid-Level Career Development Award.</p> |
| Inclusion Criteria | <p>Criteria 1 65 years or older</p> <p>Criteria 2 one or more prescription medications</p> |

| | |
|--------------------------------------|---|
| | <p>Criteria 3 Ability to participate in an English language interview</p> <p>Criteria 4 absence of cognitive impairment (defined as a score of at least 17 out of 22 on the telephone version of the folstein Mini-Mental status examination that was administered at the time of the interview),</p> <p>Criteria 5 in the case of participants recruited from physicians' offices, the ability to participate in a telephone interview.</p> |
| <p>Sample Characteristics</p> | <p>Sample size 51</p> <p>Reason for stopping recruitment The interviews ended when theme saturation was reached, the point when no new information was gained from further interviewing.</p> <p>Mean age (SD) 77 (+/- 6.6)</p> <p>Characteristic 1 Marital status: Married: 20 (39%), Single or Divorced: 6 (12%), Widowed 25 (49%)</p> <p>Characteristic 2 Education, high school or less: 18 (35%)</p> <p>Gender Female: 32 (63%)</p> <p>Profession Retired: 45 (88%)</p> <p>Ethnicity Caucasian: 40 (78%), African American: 10 (20%), Native American: 1 (2%)</p> |

| | |
|--------------------------|--|
| | <p>Characteristic 3 Location of recruitment: Senior centre: 23 (45%), Physician’s offices 28 (55%)</p> <p>Characteristic 4 Self-reported chronic conditions: Hypertension 32 (63%), Cardiovascular disease 23 (46%), Arthritis:18 (35%), Cancer - other than skin: 13 (25%), Diabetes mellitus: 12 (24%)</p> <p>Characteristic 5 Number of physicians (Mean): 2.8 (+/- 1.4), Range 1-6</p> <p>Characteristic 6 Number of prescription medications (Mean): 4 (+/- 2.1), Range: 1 - 8</p> |
| Thematic Analysis | <p>Theme 1 Variability in Perceptions of Patients Playing Any Role in Decision Making: Patients Do Not Want to Participate in Decision Making, Patients Cannot Be a Part of Decision Making, Patients Can and Should Participate in Medication Decision Making, Importance of Asking Questions, Concern About Side Effects, Active Participation in Decision Making, Trust in the Physician as Both a Barrier and Facilitator to Patient Participation, Role of Physicians’ Attitudes and Behaviours in Patient Participation, Communication and Interpersonal Skills, Physician’s Focus on Treating Numbers Rather Than Patients, Health Care System and Logistical Factors Impede or Facilitate Patient Participation in Decision Making</p> |
| CASP score | <p>Risk of bias – Low</p> <p>Relevance – Directly Applicable</p> |

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2 **Bi 2019**

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|----------------------|---|
| Study type | Focus Groups Semi structured interviews |
| Study details | Study location USA Study setting Community wellness settings |

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|-------------------------------|--|
| | <p>Study dates February 2016 to June 2017</p> |
| Inclusion Criteria | <p>Criteria 1 Self identify as AAPI</p> <p>Criteria 2 Men who have sex with men, men or women who have sex with both men and women, women who have sex with women. Identified as lesbian, gay, bisexual, transgender or gender-queer</p> |
| Exclusion criteria | <p>None reported</p> |
| Sample characteristics | <p>Sample size 50 (40 interviews, 10 focus group)</p> <p>Characteristic 1 Sexual orientation Gay 27 (54) Queer 16 (32) No labels 1 (2)</p> <p>Characteristic 2 Income: Annual individual income <\$10,000 7 (14) \$10,000–\$39,999 12 (24) \$40,000–\$79,999 17 (34) >\$80,000 3 (6)</p> <p>Gender Gender‡ Cis man 37 (74) Cis woman 3 (6) Gender nonconforming/other§ 4 (8) Trans man 4 (8) Trans woman 1 (2) Two spirited 1 (2) Asexual 1 (2) Bisexual 5 (10)</p> <p>Profession Employment status* Employed full-time 28 (56) Employed part-time 7 (14) Student 8 (16) Unable to work/not employed 7 (14) Missing 4 (8)</p> <p>Ethnicity Asian/Asian American, not otherwise specified† 22 (44) Chinese/Chinese American 5 (10) Filipino/Filipino American 6 (12) Multiracial/multiethnic 12 (24) Pacific Islander 2 (4) Other 3 (6)</p> |
| Thematic Analysis | <p>Theme 1 Provider Ignoring Patient's Intersectional Identities</p> <p>Theme 2 Provider Overemphasizing Patient's Intersectional Identities</p> <p>Theme 3 Racial Concordance Versus Discordance between Provider and Patient</p> <p>Theme 4 Prominence of AAPI and SGM Identities in Affecting SDM</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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1 **Bouma 2014**

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| Study type | <p>Semi structured interviews Each answered a 9-item SDM questionnaire and participated in a semi structured interview. From the transcribed interviews and questionnaire data, we identified themes and suggestions for introducing SDM into a safety net environment.</p> |
| Study details | <p>Study location Hennepin county medical centre, Minnesota, USA</p> <p>Study setting Medical centre</p> <p>Study methods The SDM-Q-9 asks about SDM from the patient’s perspective.⁴ We reframed the questions to be from the clinician’s perspective. Response options included completely agree, strongly agree, somewhat agree, somewhat disagree, strongly disagree, and completely disagree. We also conducted interviews to explore the feasibility of SDM. Audiotaped and transcribed interviews were reviewed by the lead author (ABB); a second reviewer assessed approximately 50% of the transcripts. A third reviewer (KT) assessed transcripts after coding was completed and agreed on the coding scheme. Themes were categorized into 3 domains: clinician barriers, patient barriers, and system barriers.</p> <p>Study dates from March to May 2011</p> <p>Sources of funding Support was provided, in part, by a Translating Information on Comparative Effectiveness into Practice (TRICEP) grant, funded by Agency for Healthcare Research and Quality (AHRQ) grant 5R18HS018339-02 (ML, DHB, SP, NDS, VMM, KT).</p> |
| Inclusion Criteria | <p>None reported "convenience sample"</p> |
| Exclusion criteria | <p>None reported convenience sample"</p> |
| Sample | <p>Sample size</p> |

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| <p>Characteristics</p> | <p>Of 23 eligible clinicians (18 physicians and 5 nurse practitioners and physician assistants), we interviewed a convenience sample of 13 physicians and 2 nurse practitioners at Hennepin County Medical Center (HCMC).</p> <p>Reason for stopping recruitment convenience sample</p> <p>Mean age (SD) NR</p> <p>Characteristic 1 HCMC's patient population is primarily low income</p> <p>Characteristic 2 HCMC population: with 65% of patients from communities of color and 25% from immigrant communities.</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Clinicians also identified patient-related barriers, such as willingness to participate and cultural differences.</p> <p>Theme 2 Action steps to increase the use of SDM in safety net settings</p> <p>Theme 3 SDM-Q-9 results</p> <p>Theme 4 Time pressure</p> |
| <p>CASP score</p> | <p>Risk of bias – High (Used an adapted SDM-q-9 tool but did not discuss how it was adapted appropriately. Relationship between patient and researcher not adequately considered. Only basic mentions of methodology)</p> <p>Relevance – Directly applicable</p> |

1 **Bradley 2017**

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| Study type | <p>Written questionnaire Open-ended questions were sent to professionals and family members, distributed in hard and electronic copies. Questions were designed to give participants the opportunity to write detailed responses, including unprompted entries.</p> |
| Study details | <p>Study location UK</p> <p>Study setting A large mental health and learning disability NHS organization.</p> <p>Study methods Question topics were identified from a literature search. Additional questions were informed from anecdotal feedback and input from a project steering group. Topics included the following: 1. Experiences of involvement to date a. Attendance at appointments b. How involvement was instigated/encouraged / prevented c. Information exchange—resources about treatment / diagnosis / potential involvement. 2. Participation in decision making during appointments or care more generally a. Perceived role of involvement b. Resolving conflict or different opinions. 3. Facilitators and barriers to involvement.</p> <p>Study dates Not reported.</p> <p>Sources of funding Otsuka Pharmaceuticals (UK) and Lundbeck, Ltd.</p> |
| Inclusion Criteria | <p>Criteria 1 1. Staff a. Current member of staff within the recruiting organization b. Registered prescriber (medical or non-medical) c. Working within adult mental health services.</p> <p>Criteria 2 Family a. Providing informal care for a service user currently in receipt of adult mental health services within the recruiting organization. b. Capacity to give informed consent.</p> |
| Exclusion criteria | <p>Criteria 1</p> |

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| | <p>Non-prescribing staff</p> <p>Criteria 2 Staff working within specialist dementia or memory clinics</p> <p>Criteria 3 staff working within child services.</p> |
| <p>Sample Characteristics</p> | <p>Sample size N=46 family members, N=55 staff members</p> <p>Mean age (SD) Not reported. Ranged from 18-80 years.</p> <p>Characteristic 1 Of the carers: N=17 were caring for a child over 18 years and two for a child under 18 years. N=19 were caring for a partner/spouse. N=4 were caring for a sibling, and two were involved in the care of a parent. N=2 declined to specify relationship.</p> <p>Characteristic 2 Diagnoses of family members were not always known or disclosed but those outlined included schizophrenia (n=3), bipolar disorder (n=1), autistic spectrum (n=1) and Aspergers (n=1).</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Defining involvement of care</p> <p>Theme 2 Rules of engagement in shared decision making.</p> |
| <p>CASP score</p> | <p>Risk of bias – High Missing information on data collection.</p> <p>Relevance – Partially applicable</p> |

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| | Concern that study includes discussion of people who may lack mental capacity to make their own decisions about healthcare at that time. |
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2 **Chong 2013**

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| Study type | Semi structured interviews In-depth semi-structured interviews were conducted with the aid of an interview guide. |
| Study details | Study location New South Wales, Australia. |
| | Study setting Healthcare providers who had direct experience with providing healthcare services to mental health consumers from a variety of settings including mental health units in hospitals, GP practices, hospital pharmacy departments and community pharmacies. |
| | Study methods open-ended questions that prompted discussion on mental health consumers' involvement in decision-making, interprofessional collaboration in mental health, and medication adherence issues in depression. Interviews were conducted by the first author. The interviews ranged from 25 to 60 min. All but one interview were audio-recorded and transcribed verbatim. Field notes were also taken during and after the interviews to describe the researcher's perceptions of the encounter and reflections on the information gathered. Thematic analysis was used to identify themes from the interview transcripts. |
| | Study dates Not reported. |
| | Sources of funding None reported. |
| Inclusion Criteria | None reported |

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| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N=31</p> <p>Mean age (SD) Not reported.</p> <p>Characteristic 1</p> <p>Gender N=17 male, N=14 female</p> <p>Profession N=4 Psychiatrists, N=4 GPs, N=11 Pharmacists, N=7 Mental health nurses, N=5 Occupational therapists/Psychologists/Social workers</p> <p>Healthcare setting N=19 hospital, N=12 primary care</p> |
| Thematic Analysis | <p>Theme 1 Factors associated with healthcare service delivery</p> <p>Theme 2 Factors associated with healthcare providers</p> <p>Theme 3 Factors associated with mental health consumers</p> <p>Theme 4 Perceived barriers and facilitators for inter professional collaboration</p> |
| | Risk of bias – Moderate |

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| | <p>Lack of information on ethical issues and consider subject/researcher relationship</p> <p>Relevance – Partially Relevant</p> <p>Concern that study includes discussion of people who may lack mental capacity to make their own decisions about healthcare at that time.</p> |
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2 **Claramita 2011**

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| Study type | Interviews and questionnaire survey. |
| Study details | <p>Study location Indonesia</p> <p>Study setting Teaching hospital</p> <p>Study methods Combined qualitative and quantitative approach with interviews and questionnaires. In-depth interviews with internal medicine residents, patients and students were conducted to explore their views concerning the ideal type of doctor–patient communication in consultations and potential barriers to implementing that style. This was conducted during 6 weeks. During this time, a questionnaire survey concerning doctors’ and patients’ contributions to the communication during real consultations observed by students was conducted.</p> <p>Study dates Not reported.</p> <p>Sources of funding Supported by The NPT Project 2008, the Netherlands Government cooperation between UGM and UM.</p> |
| Inclusion Criteria | Criteria 1 |

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| | <p>Able to engage in direct communication with the doctor.</p> <p>Criteria 2 No very serious condition or terminal illness which could affect their communication style.</p> |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N=393</p> <p>Gender Doctors: 13 F/ 17 M. Patients: 198 F/195 M, Students: 6 F/ 4 M</p> <p>Profession Doctors (year 1-3 residency), patients (primary school to high education) and senior students.</p> <p>Healthcare setting</p> <p>Age Doctors: 28 - 42 years, patients: 18-84 years, students: 24-26 years</p> |
| Thematic Analysis | <p>Theme 1 Desired doctor–patient communication style and barriers to achieving the desired style.</p> <p>Theme 2 Contributions of doctors and patients to the consultation</p> |
| CASP score | <p>Risk of bias – Moderate</p> <p>Concern around rigorousness of data analysis: lack of methods for data saturation and no introspection</p> <p>Relevance – Directly Relevant</p> |

1 **Cohen 2003**

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| Study type | Semi structured interviews |
| Study details | <p>Study location UK</p> <p>Study setting 1 General Practice</p> <p>Study methods Qualitative analysis of semi structured interviews. Nineteen men recently diagnosed with localized prostate cancer were included from patients attending a general hospital.</p> <p>Study dates 1999</p> <p>Sources of funding Scientific Foundation Board of the Royal College of General Practitioners and from the Prostate Cancer Charity.</p> |
| Inclusion Criteria | <p>Criteria 1 Men recently diagnosed with localized prostate cancer.</p> |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N=19</p> <p>Characteristic 2 All Caucasian</p> <p>Gender Male</p> |

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| | <p>Profession Technician, retired bus driver, retired labourer, salesman, retired bus driver, retired mechanic, builder.</p> <p>Healthcare setting Primary care</p> <p>Age Range: 58 - 88</p> |
| Thematic Analysis | <p>Theme 1 Decision-making styles</p> <p>Theme 2 Reaction to diagnosis</p> <p>Theme 3 Initial feelings about consultation</p> <p>Theme 4 Later reflections</p> |
| CASP score | <p>Risk of bias – Moderate Researchers didn't justify research design, no info on data saturation.</p> <p>Relevance – Directly Relevant</p> |

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2 **De Snoo-trimp 2015**

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| Study type | Interviews and focus group |
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| Study details | Study location Amsterdam |
| | Study setting Large university hospital |
| | Study methods Longitudinal qualitative study. in-depth interviews were held with three oncologists, six neurologists, and a neurosurgeon after second- or third-line treatment (of glioblastoma) decisions were made with specific patients |
| | Study dates Interviews: Sept 2010 - Sept 2013, Focus group: 2014 |
| | Sources of funding Netherlands Organization for Scientific Research |
| Inclusion Criteria | Criteria 1 Patients diagnosed with glioblastoma after 1st line of treatment. |
| Exclusion criteria | None reported |
| Sample Characteristics | Sample size N=12 interviewed |
| | Mean age (SD) Not reported |
| | Gender Not reported |
| Thematic Analysis | Theme 1 Creation of awareness of equipoise |

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| | <p>Theme 2 Mentioning benefits and harms</p> <p>Theme 3 Sharing responsibilities</p> <p>Theme 4 Eliciting the patients' ideas, expectations and concerns</p> |
| CASP score | <p>Risk of bias – Moderate</p> <p>Researchers didn't justify research design, no info on data saturation.</p> <p>Relevance – Directly Relevant</p> |

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2 **Eliacin 2015**

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| Study type | <p>Semi structured interviews Open-ended questions that focused on patients' views of shared decision making, medication and treatment decisions, illness management, and relationship with their providers.</p> |
| Study details | <p>Study location US</p> <p>Study setting Department of Veterans Affairs Medical Center</p> <p>Study methods Used the Shared Decision Making Scale to assess shared decision making. Administered questionnaires to patients to evaluate patient activation, illness management, medication adherence, and patient-provider working alliance. Conducted interviews</p> |

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| | <p>with patients after their scheduled medication-check visits, which were explicitly designed with the goal of examining patients' understanding of the concept of shared decision making.</p> <p>Study dates Not reported</p> <p>Sources of funding Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development and the VA Health Services Research & Development Fellowship.</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N=54</p> <p>Characteristic 1 75% Caucasian</p> <p>Characteristic 2 Participants had varied lengths of relationship with their providers, ranging from 3 months to 8 years.</p> <p>Gender 90% male</p> <p>Profession All were veterans receiving psychiatric care for a broad range of psychiatric conditions such as mood disorders, PTSD, and schizophrenia.</p> <p>Age 40 - 65 years</p> |
| Thematic Analysis | Theme 1 |

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| | Participants' understanding of shared decision making Theme 2 Situating the patient-provider relationship at the centre of shared decision making Theme 3 Challenges to the patient-provider relationship and shared decision making |
| CASP score | Risk of bias – Low Relevance – Partially Relevant Very specific subgroup of patients in a mental health setting. |

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2 **Elwyn 1999**

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| Study type | Focus Groups |
| Study details | Study location Wales Study setting GP Study methods 4 group interviews were held within the half day release sessions of vocational training schemes for GP registrars. Group interviews were held after each consultation and reactions explored use of an interview schedule (explored views on involving patients in decision, providing 'data' to patients, skills required). Study dates 1998 |

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| | <p>Sources of funding No external funding.</p> |
| Inclusion Criteria | <p>Criteria 1 Registrars attending 3 vocational training schemes.</p> |
| Exclusion criteria | <p>None reported</p> |
| Sample Characteristics | <p>Sample size N=39 registrars</p> <p>Mean age (SD) None reported.</p> <p>Profession GP registrars.</p> <p>Healthcare setting Primary care</p> |
| Thematic Analysis | <p>Theme 1 Views about shared decision making</p> <p>Theme 2 Reported current practice</p> <p>Theme 3 Insights into the process of sharing decisions</p> <p>Theme 4 Opinions about possible “outcomes” of sharing decisions</p> <p>Theme 5</p> |

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| | Training and skill implications |
| CASP score | <p>Risk of bias – Moderate</p> <p>Concerns around data analysis rigour.</p> <p>Relevance – Directly Relevant</p> |

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2 **Fraenkel 2007**

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| Study type | <p>Semi structured interviews</p> <p>The interviews followed a funnel structure, progressing from broader and open-ended questions to more structured questions with specific probes to clarify issues as needed.</p> |
| Study details | <p>Study location US</p> <p>Study setting 6 centres in the greater New Haven, Connecticut area.</p> <p>Study methods Individual face-to-face interviews. A formal discussion guide was developed based on pilot interviews with 2 participants. The guide included 14 open-ended questions on participants' experiences with medical decision making. Unless participants had covered a topic without being prompted, all participants were asked each of the 14 questions (on attitudes towards shared decision making).</p> <p>Study dates 2004-2005</p> <p>Sources of funding Partially funded by the Arthritis Foundation Clinical Science Grant. Dr. Fraenkel is also supported.</p> |

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| Inclusion Criteria | <p>Criteria 1 men (over the age of 65) and postmenopausal women who had recently (within 2 weeks) undergone bone densitometry</p> <p>Criteria 2 Speak and understand English</p> |
| Exclusion criteria | None reported |
| <p>Sample</p> <p>Characteristics</p> | <p>Sample size N=26</p> <p>Mean age (SD) 61 (range: 49-76)</p> <p>Gender N=25 women, N=1 man</p> <p>Ethnicity All Caucasian</p> |
| Thematic Analysis | <p>Theme 1 Patient knowledge</p> <p>Theme 2 Explicit encouragement of patient participation by physicians.</p> <p>Theme 3 Appreciation of the patient's responsibility/rights to play an active role in decision making.</p> <p>Theme 4 Awareness of choice</p> <p>Theme 5</p> |

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| | Time |
| CASP score | Risk of bias – Low |
| | Relevance – Directly Relevant |

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2 **Frerichs 2016**

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| Study type | Focus Groups Semi-structured focus groups and interviews with different health care professionals using conventional content analysis. |
| Study details | Study location Germany |
| | Study setting University Cancer Center Hamburg (UCCH) |
| | Study methods 4 focus groups of 90 to 120 minutes with 8–10 participants per group including HCPs with different clinical backgrounds. One group was planned with assistant physicians (also known as junior doctors or resident physicians in the UK and US respectively), one with senior physicians (also known as consultant or chief resident/senior staff member in the UK and US respectively), one with nurses, and one with other HCPs. |
| | Study dates April - June 2014 and interviews: May - June 2014 |
| | Sources of funding None reported |
| Inclusion Criteria | Criteria 1 Health care professionals working in UCCH |

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| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size</p> <p>Mean age (SD) 40.68 (11.45)</p> <p>Profession In focus groups: N=13 physicians, N=6 nurses, N= psycho-oncologists, N=3 other</p> <p>Healthcare setting Hospital</p> <p>Years of experience giving care mean (SD): 13.60 (10.47)</p> |
| Thematic Analysis | <p>Theme 1 Attitudes towards shared decision making</p> <p>Theme 2 Experiences</p> |
| CASP score | <p>Risk of bias – Moderate</p> <p>Recruitment strategy not reported</p> <p>Relevance – Directly Relevant</p> |

1 **Fuller 2017**

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| Study type | Semi structured interviews |
| Study details | <p>Study location USA</p> <p>Study setting Mark Etzel Patient-Centered Medical Home Initiative</p> <p>Study methods Interviews lasted 45 minutes on average. An interview guide was used, but each interviewer was encouraged to add clarifying questions or modify inquiries when needed. Interview domains included: patients' relationships with their providers and clinical staff, management of HIV or other medical care, and decision-making preferences and examples.</p> |
| Inclusion Criteria | <p>Criteria 1 At least 18 years of age</p> <p>Criteria 2 Fluent in English</p> <p>Criteria 3 Receiving HIV clinical services at a project site.</p> |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N=53</p> <p>Gender N=35 (66%) male</p> <p>Age mean 48 years, range: 30-65</p> |

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| | Ethnicity 34% Latino, Black/African American 32%. |
| Thematic Analysis | Theme 1 Factors that promote or hinder SDM |
| CASP score | Risk of bias – Moderate Lack of information around data collection Relevance – Directly Relevant |

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2 **Giacco 2018**

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| Study type | Interviews and focus group 4 focus groups and 6 individual interviews with patients who had experienced being involuntarily admitted to hospital within the previous 4 months, and four focus groups with clinicians working in hospital wards. |
| Study details | Study location UK Study setting East London National Health Service (NHS) Foundation Trust Study methods Open coding was used to explore, name and categorise topics found in the text. Three groups of transcripts were analysed together (patients' focus groups, clinicians' focus groups' and interviews with non- English-speaking patients), looking to identify emerging themes across the three groups. Study dates |

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| | <p>2016-2017</p> <p>Sources of funding National Institute for Health Research (NIHR)</p> |
| Inclusion Criteria | <p>Criteria 1 Patients who were in hospital at the time of the focus group.</p> <p>Criteria 2 Patients who had been discharged from an admission under the Mental Health Act and were being treated in the community.</p> |
| Exclusion criteria | <p>None reported</p> |
| Sample Characteristics | <p>Sample size N=38</p> <p>Reason for stopping recruitment Interim analysis indicated that 'data saturation' had been reached, as no new themes were emerging and there was redundancy in the data.</p> <p>Mean age (SD) 38.4 (12.3)</p> <p>Gender Patients: Female 56%, staff: Female: 75%</p> <p>Profession Staff members: nurses, psychiatrists, clinical psychologists</p> <p>Healthcare setting Hospital</p> <p>Diagnosis Psychotic disorder (N=9), Mood disorder (N=7), Substance misuse disorder (N=2)</p> |

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| Thematic Analysis | Theme 1 Barriers to patient involvement in decisions Theme 2 Facilitators of patient involvement in decisions |
| CASP score | Risk of bias – Moderate Unclear about the methods used for the focus groups and interviews. Relevance – Directly Relevant |

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2 **Grus 2019**

3 **Study Characteristics**

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| Study type | Semi structured interviews Observational research |
| Study details | Study location USA Study setting Breast cancer clinic Study methods We conducted interviews with clinicians (n = 6) and patients (n = 11) and conducted naturalistic, ethnographic observations of eight surgical consultations in a multidisciplinary breast cancer clinic. We analysed the data following the template method using the qualitative software NVivo 10. Study dates Start march 2016 Sources of funding Research was funded by the Kaiser Permanente Center for Health Research. |

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| Sample characteristics | <p>Sample size 17 (6 clinicians, 11 patients)</p> <p>Mean age (SD) Mean: 59.3, Median: 65.5</p> <p>Characteristic 1 Clinical stage of disease Tis 2 T1b 1 T1c 4 T2 5</p> <p>Gender Female 12 (100 %)</p> <p>Ethnicity Race Non-Hispanic white 11 (92 %) Black or African American 1 (8 %)</p> |
| Thematic Analysis | <p>Theme 1 Patients feel well informed and rely on a variety of authoritative sources of information about breast cancer surgery.</p> <p>Theme 2 Clinicians emphasize the sharing of biomedical facts (over asking about patients' goals and values).</p> <p>Theme 3 Patient contextual factors play an important role in determining how providers share information and elicit patients' goals and values. •patients must be able to process large quantities of information in a short time frame. •Patients must be willing to embrace swift decision-making. •Patients—with the help of physicians—must be able to formulate their values and assess which surgical option aligns foremost with these values.</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Hahlweg 2017**

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| Study type | <p>Observational research Participant observation with a passive level of observer participation at inpatient and outpatient physician– patient consultations as well as processes outside the patient–physician dyad (eg, physician–physician interactions, shift handovers) related to medical decision-making.</p> |
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| Study details | <p>Study location Germany</p> <p>Study setting University Cancer Center Hamburg (UCCH)</p> <p>Study methods Guideline for observational analysis based on CFIR framework. All observers are female clinical psychologists. Observations at the two inpatient wards lasted for 1 week at each ward. Observations were recorded on a form with prestructured sections capturing the name of the observer, time and place of the observation, a short description of the situational context and participating individuals.</p> <p>Study dates 2013-2014</p> <p>Sources of funding German Research Foundation</p> |
| Inclusion Criteria | <p>Criteria 1 Patients that were treated at the clinic within the time of the observations.</p> |
| Exclusion criteria | <p>Criteria 1 Severe cognitive impairment</p> <p>Criteria 2 insufficient German-language skills</p> |
| Sample Characteristics | <p>Sample size N=54</p> <p>Gender Not reported</p> |

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| | <p>Age Not reported</p> <p>Ethnicity Not reported</p> |
| Thematic Analysis | <p>Theme 1 Prerequisites for SDM</p> <p>Theme 2 Information exchange before making the decision</p> <p>Theme 3 Making the decision after information exchange</p> <p>Theme 4 Involvement of third parties during the decision-making process</p> <p>Theme 5 Facilitators and barriers for SDM</p> |
| CASP score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Hajizadeh 2015**

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| Study type | <p>Semi structured interviews</p> <p>Patients were interviewed about current practices and attitudes regarding shared decision making and end-of-life decision making.</p> |
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| Study details | Study location US |
| | Study setting Bellevue Hospital in New York City |
| | Study methods Interviews lasted approximately 30–60 min. Closed questions related to current practice and attitudes towards SDM. |
| | Study dates May - June 2013 |
| | Sources of funding Grant from the US Agency for Health care Research and Quality. |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | Sample size N=11 patients, N=5 doctors |
| | Gender Patients: 45% female, doctors: 40% female |
| | Healthcare setting Hospital |
| | Age Patients: median 60 years (range: 23–73), Patients: median 32 years (range: 30–46) |
| | Ethnicity Hispanic/Latino, Black/African American, White, Asian/Asian American |

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| Thematic Analysis | <p>Theme 1 Current practice of shared decision making and attitudes about patient involvement</p> <p>Theme 2 Experience with, and knowledge about, end-of life decision making</p> <p>Theme 3 Attitudes towards shared end-of-life decision making including doctor initiation and discussion timing</p> <p>Theme 4 Doctors' attitudes about the use of prognostic estimates for shared advance care planning</p> |
| CASP score | <p>Risk of bias – High</p> <p>Limited information on how patients were recruited or why they were the most appropriate. No information about informed consent. Doesn't appear to report contradictory findings.</p> <p>Relevance – Directly Relevant</p> |

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2 **Hamann 2016**

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| Study type | Focus Groups |
| Study details | <p>Study location Germany</p> <p>Study setting Inpatient or outpatient setting</p> <p>Study methods</p> |

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| | <p>Focus groups started with a general statement (“We want to discuss how patients and doctors can negotiate what kind of treatment is chosen”) and patients were requested to state their experiences and expectations as to how this goal could best be reached. All focus groups were audio-taped and transcribed verbatim. The transcripts were analysed using content analysis.</p> <p>Study dates Not reported</p> <p>Sources of funding German Ministry for Research and Education</p> |
| Inclusion Criteria | <p>Criteria 1 male and female psychiatrists, working either in inpatient or outpatient settings.</p> <p>Criteria 2 male and female patients, with schizophrenia/ schizoaffective psychosis or depression/bipolar disorder and with experience of both in- and outpatient treatment.</p> |
| Exclusion criteria | <p>Criteria 1 Requiring interpreter or had a learning disability.</p> |
| Sample Characteristics | <p>Sample size N=16 patients, N=17 physicians</p> <p>Mean age (SD) Patients: 41.8 (14.6), Physicians: 44.9 (7.7)</p> <p>Gender N=19 M, N=14 female</p> <p>Diagnosis N=7 Schizophrenia, N=3 Bipolar disorder, N=6 Major depression</p> |
| Thematic Analysis | <p>Theme 1</p> |

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| | Main themes about patient attitudes and behaviours that facilitate SDM Theme 2 Differences between patients and physicians regarding the main themes Theme 3 Barriers and facilitators of active patient behaviour |
| CASP score | Risk of bias – Low Relevance – Directly Relevant |

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2 **Hirpara 2016**

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| Study type | Semi structured interviews Telephone interviews were conducted with colorectal cancer surgery patients in the presence of 1 oncologist. |
| Study details | Study location Canada Study setting Gastrointestinal Oncology Clinic at Princess Margaret Cancer Centre or Toronto Western Hospital Study methods Patients were first asked to briefly recount their health care experiences since receiving the diagnosis of CRC. This provided an overview of preoperative and postoperative care, including therapies received, and enabled subsequent in-depth exploration of participation in treatment decision-making. Several open-ended questions were used to ascertain perceptions of choice, preferences for participation in decision- making, and factors that helped or hindered decision-making. Study dates Not reported Sources of funding |

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| | None reported |
| Inclusion Criteria | Criteria 1 > 18 years and had surgical resection for suspected or pathologically confirmed colorectal cancer |
| Exclusion criteria | None reported |
| Sample Characteristics | Sample size N=20 Gender N=11 M, N=9 F Age mean: 71.5 ((range 42–88) Diagnosis N=11 colon cancer and 9 patients had rectal cancer, from stage 0 to IV |
| Thematic Analysis | Theme 1 The role of family and social support Theme 2 Facilitators and barriers to decision-making Theme 3 Lack of choice and control in decision-making |
| CASP score | Risk of bias – Low Relevance – Directly Relevant |

1 **Hofstede 2013**

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| Study type | Interviews and focus group Semi-structured interviews (N=40) and N=3 focus groups |
| Study details | Study location Netherlands |
| | Study setting Workplace or home (interviews), Leiden University Medical Center (focus groups) |
| | Study methods 40 semi-structured interviews with professionals involved in sciatica care (GP's, physical therapists, neurologists, neurosurgeons and orthopaedic surgeons). The average duration of an interview was one hour and all interviews were audiotaped and transcribed in full. Interviews. professionals were asked to give an example of SDM in daily practice to determine whether the explanation was clear enough. Focus groups: participants received an information letter. They were asked to think about the decision making process for the treatment of their sciatica before attending the focus group. During the focus groups, a topic guide was used. |
| | Study dates 2012-2013 |
| | Sources of funding None reported |
| Inclusion Criteria | Criteria 1 Patients and professionals involved in sciatica care |
| Exclusion criteria | None reported |
| Sample | Sample size N=40 professionals, N=24 patients |
| Characteristics | Gender |

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| | <p>Professionals: N=29 male (73%)</p> <p>Profession Professionals: Physical therapist, GP, neurologist, neurosurgeon, orthopaedic surgeon</p> <p>Age Professionals: range 47 - 52, patients: 51-56 years</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Barriers and facilitators</p> <p>Theme 2 Innovation (SDM)</p> <p>Theme 3 Individual professional</p> <p>Theme 4 Patient</p> <p>Theme 5 Social context</p> <p>Theme 6 Organizational context</p> <p>Theme 7 External environment</p> |
| <p>CASP Score</p> | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

1 **Jansen 2019**

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|---------------------------|---|
| Study type | Semi structured interviews |
| Study details | <p>Study location Australia</p> <p>Study setting Primary care (GP)</p> <p>Study methods Semi-structured interview schedules were developed by the research team. Interviews lasted from 8 to 55 min. A Framework analysis method was used to analyse the interview transcripts, which involved 5 steps. An existing SDM framework was used to categorize data to the different steps of SDM.</p> <p>Study dates Feb - Aug 2012</p> <p>Sources of funding National Health and Medical Research Council (NHMRC).</p> |
| Inclusion Criteria | <p>Criteria 1 Elevated CVD risk factors at the time of recruitment (eg, blood pressure, cholesterol) or had recently received CVD-related lifestyle advice.</p> |
| Exclusion criteria | None reported |
| Sample | <p>Sample size N=30</p> |
| Characteristics | <p>Reason for stopping recruitment When initial data analysis indicated that meaning saturation had been reached (ie, no new concepts were being identified in the data).</p> |

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| | <p>Gender N=16 M, N=14 F</p> <p>Age N=20 75-79 years, N=4 80-84 years, N=5 85-89 years, N=1 90+ years</p> |
| Thematic Analysis | <p>Theme 1 Creating awareness that a decision needs to be made and options exist</p> <p>Theme 2 Discussing the different treatment options and their potential benefits and harms</p> <p>Theme 3 Exploring patient preferences for the different treatment options</p> <p>Theme 4 Making the decision and involving the patient to the extent they wish</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Kamara 2018**

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| Study type | <p>Observational research Cancer genetic counselling (CGC) sessions conducted in English, Spanish and Chinese dialects were observed and audio recorded (</p> |
| Study details | <p>Study location California</p> |

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| | <p>Study setting Two public county hospitals</p> <p>Study methods multiple inductive methods, including standard ethnographic techniques to conduct systematic observations, audio-recording of GC sessions, and stimulated recall interviews with observed patients. A subset of audio recordings were analysed. Three types of sessions were observed: 'pre-test' educational sessions that sometimes included consent for genetic testing and blood draw/saliva sample collection; 'pre-test 2' sessions that included review of information conveyed in the initial pretest session, consent for testing, and sample collection; and 'result' disclosure sessions.</p> <p>Study dates Subset of larger study conducted in 2012-2015</p> <p>Sources of funding Susan G. Komen for the Cure</p> |
| <p>Inclusion Criteria</p> | <p>Criteria 1 Spanish speaking female patients age 21 or older of any race or ethnicity</p> <p>Criteria 2 Referred to genetic counselling based on a personal or family history of cancer</p> <p>Criteria 3 Offered genetic testing for hereditary cancer syndromes</p> <p>Criteria 4 Use of a professional medical interpreter via telephone to conduct the session</p> |
| <p>Exclusion criteria</p> | <p>None reported</p> |
| <p>Sample Characteristics</p> | <p>Sample size N=13</p> |

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| | <p>Gender Female</p> <p>Age 26-49</p> <p>Diagnosis N=6 DCIS/breast cancer N=7 unaffected</p> |
| Thematic Analysis | <p>Theme 1 Challenges posed by hypothetical explanations</p> <p>Theme 2 Misinterpretation by the medical interpreter</p> <p>Theme 3 Communication facilitators</p> |
| CASP Score | <p>Risk of bias – Moderate Limited information about methods used to develop and conduct interviews.</p> <p>Relevance – Directly Relevant</p> |

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2 **Ladin 2017**

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| Study type | Semi structured interviews |
| Study details | <p>Study location USA</p> |

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| | <p>Study setting Two dialysis clinics in Greater Boston</p> <p>Study methods Open-ended questions explored how patients learned about and initiated dialysis; whether decisions were informed and autonomous; and treatment implications, advice for future patients and suggestions for improving SDM. Specific probes examined information, prior knowledge about dialysis and end stage renal disease and decision-making interactions. Trained interviewers conducted private face-to-face interviews at dialysis facilities and kept field notes. Interviews were audiotaped and transcribed verbatim.</p> <p>Study dates Aug 2014-June 2015</p> <p>Sources of funding National Center for Advancing Translational Sciences, National Institutes of Health, The Neubauer Faculty Fellowship at Tufts University.</p> |
| <p>Inclusion Criteria</p> | <p>Criteria 1 Receiving maintenance outpatient dialysis (>1 month)</p> <p>Criteria 2 Aged 65 years or older</p> <p>Criteria 3 English speaker</p> <p>Criteria 4 Capacity to consent</p> |
| <p>Exclusion criteria</p> | <p>None reported</p> |
| <p>Sample</p> | <p>Sample size N=31</p> |

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| Characteristics | <p>Mean age (SD) 76.2 (9.4)</p> <p>Gender Female 52%</p> <p>Ethnicity Caucasian (75%), African American (19%), Asian (6%), Hispanic (6%)</p> |
| Thematic Analysis | <p>Theme 1 decision-making experiences and satisfaction with treatment</p> <p>Theme 2 barriers to SDM</p> |
| CASP Score | <p>Risk of bias – Moderate</p> <p>Not clear if study had ethical approval of informed consent.</p> <p>Relevance – Directly Relevant</p> |

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2 **Legare 2013**

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| Study type | <p>Interviews, questionnaire and focus group</p> <p>1) A theory-based survey of all healthcare providers involved in the home care programs of a large primary care organization, 2) a focus group with the healthcare team dedicated to the frail elderly, 3) individual interviews with managers representing the diverse levels of the primary care organization.</p> |
| Study details | <p>Study location Canada</p> |

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| | <p>Study setting Home care programs in Quebec City</p> <p>Study methods A self-administered survey based on the theory of planned behaviour was used. Questionnaire was modelled on validated questionnaires developed earlier by our research team for similar projects studying the implementation of SDM in clinical practice. It provides a theoretical account of the predictors of intention, namely, attitude (the perceived advantages and disadvantages of performing a behaviour), subjective norms (perceived social pressure to perform the behaviour) and perceived behavioural control (the respondent's perception of barriers and facilitators to his or her performing the behaviour). The questions included measures of five theory-based variables: cognitive attitude; affective attitude; subjective norm; perceived behavioural control and intention to use IP-SDM. Focus group and individual interviews were used to obtain a variety of perspectives with the aim of soliciting the personal opinions of organization managers and stimulate discussion among those more directly involved in providing patient care. Interviews: structured interview guides used.</p> |
| <p>Inclusion Criteria</p> | <p>Criteria 1 Licensed and unlicensed healthcare providers in the organization.</p> <p>Criteria 2 Focus group: healthcare professionals in the only integrated home care team dedicated to the frail elderly.</p> <p>Criteria 3 Interviewees: administrators and managers who had varying levels of influence in the home care environment.</p> |
| <p>Exclusion criteria</p> | <p>None reported</p> |
| <p>Sample Characteristics</p> | <p>Sample size Survey: N=276, interviews: N=8</p> <p>Mean age (SD) 41 years (SD not reported)</p> <p>Gender Female (82.3%)</p> |

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| | <p>Profession Healthcare providers included unlicensed home support workers (34%), nurses (24%), social workers (14%), occupational therapists (9%), physiotherapists (3%), activity coordinators (1%), dietitians (2%) and other types of workers involved in social support and rehabilitation (13%).</p> |
| Thematic Analysis | <p>Theme 1 Intention and its influencing factors (IP-SDM measures)</p> <p>Theme 2 Barriers and facilitators</p> |
| CASP Score | <p>Risk of bias – Moderate Limited results included to support the findings.</p> <p>Relevance – Directly Relevant</p> |

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2 Lin 2019

3 Study Characteristics

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| Study type | Semi structured interviews |
| Study details | <p>Study location Taiwan</p> <p>Study setting Psychiatric halfway houses</p> <p>Study methods Qualitative semi-structured interviews were used to explore patient perspectives on shared decision making in secondary mental healthcare in Taiwan.</p> <p>Study dates July to August 2017</p> <p>Sources of funding This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.</p> |
| Inclusion Criteria | Criteria 1 |

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

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| | <p>aged twenty or over (research participants are legally required to be adults in Taiwan),</p> <p>Criteria 2 have a mental illness</p> <p>Criteria 3 use halfway houses</p> <p>Criteria 4 able to</p> <p>Criteria 5 able to speak and understand mandarin or english</p> |
| Exclusion criteria | None reported |
| Sample characteristics | <p>Sample size 20</p> <p>Mean age (SD) 44.55</p> <p>Characteristic 1 Schizophrenia: 17 Bipolar disorder: 1 Major depression: 1 Schizoaffective disorder: 1</p> <p>Characteristic 2 Duration of accommodation: 6 months to 6 10 years</p> <p>Gender 7/20 Female</p> |
| Thematic Analysis | <p>Theme 1 Feeling sufficient information is exchanged</p> <p>Theme 2 Desire to make decisions</p> <p>Theme 3 Professional status of health professionals</p> <p>Theme 4 Negative perception of making decisions</p> <p>Theme 5 Limited time resources</p> |
| CASP Score | <p>Risk of bias – Moderate</p> <p>Relevance – Directly Relevant</p> |

1 **Lowenstein 2019**

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| Study type | Semi structured interviews |
| Study details | <p>Study location USA</p> <p>Study setting two urban, academic primary care practices in San Francisco, California</p> <p>Study methods Semi-structured interview guides for patients and physicians based on existing literature were developed. Guides were designed to elicit knowledge and attitudes about smoking, lung cancer and LCS as well as information about patient-physician communication related to these topics. Priori themes were highlighted in the interview guides and identified emergent themes based on detailed reading of the data.</p> <p>Study dates Aug 2015-March 2017</p> <p>Sources of funding UCSF Tobacco Related Disease Research Program, the UCSF Mount Zion Health Fund Grant and UCSF Resource Allocation Program (RAP) Grant.</p> |
| Inclusion Criteria | <p>Criteria 1 age 55–80 years</p> <p>Criteria 2 A 30 pack-year smoking history</p> <p>Criteria 3 Current smokers or those who had quit within the last 15 years</p> <p>Criteria 4 English or Spanish speakers.</p> |

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| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N=12 physicians, N=30 patients</p> <p>Mean age (SD) Physicians: not reported. Patients: 62 years (5.3)</p> <p>Gender Physicians: 67% F, patients: 26% F</p> <p>Ethnicity Caucasian (65% of patients, 50% of physicians), Hispanic, African American, Asian/Pan Islander), Native American</p> <p>Years of experience giving care Physicians: mean = 13 years (range: 2 - 22)(range</p> |
| Thematic Analysis | <p>Theme 1 Physician perspectives</p> <p>Theme 2 Patient perspectives</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Lown 2009**

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| Study type | Collaborative work groups |
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| | Including both participants and physicians. Used the principles of appreciative inquiry and asked participants to discuss examples and share stories of their own experiences in which shared decision making went well. |
| Study details | <p>Study location USA</p> <p>Study setting Primary care, Massachusetts</p> <p>Study methods In patient/physician pairs or trios, participants discussed specific positive examples of shared decision making from their own experiences. participants then shared the attitudes and behaviours they had identified, working together with the researchers to group them as preliminary themes and suggest a label for each emerging theme. Researchers assured thematic saturation by checking with participants during each research work group about whether all concepts and preliminary themes were represented, and by reviewing and incorporating themes across all research work groups. Researchers analysed the data using the constant comparative method and grounded theory techniques.</p> <p>Study dates Not reported</p> <p>Sources of funding Carl J. Shapiro Institute of Education and Research, The Kenneth B. Schwartz Center, the American Academy on Communication in Healthcare.</p> |
| Inclusion Criteria | <p>Criteria 1 Physicians 3 years or more post residency and expressed interest in patient–doctor communication.</p> |
| Exclusion criteria | None reported |
| Sample | <p>Sample size N=85 participants and physicians (N=41 physicians, N= 44 participants)</p> |
| Characteristics | <p>Gender Physicians: 49% F, Patients: 68% F</p> |

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| | <p>Age 34 - 79 years</p> <p>Diagnosis Patients had a variety of chronic conditions, including diabetes, hypertension, rheumatoid arthritis, congestive heart failure, liver transplant and chronic leukaemia.</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Patient and physician: acts in a relational way</p> <p>Theme 2 Patient: understands and expresses feelings, preferences, and information about self. Physician: explores patients' feelings, preferences, and information about self.</p> <p>Theme 3 Patient and physician: discusses information and options</p> <p>Theme 4 Patient and physician: seeks information, support and advice</p> <p>Theme 5 Patient and physician: shares control/negotiates a decision</p> <p>Theme 6 Patient: acts on behalf of self. Physician: acts on behalf of the patient</p> |
| <p>CASP Score</p> | <p>Risk of bias – Moderate Study did not provide any information on obtaining informed consent.</p> <p>Relevance – Directly Relevant</p> |

1 **Maffei 2012**

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| Study type | Semi structured interviews |
| Study details | <p>Study location USA</p> <p>Study setting University of Pennsylvania medical centre</p> <p>Study methods Semi-structured interviews was developed from a) literature review of shared decision-making, medical uncertainty, and theory of reasoned action; and b) data analysis of a secondary retrospective ethnographic study involving medical encounters between men (ages 45–70) and their primary care physicians. Following the interview, a questionnaire based on Krantz et al. (Krantz Health Opinion Survey (KHOS)) was given to measure preference for healthcare information and active involvement in healthcare. The instrument has two subscales, one measuring information preference (I-Scale) and the second measuring the degree of behavioural involvement (B-Scale).</p> <p>Study dates Not reported</p> <p>Sources of funding Not reported</p> |
| Inclusion Criteria | <p>Criteria 1 African-American and Caucasian men between the ages of 45 and 70</p> <p>Criteria 2 No history of prostate cancer.</p> |
| Exclusion criteria | None reported |
| Sample | <p>Sample size N=101</p> |

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| Characteristics | <p>Mean age (SD)</p> <p>Gender Male</p> <p>Diagnosis COPD, hypertension, heart disease, diabetes or none</p> |
| Thematic Analysis | <p>Theme 1 Past experience with medical uncertainty</p> <p>Theme 2 Patient/Physician relationship</p> <p>Theme 3 Personality type</p> |
| CASP Score | <p>Risk of bias – High</p> <p>Participants were self-selected with no information about any further inclusion criteria.</p> <p>Relevance – Directly Relevant</p> |

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2 **Mahone 2011a**

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| Study type | <p>Work groups and focus groups</p> <p>Met at least once a month, a total of 10 times. Various stakeholders were consulted in the focus groups.</p> |
| Study details | <p>Study location USA</p> |

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| | <p>Study setting Mental health clinic, central Virginia</p> <p>Study methods The academic-community research team (Partnership) was formalized, representatives from both institutions were identified, and verbal commitments made to engage in exploration activities including identifying stakeholder groups, reviewing the relevant literature, and bringing in an external expert. The group consisted of: of eight experts in leadership, clinical and academic positions representing psychiatry, nursing, pharmacy, occupational therapy, social work, consumer advocacy, and health services research. From these recordings, detailed transcriptions were created for the purpose of analyzing the participatory-action process and activities.</p> <p>Study dates 2008-2009</p> <p>Sources of funding NIH-NINR</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N=8 experts</p> <p>Mean age (SD)</p> <p>Gender Not reported</p> <p>Profession Experts in leadership, clinical and academic positions representing psychiatry, nursing, pharmacy, occupational therapy, social work, consumer advocacy, and health services research.</p> |

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| <p>Thematic Analysis</p> | <p>Theme 1 Clinic values and priorities</p> <p>Theme 2 Research agenda</p> <p>Theme 3 Ground rules</p> <p>Theme 4 Communication</p> <p>Theme 5 Barriers to SDM</p> <p>Theme 6 Positive Aspects of SDM</p> <p>Theme 7 Information exchange</p> |
| <p>CASP Score</p> | <p>Risk of bias – High</p> <p>Unclear how participants were recruited, no mention of confidentiality or the methods used for discussion during meetings. Findings don't appear to meet all of the aims.</p> <p>Relevance – Partially Relevant</p> <p>Concern that study includes discussion of people who may lack mental capacity to make their own decisions about healthcare at that time.</p> |

1 **Mahone 2011b**

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| Study type | Focus Groups |
| Study details | <p>Study location USA</p> <p>Study setting Mental health clinic, central Virginia</p> <p>Study methods Each focus group started with a brief PowerPoint presentation by the investigator introducing the concept and giving an overview of shared decision making, including definitions and rationales for shared decision making in mental health. Detailed transcriptions of the qualitative interviews were created. The transcriptions identified all speakers and noted any cases of interruption in speech.</p> <p>Study dates 2008-2009</p> <p>Sources of funding NIH-NINR</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N=44</p> <p>Gender 34% Male</p> <p>Profession</p> |

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| | <p>family members (N=4), prescribers (psychiatrists and psychiatric nurse practitioners) (N= 4), other providers (nurses, case managers, support staff) (N=6), rural clinic staff (N=6) and three consumer groups (N=8)</p> <p>Ethnicity 'Caucasian and other races'</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Provider barriers</p> <p>Theme 2 Consumer barriers</p> <p>Theme 3 Information-exchange issues</p> <p>Theme 4 New skills needed</p> <p>Theme 5 Outcomes</p> |
| <p>CASP Score</p> | <p>Risk of bias – High</p> <p>Findings reported clearly but there is no clear aim, no description of how focus groups were conducted and no reference to confidentiality.</p> <p>Relevance – Partially Relevant</p> <p>Concern that study includes discussion of people who may lack mental capacity to make their own decisions about healthcare at that time.</p> |

1 **Mariani 2017**

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| <p>Study type</p> | <p>Focus Groups focus group interviews were chosen to stimulate healthcare professionals to share their opinions and thoughts about the influencing factors they experienced during the implementation of the intervention those that, in their opinion, hindered or facilitated the implementation process</p> |
| <p>Study details</p> | <p>Study location Netherlands and Italy</p> <p>Study setting It involved different European countries, among which Italy and the Netherlands. Given the attention SDM was receiving in both countries, as well as the existing collaboration between the two universities, the framework was developed and implemented in one Dutch and one Italian nursing home.</p> <p>Study methods Based on a literature review, a semi-structured interview guide (Appendix 1, Supplemental data) was developed with the aim of identifying barriers and facilitators during all stages of the implementation process. Skype and face-to-face contacts between the research teams involved were used to refine the questions, which were then translated from English into the two national languages. In each country, the interviews were conducted by an experienced moderator and an assistant moderator. The interviews were recorded and transcribed verbatim. In each country, the content of the focus group discussions was translated into English. Interview transcripts were coded by using conventional content analysis (Hsieh & Shannon, 2005). First, the interview transcripts were read carefully. Then, meaning units that seemed to capture factors influencing the implementation process were identified and labelled with appropriate codes. Two independent researchers (EM, RC) discussed the codes until consensus was reached. If no consensus could be reached, a third researcher could be consulted. Based on how the identified codes were related and linked, the researchers sorted them into categories. The categories that emerged were then organized and grouped into main themes.</p> <p>Study dates held six months after the training took place and the implementation process started.</p> <p>Sources of funding The study ran within the IMPACT project (implementation of quality indicators in palliative care study), funded under the EU seventh framework program.</p> |

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| <p>Inclusion Criteria</p> | <p>Criteria 1 having attended the communication skills training;</p> <p>Criteria 2 having been involved in the implementation process of the framework</p> <p>Criteria 3 Inclusion criteria for the professionals of the intervention group who applied the framework were (1) being a member of the multidisciplinary team; (2) being directly involved in the care planning process and (3) being a key staff member in the provision of residents' care.</p> <p>Criteria 4 Inclusion criteria for the residents and family members were that residents had a diagnosis of dementia based on DSM IV and were supported by a family caregiver who agreed to participate in the study.</p> |
| <p>Exclusion criteria</p> | <p>Criteria 1 Professionals working in the intervention nursing home wards other than those who were directly involved in the implementation process were excluded.</p> |
| <p>Sample Characteristics</p> | <p>Sample size 19</p> <p>Mean age (SD) Netherlands (41 [24-56]), Italy (49.5 [32 - 60])</p> <p>Gender Netherlands (Male: 3 Female: 6), Italy (Male: 0, Female: 10)</p> <p>Profession Netherlands (Healthcare assistants 8, Nurses 1), Italy (Healthcare assistants 5, Nurses 1, Recreational activity assistants 2, nursing director 1, Physiotherapist 1)</p> <p>Healthcare setting Nursing homes</p> |

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| | <p>Years of experience giving care Netherlands (3.7 [2-8]), Italy (4.4 [2-6])</p> |
| Thematic Analysis | <p>Theme 1 Professional outcome and tools: Quality of training, Professional advantages, Quality improvement activities</p> <p>Theme 2 Factors associated with environmental factors: Staff workload, Environment, Nursing home policy and management</p> <p>Theme 3 National economic context and regulation: Lack of funding, regulations</p> <p>Theme 4 Professionals' relational skills: Team collaboration, Communication skills</p> <p>Theme 5 Care recipients' attitude and cognition: Residents' cognitive status, Attitude of family caregivers, Family caregivers involvement</p> <p>Theme 6 Factors associated with own culture: Emotional aspects of family caregivers, Residents intimate relationships.</p> |
| CASP Score | <p>Risk of bias – Moderate No mention of ethics and limited information on data collection.</p> <p>Relevance – Directly Relevant</p> |

1 **McCarter 2016**

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| Study type | Semi structured interviews |
| Study details | <p>Study location USA</p> <p>Study setting Inpatient and outpatient oncology settings in a large metropolitan area in the Midwest region</p> <p>Study methods Semi-structured interview explored the process of cancer treatment SDM between the nurse and the patients, nurses also referred to the barriers and promoters between the nurse and the physician throughout the cancer treatment SDM process. Open-ended questions included, "What improvement can be done to enhance your participation to cancer treatment decision making?" Participants were asked specific probing question about their perceived barriers and promoters to cancer SDM participation and their personal values and preferences relevant to cancer SDM participation. Probe questions included, "Are there any barriers or promoters to your participation in cancer treatment decision making?" Saturation of data was reached.</p> <p>Study dates Aug 2014 - Nov 2014</p> <p>Sources of funding Chicago Chapter of the Oncology Nursing Society</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample | <p>Sample size N=30</p> |
| Characteristics | <p>Gender 'Majority' Female</p> |

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| | <p>Profession 19 oncology nurses and 11 oncology nurse practitioners.</p> <p>Age 49 - 59 years</p> <p>Years of experience giving care 80% with 10 years of experience and above</p> |
| Thematic Analysis | <p>Theme 1 Major themes pertaining to the barriers category</p> <p>Theme 2 Major themes pertaining to the promoter's category</p> |
| CASP Score | <p>Risk of bias – Moderate No mention of informed consent.</p> <p>Relevance – Directly Relevant</p> |

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2 **Molenaar 2018**

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| Study type | <p>Focus Groups N=11 focus groups</p> |
| Study details | <p>Study location Netherlands</p> |

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| | <p>Study setting hospitals, health care centres, or in research centre.</p> <p>Study methods A semi-structured topic guide was used consisting of conversationally worded open questions based on earlier research, covering three areas for exploration: experiences with shared decision making in everyday practice, barriers and facilitators to shared decision making, and the needs for an intervention to support shared decision making. To check validity and Relevance, the questions were orally pretested with parents and midwives for comprehensibility and clarity. Categories were grouped into main themes and themes by searching for similarities, differences, and relations, and through discussion with the research team.</p> <p>Study dates Nov - Dec 2016</p> <p>Sources of funding Not reported</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size</p> <p>Profession parents (two groups, n = 10), primary care midwives (two groups, n = 13), obstetricians (two groups, n = 15), maternity care assistants (two groups, n = 15), hospital-based midwives (one group, n = 5), obstetric nurses (one group, n = 5), and one mixed group of hospital-based midwives and obstetric nurses (n = 8).</p> <p>Age Varied from mean 32 years (parents) to mean 48 years (maternity care assistants).</p> <p>Years of experience giving care Varied from mean 5.5 years (obstetricians) to mean 15 years (maternity care assistants)</p> |

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| Thematic Analysis | <p>Theme 1 Shared decision making process in everyday practice</p> <p>Theme 2 Barriers and facilitators to practicing shared decision making</p> <p>Theme 3 Needs of an intervention to practice shared decision making</p> |
| CASP Score | <p>Risk of bias – Moderate</p> <p>No mention of informed consent.</p> <p>Relevance – Directly Relevant</p> |

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2 **Moreau 2012**

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| Study type | <p>Focus Groups N = 4 focus group interviews</p> |
| Study details | <p>Study location France</p> <p>Study setting Retirement home, Lyon health support group, students of the Institute for Industrial Art and Design, and residents of rural area</p> <p>Study methods Focus groups explored three clinical scenarios: a patient with hypertension, an asymptomatic chronic health problem that is neither serious nor an emergency; and patients with breast and prostate cancer, which are potentially serious cancers involving complex therapeutic choices. These scenarios were developed to encourage better patient involvement for men and women. Participants were asked to read the scenarios and to answer the following question immediately thereafter:</p> |

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| | <p>How do you perceive that decisions were made in these three situations? The observer transcribed the audio recording of each session to obtain a verbatim report. Analysis: transversal analysis of the topics after the four focus-group sessions had been carried out.</p> <p>Study dates Not reported</p> <p>Sources of funding No funding obtained.</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size N = 25</p> <p>Gender N=6 Male, N = 19 Female</p> <p>Age Retirement home: > 65 years old, Lyon health support group: 35 - 65 years old, students: 20 - 25 years old, rural area residents: 40 - 50 years old</p> |
| Thematic Analysis | <p>Theme 1 Decision making as an interactive process between a physician who considers the patient as a person, and a patient who gives his/ her consent freely.</p> <p>Theme 2 Patient could better understand his/ her disease and be involved in his/her care.</p> <p>Theme 3 Trust</p> |

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| | Theme 4 Decision-making process |
| CASP Score | Risk of bias – Moderate No information about ethics, consent or confidentiality and limited information on methods used. Relevance – Directly Relevant |

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2 **Muscat 2016**

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| Study type | Semi structured interviews |
| Study details | <p>Study location New South Wales (NSW), Australia.</p> <p>Study setting Recruitment occurred at five Technical and Further Education (TAFE) colleges</p> <p>Study methods Purposive sampling using a maximum variation strategy was used to select a range of adults from English-speaking and non-English-speaking backgrounds (NESB) from regional and metropolitan areas. Students enrolled in Level 2 Adult Learning Literacy and Numeracy courses at any of five colleges were invited by their teacher to participate in a 30-min face-to-face interview. Ethics approval was obtained from the University of Sydney and TAFE NSW. Interviews were semi-structured using a topic guide allowing flexibility to explore issues raised by interviewees. Topics covered participants' experiences and confidence participating in health decision-making. Participants were asked to read one of the two sets of consumer questions (Smart Health Choices or AskShareKnow) aloud. Question sets were assigned prior to the interview to ensure approximately equal numbers of participants from English-speaking backgrounds and non-English-speaking backgrounds were assigned to the Smart Health Choices and AskShareKnow questions. Interviews were analysed using Framework Analysis that uses a thematic matrix to organise data.</p> |

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| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size 26 interviewees (13 English speaking background, 13 non-English speaking background)</p> <p>Mean age (SD) 42 (18-63 range)</p> <p>Characteristic 1 English spoken at home 13 (50%)</p> <p>Characteristic 2 Region: Metropolitan 13 (50%)</p> <p>Gender 77% Female (20)</p> <p>Diagnosis Existing health condition: 12</p> |
| Thematic Analysis | <p>Theme 1 consultation and decision-making experiences</p> <p>Theme 2 understanding of the questions</p> <p>Theme 3 perceived usefulness</p> <p>Theme 4 question-asking barriers</p> |

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| CASP Score | Risk of bias – Moderate |
| | No information about informed consent or confidentiality and limited information about analysis methods. |
| | Relevance – Directly Relevant |

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2 **Naik 2005**

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| Study type | Focus Groups focus groups with older adults and 2 with clinicians. |
| Study details | Study location Not reported |
| | Study setting Older adult participants were recruited from 2 urban, subsidized assisted living facilities, 1 suburban assisted living facility, and 1 affluent senior residential community. Participants had at least 1 chronic illness or functional impairment. Clinician focus groups consisted of physicians and nurses in an academic medical centre who expressed interest and experience in collaborative health care. |
| | Study methods Focus groups, which lasted 45 to 60 minutes, consisted of open-ended questions regarding how participants set goals and made treatment decisions in clinical encounters. Participants were also shown the SDM instrument (Fig. 1) and asked “How might this instrument help or hinder your discussions with your clinicians (patients)?” and “What changes would you make?” We used standardized probes to encourage elaboration and discussion of participants’ initial responses. ¹⁸ In all cases, participants were encouraged to give examples and detailed stories that illustrated their statements. The Human Investigation Committee of Yale School of Medicine approved the study protocol. We analysed focus group transcripts using the constant comparative method of qualitative data analysis to describe common themes from the groups. |
| | Study dates Not reported |

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| | <p>Sources of funding This research was supported by a center grant from a joint program of the Hartford and RAND foundations: Building Interdisciplinary Geriatric Health Care Research.</p> |
| Inclusion Criteria | <p>Criteria 1 Participants had at least 1 chronic illness or functional impairment.</p> |
| Exclusion criteria | <p>None reported</p> |
| Sample Characteristics | <p>Sample size 52 participants, Older persons: 41 participants, Nurses 5, Clinicians 6</p> <p>Mean age (SD) Patient participants: 82 +/- 7</p> <p>Characteristic 1 Patients: Two thirds lived alone</p> <p>Gender Patients: Two thirds female</p> <p>Profession Patients (41), Nurses (5) and Physicians (6)</p> <p>Years of experience giving care Nurse participants worked in a geriatrics clinic or rehabilitation ward and had, on average, more than 20 years of clinical experience.</p> <p>Diagnosis Average of 2 chronic illnesses, difficulty with 2 instrumental activities of daily living, and high self-rated health.</p> |
| Thematic Analysis | <p>Theme 1 Desire for SDM</p> |

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| | <p>Theme 2 Existing Strategies to Facilitate Shared Decision Making</p> <p>Theme 3 Acceptance and Functions of a Shared Decision making Instrument</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Patel 2014**

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| Study type | <p>Semi structured interviews An interview guide (see Appendix) was developed with senior qualitative experts (PJG, KH) and was informed by the conceptual framework described above.</p> |
| Study details | <p>Study location New York, USA</p> <p>Study setting Federally qualified health centres (FQHCs)</p> <p>Study methods Recruitment was conducted via a random sampling of primary care health care professionals employed at the FQHCs. a random sample of sixteen primary care professionals were approached using a ward off letter and research project fact sheet to reach our recruitment goal of two types of professionals from each category (i.e. practice administrator, nurse, primary care physician, psychiatrist, and social worker).The Charles treatment decision making framework adapted for primary care practice..</p> <p>Study dates NR</p> |

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| | <p>Sources of funding NIMH K23 MH082118-01A1 awarded to first author</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size 15</p> <p>Mean age (SD) M (Mean/Median?) = 39 years</p> <p>Gender Female (13/15) 87%</p> <p>Profession primary care healthcare professionals (5 Nurse Practitioners, 5 Physicians, 1 Psychiatrist, 2 Social workers and 2 Practice administrators)</p> <p>Ethnicity Nine out of 15 providers were African American, mostly non-Hispanic (12/15) and 3 were bilingual Spanish speaking</p> <p>Years of experience giving care In role average of 11 years</p> |
| Thematic Analysis | <p>Theme 1 Information exchange: Discordant models of illness, Stigma surrounding depression diagnosis and treatment</p> <p>Theme 2 Deliberation: Varying role expectations, Deciding on a treatment to implement</p> |

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| CASP Score | Risk of bias – Low Relevance – Directly Relevant |
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2 **Peek 2013**

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| Study type | <p>Focus Groups 5 focus groups</p> <p>Semi structured interviews in depth semi-structured interviews</p> |
| Study details | <p>Study location Midwest USA</p> <p>Study methods Participants were recruited using criterion sampling (Patton, 2002). We utilized a thematic analysis approach to the data (Braun & Clarke, 2006).</p> <p>Study dates Interviews: September 2006 and February 2007, Focus groups: January 2007 and March 2007</p> |
| Inclusion Criteria | <p>Criteria 1 African American</p> <p>Criteria 2 Diabetes</p> <p>Criteria 3 >= 21 years old</p> |

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| | <p>Criteria 4 established relationship with an attending primary care physician at an academic internal medicine practice (defined as at least three visits over the preceding 2 years with the same attending)</p> |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size See Peek 2009</p> |
| Thematic Analysis | <p>Theme 1 Race and trust</p> <p>Theme 2 Interpersonal/relationship aspects of trust</p> <p>Theme 3 Medical skills/technical competence aspects of trust—</p> <p>Theme 4 The influence of patient trust on shared decision making</p> <p>Theme 5 The influence of shared decision making on patient trust</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

1 **Roodbeen 2020**

2 **Study Characteristics**

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| Study type | Semi structured interviews |
| Study details | <p>Study location Holland</p> <p>Study setting 4 hospitals</p> <p>Study methods The theoretical framework underpinning this qualitative interview study is based on a phenomenological approach. All participants were selected using convenience sampling. The interviews were semi-structured and conducted with a topic list.</p> <p>Study dates April and October in 2018</p> <p>Sources of funding This work was supported by awards from ZonMw (the Netherlands Organisation for Health and Research Development) project number 844001403 to authors RR, GB, JR, MvdM, JN, and SvD. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. No commercial companies funded the study or authors</p> |
| Inclusion Criteria | <p>Criteria 1 Physicians and nurses who regularly conduct consultations with patients with cancer or chronic obstructive pulmonary disease (COPD), and discuss palliative care and treatment options</p> |
| Exclusion criteria | None reported |
| Sample characteristics | <p>Sample size 17 (11 medics, 6 nurses)</p> <p>Characteristic 1 Department: Palliative care: 29% Pulmonology: 29% Radiotherapy: 18% Oncology: 18% Anaesthesiology: 60%</p> <p>Gender Sex: Female: 59%</p> <p>Profession Nurses 35% Physician 65%</p> |

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| Thematic Analysis | <p>Theme 1 Time management</p> <p>Theme 2 Communication skills</p> <p>Theme 3 Tailoring.</p> <p>Theme 4 Characteristics of patients and significant others.</p> <p>Theme 5 Content of medical information.</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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Peek 2009

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| Study type | <p>Focus Groups</p> <p>Semi structured interviews</p> |
| Study details | <p>Study location Chicago USA?</p> <p>Study setting Urban academic medical centre</p> <p>Study methods This study utilized a qualitative research design, specifically, a phenomenological research method, that consisted of individual semi-structured interviews (n=24) and five focus groups (n= 27). Each focus group consisted of five to six people and lasted</p> |

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| | <p>approximately 90 min; individual interviews lasted approximately 60 min. Enrolment continued until theme saturation was met¹². Themes were similar in focus groups and individual interviews.</p> <p>Study dates NR</p> <p>Sources of funding This research was supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Diabetes Research and Training Center (P60 DK20595). Dr. Peek is supported by the Robert Wood Johnson Foundation (RWJF) Harold Amos Medical Faculty Development program and the Mentored Patient-Oriented Career Development Award of the National Institute of Diabetes and Digestive and Kidney Diseases (K23 1138 Peek et al.: SDM Barriers/Facilitators Among AA Diabetics JGIM DK075006). Support for Dr. Chin is provided by a Midcareer Investigator Award in Patient-Oriented Research from the NIDDK (K24 DK071933-01).</p> |
| <p>Inclusion Criteria</p> | <p>Criteria 1 African-American</p> <p>Criteria 2 Diabetes</p> <p>Criteria 3 >= 21 years old</p> <p>Criteria 4 Established attending primary care physician at an urban academic medical centre</p> |
| <p>Sample Characteristics</p> | <p>Sample size 51</p> <p>Mean age (SD) 18-39: 4%, 40-54: 18%, 55-64: 31%, 65-74: 37%, >75: 10%</p> <p>Characteristic 1 Marital status: Single: 24%, Married/Living as married: 30%, Separated/Divorced/Widowed: 46%</p> |

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| | <p>Characteristic 2 Education: Some high school or less: 7%, High school graduate: 35%, Some college: 36%, College graduate or higher: 22%</p> <p>Gender Female: 82%</p> <p>Diagnosis Years of diabetes: average 14</p> <p>Characteristic 3 Employment: Employed: 15%, Unemployed: 37%, Retired: 48%</p> <p>Characteristic 4 Income, \$: <15,000: 22%, 15,000-24,999: 15%, 25,000-49,999: 24%, >50,000: 24%, Refused: 15%</p> <p>Characteristic 5 Living space: Rent: 50%, Own: 48%, Other: 2%</p> <p>Characteristic 6 Insurance: Uninsured: 0, Medicare: 4%, Medicaid: 18%, Medicare + Medicaid: 24%, Private insurance: 29%, Medicare + private: 25%</p> <p>Co-morbidities Stroke: 8%, Coronary artery disease: 19%, Hypertension: 70%, Hyperlipidaemia: 47%, Peripheral vascular disease: 20%</p> <p>Characteristic 7 Medication regimen: Diet changes: 16%, Pills/tablets: 47%, Insulin: 11%, Pills and insulin: 26%</p> <p>Characteristic 8 Diabetes complication: 0: 43%, 1: 29%, 2: 22%, 3+: 6%</p> |
| Thematic Analysis | <p>Theme 1 Patient/physician power imbalance</p> |

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| | <p>Theme 2 Patient factors: health literacy, trust, family experiences, fear/denial, self-efficacy</p> <p>Theme 3 Physician factors: Information-sharing and patient education, Validation of health concerns, Physician medical knowledge/technical skills, Accessibility and availability, Interpersonal skills</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Rose 2019**

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| Study type | Semi structured interviews |
| Study details | <p>Study location South-West England</p> <p>Study setting two intermediate care rehabilitation settings (Inpatient community rehabilitation centre. Patient's own home.</p> <p>Study methods Purposive sampling was chosen with a target sample size of between 35-40 participants for the first phase. If patient participants scored 0 or 1, more than once on the MAPPIN'SDM questionnaire, which indicated low involvement in SDM in goal-setting, then these patients were approached for interviews for the second phase. For phase two, an interview guide was used. During Phase one, goal-setting meetings with patient participants were observed and SDM within these meetings were scored using the MAPPIN'SDM questionnaire [18] by patient, staff involved in the meeting and by the observer. Patients' questionnaires were then examined immediately by the researcher to identify those patients who achieved low SDM scores (sample for phase two). These low scorers were then approached for participation in the phase two interview study. Interviews lasted on average 30 minutes, all interviews were undertaken by the lead researcher (AR; a 28-year-old white female) who had received training in qualitative methods prior to data collection. Phase 2 the data collected from the</p> |

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| | <p>interviews was transcribed and analysed using thematic analysis described by Braun and Clarke. The themes were named according to those derived from a recent systematic review of patient-reported barriers to SDM [Joseph-Williams]</p> <p>Study dates NR</p> <p>Sources of funding NR</p> |
| Inclusion Criteria | <p>Criteria 1 Referred</p> <p>Criteria 2 frailty syndrome as defined by the British Geriatric Society</p> |
| Exclusion criteria | <p>Criteria 1 a severe communication impairment (those who were unable to express their views on their involvement)</p> <p>Criteria 2 no mental capacity to consent</p> <p>Criteria 3 if their first language was not English since translating the questionnaire could affect its validity and reliability.</p> |
| Sample Characteristics | <p>Sample size 15 patients for phase two, 9 consenting</p> <p>Mean age (SD) 60-69: 5%, 70-79: 25%, 80-89: 42%, 90-99: 28%</p> <p>Characteristic 1 Frailty syndrome: Falls: 55%, Immobility: 43%, Incontinence: 2%</p> <p>Characteristic 2</p> |

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| | <p>Fall history (past 12 months): 0: 23%, 1: 35%, 2: 25%, 3: 10%, 4: 2%, 5+, 5%</p> <p>Ethnicity White British: 100%</p> <p>Years of experience giving care 1-26 years (range)</p> |
| Thematic Analysis | <p>Theme 1 Predisposing factors: Intrinsic patient factors, Patient’s social situation, Past experiences of goal-setting</p> <p>Theme 2 Interaction context factors and the impact on experiences of patients: Communication breakdown, Relational aspects,</p> <p>Theme 3 Preparation for the SDM encounter: Patients not being entitled to a choice, Patients accepting the responsibility to be involved in decision-making</p> <p>Theme 4 Preparation for the SDM process: Providing information about rehabilitation options, Explanation of goal-setting, Decision support,</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Rosenberg-Yunger 2018**

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| Study type | <p>Semi structured interviews Interviews were digitally recorded and were 45–90 min in length, semi structured in style and followed an interview guide</p> |
| Study details | <p>Study location</p> |

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| | <p>Ontario Canada</p> <p>Study setting Pharmacy</p> <p>Study methods To maximize recruitment of CDE pharmacists, members with this designation were called and snowball sampling was used. Thematic analysis was conducted on the transcripts.[25] Analysis was inductive and involved line-by-line coding of the transcripts. Constant comparison was used to examine relationships within and across codes and categories. Focused and theoretical codings were used to develop core themes. Interviewing continued until no new data emerged, and saturation had occurred.</p> <p>Study dates NR</p> <p>Sources of funding grant from the Government of Ontario (Ministry Grant No. 06674) and was supported by the Ontario Pharmacy Evidence Network (OPEN).</p> |
| Inclusion Criteria | <p>Criteria 1 Pharmacist from rural or urban setting</p> |
| Exclusion criteria | <p>None reported</p> |
| Sample Characteristics | <p>Sample size 16</p> <p>Mean age (SD) 46.25 (12.79)</p> <p>Characteristic 1 Services provided: Medscheck: 14, Medscheck for diabetes: 14, Smoking cessation: 11</p> <p>Characteristic 2 Certified diabetes educator (9)</p> |

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| | <p>Gender 62.5% female (10)</p> <p>Profession Pharmacy owner: 6, Full-time staff pharmacist: 4, Part-time staff pharmacist: 2, Retired pharmacist: 1, Relief pharmacist: 1, Corporate pharmacist: 1, Consultant: 1</p> <p>Years of experience giving care Years as pharmacist: 22.44 (15.31)</p> <p>Characteristic 3 Access to private counselling room: (15)</p> |
| Thematic Analysis | <p>Theme 1 Pharmacists' awareness of SDM</p> <p>Theme 2 Incorporation of SDM within MedsCheck for Diabetes consultation process</p> <p>Theme 3 Communication and education during consultation process</p> <p>Theme 4 Supporting patient-centred choice during MCD consultation</p> <p>Theme 5 Pharmacy-related barriers and facilitators to implementing SDM</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

1 **Savelberg 2019**

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| Study type | Semi structured interviews |
| Study details | <p>Study location West and South Netherlands</p> <p>Study setting Breast cancer teams from 7 hospitals</p> <p>Study methods Web based PtDA. The interviews were transcribed verbatim and processed anonymously. Each interview was independently coded by two authors applying thematic content analysis, using NVivo software. Identified key themes by grouping the codes into larger themes, which were further explored, restructured, refined and reduced in number</p> <p>Study dates July 2015 until June 2017</p> <p>Sources of funding Pink Ribbon, Netherland: grant number 2012.PS23.C152 and Alpe d’HuZes KWF, Netherland: grant number MAC2014-7024</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size 27</p> <p>Profession Breast cancer surgeon: 9, Nurse practitioner: 11, Breast cancer nurse: 7</p> |
| Thematic Analysis | <p>Theme 1 Diverging attitudes of clinicians towards SDM: Team effort, Critical attitude,</p> |

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| | <p>Theme 2 Facilitating delivery of the PtDA: Delivering the PtDA, Clinician experiences in regard to the PtDA, Extra Cost</p> <p>Theme 3 Barriers in the implementation of SDM behaviour: SDM performance, Conflicting interests,</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Schoenfeld 2016**

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| Study type | Semi structured interviews |
| Study details | <p>Study location Massachussets, USA</p> <p>Study setting Emergency department</p> <p>Study methods The initial interview guide was developed using an integrative theoretical model that combined the Theory of Planned Behaviour and Social Cognitive. We also incorporated findings from qualitative studies of non-EPs, due to the paucity of related studies with EPs. We chose a purposeful sample of EP physicians based on sex, years in practice since residency, region (rural/suburban vs. urban) of primary employment, academic versus community practice setting, and location of training (inside versus outside of the state). Transcripts were entered into Dedoose qualitative data management and analysis software. combined a priori codes drawn from previous literature and our theoretical framework with emergent codes that came directly from line by line coding of the transcripts.</p> <p>Study dates June 2015 and November 2015,</p> |

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| | <p>Sources of funding This study was funded by a grant from AHRQ: 1R03HS024311-01. Also, the project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health (NIH), award number UL1TR001064.</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size 15</p> <p>Mean age (SD) 46 (31-65)</p> <p>Characteristic 1 Residency in EM: 13 (87%),</p> <p>Characteristic 2 Residency training location: Regional academic hospital (one site) 4 (27%), In current state of practice but not at regional training site: 3 (20%), Outside current state of practice: 8 (53%)</p> <p>Healthcare setting 100% Academic: 6 (40%), 100% community: 4 (27%), Combined academic/community: 5 (33%)</p> <p>Ethnicity White: 10 (67%), Black: 1 (7%), Asian/Indian 2 (13%), Did not answer: 2 (13%)</p> <p>Years of experience giving care Mean years since residency: 13.1 (range 1-30)</p> <p>Characteristic 3</p> |

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| | total different practice sites where participants worked last year: 14 |
| Thematic Analysis | <p>Theme 1 The physicians agenda ("intention"): Avoiding the "Medicolegal Path" or Algorithmic Care, The Management of Uncertainty and Perceived Mitigation of Risk, "Guided" SDM,</p> <p>Theme 2 Attitudes: Toward the importance of patient satisfaction, Toward the importance of resource utilization</p> <p>Theme 3 The importance of research outcomes of policy: Attitudes toward guidelines, Medicolegal protection, Patient satisfaction</p> <p>Theme 4 Norms: SDM as part of the culture</p> <p>Theme 5 Patient characteristics</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Schoenfeld 2018a**

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| Study type | Semi structured interviews |
| Study details | <p>Study location USA, New england</p> <p>Study setting</p> |

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| | <p>Emergency department. first ED is an urban, academic, tertiary care, level 1 trauma centre with >115,000 visits/year. The second ED is a community site located in a rural community, with <30,000 visits/year.</p> <p>Study methods The research team approached a purposive sample of clinically stable ED patients (i.e. not requiring constant nursing or clinician presence) or their proxies, aiming for variation in sex, age, race/ethnicity, primary language, experience with ED care, chronic medical conditions, and disposition (admission versus discharge). Transcripts were entered into Dedoose qualitative data management and analysis software. three trained members of the research team coded transcripts and field notes using a directed approach to qualitative content analysis: that is, we combined a priori codes drawn from the literature and our framework (Figure 1) with emergent themes.</p> <p>Sources of funding Grant Funding: The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, Award Number UL1TR001064. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.</p> |
| Inclusion Criteria | <p>Criteria 1 Haemodynamically stable</p> <p>Criteria 2 Spoke conversational English</p> <p>Criteria 3 not immediately leaving the department for testing, admission or discharge</p> |
| Exclusion criteria | <p>Criteria 1 Require constant nursing or clinician presence</p> |
| Sample Characteristics | <p>Sample size 29</p> <p>Mean age (SD) 56 (20 - 89 range)</p> |

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| | <p>Characteristic 1 Proxy: 2 (7%)</p> <p>Characteristic 2 Level of education: Some high school (did not complete): 4 (14%), High school graduate or GED: 12 (41%), Some college or 2-year degree: 8 (28%), 4-year college graduate: 1 (3%), More than 4-year college degree: 3 (10%), Did not answer: 1 (3%)</p> <p>Gender 13 female (45%)</p> <p>Ethnicity Caucasian: 18 (62%), African-American: 6 (21%), Hispanic: 4 (14%), Multi-racial: 1 (3%)</p> <p>Characteristic 3 Language spoken at home: Primarily English: 27 (93%), Primarily Spanish: 2 (7%)</p> <p>Characteristic 4 Prior experience with SDM: Shared experience during interview: 20 (69%), Unable to recall an experience with SDM: 9 (31%)</p> <p>Characteristic 5 Insurance: Private: 11 (38%), Medicare 5 (17%), Medicaid 9 (31%), Other/did not answer: 4 (14%)</p> <p>Characteristic 6 Disposition: Admission: 17 (59%), Discharge: 7 (24%), Don't know: 5 (17%)</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Do ED patients want to be involved in medical decision making during an ED encounter?</p> <p>Theme 2 What factors affect patients desired level of involvement? (Factors that increase/decrease desire)</p> <p>Theme 3 What are the patient-perceived barriers and facilitators to SDM in the ED?</p> |

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| | Theme 4 Non-verbal qualitative analysis (Barriers and facilitators) |
| CASP Score | Risk of bias – Low Relevance – Directly Relevant |

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2 **Schoenfeld 2018b**

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| Study type | Semi structured interviews |
| Study details | <p>Study location USA, New England</p> <p>Study setting Emergency medicine in community and academic departments.</p> <p>Study methods Chose a purposeful sample of EM physicians based on sex, years in practice, region, employment setting (rural/suburban/urban), academic versus community practice setting, and location of training. Transcripts were entered into Dedoose qualitative data management and analysis software. The codebook was developed using a directed approach to content analysis; we combined a priori codes drawn from previous literature and our theoretical framework with emergent codes that came from the line-by-line coding of transcripts.</p> <p>Study dates June to November 2015</p> <p>Sources of funding This study was funded by grant number 1R03HS024311- 01 from Agency for Healthcare Research and Quality. The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, award number</p> |

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| | UL1TR001064. Dr Lindenauer is supported by grant number K24 HL132008: Research and Mentoring in Comparative Effectiveness and Implementation Science. |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | Sample size 15 Years of experience giving care 1- 30 years |
| Thematic Analysis | <p>Theme 1 Relationships matter: Attending-Patient relationship, Attending-resident relationship: trust knowledge and risk tolerance, attending resident-patient: diagnostic momentum and expectations</p> <p>Theme 2 Skills matter: Emergency physicians use of SDM to avoid algorithmic care, a clear understanding of patients' risk helps clinicians engage in SDM, Experience as a facilitator</p> <p>Theme 3 Setting matter: Time pressures, Patient characteristics, Lack of follow-up, Interruptions, Lack of privacy</p> <p>Theme 4 Attendings matter: Attendings have variable "grey zones", Attendings lack formal training in SDM, Attendings were uncomfortable teaching the skills of SDM.</p> <p>Theme 5 Facilitators to SDM training in residency: Changing culture</p> |

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| CASP Score | Risk of bias – Low Relevance – Directly Relevant |
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2 **Schoenfeld 2019**

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| Study type | Semi structured interviews |
| Study details | <p>Study location Massachusetts, USA</p> <p>Study setting See 2016</p> <p>Study methods Our previous analysis of this data focused on fully exploring physicians’ motivators, however the interview guide was designed to facilitate a discussion of barriers and facilitators to SDM in the ED, and this analysis was planned a priori. Although lack of motivation could be interpreted as a barrier, emergent themes were distinct between ‘motivators’ and ‘barriers and facilitators’, and the research team felt that an in-depth analysis of barriers and facilitators was warranted.13</p> <p>Study dates see 2016</p> <p>Sources of funding This study was funded by a grant from AHRQ (1R03HS024311-01). Also, the project described was supported by the National Center for Advancing Translational Sciences, the National Institutes of Health (award number UL1TR001064).</p> |
| Sample Characteristics | <p>Sample size See 2016 Characteristics</p> |

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| Thematic Analysis | <p>Theme 1 Emotional: The effects of certainty and uncertainty, Fear of a bad outcome, The challenge of confidence and trust building with ED patients</p> <p>Theme 2 Logistical: Time, Scenario, Follow-up care, Frequent interruptions, Challenges due to multiple clinicians, Effort, Challenges due to physical space</p> <p>Theme 3 Norms: Culture of the institution</p> <p>Theme 4 Attitudes towards patients: Stubborn or aggressive patients, Capacity, Desire to be involved, Education/Intelligence, Cultural/Language barriers, Patient does not tolerate or understand risk uncertainty</p> <p>Theme 5 Skills: Clinical skills, SDM skills</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Seale 2006**

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| Study type | <p>Semi structured interviews The interview was loosely structured around key topics.</p> |
| Study details | <p>Study location England, UK</p> |

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| | <p>Study setting two mental health care trusts</p> <p>Study methods Interview transcripts were indexed with a coding scheme that allocated passages to key themes identified in team discussions. we provide counts of how many doctors in the sample exhibited the themes reported. This is aimed at assisting readers in gaining a rough sense of prevalence across the data set.</p> <p>Study dates NR</p> <p>Sources of funding NR</p> |
| Inclusion Criteria | <p>Criteria 1 all consultant psychiatrists in the two trusts whom we understood to be responsible for providing community psychiatric services to adults.</p> |
| Sample Characteristics | <p>Sample size 21</p> <p>Mean age (SD) 46 (33-59)</p> <p>Characteristic 1 Nationals of other countries: 3 (14%)</p> <p>Gender 4 (19%)</p> <p>Years of experience giving care As a psychiatrist: 19 (7-33), As a consultant: 10 (2-24)</p> |

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| Thematic Analysis | <p>Theme 1 Background to consultations (Commitment to patient centred practice), A central dilemma: medication and adverse effects,</p> <p>Theme 2 Conduct of consultations: Building a therapeutic alliance, Honesty and dishonesty, Becoming directive or coercive, Non-compliance</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Partially Relevant</p> <p>Concern that study includes discussion of people who may lack mental capacity to make their own decisions about healthcare at that time.</p> |

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2 **Shepherd 2014**

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| Study type | Semi structured interviews |
| Study details | <p>Study location Manchester, UK</p> <p>Study setting Psychiatry in mental health foundation trusts.</p> <p>Study methods qualitative research design allowed the experiences and beliefs of participants in relation to shared decision making to be elicited. Purposive sampling was used to recruit participants from a range of clinical backgrounds and with varying length of clinical experience. A semi-structured interview schedule was utilised and was adapted in subsequent interviews to reflect emergent themes. Data analysis was completed in parallel with interviews in order to guide interview topics and to inform recruitment. A directed analysis method was utilised for interview analysis with themes identified being fitted to a framework identified from the research literature as applicable to the practice of shared decision making. Examples of themes</p> |

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| | <p>contradictory to, or not adequately explained by, the framework were sought. Themes identified from analysis of transcripts were subsequently compared with the framework of shared decision making described by Charles and colleagues.</p> <p>Study dates NR</p> <p>Sources of funding With thanks to the staff of Greater Manchester West NHS Foundation Trust and Manchester Mental Health and Social Care. AS receives funding from the National Institute for Health Research as a doctoral research fellow</p> |
| Inclusion Criteria | <p>Criteria 1 participant currently hold a post working as a consultant psychiatrist</p> |
| Exclusion criteria | <p>Criteria 1 Participants working specifically in Child and Adolescent, Later Life or Learning Disability fields</p> |
| Sample Characteristics | <p>Sample size 26</p> <p>Profession variety of clinical backgrounds including; Inpatient general adult, community general adult, medical liaison psychiatry, forensic psychiatry and medical psychotherapy</p> <p>Years of experience giving care Mean 13 years, Range 3 months - 31 years</p> |
| Thematic Analysis | <p>Theme 1 Information sharing: Eliciting service user preference, improving compliance, clinician prescribing bias</p> <p>Theme 2 Deliberation: Engagement and discussion, the role of insight, External factors influencing clinicians (The nature of the clinical environment, pressures to discharge, other clinical staff, financial pressure(, External factors influencing the client (expectations and beliefs, the role of Mental Health Law)</p> |

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| | <p>Theme 3 Deciding on treatment options: Methods of information provision, Manner of information delivery, Revisiting treatment decisions</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Partially Relevant</p> <p>Concern that study includes discussion of people who may lack mental capacity to make their own decisions about healthcare at that time.</p> |

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2 **Siegel 2015**

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| Study details | <p>Study location USA</p> <p>Study setting Gastroenterology</p> <p>Study methods Physician interviews and online surveys were conducted from a panel of gastroenterologists in April 2012. Gastroenterologists were asked about their barriers to SDM, SDM practices, relationship to their patients, knowledge of SDM, and insights into SDM implementation. Key audio excerpts adapted from the interviews were used for moment to moment affect trace analysis in an online survey. Cluster analysis was used to segment gastroenterologists into mutually exclusive provider groups.</p> <p>Study dates April 2012</p> <p>Sources of funding This study was sponsored by Janssen Scientific Affairs, LLC (Horsham, PA). The authors wish to acknowledge the following individual for their contributions and critical review during the development of this manuscript on behalf of Janssen Scientific Affairs, LLC: Kim Poinsett-Holmes, PharmD of Poinsett Publications, Inc. for medical writing and editorial assistance.</p> |
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| <p>Sample Characteristics</p> | <p>Sample size 106</p> <p>Mean age (SD) Over half <50 (55%)</p> <p>Gender 93 male (88%)</p> <p>Healthcare setting Private setting: 46%, Hospital setting: 34%</p> <p>Age 30-39: 33%, 40-49: 22%, 50-59: 32%, 60-69: 9%, >70: 4%</p> <p>Years of experience giving care !0 years or more: 63%, 20 years or more 37%</p> <p>Characteristic 3 26-75 IBD patients per month: 42%, 10-25 IBD patients per month: 37%</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Attitudes</p> <p>Theme 2 Key barriers</p> <p>Theme 3 Shared decision making tools</p> |
| <p>CASP Score</p> | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Stevenson 2003**

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| Study type | Focus Groups |
| Study details | <p>Study location Birmingham and London: UK</p> <p>Study setting GPs</p> <p>Study methods Twenty GPs who had participated in a study of doctor– patient communication about drugs [15] were invited to take part in a focus group to discuss the results. Each group lasted 2.5 h. The aims were: (1) to identify examples of good and bad practice in communication about treatment using anonymised case study material based on interviews with patients and doctors and audio-taped consultations, (2) to critique GPs’ own performance and identify strategies for improvement using transcripts of their own audio-taped consultations and (3) to explore the potential barriers to, and possible solutions for, better communication.</p> <p>Study dates Six participated in a group in Birmingham in July 1998 and five participated in a group in London in October 1998.</p> <p>Sources of funding Department of Health prescribing research initiative</p> |
| Sample Characteristics | <p>Sample size 11</p> <p>Gender 45.5% Female (5)</p> <p>Profession GPs (100%)</p> |

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| | <p>Years of experience giving care Mean: 9, Range 9 months to 17 years.</p> <p>Characteristic 3 Size of practice: 1: 1, 2: 1, 3: 1, 5: 3, 5+: 4, Varied: 1</p> <p>Characteristic 4 Location: Suburban: 4, Urban: 5, Rural: 2</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 How to ensure decisions are shared</p> <p>Theme 2 Insufficiency of time</p> <p>Theme 3 Patient desire for SDM</p> <p>Theme 4 Practitioner acting in patient-centred way.</p> |
| <p>CASP Score</p> | <p>Risk of bias – Moderate There was not a clear description about why the method was chosen. Recruitment and ethical issues were not well described.</p> <p>Relevance – Partially Relevant Concern that study includes discussion of people who may lack mental capacity to make their own decisions about healthcare at that time.</p> |

1 **Towle 2006**

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| Study type | Unstructured interviews Participant observation |
| Study details | <p>Study location British Columbia, Canada.</p> <p>Study setting Department of Family practice.</p> <p>Study methods Six family physicians received training in the ISDM competencies. Audiotapes of office consultations were made before and after training. Transcripts of consultations were examined to identify behavioural markers associated with each competency and the range of expression of the competencies. The physicians attended group interviews at the end of the study to explore experiences of ISDM.</p> <p>Study dates NR</p> <p>Sources of funding Vancouver Foundation, British Columbia Medical Services Foundation.</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample | Sample size 198 data sets |
| Characteristics | Characteristic 1 seeing same physician for a year or more 69% (range 17-90%) |

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| | <p>Characteristic 2 education beyond high school: 69%</p> <p>Gender female 65%</p> <p>Profession Physicians</p> <p>Healthcare setting Department of family practice.</p> |
| Thematic Analysis | <p>Theme 1 Physician views of ISDM</p> <p>Theme 2 The ISDM competencies in practice: Partnership, Information, Role, Ideas, Choices, Evidence, Decision, Plan</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Upton 2011**

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| Study type | <p>Semi structured interviews Semi-structured interviews were conducted</p> |
| Study details | <p>Study location UK</p> |

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| | <p>Study setting post-qualification nurses registered on a distance learning respiratory course and attending a study day at a training centre</p> <p>Study methods Interviews were recorded, transcribed and analysed using the Framework approach.</p> <p>Study dates June 2007 and February 2008</p> <p>Sources of funding AstraZeneca via an unrestricted research grant. AstraZeneca had no input into the study design, data collection, analysis or interpretation of the findings. MF and SW have received travel bursaries and consultancy payment from AstraZeneca as well as other manufacturers of other asthma medications including GlaxoSmithKline, Trinity Chiesi, Merck, Sharp and Dohme and Boehringer Ingelheim. Supporting</p> |
| <p>Inclusion Criteria</p> | <p>Criteria 1 nurse currently worked in UK general practice and had undertaken at least three asthma consultations per week during the previous 12 weeks</p> <p>Criteria 2 three less experienced nurses were also included to explore if they held the same views of shared decision making as more experienced nurses.</p> |
| <p>Sample Characteristics</p> | <p>Sample size 20</p> <p>Reason for stopping recruitment Based on our experience of conducting other qualitative studies, we set a provisional target sample size of 20 participants; there was however provision for the sample size to be increased if topics required further exploration</p> <p>Mean age (SD) 43.9 years (range 34-61 years)</p> <p>Characteristic 1</p> |

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| | <p>Education at time of interview: BSc: 6 (30%), MSc: 2 (10%), Diploma: 12 (60%)</p> <p>Characteristic 2 Experience of running asthma consultations: under supervision: 3 (15%), Missing: 1 (5%), Lead: 16 (80%).</p> <p>Years of experience giving care Mean 16.8 years (range: 1-32) post-qualification experience</p> <p>Characteristic 3 Recieved shared decision making training in the past: 1 (5%)</p> |
| Thematic Analysis | <p>Theme 1 Nurses understanding of shared decision making</p> <p>Theme 2 Providing information and offering limited choice</p> <p>Theme 3 Power and persuasion</p> <p>Theme 4 Sharing decisions to increase adherence</p> <p>Theme 5 Assumptions made by nurses</p> <p>Theme 6 Barriers and facilitators of shared decision making</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

1 **Van Veenendal 2018**

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|-------------------------------|---|
| Study type | Focus Groups Semi structured interviews Written feedback |
| Study details | <p>Study location Netherlands</p> <p>Study setting selection of clinicians from different healthcare areas, researchers, patient advocates and policymakers</p> <p>Study methods Methods: This was a qualitative, exploratory investigation involving: Interviews (N = 43) to elicit perceived barriers to and facilitators of change, focus group discussions (N = 51) to develop an implementation strategy, and re-affirmation through written feedback (n = 19). Professionals, patients, researchers and policymakers from different healthcare sectors participated. Determinants for change were addressed at four implementation levels: (1) the concept of SDM, (2) clinician and/or patient, (3) organizational context and (4) socio-political context.</p> <p>Study dates Recruitment: January 2015 and April 2016, Write-up: Analysis of the data and writing of the report took place from May 2016 to December 2016.</p> <p>Sources of funding ZonMw, The Netherlands Organization for Health Research and Development.</p> |
| Sample Characteristics | <p>Sample size Interviews: 43 Focus groups: 51</p> <p>Reason for stopping recruitment Recruitment of participants continued until the investigators concluded that participants no longer provided new insights</p> <p>Profession</p> |

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| | Interviews: Healthcare professional 14 (33%), Patient advocate 3 (7%), Researcher 15 (35%), Policy maker 7 (16%), Other 4(9%). Focus groups: Healthcare professional: 16 (31%), Patient advocate: 5 (10%), Researcher, 14 (27%), Policy maker 15 (29%), Other 1 (2%) |
| Thematic Analysis | <p>Theme 1 Barriers for the implementation of SDM: Concept of SDM itself, Healthcare professional, Patient, Organisational context, Socio-political context</p> <p>Theme 2 Designing a nationwide approach to the implementation of SDM: An integrated programmatic approach to build intrinsic motivation, Training and implementation of SDM in routine practice, Stimulating the empowerment of patients and citizens, Creating a rewarding socio-political context</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Walter 2004**

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|----------------------|---|
| Study type | <p>Focus Groups</p> <p>Semi structured interviews</p> |
| Study details | <p>Study location Cambridge, UK</p> <p>Study setting Primary care</p> <p>Study methods</p> |

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| | <p>A combination of focus groups and semi-structured interviews were used to gain insight into the range of women’s views on risk communication and decision making in general practice consultations about the menopause and HRT. In order to facilitate productive interaction between focus group participants we organised the groups according to women’s HRT experiences. Individual views were then explored in-depth during a small number of interviews conducted by one author (FMW).</p> <p>Study dates NR</p> <p>Sources of funding Enterprise Award from the R&D Directorate, NHS Executive, Eastern Region.</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size 40</p> <p>Characteristic 1 HRT status: Group 1: NU, Group 2: CU, Group 3: Mixed, Group 4: Mixed, Group 5: Mixed, Group 6, CU Interviews: CU/NU/NU/EU</p> <p>Characteristic 2 Practice: Group 1: 1+2, Group 2: 1, Group 3: 1, Group 4: 2, Group 5: 1, Group 6 : 1+2, Group 7: 1+2</p> <p>Gender Female 100%</p> <p>Profession Full time: approx half, unemployed: 15%</p> <p>Characteristic 3 First language English: 34, not first language: 6</p> |

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| | <p>Characteristic 4 Some secondary education: 10, Completed o-levels: 6, Completed A-levels: 9, University graduate: 15</p> <p>Characteristic 5 Self-described "good or excellent health": 80%</p> <p>Characteristic 6 non-smokers: 87.5%</p> <p>Co-morbidities Alcohol use: 65%</p> <p>Characteristic 7 Regular exercise: 53%</p> <p>Characteristic 8 Married: 80%, with kids: 90%</p> |
| <p>Thematic Analysis</p> | <p>Theme 1 Goals of a risk consultation</p> <p>Theme 2 Facilitating improvements in risk consultations: Information resources, Personalised care,</p> <p>Theme 3 Barriers to optimal risk communication and decision making: GP barriers, Patient barriers</p> |
| <p>CASP Score</p> | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

1 **Watson 2008**

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|-------------------------------|--|
| Study type | Focus Groups |
| Study details | <p>Study location Northern England</p> <p>Study setting 5 GP surgeries</p> <p>Study methods Health care practitioners from five general practice surgeries in northern England participated in focus group sessions around the themes of patient decision aids, patient and practitioner preferences and SDM. Participants included general practitioners (n = 19), practice nurses (n = 5) and auxiliary staff (n = 3). Transcripts were analysed using a framework approach.</p> <p>Study dates NR</p> <p>Sources of funding NR</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size 27: G1: 7, G2: 8, G3: 3, G4: 6, G5: 3</p> <p>Gender G1: 3 male, 4 female, G2: 3 male, 5 female, G3: 3 female, G4: 2 male, 4 female, G5: 1 male, 2 female</p> <p>Profession G1: 4 GP, 1 Nurse practitioner, G2: 5 GP, 1 Nurse practitioner, 1 health visitor, G3: 3 GPs, G4: 4 GPs, 1 Nurse practitioner, 1 Health visitor, G5: 3 GPs</p> |

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| Thematic Analysis | Theme 1 Sharing decisions |
| | Theme 2 Risk communication |
| | Theme 3 Using patient decision aids |
| | Theme 4 Patient decision aids in practice |
| | Theme 5 Time |
| CASP Score | Risk of bias – Low Relevance – Directly Relevant |

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2 **Wiener 2018**

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| Study type | Focus Groups |
| | Semi structured interviews |
| Study details | Study location Massachusetts, USA |
| | Study setting 3 VA facilities |

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| | <p>Study methods Qualitative study entailing semi-structured interviews and focus groups. Using content analysis, we analysed transcripts to characterize communication and decision making about lung cancer screening.</p> <p>Study dates October 2013 and March 2015, February and June 2016,</p> <p>Sources of funding This study was funded by VA QUERI RRP 12-533, NIH 1UL1TR001430, and with resources from the Edith Nourse Rogers Memorial VA Hospital, the Portland VAMC, and the Puget Sound VAMC</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size (15 clinicians, 37 patients) - (21 clinician and 12 patients)</p> <p>Characteristic 1 Geographic region: A: Northeast B: Northeast C: South D: Northeast</p> <p>Gender Male: 40, Female: 9</p> <p>Profession Primary care providers: 16, Pulmonologist: 15, LCS nurse coordinator: 5, Patients: 49</p> <p>Healthcare setting A: Large VA hospital B: Large VA hospital C: Medium VA hospital D: Urban safety net hospital</p> |
| Thematic Analysis | <p>Theme 1 information sharing</p> |

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| | <p>Theme 2 deliberation and decision-making</p> <p>Theme 3 decision aids</p> <p>Theme 4 clinician-perceived barriers to shared decision making,</p> |
| CASP Score | <p>Risk of bias – Moderate It is unclear how the research was explained to participants and whether consent was asked.</p> <p>Relevance – Partially Relevant Very specific subgroup of patients (veterans).</p> |

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2 **Zeuner 2015**

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| Study type | Semi structured interviews |
| Study details | <p>Study location MO, USA</p> <p>Study setting Multiple</p> <p>Study methods Our qualitative interview guide drew on Fishbein’s Integrative Model of Behaviour Prediction. The goal of the interview was to elicit physicians’ underlying beliefs about attitudes, perceived social norms and self-efficacy to engage in four key SDM communication behaviours: (i) acknowledging a decision to a patient, (ii) describing potential benefits, potential risks and</p> |

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| | <p>cost of options, (iii) eliciting patients' values and preferences and (iv) responding to a patient who disagreed with a recommendation. All transcripts were then coded by at least two research staff using the refined codebook. Through this systematic thematic analysis process.</p> <p>Study dates October 2012 and April 2013</p> <p>Sources of funding Washington University School of Medicine, the Barnes-Jewish Hospital Foundation and Siteman Cancer Center.</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size 20</p> <p>Reason for stopping recruitment Recruitment ceased once we reached thematic saturation and no new themes were emerging from the interviews</p> <p>Characteristic 1 Knowledge of SDM: Heard of SDM 19 (95%), Full understanding 6 (30%)</p> <p>Gender Female 13 (65%)</p> <p>Profession Internal medicine: 5 (25%), Emergency medicine: 1 (5%), Medical oncology: 4 (20%), OB/GYN: 5 (25%), Surgery: 5 (25%)</p> <p>Years of experience giving care 0-2: 2 (10%), 3-5: 10 (50%), 6-10: 7 (35%), >10: 1 (5%)</p> |
| Thematic Analysis | <p>Theme 1 General support for SDM amongst participants and institutional leaders</p> |

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| | <p>Theme 2 Fears about being perceived as incompetent when discussing equipoise</p> <p>Theme 3 Physician biases when engaging in SDM with particular patients</p> <p>Theme 4 Trainees' concerns about practicing SDM with less supportive mentors</p> <p>Theme 5 Dealing with disagreements during SDM</p> <p>Theme 6 Concerns about SDM adding time pressure to a busy consultation</p> <p>Theme 7 Uncertainty discussing costs with patients</p> |
| CASP Score | <p>Risk of bias – Low</p> <p>Relevance – Directly Relevant</p> |

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2 **Ziebland 2015**

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|----------------------|---|
| Study type | Unstructured interviews |
| Study details | <p>Study location UK</p> <p>Study setting</p> |

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| | <p>Cancer</p> <p>Study methods Thematic analysis of narrative interviews with 32 people diagnosed with pancreatic cancer in the UK; interviews with a social scientist, usually in people's homes.</p> <p>Study dates 2010–11</p> <p>Sources of funding The actor Hugh Grant funded the work through the DIPEX charity</p> |
| Inclusion Criteria | None reported |
| Exclusion criteria | None reported |
| Sample Characteristics | <p>Sample size 32</p> <p>Gender Men: 17, Women: 15</p> <p>Profession Professional: 15, Other non-manual: 10, Skilled Manual: 5, Other, for example housewife: 2</p> <p>Age 35-44: 3, 45-54: 7, 55-64: 9, 65-74: 10, 75-84: 3</p> <p>Ethnicity White British: 30, Indian: 1, Afro-Caribbean: 1</p> <p>Diagnosis 1995-99: 1, 2000-2006: 5, 2007-2010: 26</p> |

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|--------------------------|---|
| Thematic Analysis | Theme 1 'Qualifying' for surgery Theme 2 Pressure and persuasion Theme 3 No 'real' options Theme 4 Confusion caused by changing options and different opinions |
| CASP Score | Risk of bias – Low Relevance – Directly Relevant |

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2 Qualitative – CASP score

Barker, 2019

Bibliographic Reference Barker, C.; Dunn, S.; Moore, G.P.; Reszel, J.; Lemyre, B.; Daboval, T.; Shared decision making during antenatal counselling for anticipated extremely preterm birth; Paediatrics and Child Health (Canada); 2019; vol. 24 (no. 4); 240-249

Aims of the research

Was there a clear statement of the aims of the research?

Yes

To explore health care providers' (HCPs) perceptions of using shared decision making (SDM) and to identify facilitators of and barriers to its use with families facing the anticipated birth of an extremely preterm infant at 22+0 to 25+6 weeks gestational age.

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Used a qualitative descriptive study design as this method increases the understanding of poorly described phenomena that are not easily quantifiable.

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

A research assistant screened hospital records daily for women admitted to the birthing unit (BU) or mother-baby unit (MBU) at the Ottawa Hospital General Campus who were likely to deliver or were in labour with an EPI. Five cases presented during the two months after implementation of the guideline and the HCPs involved in these cases were invited to participate in the study. Participants agreed to be contacted by our research assistant who then introduced the study, its aims and methods.

Data collection

[Was the data collected in a way that addressed the research issue?](#)

Yes

A semi-structured interview guide (Figure 1), adapted from the GUIDE-IT tool and published framework (23,24), was developed and pilot tested with three HCPs. Modifications were made to the interview guide based on the feedback obtained. A female registered nurse (JR) with qualitative research and interview expertise and no relationship with the participants conducted single one-to-one interviews over the phone (n=11) or in person at the workplace (n=14). The 25 interviews ranged from 13 to 68 minutes, and were audio-recorded with consent and transcribed verbatim. Demographic data about each participant was collected and all but one interviewee consented to be audio-recorded. Detailed field notes of this participant's responses were used in the analysis. No further comments or feedback were collected from participants.

Researcher and participant relationship

[Has the relationship between researcher and participants been adequately considered?](#)

Yes

Ethical Issues

[Have ethical issues been taken into consideration?](#)

Yes

Ethics approval was obtained from the Ottawa Health Science Network and the Children's Hospital of Eastern Ontario Research Ethics Boards. Patient consent sought for recording. SDM involves explanation of health settings to patients

Data analysis

Was the data analysis sufficiently rigorous?

Yes

We used an inductive, content analysis approach to code, categorize, and thematically analyse the data. Transcripts of each interview were imported into NVivo 11TM and independently coded by two authors (JR and CB). The two authors individually reviewed and coded the first three transcripts, then met together and compared coding to ensure a uniform approach was being applied and resolve differences. At that point, a coding template was established and was continually updated as further transcripts were analysed. Following the complete coding of nine transcripts, definitions, examples, and criteria of each code were established. Coding saturation (25) was achieved by transcript 18. An audit trail of each transcript's coding and code template development was maintained. Quotes to support the findings were chosen to give evidence and examples of the themes identified (26). We used the Theoretical Domains Framework (TDF) to facilitate analysis and interpretation of the qualitative findings (27) (Table 1). We mapped the facilitators and barriers to the use of SDM during antenatal counselling for EPIs identified in our study against the domains of the TDF (27).

Findings

Is there a clear statement of findings?

Yes: Results clearly organised into themes and discussed. Organized into framework with quotes

Research value

How valuable is the research?

Somewhat valuable, analysing a new area of SDM. Does not go into detail on future work though

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Directly applicable

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2

Belcher, 2006

Bibliographic Reference Belcher, Vernee N.; Fried, Terri R.; Agostini, Joseph V.; Tinetti, Mary E.; Views of older adults on patient participation in medication-related decision making; Journal of general internal medicine; 2006; vol. 21 (no. 4); 298-303

Aims of the research

Was there a clear statement of the aims of the research?

Yes

To explore the views of older adults regarding participation in medication decision making. Although patient participation in clinical decision making is an active area of investigation, little is known about the desires or concerns of older patients when faced with medication decisions.

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

To explore the perceptions of older adults regarding patient involvement in medication decision making in a qualitative study using in-depth, semi structured interviews. To explore the perceptions of older adults regarding patient involvement in medication decision making in a qualitative study using in-depth, semi structured interviews.

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(how selected: older adults with multiple chronic conditions were recruited from 3 senior centres, and the offices of a primary care practice, a geriatric rheumatologist, a nephrologist, and an ophthalmologist. To have a broad spectrum of older adults. They did not know how many, or who, did not chose to participate or whether nonparticipants might have perceptions different from those expressed by participants.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes: (in-depth, semi-structured interviews), (To explore the perceptions of older adults regarding patient involvement in medication decision making), (interview guide), (The interviews were audio taped, transcribed and verified for accuracy), (The interviews ended when theme saturation was reached, the point when no new information was gained from further interviewing.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

(The Yale University School of Medicine Human Investigation Committee approved the protocol.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes (The transcripts were analysed with multiple close readings by the authors. Two of the authors independently coded all transcripts and then met to assign codes to the text collaboratively.) (There were quotes for most of the findings.)

Findings

Is there a clear statement of findings?

Yes: (Two of the authors independently coded all transcripts. All authors then reviewed the coding scheme; consensus was reached through discussion.)

Research value

How valuable is the research?

Valuable (The perceptions and views expressed by interviewees in this study can help inform movement toward greater involvement of older patients in medication decision making.) (Further research is needed to quantify the perceptions expressed by participants and to determine the spectrum of desired participation.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Directly applicable

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Bi, 2019

Bibliographic Reference

Bi, Stephanie; Gunter, Kathryn E; Lopez, Fanny Y; Anam, Seeba; Tan, Judy Y; Polin, Danielle J; Jia, Justin L; Xu, Lucy J; Laiteerapong, Neda; Pho, Mai T; Kim, Karen E; Chin, Marshall H; Improving Shared Decision Making For Asian American Pacific Islander Sexual and Gender Minorities.; Medical care; 2019; vol. 57 (no. 12); 937-944

Aims of the research

Was there a clear statement of the aims of the research?

Yes

The objective of this study was to identify barriers and facilitators for shared decision making (SDM) between AAPI SGM and providers, especially surrounding mental health.

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

Recruitment occurred through purposive sampling without particular quotas for subpopulations. Eligible individuals self identified as AAPI and were either men who have sex with men, men who have sex with both men and women, women who have sex with women, women who have sex with men and women, and/or identified as lesbian, gay, bisexual, transgender, or genderqueer. The Morten Group, a national consulting firm, recruited individuals in Chicago. In San Francisco, the Asian and Pacific Islander (API) Wellness Center, a community health and social services centre that particularly serves the API SGM community, recruited AAPI individuals who were men who have sex with men, men who have sex with both men and women, gay or bisexual men, transgender, or genderqueer.

Data collection

Was the data collected in a way that addressed the research issue?

Yes: (Interviews and focus groups were conducted in community or health care organizations from February 2016 to June 2017. Participants were asked open-ended questions about their health care experiences and how their identities impacted these encounters. Follow-up probes explored SDM and mental health. The interview guide was informed by our prior research,20 literature review, expert opinion, and community forums with SGM of colour.. Interviewers who identified as AAPI SGM were utilized to increase empathy, trust, comfort, and honesty within the interview. Interviews were audio-recorded. Participants also completed a paper survey about health

care utilization, perceptions of the health care setting, communication with providers, discrimination, experiences with and preferences for SDM, health behaviour and status, and demographic information. “Health care providers” were defined as “doctors, nurse practitioners, physician assistants, psychologists, counsellors, etc.” All participants received \$40 as compensation, and focus group participants also received refreshments)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

(approved by the University of Chicago Institutional Review Board)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Audio recordings of these interviews and focus groups were transcribed. The codebook was initially developed from questions and themes in the interview guide. The first 10 transcripts were coded by (F.Y.L., S.A., J.Y.T., L.J.X., D.J.P., J.L.J., M.H.C., and K.E.K.) and the codebook was amended iteratively to a consensus to establish intercoder reliability. The remaining transcripts were each randomly assigned to 2 coders of the team (F.Y.L., S.A., J.Y.T., L.J.X., D.J.P., J.L.J., M.H.C., and K.E.K.). Repeat pairings of coders together were minimized to reduce coder bias. Team members coded the transcripts individually, then met in pairs to discuss until consensus. Final codes and transcripts were uploaded to NVivo 11. The team conducted secondary analysis inductively to identify major themes and recommendations for clinicians based upon these themes and quotations from the subjects. The team also developed a conceptual model for SDM between clinicians and AAPI SGM persons, building upon the model of Peek et al. They identified actionable recommendations for providers from both direct recommendations from the participants as well as our own inductions from participant quotations)

Findings

Is there a clear statement of findings?

Yes: (Themes sorted and expanded upon with exemplary quotes.)

Research value

How valuable is the research?

Can't tell

Overall risk of bias and directness

Overall risk of bias

Moderate (*Lack of clarity of value and clarity around researcher/study member relationship*)

Directness

Partially applicable

1

2

Bouma, 2014

Bibliographic Reference Bouma, Angelique B.; Tiedje, Kristina; Poplau, Sara; Boehm, Deborah H.; Shah, Nilay D.; Commers, Matthew J.; Linzer, Mark; Montori, Victor M.; Shared decision making in the safety net: where do we go from here?; Journal of the American Board of Family Medicine : JABFM; 2014; vol. 27 (no. 2); 292-4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(Sought to identify perceptions, barriers, and corrective steps to implement SDM in resource-constrained environments.) (The work adds to that of the systematic review by Legare et al and may be the first to focus on SDM adoption in safety net care. The results show that physician-identified barriers to SDM may be of similar nature throughout the health care system.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes (The SDM-Q-9 asks about SDM from the patient's perspective.⁴ They reframed the questions to be from the clinician's perspective. Response options included completely agree, strongly agree, somewhat agree, somewhat disagree, strongly disagree, and completely disagree. They also conducted interviews to explore the feasibility of SDM.) (Subjective: No evidence one way or the other)

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

(Adapted a patient SDM-Q-9 score but have not discussed how they made this appropriate for clinicians. However, the interviews are a more appropriate method.) (A conceptual framework of SDM (Figure 1) from Kriston et al structured our approach.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(This study was conducted with clinicians enrolled in a randomized trial testing SDM diabetes decision aids.)

(Clinics serving minority patients have more hectic workplaces and fewer resources, thus providing challenging settings for SDM. HCMC's patient population is primarily low income, with 65% of patients from communities of colour and 25% from immigrant communities.)

(Of 23 eligible clinicians (18 physicians and 5 nurse practitioners and physician assistants), authors interviewed a convenience sample of 13 physicians and 2 nurse practitioners at Hennepin County Medical Center (HCMC). One clinician declined to participate.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Data collection format clear but some concerns around methodology) (HCMC's patient population is primarily low income, with 65% of patients from communities of colour and 25% from immigrant communities.) (Questionnaire and semi-structured interview) (Audiotaped and transcribed interviews)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No: (Didn't discuss change of research design as research design change not mentioned.)

Ethical Issues

Have ethical issues been taken into consideration?

No

(No, need to consider how wide-reaching ethical implications are of interviews. Clinicians already enrolled in RCT so suggests there may have been ethics approval sought there.) (received local institutional review board approval but not specifically an ethics committee)

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Not enough info on DA processes.)

(Basic description: Audiotaped and transcribed interviews were reviewed by the lead author (ABB); a second reviewer assessed approximately 50% of the transcripts. A third reviewer (KT) assessed transcripts after coding was completed and agreed on the coding scheme. Themes were categorized into 3 domains: clinician barriers, patient barriers, and system barriers.) (Themes were categorized into 3 domains: clinician barriers, patient barriers, and system barriers. Not clear how these were derived from conceptual framework mentioned in paper.) (No mention of data saturation.) (Multiple reviewers, third reviewer to agree on coding scheme. Rudimentary but applicable process.)

Findings

Is there a clear statement of findings?

No

(Not enough information to clearly see all findings, reporting patchy.)

(Themes not organised and not all listed clearly.)

(Multiple analysts, but no more complex discussion.)

(may be the first to focus on SDM adoption in safety net care. Our results show that physician-identified barriers to SDM may be of similar nature)

Research value

How valuable is the research?

Yes

(Small interest in very specific field but still has value and ensuring less represented populations have data captured.)

(Work adds to that of the systematic review by Legare et al and may be the first to focus on SDM adoption in safety net care.)

(Results from ongoing trials of SDM implementation at HCMC may offer more insights into the effect these barriers may have on the efficacy of such interventions)

Overall risk of bias and directness

Overall risk of bias

High

Directness

Directly applicable

Bradley, 2018

1

Bibliographic Reference

Bradley, Eleanor; Green, Debra; Involved, inputting or informing: "Shared" decision making in adult mental health care; Health expectations : an international journal of public participation in health care and health policy; 2018; vol. 21 (no. 1); 192-200

2

Aims of the research

Was there a clear statement of the aims of the research?

No

(General introduction to the topic but no specific aims)

(No clear aim)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

(Questions were designed to cover experiences and participation in SDM)

(Subjective outcome)

Research Design

Was the research design appropriate to address the aims of the research?

Yes (Question topics were identified from a literature search. Additional questions were informed from anecdotal feedback and input from a project steering group)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(List of inclusion criteria included)

(Non-prescribing staff were excluded as the study was designed to explore the views of those with prescribing rights towards the role of family within SDM, to consider family input to decisions about medicines (as a first-line treatment).)

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(Previous work within this region has experienced difficulties with face-to-face methods of data collection due to travel constraints. To overcome this, qualitative feedback was gathered on a written questionnaire, distributed in hard and electronic copies)

(Justified for questionnaires 'Previous work within this region has experienced difficulties with face-to-face methods of data collection due to travel constraints. To overcome this, qualitative feedback was gathered on a written questionnaire, distributed in hard and electronic copies'. No information on the interviews mentioned in the results section)

(Yes for questionnaires 'Question topics were identified from a literature search. Additional questions were informed from anecdotal feedback and input from a project steering group (funder, research team, carer representative, Research & Innovation (R&I) lead).' but no information on interviews mentioned in the results section)

(Questionnaires appear to address the issue but there is no information about the interviews that are mentioned in the results section)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(Paper outlines that the study had ethical approval but there is no information about informed consent or confidentiality)

(The study was granted ethical permission from the University ethics committee and given formal approval by the relevant R&I department.)

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Basic description 'Techniques of thematic analysis were used,39 including the early identification of concepts from written comments for comparison and contrast across instances')

('A thematic analysis of the qualitative feedback was undertaken by the two authors.' 'Concepts were grouped together as themes with member checking across both the research team and the project steering group. At the end of the analysis, overarching themes included the following: Defining Involvement and Rules of Engagement.')

(No mention of data saturation)

Findings

Is there a clear statement of findings?

Yes

(Results clearly organised into themes and discussed)

(Some basic description - two analysts and validation across the research team)

(Making explicit the “rules of engagement” for family input, heightening awareness of the barriers, increasing awareness of policy (including patient confidentiality policies) and disseminating the potential benefits of family input would be important first steps in terms of encouraging staff to further consider family involvement as a core constituent of shared decision making.)

Research value

How valuable is the research?

Yes

(Making explicit the “rules of engagement” for family input, heightening awareness of the barriers, increasing awareness of policy (including patient confidentiality policies) and disseminating the potential benefits of family input would be important first steps in terms of encouraging staff to further consider family involvement as a core constituent of shared decision making.)

(Future research will include mental health nurses and care coordinators to encourage a broader discussion of family involvement.)

Overall risk of bias and directness

Overall risk of bias

High

Directness

Direct

1

Chong, 2013

Bibliographic Reference

Chong, Wei Wen; Aslani, Parisa; Chen, Timothy F.; Shared decision-making and interprofessional collaboration in mental healthcare: a qualitative study exploring perceptions of barriers and facilitators; Journal of interprofessional care; 2013; vol. 27 (no. 5); 373-9

2

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(The purpose of this article is to present qualitative data on the perceived barriers and facilitators of shared decision making and interprofessional collaboration among a range of healthcare providers involved in the provision of healthcare services to mental health consumers)

(In addition to promoting consumer-centred care in mental health, a better understanding of barriers and facilitators for both shared decision making and interprofessional collaboration from healthcare providers' perspectives may be valuable for the effective implementation of an interprofessional approach to shared decision making)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('The interview guide consisted of open-ended questions that prompted discussion on mental health consumers' involvement in decision-making, interprofessional collaboration in mental health, and medication adherence issues in depression.')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(The interview guide consisted of open-ended questions that prompted discussion on mental health consumers' involvement in decision-making, interprofessional collaboration in mental health, and medication adherence issues in depression.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

('Purposeful sampling was used to recruit healthcare providers from a range of professions, specialty backgrounds and healthcare settings (see Table 1). Healthcare providers were selected based on their experience and diverse backgrounds in mental health. Some of the healthcare providers nominated other potential participants; thus a snowball sampling method was also used in identifying participants')

('All healthcare providers who were recruited had direct experience with providing healthcare services to mental health consumers from a variety of settings including mental health units in hospitals, GP practices, hospital pharmacy departments and community pharmacies.')

('Of those who did not participate, one did not respond to our invitation and two indicated that their current work did not involve mental health consumers.')

Data collection

Was the data collected in a way that addressed the research issue?

Yes

('In-depth semi-structured interviews were conducted with the aid of an interview guide')

('The interview guide consisted of open-ended questions that prompted discussion on mental health consumers' involvement in decision-making, interprofessional collaboration in mental health, and medication adherence issues in depression.')

('The interview guide consisted of open-ended questions that prompted discussion on mental health consumers' involvement in decision-making, interprofessional collaboration in mental health, and medication adherence issues in depression.'. 'Field notes were also taken during and after the interviews to describe the researcher's perceptions of the encounter and reflections on the information gathered; these were used to explore researcher reflexivity and further support the interpretation of data')

('All but one interview were audio-recorded and transcribed verbatim; one healthcare provider requested note-taking only.')

('Interviews were conducted until thematic saturation was reached and no new themes appeared.')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

('Field notes were also taken during and after the interviews to describe the researcher's perceptions of the encounter and reflections on the information gathered; these were used to explore researcher reflexivity')

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(Some information about informed consent and about interviews not being audio recorded where requested but no information about confidentiality)

('Ethical approval for this study was obtained from the University of Sydney Human Research Ethics Committee.')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of how data was coded and how themes emerged and were discussed within the research team)

('Thematic analysis was used to identify themes from the interview transcripts')

('interviews were conducted until theme saturation was achieved')

Findings

Is there a clear statement of findings?

Yes

(Findings clearly organised into themes and discussed)

(Some discussion of credibility including reading transcripts multiple times and comparing themes across the research team)

('Healthcare providers in this study identified barriers and facilitators at different levels (consumer, provider and environmental), that may have influenced the translation of advocacy for shared decision making into clinical practice.')

Research value

How valuable is the research?

Yes

('The use of in-depth interviews and an interprofessional approach in this study provided the opportunity to identify novel information on what is important and relevant to various healthcare providers in implementing shared decision making and achieving interprofessional collaboration in mental healthcare.')

('Further research is needed on the barriers and facilitators that were identified. It is also important for future research to explore mental health consumers' perspectives on an interprofessional approach to shared decision making, in order to facilitate collaborative strategies for consumer centred care.')

Overall risk of bias and directness

Overall risk of bias

Moderate

Directness

Direct

1

Claramita, 2011

2

Bibliographic Reference

Claramita, Mora; Utarini, Adi; Soebono, Hardyanto; Van Dalen, Jan; Van der Vleuten, Cees; Doctor-patient communication in a Southeast Asian setting: the conflict between ideal and reality; Advances in health sciences education : theory and practice; 2011; vol. 16 (no. 1); 69-80

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('In the present study we explored the views of doctors, patients of different education levels and medical students concerning their preferred style of doctor–patient communication and barriers to the use of that style.')

('In order to determine what type of doctor– patient communication style might be most suitable for Southeast Asian countries, it is important to explore which style is preferred by stakeholders and what barriers they perceive to stand in the way of the ideal style.')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('In-depth interviews with internal medicine residents, patients and students were conducted to explore their views concerning the ideal type of doctor–patient communication in consultations and potential barriers to implementing that style')

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

(Qualitative design seems most appropriate but the reasons aren't discussed in detail)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

('A maximum variation sampling technique was used to compose four groups of stakeholders: 10 internal medicine residents, 10 attending internal medicine specialists, 8 patients who had completed primary school, junior high school or high school 8 patients who had completed education at a higher level than high school (high education level) and 10 of the most senior medical students')

(Groups that they considered to be stakeholders)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

('We chose internal medicine as the setting for the study, because it offers case variety and resembles the primary care setting and hence affords optimal observation of doctor– patient communication during consultations')

(Interviews and questionnaires)

('The standardized in-depth interviews were guided by key questions.' 'A two-item questionnaire was developed to assess communication style. The items asked doctors and patients to rate their respective contributions to the doctor–patient communication during a consultation they had just completed. The rating scales of both items were inspired by the Global Affect Rating explained in The Roter Method of Interaction Process Analysis')

('The audiotapes of the interviews were transcribed within 48 h after each interview')

('Sampling of participants for the interviews continued until saturation of information was reached')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Some information about informed consent but not about confidentiality. 'Participation was voluntary and all participants completed a consent form before the interview.')

(This study had been approved by The Committee of Ethics Faculty of Medicine Gadjah Mada University, Yogyakarta on 7 November 2007 on the document no: KE/FK/251/EC.)

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Audiotapes transcribed and analysed using grounded theory approach)

('The first and second authors individually coded the transcripts into categories and then met regularly to discuss their analysis of the data. This iterative process continued until agreement on the categories and the core category was reached')

(No mention of data saturation)

Findings

[Is there a clear statement of findings?](#)

Yes

(Results presented by themes and discussed)

(The first and second authors individually coded the transcripts into categories and then met regularly to discuss their analysis of the data. This iterative process continued until agreement on the categories and the core category was reached)

('The doctors, patients and students that participated in this study uniformly stated that they preferred a partnership communication style')

Research value

[How valuable is the research?](#)

Yes

('doctors' inadequate communication training could be one of the keys to the prevailing usage of a paternalistic communication style during consultations')

('Further studies should examine ways to promote the desired style of doctor patient communication and examine the impact of cultural factors on communication.')

('We therefore believe that the results of this study are also representative of doctor–patient communication in other Southeast Asian contexts.')

Overall risk of bias and directness

Overall risk of bias

Moderate

Directness

Direct

1

Cohen, 2003

2

Bibliographic Reference

Cohen, Howard; Britten, Nicky; Who decides about prostate cancer treatment? A qualitative study; Family practice; 2003; vol. 20 (no. 6); 724-9

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('The aim of this paper is to gain an in depth understanding of the perspectives of men recently diagnosed with localized prostate cancer, and to explore the value of decision-making models in the setting of NHS Practice.')

('Men newly diagnosed with prostate cancer need to make difficult decisions with their doctors against a background of uncertainty')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('The men were encouraged to recollect their experiences of being diagnosed with prostate cancer and of having their treatment planned. They were asked to discuss their concerns and perceptions, as well as the factual details of their cases.')

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

('The pathology department records of a single District General Hospital were then used to identify a group of men with a positive prostate cancer biopsy during 1999. Out of 119 positive biopsies, 90 patient records were examined and 74 prostate cancer patients were identified, 47 of whom had localized disease. The permission of these 47 patients' GPs was then sought, to invite the patients to join the study. Permission was granted in 38 cases and 13 men agreed to be interviewed about their experiences. A further 4 men were recruited directly from a survey of referral letters to the Urology department, and were interviewed both before and after their hospital consultations.')

('The resulting group of men (n = 19) were of varying age and background, and received a range of treatments')

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(No information about data saturation)

('The interviews were semi-structured, using open-ended questions')

('The interviews were semi-structured, using open-ended questions, facilitated by a topic guide')

('The interviews were audio taped and transcribed')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Yes

('The status of the interviewer being a GP will have had an influence on the nature of the interviews, which was considered in the analysis')

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(This study was granted ethical approval by the Croydon Local Research Ethics Committee)

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

('After a period of familiarization and immersion in the transcripts, a coding structure was developed by HC. NB, as project supervisor, independently applied the coding structure to three of the early interviews to ensure reliability. The application of the codes was discussed and minor adjustments were made before the coding structure was applied consistently across all the interviews.')

('Responses in each of the codes were collected and organized using Atlas Ti software, allowing detailed description of key themes')

(No mention of data saturation)

Findings

Is there a clear statement of findings?

Yes

(Data is presented by themes and described)

(Reported the use of respondent validation)

Research value

How valuable is the research?

Yes

('A willingness to vary our approach, calling on a range of styles, will be demanding both in time and personal skills. Sharing with patients how we might go about deciding their care may be the key first stage to effective shared decision making.')

Overall risk of bias and directness

Overall risk of bias

Moderate

Directness

Direct

1

De, 2015

2

Bibliographic Reference

De Snoo-Trimp, Janine C.; Brom, Linda; Pasman, H. Roeline W.; Onwuteaka-Philipsen, Bregje D.; Widdershoven, Guy A. M.; Perspectives of Medical Specialists on Sharing Decisions in Cancer Care: A Qualitative Study Concerning Chemotherapy Decisions With Patients With Recurrent Glioblastoma; The oncologist; 2015; vol. 20 (no. 10); 1182-8

3

1

2

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('The study aims to answer the following questions: what are specialists' experiences with and views on shared decision making, and how do specialists apply the four elements of the shared decision making model in practice?')

('Little attention has been paid to the perspectives of medical specialists on chemotherapy in the last phase of life and shared decision making.')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('The medical specialists were asked individually about the process of deciding whether to start second or subsequent lines of treatment in general and in specific cases')

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

(Probably appropriate but this was not explained in the paper)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

('medical specialists were recruited through the patients included in the longitudinal study and were from the neurology department of a large university hospital')

('interviewed medical specialists were neurologists, oncologists, and neurosurgeons who were all involved in the decision making process')

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Specialists who had been involved in decisions with patients with recurrent glioblastoma)

(In-depth interviews and focus group)

(Interviews - open-ended questions using a topic list. Focus group - topic list based on literature and analysis of interviews)

(Audio taped and transcribed)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Includes informed consent but no information about confidentiality)

(The study was approved by the medical ethics committee of the VU University Medical Center Amsterdam)

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Information about coding, methods of iterative analysis and author consensus)

('The study was explorative and used open coding'. 'The transcripts were examined independently to create a list of codes (e.g., mentioning the option of not starting treatment, the role of the team meeting, discussing the poor prognosis, sharing responsibility, and the role of the patient')

(No mention of data saturation)

('Some specialists emphasized the importance of involving the patient in the decision-making process. Others stated that sharing the decision making is not in the best interests of the patient because the patient does not have an adequate understanding of the disease and the treatment')

Findings

[Is there a clear statement of findings?](#)

Yes

(Results presented by theme and discussed)

(Three analysts but no information about other methods of validation)

('This study showed that it is not easy to share the decision-making process in practice with patients with recurrent glioblastoma because of the preference of both specialists and patients to start second-line treatment and the assumption of specialists about knowing patients' wishes')

Research value

[How valuable is the research?](#)

Yes

('A future observational study in the clinical setting might provide information about this aspect')

Overall risk of bias and directness

[Overall risk of bias](#)

Moderate

Directness

Direct

1

Eliacin, 2015

2

Bibliographic Reference

Eliacin, Johanne; Salyers, Michelle P.; Kukla, Marina; Matthias, Marianne S.; Patients' understanding of shared decision making in a mental health setting; Qualitative Health Research; 2015; vol. 25 (no. 5); 668-678

3

4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('The purpose of this study was to investigate how patients understand the concept of shared decision making')

('We also have limited understanding of patients' views of shared decision making in mental health and the factors that facilitate or impede their participation in this process')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('In addition, we conducted interviews with patients after their scheduled medication-check visits, which were explicitly designed with the goal of examining patients' understanding of the concept of shared decision making')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('The questions were formulated to facilitate participants' descriptions of their own experiences, while exploring in-depth issues related to patient-provider communication and treatment decision making')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

('recruited using a convenience sampling method. This involved approaching patients of participating providers while they waited for their visits and asking them to participate in the study')

('The diagnostic diversity of this sample closely mirrors the diversity of patients in psychiatric clinics, where providers are likely to treat patients with a wide variety of diagnoses, co-morbid disorders, and considerable variation in relationship duration')

('The main reason given for non-participation was time constraints')

Data collection

Did the researchers justify the setting for the data collection?

Yes

Is it clear how data were collected (e.g. focus group, semi-structured interview etc.)?

Yes

Did the researcher has justify the methods chosen?

Yes

Has the researcher made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)?

No

Were methods modified during the study? If so, has the researcher explained how and why?

Can't tell

Is the form of data clear (e.g. tape recordings, video material, notes etc.)?

Yes

Has the researcher discussed saturation of data?

Yes

Was the data collected in a way that addressed the research issue?

Yes

('We focused on patients with mental illness and examined routine outpatient medication management visits with providers in a psychiatric clinic. The context of routine outpatient medication management visits provided opportunities to assess how patients made treatment decisions with their providers as well as health communication in everyday clinical practice')

(Questionnaires and semi-structured interviews)

(The interviews consisted of open-ended questions that focused on patients' views of shared decision making, medication and treatment decisions, illness management, and relationship with their providers. Questions about medication assessed patients' knowledge about their medication, 7 medication treatment decisions, and history of medication adherence.)

(Audio recordings, transcribed verbatim)

('We determined saturation in the sample once we could not identify new information or variations of a given theme in the data, and based on evidence of multiple repeated coding within the same core category')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Are there sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained?

No

Has the researcher discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)?

Yes

Has approval been sought from the ethics committee?

Yes

Have ethical issues been taken into consideration?

Yes

('Written, signed consent forms were obtained from all participants prior to the interviews' 'All interviews were audio-recorded, transcribed verbatim, de-identified')

('Research procedures were approved by the local institutional review board and medical center research and development committee')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Information about transcribing, coding and developing thematic analysis)

(We conducted open coding by dividing portions of the text into meaningful units of analysis or codes and common themes that emerged across the transcripts. We discussed this list of preliminary codes identified during this initial open coding procedure and sorted them into categories that reflected important ideas and themes (axial 8 coding))

('We determined saturation in the sample once we could not identify new information or variations of a given theme in the data, and based on evidence of multiple repeated coding within the same core category')

('We determined saturation in the sample once we could not identify new information or variations of a given theme in the data, and based on evidence of multiple repeated coding within the same core category')

Findings

Is there a clear statement of findings?

Yes

(Findings are presented in themes and discussed)

(More than one analyst. No information about respondent validation)

('Patients with mental illness understood the concept of shared decision making and desired to be engaged at some level in this model of treatment decision making')

Research value

How valuable is the research?

Yes

('providers should assess and match patients' preferences for degree of involvement in shared decision making. Additionally, even if patients appear passive in the decision making process, this does not preclude implementation of the core elements of shared decision making. In particular, clear communication about treatment options, 25 eliciting patients' perspectives and opinions—and continuing to foster a trusting patient-provider relationship—are all critical to deliver patient-centred care.')

('Future studies should seek to include a more diverse patient sample, and assess how different socio-demographic factors, as well as a wider range of patient-provider relationships could impact shared decision making')

(Discussed that the study population was predominantly white male veterans, aged 40-65, and the reasons that these findings may not be applicable to the wider population)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Partially applicable

(Participants were predominantly white male veterans, aged 40-65)

1

Elwyn, 1999

2

Bibliographic Reference

Elwyn, G.; Edwards, A.; Gwyn, R.; Grol, R.; Towards a feasible model for shared decision making: focus group study with general practice registrars; BMJ (Clinical research ed.); 1999; vol. 319 (no. 7212); 753-6

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To know if the theoretical constructs of decision making need to be adapted for use in clinical settings)

('how the principle of "involving" patients resonates with practice has not been explored.')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('the sample was purposefully selected to enable us to gauge the reactions of new general practitioners to the concept of involving patients in decision making')

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

(Likely to be an appropriate method but very limited information about research design)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

(Limited information provided other than new general practitioners)

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(Focus groups)

(Limited information on how focus group questions were decided on)

('audiotaped and transcribed')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Brief description of developing themes)

(No mention of data saturation)

(Positive and negative views of shared decision making included)

Findings

Is there a clear statement of findings?

Yes

(Results presented by themes and described)

(Positive and negative views of shared decision making included)

(More than one analyst but no information about respondent validation)

('Our results show that practitioners need to adapt to varying contexts, preferences of patients, and types of decisions')

Research value

How valuable is the research?

Yes

('Our results show that practitioners need to adapt to varying contexts, preferences of patients, and types of decisions')

Overall risk of bias and directness

Overall risk of bias

Moderate

Directness

Direct

1

Fraenkel, 2007

2

Bibliographic Reference

Fraenkel, Liana; McGraw, Sarah; What are the essential elements to enable patient participation in medical decision making?; Journal of general internal medicine; 2007; vol. 22 (no. 5); 614-9

3

4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('We conducted this study to gain a more complete understanding of the essential elements, or the prerequisites, critical to active patient participation in medical decision making, from the patients' perspective')

('Identification of these factors is needed before methods can be developed to promote and facilitate SDM in clinical practice for patients who prefer to be active participants')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('in depth exploration of each respondent's experiences and thoughts')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('Individual face-to-face interviews were chosen over focus groups for this study because interviews allow for more indepth exploration of each respondent's experiences and thoughts')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

('Participants were drawn from a larger study examining patient treatment preferences for osteoporosis' 'Subjects for this qualitative study were drawn consecutively from the group of patients whose bone densitometry measures were too high to make them eligible to participate in the parent study')

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Semi-structured interview)

('Individual face-to-face interviews were chosen over focus groups for this study because interviews allow for more indepth exploration of each respondent's experiences and thoughts')

('Using a semistructured discussion guide, the interviews followed a funnel structure, progressing from broader and open-ended questions to more structured questions with specific probes to clarify issues as needed')

('The interviews were audiotaped and transcribed by a professional transcription service')

('Interviews were conducted until thematic saturation was reached')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

('All participants gave informed consent')

('Yale University Institutional Review Boards approved the protocol')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Information on coding, constant comparative method and analysis package used)

(The constant comparative method approach was employed to ensure that the analysts defined and applied the codes in a consistent manner across all transcripts. Using 2 readers ensured that a broader range of codes was identified. QSR*NUDIST (Sage Publications Software, Thousand Oaks, California) was used to identify and sort the relevant text across the transcripts for each code;)

('Interviews were conducted until thematic saturation was reached')

('Interviews were conducted until thematic saturation was reached')

(Contradictory opinions presented in the analysis)

Findings

Is there a clear statement of findings?

Yes

(Findings are presented by theme and discussed)

(Contradictory opinions presented in the analysis)

(More than one analyst but no information on respondent validation)

('our findings have important clinical implications and suggest that several needs must be met before patients can become active participants in decisions related to their health care. These needs include ensuring that patients (1) appreciate that there is uncertainty in medicine and buy in to the importance of active patient participation, (2) understand the trade-offs related to available options, and (3) have the opportunity to discuss these options with their physician to arrive at a decision concordant with their values')

Research value

How valuable is the research?

Yes

('the need for patients to be adequately informed and for physicians to give patients the opportunity to participate.')

(Male patients and patients with more varied educational backgrounds)

(Stated that participants were predominantly well-educated post-menopausal women who are likely to want to participate in shared decision making. Not necessarily applicable to other groups.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Partially applicable

(Stated that participants were predominantly well-educated post-menopausal women who are likely to want to participate in shared decision making. Not necessarily applicable to other groups (e.g. male patients and patients with more varied educational backgrounds))

1

Frerichs, 2016

2

Bibliographic Reference

Frerichs, Wiebke; Hahlweg, Pola; Muller, Evamaria; Adis, Christine; Scholl, Isabelle; Shared Decision-Making in Oncology - A Qualitative Analysis of Healthcare Providers' Views on Current Practice; PloS one; 2016; vol. 11 (no. 3); e0149789

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('Thus, the aim of this study is to explore the views of different HCPs regarding the current practice of decision-making in oncology in Germany')

('to successfully implement SDM in routine cancer care in Germany, it is indispensable to understand the whole process of decision-making from a multidisciplinary perspective')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('What are the attitudes of the different HCPs towards SDM? • What are HCPs' experiences with treatment decisions in current practice?')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('Qualitative research is an ideal approach for exploring new areas of study [37] and to uncover beliefs, values, and motivations')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

(Explained how physicians and nurses were recruited from UCCH)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Focus groups for assistant physicians and nurses. Interviews for senior physicians)

('Focus group discussions have been shown to be a useful approach for actively exchanging ideas and opinions among participants, for exploring participants' knowledge and experiences' 'As it would have been difficult to schedule a focus group for head physicians (comparable to senior or principal consultants in the UK and US respectively) and management staff (e.g. nursing management or quality management), individual face-to-face interviews were conducted')

(Brief description of how focus groups and interviews were conducted)

(Audio recording and transcription)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Are there sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained?

Yes

Has the researcher discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)?

Yes

Has approval been sought from the ethics committee?

Yes

Have ethical issues been taken into consideration?

Yes

('Before the conduction of the focus groups and interviews, participants received an information sheet and signed an informed consent for participation')

('The study was carried out in accordance with the Code of Ethics of the Declaration of Helsinki and was approved by the Ethics Committee of the Medical Association Hamburg, Germany')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of transcription and coding methods, software used and analysis)

(Full description in the methods)

(No mention of data saturation)

(Conflicting opinions of SDM presented)

Findings

Is there a clear statement of findings?

Yes

(Findings presented in themes and discussed)

(Conflicting opinions of SDM presented)

('The methodological approach including data analysis conducted by two researchers, and multiple revisions and crosschecking can be seen as a further major strength of this study')

('German HCPs gave mixed reports about their current attitudes and experiences with SDM in daily practice')

Research value

How valuable is the research?

Yes

('In order to develop a successful implementation program, it will be crucial to take these attitudes and experiences into account and to subsequently disentangle existing misconceptions, e.g., through SDM trainings for providers')

('adds new knowledge that can be used for the implementation of SDM in oncology in Germany and possibly in other countries with similar healthcare systems')

Overall risk of bias and directness

Overall risk of bias

Moderate

Directness

Direct

1

Fuller, 2017

2

Bibliographic Reference

Fuller, Shannon M.; Koester, Kimberly A.; Guinness, Ryan R.; Steward, Wayne T.; Patients' perceptions and experiences of shared decision-making in primary HIV care clinics; JANAC: Journal of the Association of Nurses in AIDS Care; 2017; vol. 28 (no. 1); 75-84

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('describe patient experiences in HIV primary care, focusing on factors that shape participation in medical decision-making and highlighting situations unique to this care setting that may warrant tailoring of the traditional SDM approach')

('What remains needed is a description of how SDM operates in HIV care encounters')

Appropriateness of methodology

Does the research seek to interpret or illuminate the actions and/or subjective experiences of research participants?

Yes

Is qualitative research the right methodology for addressing the research goal?

Yes

Is a qualitative methodology appropriate?

Yes

('We sought to understand the worldview of our research participants through their lived experiences; specifically, we sought to explore the phenomenon of what it means to be a patient living with HIV in a care setting that is striving to become a PCMH.')

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Description of inclusion criteria)

(Included patients with HIV)

Data collection

(Semi-structured interviews)

('We used an interview guide; however, each interviewer was encouraged to add clarifying questions or modify inquiries when needed')

('All interviews were recorded with the participant's consent and transcribed verbatim')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

('Interviewers obtained verbal informed consent and documented the receipt of consent on a tracking sheet. Consent was obtained verbally, instead of in writing, so that participants would not be required to disclose their names, thereby preserving anonymity')

('The University of California San Francisco Institutional Review Board reviewed and approved all procedures.')

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Description of coding and analysis methods)

('The a priori codes came directly from domains or particular questions in our interview guide, such as the code "role in health care decisions" to capture participant responses to that question in our guide. Our a priori codes related to the decision-making domain (e.g., active, passive, or shared decision making) came from terminology and conceptualizations presented in published literature')

(No mention of data saturation)

(Presented conflicting opinions on SDM)

Findings

[Is there a clear statement of findings?](#)

Yes

(Findings presented in themes and discussed)

(Presented conflicting opinions on SDM)

(More than one analyst but no information about respondent validation)

Research value

[How valuable is the research?](#)

Yes

('Rather than recommend SDM as the gold standard of patient care, the standard should be to assess and respect preferences around SDM')

('Further qualitative research could explore SDM from the perspective of HIV care providers to present a more comprehensive picture of how SDM operates in this care setting')

Overall risk of bias and directness

[Overall risk of bias](#)

Moderate

[Directness](#)

Direct

1

Giacco, 2018

2

Bibliographic Reference

Giacco, Domenico; Mavromara, Liza; Gamblen, Jennifer; Conneely, Maev; Priebe, Stefan; Shared decision-making with involuntary hospital patients: a qualitative study of barriers and facilitators; BJPsych open; 2018; vol. 4 (no. 3); 113-118

3

4

Aims of the research

[Was there a clear statement of the aims of the research?](#)

Yes

('explored the views of both patients and clinicians on barriers and facilitators to shared decision making during involuntary hospital treatment')

('This could inform changes in clinical practice to make sure that patients are involved in care')

Appropriateness of methodology

[Is a qualitative methodology appropriate?](#)

Yes

('explored the views of both patients and clinicians on barriers and facilitators to shared decision making during involuntary hospital treatment')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('We collected patients' and clinicians' views in focus groups, as group discussions are particularly helpful for generating new ideas to improve practice')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Brief description of inclusion criteria)

(Patients who had an admission under the Mental Health Act, either still in hospital or had been discharged)

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(Unclear about the methods used for the focus groups and interviews)

('Three focus groups with patients were conducted within the ward and one with patients who had been discharged.')

(Focus groups for most patients. Interviews with an interpreter for patients who did not speak English)

(Details of who was involved with the focus groups and interviews but no details about the structure of the data collection sessions)

(Audio recorded and transcribed)

('We stopped at a sample size of 38 participants, as interim analysis indicated that 'data saturation' had been reached, as no new themes were emerging and there was redundancy in the data')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(After being given a complete description of the study, they gave written informed consent to participate)

('respected the same standards of confidentiality used in the NHS')

('The London – London Bridge Research Ethics Committee (ref: 16/LO/0384) approved the study, which has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of transcription, coding and thematic analysis)

('the researchers coded all of the transcripts, using N-VIVO software' 'Core themes emerging from the data were identified and refined through discussion among the authors, 14 who have different backgrounds (research methodology, social sciences, psychology, psychiatry)')

('each group of clinicians (psychiatrists, psychologists and nurses). We stopped at a sample size of 38 participants, as interim analysis indicated that 'data saturation' had been reached, as no new themes were emerging and there was redundancy in the data')

Findings

Is there a clear statement of findings?

Yes

(Findings reported in themes and discussed)

(More than one analyst but no information about respondent validation)

(Discussed both barriers and facilitators to SDM)

Research value

How valuable is the research?

Yes

(Detailed discussion of how the findings relate to patient involvement, barriers to communication and training)

('Novel interventions to improve involuntary hospital care should be tested in experimental studies which have the same rigour as research carried out with other patients and in other contexts of care')

(Discussed how the findings are mostly related to people within an area with a high deprivation index. But suggested these could still be applied elsewhere (although why was not explained in detail))

Overall risk of bias and directness

Overall risk of bias

Moderate

Directness

Partially applicable

(Participants all from an area in East London with a high deprivation index)

1

Grus, 2019

Grus, Inga; McMullen, Carmit K; Barriers to eliciting patient goals and values in shared decision-making breast cancer surgery consultations: An ethnographic and interview study.; *Psycho-oncology*; 2019; vol. 28 (no. 11); 2233-2239

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(This study assessed how clinicians balanced sharing medical information and considering patients' goals and values during breast cancer surgery consultation in an integrated health care system.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

Observed SDM conversations between surgeons and patients during MDCs. All participating surgeons were eligible for observation. Surgeons were approached by researchers and asked to participate; those who agreed provided written consent. The only recruitment criterion for patients was eligibility for SDM. Nurse navigators recruited and obtained informed consent from patients. All surgeons (n = 6), radiation oncologists (n = 2), and patients (n = 8) approached during 8 weeks of MDCs agreed to participate.

Data collection

Was the data collected in a way that addressed the research issue?

Yes

One researcher (I.G.) conducted ethnographic observations during SDM conversations between clinicians (surgeons and radiation oncologists) and patients to capture how patients and clinicians engaged in SDM. These observations resulted in field notes that captured verbal exchanges and other activities. Observations of conversations between radiation oncologists and patients were excluded from this analysis, as the conversations between surgeons and patients were our focus. Interviews were conducted by one researcher (I.G.); all were recorded with participants' permission. Separate interview guides for patients and clinicians were developed (see appendices). Clinician guides focused on their views of the role of SDM in providing breast cancer treatment. Questions included prompts about clinicians' approaches to informing breast cancer patients about treatment options, typical concerns patients share about treatment options, and the involvement of patients in SDM over the course of clinicians' careers. Interview guides for patients focused on how patients learned about breast cancer, and whether the surgical consultations in the MDC provided all the information they needed to make an informed decision. A seven-item knowledge test made up of true or false questions about breast cancer treatment was used during the interview to assess patient understanding of treatment options.

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

No

All study activities were approved by the Kaiser Permanente Northwest Institutional Review Board (reference number CR573) and followed the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.

Data analysis

Was the data analysis sufficiently rigorous?

Yes

Field notes from both the observations and transcribed interviews were analyzed following template analysis,²² using the qualitative analysis software NVivo10. We followed an inductive strategy to develop a code book for all sources of data. After a review of the full data set, one researcher (I.G.) developed codes for field notes, patient, and clinician interviews separately. These codes were applied by I.G. and a second researcher (C.M.) to sample transcripts, results were compared and discussed, and the researchers adjusted code definitions as necessary to ensure agreement. I.G. then applied the codes received during the decision-making process; SDM, defined as clinicians' explanations and approaches to empowering patients to make surgical decisions; and SDM tool and patient support, defined as clinicians' comments about the tool and any support they described as useful for patient empowerment. to all transcripts and fieldnotes. The current analysis focused on the following codes: assessment of care processes by patients, defined as capturing any comments, information and observations about consultations, and the overall care process; preparation for treatment decision, defined as any information that patients highlighted as important.

Findings

Is there a clear statement of findings?

Yes

Split into findings with explanations. Multiple researchers.

Research value

How valuable is the research?

Yes

Valuable, implications on practice and future research areas discussed.

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Directly applicable

1

Hahlweg, 2017

2

Bibliographic Reference

Hahlweg, Pola; Harter, Martin; Nestoriuc, Yvonne; Scholl, Isabelle; How are decisions made in cancer care? A qualitative study using participant observation of current practice; BMJ open; 2017; vol. 7 (no. 9); e016360

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('this study aimed to gain insight on how cancer treatment decisions are made (where, when, by whom) and to extend the understanding of decision-making beyond the dyadic physician–patient interaction' 'Furthermore, this study sought to identify barriers and facilitators to the SDM process.')

('Existing process evaluations revealed that for successful implementation of SDM into routine care barriers and facilitators need to be analysed')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

(via observation of current practice in a cancer centre)

('Qualitative research using observation methodology has been shown to be useful to generate a comprehensive description of processes in clinical care')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('Qualitative research using observation methodology has been shown to be useful to generate a comprehensive description of processes in clinical care')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(All patients at the University Cancer Center Hamburg)

(Patients currently receiving treatment for cancer)

Data collection

Did the researchers justify the setting for the data collection?

Yes

Is it clear how data were collected (e.g. focus group, semi-structured interview etc.)?

Yes

Did the researcher has justify the methods chosen?

Yes

('Qualitative research using observation methodology has been shown to be useful to generate a comprehensive description of processes in clinical care')

Has the researcher made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)?

Yes

Were methods modified during the study? If so, has the researcher explained how and why?

Can't tell

Is the form of data clear (e.g. tape recordings, video material, notes etc.)?

Yes

Has the researcher discussed saturation of data?

No

Was the data collected in a way that addressed the research issue?

Yes

('In this academic cancer centre, setting observation of practice (eg, by undergraduate students or residents) is very common. Furthermore, physicians were only vaguely informed about the purpose of the study to minimise the probability of physicians systematically changing their behaviour due to the awareness of being observed')

('Form with pre-structured sections')

(Pre-structured form based on literature on writing field notes)

(Field notes from observations)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Yes

(Study was conducted in the hospital setting and observations were made based on routine clinical practice. Observation considered to be less disruptive to the process than audio or video recording)

Ethical Issues

Have ethical issues been taken into consideration?

Yes

('Prior to observations, we contacted physicians at the inpatient wards and outpatient clinics to discuss the realisation of the observation. We also informed the nursing staff about the project')

('Informed consent was obtained from all patients prior to observations')

('The study was carried out in accordance with the Code of Ethics of the Declaration of Helsinki and was approved by the Ethics Committee of the Medical Association Hamburg (Germany).')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of digitising notes, coding and thematic analysis)

(Details of coding and presentation of thematic analysis in methods)

(No mention of data saturation)

(No mention of data saturation)

(Study presents contradictory findings)

(Stated that they tried to cause minimum disruption to clinical processes)

Findings

Is there a clear statement of findings?

Yes

(Findings presented in themes and discussed)

(Study presents contradictory findings)

(More than one analyst, Respondent validation not applicable for this method)

('Although aspects of SDM were observed on some occasions, the whole process of making medical decisions was not observed to follow the principles of SDM')

Research value

How valuable is the research?

Yes

('Most of the time, either one physician alone or a group of physicians made the treatment decisions. Patients were seldom actively involved. If patients were 'active patients', this behaviour facilitated SDM. The main observed barriers were time pressure, frequent alternation of responsible physicians and poor coordination of care')

('Linking qualitative data as ours to quantitative descriptives such as clinical status, and linking data from multidisciplinary team discussions and data from patient– physician encounters would be valuable')

('generalisability to other institutions and countries is a limitation of this study. Further research is needed to find out whether our findings are applicable to other cancer care institutions nationally and internationally')

Overall risk of bias and directness

Overall risk of bias

Low

(Study used observation but clinicians were unaware of the aims of the study)

Directness

Direct

1

Hajizadeh, 2015

2

Bibliographic Reference

Hajizadeh, Negin; Uhler, Lauren M.; Perez Figueroa, Rafael E.; Understanding patients' and doctors' attitudes about shared decision making for advance care planning; Health expectations : an international journal of public participation in health care and health policy; 2015; vol. 18 (no. 6); 2054-65

1

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('We sought to gain insights into whether patients and doctors were engaging in shared decision making in general and attitudes about patient involvement in shared decision making.')

('As patient preferences vary, recommendations suggest that end-of-life conversations be patientcentred, with the content, timing and place determined by the patient, but more research is needed on patient preferences for these discussions')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('interviewers asking questions about patients' and doctors' attitudes and perceptions towards shared decision making and end-of-life decision making')

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(Semi-structured interviews)

(Pre-specified open and closed-questions)

(Notes from the interview)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(Study had ethical approval but no information about informed consent)

('The New York University School of Medicine Institutional Review Board approved all the study protocols')

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Description of coding and thematic analysis)

('The analysis centred on key issues related to end-of-life decision making such as the timing, characteristics of the context in which these discussions should take place, the use of prognostic estimates and doctors' and patients' attitudes towards end-of-life decision making')

(No mention of data saturation)

(Some of the results report what most people said but don't report if other people didn't answer the question or if they had a contradictory opinion)

Findings

Are the findings explicit?

Yes

Was there adequate discussion of the evidence both for and against the researcher's arguments?

No

Did the researcher discuss the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)?

Yes

Were the findings discussed in relation to the original research question?

Yes

Is there a clear statement of findings?

Yes

(Findings are separated by themes and discussed)

(Some of the results report what most people said but don't report if other people didn't answer the question or if they had a contradictory opinion)

('several strategies to increase the rigour of the study were pursued including peer debriefing, independent and collaborative coding, memowriting and the use of a decisional audit trail')

(Reports results in relation to clinician and patient opinion)

Research value

How valuable is the research?

Yes

('Our study results can inform the development of tools such as decision aids which may empower patients to participate in decision making regarding their health care and can support doctors with prognostic estimates pertinent to individual patients')

('Although the results are not intended to be generalizable, the use of an urban clinical population may limit the breadth of the data. First, the experience of patient and doctor participants may be limited by the context. Further, variability may exist by age, gender, race/ethnicity and characteristics of the clinical diagnosis')

Overall risk of bias and directness

Overall risk of bias

High

(Limited information on how patients were recruited or why they were the most appropriate. No information about informed consent. Doesn't appear to report contradictory findings)

Directness

Direct

1

Hamann, 2016

2

Bibliographic Reference

Hamann, Johannes; Kohl, S.; McCabe, R.; Buhner, M.; Mendel, R.; Albus, M.; Bernd, J.; What can patients do to facilitate shared decision making? A qualitative study of patients with depression or schizophrenia and psychiatrists; Social psychiatry and psychiatric epidemiology; 2016; vol. 51 (no. 4); 617-25

1

2

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(The aim of this study was to explore both patients' and psychiatrists' views on how patients can facilitate shared decision making in acute mental health settings)

(To date, there have been no studies of how patients may facilitate SDM in the field of mental health, especially in more acute settings)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Purposively sampled)

('male and female patients, with schizophrenia/ schizoaffective psychosis (ICD 10: F20/F25) or depression/ bipolar disorder (ICD 10: F31/F33) and with experience of both in- and outpatient treatment')

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Focus groups)

('Data were collected within focus groups for which a topic guide was developed by the research team resulting in slightly different versions for professionals and patients')

(Audio taped and transcribed)

('After conducting the 4 patient and 3 psychiatrist focus groups, it became evident that similar themes were discussed across the groups and as no new themes were emerging, no further groups were conducted')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Yes

('Patients were aged between 18 and 65 years and capable of providing written informed consent')

('The study received ethical approval from the Ethikkommission at the Technische Universität München')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of transcription, coding and thematic analysis)

(Codes were compared between analysts and organised into 7 higher order themes)

(Organised into higher order themes)

('After conducting the 4 patient and 3 psychiatrist focus groups, it became evident that similar themes were discussed across the groups and as no new themes were emerging, no further groups were conducted')

(Reported differences between patient and physician opinions)

Findings

Is there a clear statement of findings?

Yes

(Findings are presented in themes and discussed)

(Reported differences between patient and physician opinions)

(More than one analyst but no information about respondent validation)

('Focused interventions to support patients' decisional capacity, participation preferences and active behavior may considerably enhance SDM in mental health.')

Research value

How valuable is the research?

Yes

('Ensuring meaningful SDM in mental health care suggests no longer neglecting the patients' side of SDM and emphasizing "competent" or "active" patient behaviour and helping patients to overcome these barriers. To overcome these barriers, it must be emphasized that decisional incapacity is rather a state than a trait and may be addressed in training')

('The impact of, e.g., experiences of coercive measures may be of less importance for patients with a more benign course of illness')

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Hirpara, 2016

2

Bibliographic Reference

Hirpara, Dhruvin H.; Cleghorn, Michelle C.; Sockalingam, Sanjeev; Quereshey, Fayez A.; Understanding the complexities of shared decision-making in cancer: a qualitative study of the perspectives of patients undergoing colorectal surgery; Canadian journal of surgery. Journal canadien de chirurgie; 2016; vol. 59 (no. 3); 197-204

3

4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(to examine the complexities of the longitudinal and interactive process of SDM among patients, their families and the health care team in colorectal cancer (CRC) surgery)

('While the literature on SDM focuses on the patient's direct encounter with the physician and health care team, there is little to no emphasis on the interplay between familial and cultural influences and decision-making within a model of patient-centred care. Research on this topic is especially scarce in the field of surgical oncology')

Appropriateness of methodology

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Is a qualitative methodology appropriate?

Yes

('The interview guide, consisting of both open-ended questions and question probes used to facilitate the discussion, allowed flexibility to elicit individual views and descriptions of experiences')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('The interview guide, consisting of both open-ended questions and question probes used to facilitate the discussion, allowed flexibility to elicit individual views and descriptions of experiences')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Description of inclusion criteria and sampling methods (convenience sampling))

('All patients approached to take part in the study were fully aware of their diagnosis and were considered physically and psychologically able to cope with the interview process')

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Semi-structured interview)

('The interview guide, consisting of both open-ended questions and question probes used to facilitate the discussion, allowed flexibility to elicit individual views and descriptions of experiences')

(Interview guide developed by interdisciplinary team or a psychiatrist, surgical oncologist and nurse navigator)

(Audio recorded and transcribed)

('Upon achieving data saturation (the point at which no new information that was relevant to the research question emerged), these categories were further analysed and refined to identify overarching themes in the attitudes, perceptions and experiences of patients')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Yes

('We obtained informed consent from all patients before their participation in the study')

('The protocol was approved by the University Health Network Research Ethics Board before study initiation')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of transcription, coding and thematic analysis)

(Categories analysed and refined to overarching themes)

(Results categorised into overarching themes)

('Upon achieving data saturation (the point at which no new information that was relevant to the research question emerged), these categories were further analyzed and refined to identify overarching themes in the attitudes, perceptions and experiences of patients')

Findings

Are the findings explicit?

Yes

Was there adequate discussion of the evidence both for and against the researcher's arguments?

Can't tell

Did the researcher discuss the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)?

Yes

Were the findings discussed in relation to the original research question?

Yes

Is there a clear statement of findings?

Yes

(Findings reported by theme and discussed)

(More than one analyst. No information about respondent validation)

('Three major themes were identified that represent factors shaping decision-making in this setting: 1) family plays a central role in supporting patients, and social support reduces patient burden; 2) patient confidence in care and the decision-making process is influenced by facilitators and barriers, such as provider communication and information; and 3) patients experience and accept a lack of control and limited choice in treatment decisions')

Research value

How valuable is the research?

Yes

('Institutional measures must be undertaken to enhance patient education about SDM. Instructive resources, including information packages and brochures in a patient's primary language, can help patients and their families make informed and meaningful treatment decisions.')

('Future studies should aim to recruit a diverse cross-section of patients undergoing CRC surgery with unique treatment experiences')

(Discussed that findings might not be generalisable to other populations (i.e. patients under 65 or those who declined surgery))

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Partially applicable

(All patients were under the care of a single surgical oncologist. Experiences of SDM may differ based on the clinician involved)

1

Hofstede, 2013

2

Bibliographic Reference

Hofstede, Stefanie N.; Marang-van de Mheen, Perla J.; Wentink, Manon M.; Stiggelbout, Anne M.; Vleggeert-Lankamp, Carmen L. A.; Vliet Vlieland, Thea P. M.; van Bodegom-Vos, Letj; group, Disc study; Barriers and facilitators to implement shared decision making in multidisciplinary sciatica care: a qualitative study; Implementation science : IS; 2013; vol. 8; 95

3

4

Aims of the research

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Was there a clear statement of the aims of the research?

Yes

('to explore and categorize all barriers and facilitators associated with the implementation of SDM in sciatica care perceived by professionals and patients')

(SDM in multidisciplinary sciatica care involves separate primary and hospital care appointments which may involve more barriers/facilitators than healthcare within the same organisation)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Purposive sampling)

(Included a range of professionals from different backgrounds and care settings. Any patients who responded to a newspaper advert were included)

('lack of time or not seeing (many) patients with sciatica in their practice')

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Semi-structured interview for professionals. Focus groups for patients)

('This type of data collection can provide rich and in-depth information about the cognitions, motivations and experiences of individuals')

(Topic guides)

(Audio taped and transcribed)

('We applied purposive sampling by selecting participants from regions with respectively low and high surgery rates, and continued interviewing until data saturation was reached')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Use of an information letter before the patient focus groups. Less information about explanations for professionals)

(Written informed consent was obtained)

('This study protocol was presented to the Medical Ethical Committee of the Leiden University Medical Center. An exemption was obtained, as ethical approval for this type of study is not required under Dutch law')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of coding, thematic analysis and discrepancy resolution)

(Themes based on a predetermined framework with new codes for text that did not fit those categories)

(Data extracted to themes and compared between patients and professionals)

(continued interviewing until data saturation was reached)

(Described conflicting opinions between patients and professionals)

Findings

Is there a clear statement of findings?

Yes

(Findings presented by theme and discussed)

(More than one analyst but no information about respondent validation)

(Discusses SDM in relation to multi-disciplinary care)

Research value

Did the researchers discuss the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature)?

Yes

Did they identify new areas where research is necessary?

Yes

Did the researchers discuss whether or how the findings can be transferred to other populations or consider other ways the research may be used?

Yes

How valuable is the research?

Yes

(Adds to previous research which was predominantly from non multi-disciplinary settings)

('a quantitative study to determine which barriers and facilitators mentioned in this qualitative study are the most important for the adoption of SDM, and professionals' behaviour towards SDM and differences in most important barriers and facilitators between these groups will be determined')

(Other groups receiving multi-disciplinary care)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Directly applicable

1

Jansen, 2019

2

Bibliographic Reference

Jansen, Jesse; McKinn, Shannon; Bonner, Carissa; Muscat, Danielle Marie; Doust, Jenny; McCaffery, Kirsten; Shared decision-making about cardiovascular disease medication in older people: a qualitative study of patient experiences in general practice; BMJ open; 2019; vol. 9 (no. 3); e026342

3

4

1

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(we explore older people's perspectives and experiences with decisions about medication for CVD prevention and describe the implications of our findings for SDM in the context of preventive medicine in older people)

('studies describing the experience of older patients [for SDM] with health decisions are still scarce')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Description of inclusion criteria and where they were recruited)

(diverse sample with varying CVD risk factors)

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(No clear description of how the methods used for the interviews)

(Semi-structured interviews)

(Says they were developed by the research team but no information on the methods used)

(Audio recorded and transcribed)

(Recruitment was stopped when initial data analysis indicated that meaning saturation had been reached (ie, no new concepts were being identified in the data))

Researcher and participant relationship

[Has the relationship between researcher and participants been adequately considered?](#)

Can't tell

Ethical Issues

[Have ethical issues been taken into consideration?](#)

Yes

('Participants signed a consent form before being interviewed')

('Ethics approval was obtained through the Sydney Local Health District Human Research Ethics Committee')

Data analysis

[Was the data analysis sufficiently rigorous?](#)

Yes

(Brief description of the analysis process)

(Yes but only a brief description is included)

(Using an existing SDM framework)

(Data was analysed until saturation was reached)

Findings

Is there a clear statement of findings?

Yes

(Findings presented by theme and discussed)

(Included contrasting opinions of different patients)

(More than one analyst but no information about responder validation)

Research value

How valuable is the research?

Yes

('patients should be encouraged and supported by GPs to be involved, but ultimately it is up to the patient to decide how much they want to participate')

(Development of decision aids with an understanding of how to adapt the evidence for older people)

(Stated that the results may be generalisable to older people with other conditions but a follow-up study may be required)

Overall risk of bias and directness

Overall risk of bias

Moderate

(Limited information about the methods used to develop and conduct interviews)

Directness

Direct

1

Kamara, 2018

2

Bibliographic Reference

Kamara, Daniella; Weil, Jon; Youngblom, Janey; Guerra, Claudia; Joseph, Galen; Cancer Counseling of Low-Income Limited English Proficient Latina Women Using Medical Interpreters: Implications for Shared Decision-Making; Journal of genetic counseling; 2018; vol. 27 (no. 1); 155-168

3

4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('(1) identify communication patterns in CGC sessions utilizing medical interpreters via telephone with low-income LEP Latina women, and (2) assess how the communication patterns facilitate or inhibit the decision-making process during the sessions')

('research is needed to assess how telephone interpretation, which does not allow for non-verbal communication, impacts communication effectiveness and health outcomes')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Description of inclusion criteria)

(Patients referred to genetic counselling using a medical interpreter via telephone)

Data collection

(Observation of cancer guidance counselling sessions which included a telephone-based interpreter (as would be used in standard practice))

(Observation of cancer guidance counselling session)

(Conducted during normal appointments)

(Observation of cancer counselling session)

(Audio recordings of conversation)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Obtained verbal consent from the counsellors and patients)

('All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration')

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Description of coding and thematic analysis)

(Initial codes converted to themes in an iterative process)

(Iterative approach for thematic analysis)

Findings

Is there a clear statement of findings?

Yes

(Findings presented in themes and discussed)

(More than one analyst but no evidence of respondent validation)

Research value

How valuable is the research?

Yes

(Discusses methods that should be used to engage patients and avoid misunderstandings. Discusses the need for training)

('further research on specific communication strategies that might facilitate shared decision making with limited English proficiency patients')

(Briefly - suggests results support previous findings and so may be generalisable)

Overall risk of bias and directness

Overall risk of bias

Moderate

Directness

Direct

1

Ladin, 2017

2

Bibliographic Reference

Ladin, Keren; Lin, Naomi; Hahn, Emily; Zhang, Gregory; Koch-Weser, Susan; Weiner, Daniel E.; Engagement in decision-making and patient satisfaction: a qualitative study of older patients' perceptions of dialysis initiation and modality decisions; Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association; 2017; vol. 32 (no. 8); 1394-1401

3

4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('to examine patient perspectives of the dialysis initiation process (i.e. decision to start dialysis) and the relationship between patient engagement and treatment satisfaction')

(States that there is 'an important gap, namely, understanding how SDM affects patient satisfaction and confidence in treatment selection')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('Open-ended questions explored how patients learned about and initiated dialysis; whether decisions were informed and autonomous; and treatment implications, advice for future patients and suggestions for improving SDM')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Describes where patients were recruited and inclusion criteria)

(Undergoing dialysis and representing a range of ages, gender, race and time on dialysis)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Semi-structured interview)

('Open-ended questions explored how patients learned about and initiated dialysis; whether decisions were informed and autonomous; and treatment implications, advice for future patients and suggestions for improving SDM. Specific probes examined information, prior knowledge about dialysis and end stage renal disease and decision-making interactions')

(Interviews using a guide)

(Audio taped and transcribed)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(Ethical approval not stated)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of coding and thematic analysis)

(Codes organised into themes and subthemes using inductive and deductive coding)

(No information about data saturation)

(No information about data saturation)

(Presented some conflicting patient opinions)

Findings

Is there a clear statement of findings?

Yes

(Findings presented by themes and subthemes and described)

(Conflicting patient opinions reported)

(More than one analyst and reports of how coding differences were resolved. No information on respondent validation)

Research value

How valuable is the research?

Yes

('Our study links decision-making experiences and patient satisfaction, illustrating key barriers in the process, beginning with patients not identifying dialysis initiation as a decision and continuing with understanding how the patient voice is obscured during decision-making and how physicians and families may convince patients to pursue treatment')

('Future studies should evaluate individuals with advanced Chronic Kidney Disease prospectively to evaluate the process of dialysis decision-making')

(Suggests the study should be replicated with patients from another location to ensure generalisability)

Overall risk of bias and directness

Overall risk of bias

Moderate

(Not clear if the study had ethical approval or informed consent)

Directness

Direct

1

Legare, 2013

2

Bibliographic Reference

Legare, France; Stacey, Dawn; Briere, Nathalie; Fraser, Kimberley; Desroches, Sophie; Dumont, Serge; Sales, Anne; Puma, Carole; Aube, Denise; Healthcare providers' intentions to engage in an interprofessional approach to shared decision-making in home care programs: a mixed methods study; Journal of interprofessional care; 2013; vol. 27 (no. 3); 214-22

1
2
3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('to evaluate healthcare providers' intentions to engage in IP-SDM and to identify factors associated with their intentions')

('Older patients are of particular relevance in both IP and SDM endeavours. They face more complex decisions and may face greater risks linked to healthcare interventions than younger patients. In addition, factors such as cognitive impairment and cultural origins may also limit the ability to actively participate in the decision-making process')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('evaluate healthcare providers' intentions to engage in IP-SDM and identify factors associated with their intentions')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('We chose the sequential explanatory mixed methods design to be able to triangulate quantitative and qualitative findings from the different sources so that we could evaluate healthcare providers' intentions to engage in IP-SDM and identify factors associated with their intentions')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Includes details of where people were included and inclusion criteria)

('This home care team was also singled out for the following reasons: (1) it focuses on a clinical issue with high prevalence and (2) it includes the most diverse group of health professionals')

Data collection

Was the data collected in a way that addressed the research issue?

Yes

('The focus group took the form of a round-table discussion to facilitate exchange between participants' 'Due to multiple locations and availability restrictions, interviews with managers/ administrators were conducted individually')

(Survey based on validated questionnaires, Focus groups, Structured interviews)

(Self-administered survey, focus group and interview using structured interview guides)

(Paper-based surveys and audio recorded and transcribed interviews)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Yes

('The past experience of investigators and interviewers may have affected how focus groups and interviews were designed and run, but we used a structured interview grid and standardized forms to keep the process systematic')

Ethical Issues

Have ethical issues been taken into consideration?

Yes

('All participants signed consent forms for the survey, the focus groups and the interviews')

('Ethics approval was obtained from the local institution's ethics board')

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Very few results shown to support the findings)

(Description of quantitative and qualitative analysis methods)

(Themes developed using an adapted version of a coding framework for barriers and facilitators)

(Thematic analysis using the theory-based tree structure)

(Limited results section to support the findings)

(Includes some contrasting findings from different providers)

Findings

Is there a clear statement of findings?

Yes

(Includes some contrasting findings from different providers)

(Included triangulation and more than one analyst)

('Overall, healthcare providers involved in home care demonstrated a positive intention to engage in IP-SDM when caring for elderly patients losing their ability to live alone')

Research value

How valuable is the research?

Can't tell

(Not clear how well these findings can be transferred to other populations)

('Future studies will involve the development of standardized evaluation and tools such as decision aids to support the implementation of IP-SDM')

Overall risk of bias and directness

Overall risk of bias

Moderate

(Limited results included to support the findings)

Directness

Direct

1

Lin, 2019

2

Bibliographic Reference

Lin, C.-Y.; Renwick, L.; Lovell, K.; Patients' perspectives on shared decision making in secondary mental healthcare in Taiwan: A qualitative study; Patient Education and Counseling; 2020

3

1

2

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(The aim of this study is to explore patient perspectives on shared decision making in secondary mental healthcare in Taiwan)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

Inadequate info on recruitment strategies

Data collection

Was the data collected in a way that addressed the research issue?

Yes

Potential participants were provided with an information sheet about this study by the first author. Any patient interested in taking part could contact the author. Each participant signed an informed consent form. Data saturation has been defined as the point at which additional data do not generate any new codes or themes [25]. In this study, data collection continued until the data saturation point was reached. Data analysis was carried out as the first author completed the interviews. Initial codes and themes were identified and agreed between the team. After interviewing eighteen participants, no more new themes were identified and then the authors agreed to interview two more participants to ensure data saturation. Demographic information, such as gender and age, was gathered. In-depth semi-structured, face-to-face interviews were conducted, using a topic guide. Field notes were taken for all interviews to encourage the author's reflection and provide valuable context to inform data analysis and facilitate the initial coding. All interviews were digitally recorded and transcribed verbatim in Mandarin by the first author)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

This study was approved by the Institutional Review Board of the University of Manchester (ref: 2017-2009-3358), and research committees (ref: 201700879B0) in Taiwan. Participants were informed of their right to withdraw from the study at any point during the interview without giving any reason, and up until the data was anonymised and analysed. All audio-recordings and transcripts and written consents were stored securely)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

To ensure rigour, the principles of credibility, transferability, dependability, and confirmability were considered. Peer debriefing was used to seek guidance from the other two authors, to improve credibility. To ensure transferability, a rich description of the research process and details of the participants is provided. In terms of dependability, an audit trail was used and details of features of the study design are presented. A reflective journal was used to support confirmability.

Findings

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Is there a clear statement of findings?

Yes

Research value

How valuable is the research?

Valuable

This study could be an important and unique opportunity for patients to explain their perspectives on shared decisions making, and a key foundation for further developing effective strategies to overcome the barriers, such as using various decision aids to develop strategies to overcome the challenge of limited time resources in decision making.

Overall risk of bias and directness

Overall risk of bias

Moderate

Lack of info around recruitment and relationship of author to people in study

Directness

Direct

1

2

Lowenstein, 2019

3

Bibliographic Reference

Lowenstein, M.; Vijayaraghavan, M.; Burke, N. J.; Karliner, L.; Wang, S.; Peters, M.; Lozano, A.; Kaplan, C. P.; Real-world lung cancer screening decision-making: Barriers and facilitators; Lung Cancer; 2019; vol. 133; 32-37

1

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(1) understand the attitudes and priorities among physicians and patients that inform shared decision making in real-world settings and 2) explore physician and patient perceptions of shared decision making in real-world practice)

('most studies occurring since the U.S. screening guidelines were put into place are limited to settings with robust screening protocols that may not reflect widespread practice')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Stated a convenience sample was used and outlined inclusion criteria)

(People who had received LDCT or met guideline-screening criteria)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Semi-structured interviews)

(Based on existing literature)

(Interview guides)

(Audio recorded and transcribed)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

('informed consent was obtained from all participants.')

('All study procedures were approved by the UCSF Committee on Human Research prior to any subject recruitment or data collection')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Describes coding, thematic analysis and resolving any discrepancies)

(Codebook revised using iterative measures)

(Presenting contrasting patient and physician perspectives)

Findings

[Is there a clear statement of findings?](#)

Yes

(Findings reported in themes and discussed)

(Presented contrasting patient and physician perspectives)

(More than one analyst. No information about respondent validation)

Research value

[How valuable is the research?](#)

Yes

('These results add to the literature by providing a lens into real-world discussions about LCS among diverse patients and in diverse settings')

('it will be important to incorporate safety net settings into future studies to ensure that screening guidelines are implemented in an equitable manner')

('Physicians and patients included in the study were a non-random sample from two clinics whose attitudes and experiences may not have been reflective of all physicians or patients in the clinic or the general population of PCPS and patients eligible for lung cancer screening')

Overall risk of bias and directness

[Overall risk of bias](#)

Low

[Directness](#)

Direct

1

Lown, 2009

2

Bibliographic Reference

Lown, Beth A.; Clark, William D.; Hanson, Janice L.; Mutual influence in shared decision making: a collaborative study of patients and physicians; Health expectations : an international journal of public participation in health care and health policy; 2009; vol. 12 (no. 2); 160-74

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('we sought to add to current understanding by exploring both patients and physicians' perspectives about attitudes and behaviours in the patient–physician encounter when shared decision making goes well.')

('In summary, three gaps emerge in this literature on shared decisions. First, what is the patient's role (beyond becoming informed) in a decision shared with a physician? Second, how do patients and physicians influence each other during encounters in which they try to share decisions? Third, what can both parties do to facilitate shared decisions?')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('exploring both patients and physicians' perspectives about attitudes and behaviours in the patient–physician encounter')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('As we aimed to learn about patient and physician behaviours and attitudes in successful shared decision making, we used the principles of appreciative inquiry and asked participants to discuss examples and share stories of their own experiences in which shared decision making went well')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Described where participants were recruited from and inclusion criteria)

(Physicians who expressed an interest in SDM and patients who had experienced SDM referred by primary care physicians)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Some justification of physicians being in different groups to their patients. No specific justification of setting)

(Research (focus) groups)

(Appropriate method for people to share their experiences of successful SDM)

(Discussion of SDM, participants gave examples of their experiences, then small groups discussed communication strategies to implement SDM)

(Audio recorded and transcribed)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

(Partly)

(Partly. Discussed how their decision to include both physicians and patients in a group could have led to either of these groups being less reluctant to speak openly. But did not examine their role on potential bias)

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(No information about informed consent)

('The research protocol was approved by Institutional Review Boards at Mount Auburn Hospital in Cambridge, MA, USA, Beth Israel Deaconess Medical Center in Boston, MA, USA and the Uniformed Services University of the Health Sciences in Bethesda, MD, USA')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Details about transcription and thematic analysis using open and axial coding)

(Open and axial coding)

(Ensured data saturation)

(Ensured data saturation and quotes used to support the findings)

(Study was looking at positive experiences so there weren't contradictory opinions)

(Partly. Discuss how the groups were structured but not their effects on bias)

Findings

Is there a clear statement of findings?

Yes

(Findings presented by themes and discussed)

(N/A - participants were recruited to show evidence of positive experiences)

(More than one analyst and respondent validation)

Research value

How valuable is the research?

Yes

('The contribution of mutual influence between patients and physicians was perhaps, therefore, more clearly elucidated than in previously reported studies')

('Future research may explore in more detail how patients facilitate the shared decision making behaviours of their physicians, how physicians respond to patients influence and what conditions increase the likelihood that effective sharing of decisions will occur')

('Future educational efforts may apply the themes described here for teaching and assessing collaboration for both patients and physicians')

Overall risk of bias and directness

Overall risk of bias

Moderate

(Study did not provide any information on obtaining informed consent)

Directness

Direct

1

Maffei, 2012

2

Bibliographic Reference

Maffei, Roxana M.; Dunn, K.; Zhang, J.; Hsu, C. E.; Holmes, J. H.; Understanding behavioral intent to participate in shared decision-making in medically uncertain situations; Methods of information in medicine; 2012; vol. 51 (no. 4); 301-8

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('The purpose of this ethnographic study was to do just that: to understand the factors involved in a patient's behavioural intent to participate in shared decision making in the event of a medically uncertain situation')

('behavioural intent has never been studied to understand the behavioural action or preference for shared decision-making')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(Based on previous literature and the theory of reasoned action)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

(Information about how potential participants were identified but no information about inclusion criteria)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

('This process ensured that the questions being asked were structured in a manner that a) facilitated dialogue among subjects, b) did not lead subject responses, and c) maximized the likelihood that behavioural and normative beliefs could be elicited in regards to shared decision making in medically uncertain situations')

(Open-ended interview guide)

(Audio recorded and transcribed)

('Data saturation was considered to be attained when no new information related to the research question resulted from the subject interviews')

Same campus as recruitment)

(Semi-structured interviews)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Study mentions informed consent and methods to ensure confidentiality)

('The research protocol for this study was reviewed and approved by The Institutional Review Boards for University of Texas and University of Pennsylvania')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of coding and thematic analysis using deductive reasoning approach)

(Deductive reasoning approach)

(Use of data saturation)

(Data saturation achieved)

Findings

Is there a clear statement of findings?

Yes

(Findings presented in themes and discussed)

(Reported conflicting opinions of participants)

(Triangulation and more than one analyst)

Research value

How valuable is the research?

Yes

('This study adds to the findings that patients having high levels of trust may believe that their physicians understand their values and know already what are best for them.')

('This framework should be incorporated in future studies in order to provide a comprehensive and systematic exploration of variables and processes associated with uncertainty and behavioural intent outcomes for shared decision making')

Overall risk of bias and directness

Overall risk of bias

High

(Participants were self-selected with no information about any further inclusion criteria)

Directness

Direct

1

Mahone, 2011

2

Bibliographic Reference

Mahone, Irma H.; Farrell, Sarah P.; Hinton, Ivora; Johnson, Robert; Moody, David; Rifkin, Karen; Moore, Kenneth; Becker, Marcia; Barker, Margaret; Participatory Action Research in Public Mental Health and a School of Nursing: Qualitative Findings from an Academic-Community Partnership; Journal of participatory medicine; 2011; vol. 3

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Aims of the research

Was there a clear statement of the aims of the research?

Yes

('Specific aims of this one-year study included 1) information-gathering on SDM from stakeholder groups in the local community, 2) information-gathering on SDM from the literature and national experts, and 3) consensus-building related to a specific SDM intervention to be tested at the mental health clinic based on the information gathered')

('Although illness self-management strategies have long been accepted as evidence-based practice in mental health,[9] some consumers, caretakers, and professionals are still reluctant to embrace self management in relation to medication use')

Appropriateness of methodology

Does the research seek to interpret or illuminate the actions and/or subjective experiences of research participants?

Yes

Research Design

Have the researchers justified the research design, e.g. have they discussed how they decided which method to use?

No

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

(Reasons for recruitment not entirely clear)

(Partially 'A core group of mental health service providers were identified at the mental health clinic who were interested in advancing SDM in persons with serious mental illness and in forming an academic-community liaison'. Didn't explain why people within these groups were chosen)

(Some brief discussion but this was not explained clearly)

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(Methods used, i.e. how the discussion was guided at each meeting are unclear)

(The clinic from which participants were selected worked with the correct patient population)

(Working group with multiple meetings)

(Stated that the working group met once per month but no information regarding what was discussed/how it was decided what needed to be discussed)

(Recorded and transcribed)

(N/A to the method of analysis)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

No

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Some description of coding and thematic analysis)

(Brief explanation of analysis methods)

Findings

Is there a clear statement of findings?

No

(Findings were reported but these did not appear to meet all the aims of the study (e.g. specific SDM intervention to be tested at the mental health clinic))

(Yes but not entirely related to the use of SDM)

(Findings don't appear to be entirely related to the aims. More about development of the centre than issues associated with SDM)

Research value

How valuable is the research?

Can't tell

Overall risk of bias and directness

Overall risk of bias

High

(Unclear how participant were recruited, no mention of confidentiality or the methods used for discussion during meetings. Findings don't appear to meet all of the aims)

Directness

Direct

1

Mahone, 2011

2

Bibliographic Reference

Mahone, Irma H.; Farrell, Sarah; Hinton, Ivora; Johnson, Robert; Moody, David; Rifkin, Karen; Moore, Kenneth; Becker, Marcia; Barker, Missy Rand; Region Ten, C. S. B. U. V. A. School of Nursing Partnership; Shared decision making in mental health treatment: qualitative findings from stakeholder focus groups; Archives of psychiatric nursing; 2011; vol. 25 (no. 6); e27-36

3

Aims of the research

Was there a clear statement of the aims of the research?

No

Appropriateness of methodology

Is a qualitative methodology appropriate?

Can't tell

(Research goal not entirely clear)

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

(Partly. Explained that they were nominated by core members of the research group but no further information)

('based on their personal interactions with them in other settings and their knowledge of their work and effectiveness in the local community')

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(Focus groups)

('designed to stimulate discussion')

(Stated that there was a distinct set of questions but no information about how these were developed or delivered)

(Recorded and transcribed)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

Insufficient details on how ethics explained to participants

('Approval for this study was obtained from the UVA Institutional Review Board (IRB) for the Social and Behavioral Sciences')

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Brief description of thematic analysis)

(Method to perform thematic analysis not clear)

Findings

Is there a clear statement of findings?

Can't tell

(Findings presented by theme and discussed)

(Discussion of different group's opinions but no clear aim to the study to compare against)

(Unclear what the original research question was)

(Findings presented but not entirely clear what the aim of the study is)

Research value

How valuable is the research?

Yes

(Stated the issues that need to be considered for SDM)

('Shared decision making trials in public mental health are needed to identify other barriers and facilitators of this practice, perhaps looking at first episode consumers, using peer specialists as decision-coaches, methods to integrate this concept into transformation initiatives, and exploring sustainability issues.')

Overall risk of bias and directness

Overall risk of bias

High

(Findings reported clearly but there is no clear aim, no description of how focus groups were conducted and no reference to confidentiality)

Directness

Direct

1

Mariani, 2017

2

Bibliographic Reference

Mariani, Elena; Vernooij-Dassen, Myrra; Koopmans, Raymond; Engels, Yvonne; Chattat, Rabih; Shared decision-making in dementia care planning: barriers and facilitators in two European countries; Aging & mental health; 2017; vol. 21 (no. 1); 31-39

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('the aim of this study was to identify barriers, facilitators and influencing factors to the implementation of an SDM framework for care planning in two nursing homes')

('this approach overcomes the idea that people with dementia are only passive participants in the decision-making process and are unable to express their own opinions and perspectives')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('to stimulate healthcare professionals to share their opinions and thoughts about the influencing factors they experienced during the implementation of the intervention, those that, in their opinion, hindered or facilitated the implementation process')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('focus group interviews were chosen to stimulate healthcare professionals to share their opinions and thoughts')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Description of inclusion criteria)

(Had been involved in implementing a SDM framework)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Focus groups)

(Based on a literature review. Used to stimulate discussions)

(Focus groups with semi-structured interview guide)

(Recorded and transcribed)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

(Partly. Discussed issues with conducting interviews in different languages but no mention of influence on bias, etc.)

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(No mention of informed consent. But formed part of the IMPACT trial which may have already included informed consent) (Not reported but is part of the wider IMPACT project)

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Brief description of thematic analysis)

(Brief description)

(No mention of data saturation)

(Reports conflicting views from different participants)

Findings

Is there a clear statement of findings?

Yes

(Findings presented by theme and discussed)

(Reports conflicting views from different participants)

(More than one analyst but no information about respondent validation)

('Despite small dissimilarities between the two nursing homes that are mainly due to setting-specific and organizational factors, professionals in both countries experienced similar barriers and facilitators')

Research value

How valuable is the research?

Yes

(Highlights the factors that need to be considered when implementing a SDM framework in nursing homes)

Overall risk of bias and directness

Overall risk of bias

Moderate

(No mention of ethics and limited information on data analysis)

Directness

Direct

1

McCarter, 2016

2

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Bibliographic Reference

McCarter, Sarah P.; Tariman, Joseph D.; Spawn, Nadia; Mehmeti, Enisa; Bishop-Royse, Jessica; Garcia, Ima; Hartle, Lisa; Szubski, Katharine; Barriers and Promoters to Participation in the Era of Shared Treatment Decision-Making; Western journal of nursing research; 2016; vol. 38 (no. 10); 1282-97

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Aims of the research

Was there a clear statement of the aims of the research?

Yes

('to identify the barriers and promoters for nurse and nurse practitioner participation in cancer treatment decision in the era of SDM process')

('despite the greater number of hours spent by nurses and nurse practitioners with the patient providing direct patient cancer care, studies examining the barriers and promoters to participation in the SDM process from the nursing perspective are limited')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('qualitative approach was used to gain broad perspectives on the nurse and nurse practitioner's participation and role throughout the cancer SDM process')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

(Probably but no information on inclusion criteria)

(Partly. Recruited through email lists but no further information)

('mostly outpatient nurse clinicians and nurse practitioners who have identified themselves as having a role in the cancer SDM process')

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Could ask both probe questions and specific questions to gain opinions)

(Conducted in research-related conference room)

(Semi-structured interview)

(Audio recorded and transcribed)

('Saturation of data was reached and determined by the principal investigator who performed all the interviews for this study.')

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(No information on informed consent)

(Partly. Information on confidentiality but not informed consent)

('Institutional Review Board approval was obtained from DePaul University Office of Research Services, Research Protections Division')

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Description of coding, thematic analysis and validity)

(Description of how codes and themes were developed)

(Description of analysis process)

(Reached data saturation)

Findings

Is there a clear statement of findings?

Yes

(Findings presented in themes and discussed)

(More than one analyst and information about validation)

('This study highlights the many barriers and promoters to participation in SDM as perceived by oncology nurses and nurse practitioners')

Research value

How valuable is the research?

Yes

('This study provides initial evidential support that the role of the oncology nurses and nurse practitioners in this era of SDM process is dynamic and evolving')

('develop a measure of nursing competency in oncology SDM process to objectively measure the capacity to participate safely and effectively in cancer treatment SDM process')

(Reported that some of the findings would only be specific to cancer SDM)

Overall risk of bias and directness

Overall risk of bias

Moderate

(No mention of informed consent)

Directness

Direct

1

Molenaar, 2018

2

Bibliographic Reference

Molenaar, Joyce; Korstjens, Irene; Hendrix, Marijke; de Vries, Raymond; Nieuwenhuijze, Marianne; Needs of parents and professionals to improve shared decision-making in interprofessional maternity care practice: A qualitative study; Birth (Berkeley, Calif.); 2018; vol. 45 (no. 3); 245-254

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('aimed to explore the experiences and needs of parents and professionals regarding shared decision making in interprofessional antenatal, natal, and postnatal care')

('Motivated by these observations about shared decision making, we collaborated with parents and professionals to develop a practical intervention to improve the practice [of SDM]')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

('We aimed to explore the experiences and needs of parents and professionals regarding shared decision making in interprofessional antenatal, natal, and postnatal care')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('A qualitative design using focus groups was chosen as a suitable strategy to examine different experiences, perceptions, thoughts, and feelings among a variety of parents and professionals. 17,18 This approach stimulates developing new ideas through interaction between participants.')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Purposive sampling. Includes description of inclusion criteria)

(Pregnant women or women who had recently given birth)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

('Representatives from the parents and professional groups in the project team supported recruitment by suggesting the most feasible dates and places for the focus groups')

(Focus groups)

(Semi-structured topic guide)

(Audio recorded and transcribed)

('After 10 focus groups, data-saturation was achieved')

Researcher and participant relationship

[Has the relationship between researcher and participants been adequately considered?](#)

Yes

(Stated that moderators running the sessions explored both positive and negative remarks to maintain neutrality)

Ethical Issues

[Have ethical issues been taken into consideration?](#)

Yes

(Obtained informed consent and stated that participation was confidential)

('The Medical Ethics Committee Zuyderland— Zuyd decided that ethical approval was not needed')

Data analysis

[Was the data analysis sufficiently rigorous?](#)

Yes

(Description of coding, thematic analysis, validation and data saturation)

(Description of thematic analysis included)

(Achieved data saturation)

(Achieved data saturation)

(Presented both facilitators and barriers to SDM)

(Stated how they tried to maintain neutrality during focus groups)

Findings

[Is there a clear statement of findings?](#)

Yes

(Findings reported by themes and discussed)

(Presented both facilitators and barriers to SDM)

(More than one analyst, gave an overview of methods used for triangulation and validation)

('Our study offers insight into the experience of parents and professionals with shared decision making and the best type of intervention to support shared decision making in antenatal, natal, and postnatal care')

Research value

[How valuable is the research?](#)

Yes

('To prepare parents for shared decision making in maternity care, several tools and interventions are available, including decision aids and birth plans.⁴³ Our results showed a need for further improvement and development of these tools, including health information, to support parents' preparation for consultations and deliberation')

(Limitation that mostly higher educated parents took part. Lower educated parents may have different needs)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Moreau, 2012

2

Bibliographic Reference

Moreau, Alain; Carol, Laurent; Dedienne, Marie Cecile; Dupraz, Christian; Perdrix, Corinne; Laine, Xavier; Souweine, Gilbert; What perceptions do patients have of decision making (DM)? Toward an integrative patient-centered care model. A qualitative study using focus-group interviews; Patient education and counseling; 2012; vol. 87 (no. 2); 206-11

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('What are patients' perceptions of DM? How can these perceptions contribute to the discussion about conceptual definitions and interactions between Charles's three models?')

('Misunderstandings are common. Not all authors agree with the SDM concept, especially when combined with patient-centred care')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes ('The organization of our four focus groups was based on the hypothesis that patients' attitudes toward DM might vary according to age, health-promotion activism, and/or residential context')

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

(May be but limited information on inclusion criteria)

(Partly. Described where participants were recruited from but not the inclusion criteria)

(Covered a variety of backgrounds and ages)

Data collection

Was the data collected in a way that addressed the research issue?

Can't tell

(Methods used in focus groups are unclear)

(Focus groups)

(Audio recorded and transcribed)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No (unexamined and not reported responding to events)

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(No information about informed consent or confidentiality)

(No information about ethical approval)

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Description of coding and thematic analysis)

(Open coding and axial coding)

(No mention of data saturation)

Findings

Is there a clear statement of findings?

Yes

(Various opinions presented but the individual themes are not clearly highlighted)

(More than one analyst and validation methods used)

Research value

How valuable is the research?

Yes

('Generally, the principles of SDM correspond to finding common ground, one of the six components of the patient-centred care. However, our results show that SDM cannot be reduced to this single dimension of the patient centred care.')

Overall risk of bias and directness

Overall risk of bias

Moderate

(No information about ethics, consent or confidentiality and limited information on methods used)

Directness

Direct

1

Muscat, 2016

2

Bibliographic Reference

Muscat, Danielle M.; Shepherd, Heather L.; Morony, Suzanne; Smith, Sian K.; Dhillon, Haryana M.; Trevena, Lyndal; Hayen, Andrew; Luxford, Karen; Nutbeam, Don; McCaffery, Kirsten; Can adults with low literacy understand shared decision making questions? A qualitative investigation; Patient education and counseling; 2016; vol. 99 (no. 11); 1796-1802

3

4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('Among adults with lower levels of literacy and/or poor English language, we used a qualitative approach to investigate (a) understandability of the questions, (b) which question-set was easier for participants (AskShareKnow or Smart Health Choices) (c) perceived usefulness of SDM question-sets, and (d) perceived barriers to use')

('This work represented the initial step in a body of work to create a SDM learning module incorporating a generic question-asking intervention for adults with lower literacy')

Appropriateness of methodology

[Is a qualitative methodology appropriate?](#)

Yes

(aimed to 'investigate participants' ability to comprehend information and explore personal opinions of consumer questions')

Research Design

[Was the research design appropriate to address the aims of the research?](#)

Yes

('Qualitative interviews are appropriate when addressing potentially sensitive matters and examining detailed personal perspectives')

Recruitment Strategy

[Was the recruitment strategy appropriate to the aims of the research?](#)

Yes

(Purposive sampling using maximum variation strategy)

(People from English-speaking and non-English speaking backgrounds from different regions)

Data collection

[Was the data collected in a way that addressed the research issue?](#)

Yes

(Semi-structured interviews)

('allowing flexibility to explore issues raised by interviewees')

(Topic guide)

(Audio recorded and transcribed)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

No

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(No information about informed consent or confidentiality)

(No mention of informed consent or confidentiality)

('Ethics approval was obtained from the University of Sydney and TAFE NSW.')

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(Some description of coding and thematic analysis)

(Thematic analysis used but very brief description of coding framework)

(No mention of data saturation)

(Includes opinions of different patient groups)

Findings

Is there a clear statement of findings?

Yes

(Included views of different patient groups)

(Limited information about analysis methods used)

('Participants from both language groups had difficulty understanding words (e.g. 'benefits' and 'harms') and phrases (e.g. 'wait and watch') within both question-sets')

Research value

How valuable is the research?

Yes

(Suggests that training and translation of SDM tools is needed)

Overall risk of bias and directness

Overall risk of bias

Moderate

(No information about informed consent or confidentiality and limited information about analysis methods)

Directness

Direct

Naik, 2005

1

Bibliographic Reference

Naik, Aanand D.; Schulman-Green, Dena; McCorkle, Ruth; Bradley, Elizabeth H.; Bogardus, Sidney T., Jr.; Will older persons and their clinicians use a shared decision-making instrument?; Journal of general internal medicine; 2005; vol. 20 (no. 7); 640-3

2

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4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To examine experiences of older persons and their clinicians with shared decision making (SDM) and their willingness to use an SDM instrument.)

(few studies have described processes for developing shared treatment plans that older adults might find acceptable.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(focus group methodology to elicit breadth of responses and to encourage intragroup dialogue and exchange of experiences.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(participants were purposively sampled to ensure diversity in gender, socioeconomic variables, and clinical and functional status.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(4 focus groups with older adults and 2 with clinicians (physicians and nurses)

(focus group methodology to elicit breadth of responses and to encourage intragroup dialogue and exchange of experiences.)

(open-ended questions regarding how participants set goals and made treatment decisions in clinical encounters. Standardized probes were used to encourage elaboration and discussion of participants' initial responses. In all cases, participants were encouraged to give examples and detailed stories that illustrated their statements.)

(focus group transcripts)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(The Human Investigation Committee of Yale School of Medicine approved the study protocol.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(constant comparative method of qualitative data analysis to describe common themes from the groups.)

(Three investigators independently reviewed each transcript line by line, coding quotations with similar concepts into distinct content areas. Using established procedures in qualitative analysis, a code key was drafted from a review of the first two transcripts. During coding, new data were constantly compared with previous quotes in the same content areas. When all focus groups were completed, the final code key was reapplied to each transcript.)

(There were quotes for most of the findings.)

Findings

Is there a clear statement of findings?

Yes

(After additional rounds of independent coding, discrepancies among investigators were resolved by careful review, negotiation, and consensus building.)

Research value

How valuable is the research?

Yes

(this study suggests that SDM for older patients is feasible, but may require more than physician-directed decision aides. Additional empirical research in this area will be necessary to confirm this hypothesis.)

(The results of this qualitative study are not universally generalizable as researchers sampled only a small group of older persons, nurses, and physicians. Clinicians from other specialties or practice locations may offer different insights regarding SDM.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Patel, 2014

2

Bibliographic Reference

Patel, Sapana R.; Schnall, Rebecca; Little, Virna; Lewis-Fernandez, Roberto; Pincus, Harold Alan; Primary care professional's perspectives on treatment decision making for depression with African Americans and Latinos in primary care practice; Journal of immigrant and minority health; 2014; vol. 16 (no. 6); 1262-70

3

4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(The aims of this exploratory study were: 1) to elicit primary care professionals' perspectives of treatment decision making with depressed minorities in primary care; 2) to identify content addressed during each stage of decision making process and characterize the model providers follow; and 3) to understand barriers faced in depression management and strategies used to engage patients in decision making and care.)

(Hardly any attention has been paid to professionals' perspectives on the depression treatment decision making process with ethnic minority immigrant patients. With the goal of designing a SDM intervention for primary healthcare professionals, this article reports the results of a

descriptive qualitative study of 15 primary care healthcare professionals who provide collaborative depression care for depressed ethnic minority and immigrant patients in two Federally Qualified Health Centres in New York.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the recruitment strategy appropriate to the aims of the research?

Yes

(but the aim of the research justifies the research design.)

(a random sampling of primary care health care professionals employed at the FQHCs)

(two types of professionals from each category (i.e. practice administrator, nurse, primary care physician, psychiatrist, and social worker) including practice administrators, as they all play a role in the depression care management (IMPACT) of primary care patients.)

(one primary care physician refused participation citing lack of interest.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Researchers described the setting as medically underserved areas with a growing number of new immigrants from Africa, US born Latinos and immigrants from Caribbean, Central and South America.)

(in-depth interviews)

(Charles treatment decision making framework adapted for primary care practice outlines each stage of treatment decision making (e.g., information exchange, deliberation and choosing a treatment), provides a dynamic view of treatment decision-making by recognizing that the approach adopted at the outset of a medical encounter may change as the interaction evolves; identifies decision-making approaches which lie

between the three predominant models three predominant models of decision making (e.g., paternalistic, shared and informed decision making) and has practical applications for clinical practice and medical education.)

(The Charles treatment decision making framework adapted for primary care practice was used to guide interview development.)

(All interviews were audiotaped using a digital recorder.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Informed consent was obtained from all providers.)

(This study was approved by the FQHC and academic-research partner Institutional Review Boards.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Interviews were analysed using grounded thematic analysis.)

(Through a series of open and axial coding, and constant comparison processes, the coders identified provider perspectives on treatment decision making. Each coder independently coded 15 transcripts, meeting at 3 points during the process to establish consensus and discuss the implications of their coding.)

(Through a series of open and axial coding, and constant comparison processes, the coders identified provider perspectives on treatment decision making.)

(There were quotes for each finding.)

Findings

Is there a clear statement of findings?

Yes

(Each coder independently coded 15 transcripts, meeting at 3 points during the process to establish consensus and discuss the implications of their coding.)

Research value

How valuable is the research?

Yes

(The qualitative data about healthcare professional's perspectives that were documented in this research is one step towards understanding the topics and type of information discussed during depression treatment decision making with diverse groups, the model of decision making during each stage of the process, and it identifies barriers to conducting SDM with suggested strategies from providers who work with diverse immigrant groups of individuals who present for treatment in primary care practice.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Partially applicable

(African Americans and Latinos)

1

Peek, 2013

2

Bibliographic Reference

Peek, Monica E.; Gorawara-Bhat, Rita; Quinn, Michael T.; Odoms-Young, Angela; Wilson, Shannon C.; Chin, Marshall H.; Patient trust in physicians and shared decision-making among African-Americans with diabetes; Health communication; 2013; vol. 28 (no. 6); 616-23

1
2

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To explore patient trust in physicians and its relationship to shared decision making (SDM) among African-Americans with diabetes (types 1 and 2)

(This study builds upon a prior work exploring shared decision making among African-Americans with diabetes, including how members of this group define SDM themselves, and seeks to address gaps in the existing literature.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(but the aim of the research justifies the research design.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(participants were recruited using criterion sampling.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(semi structured interviews and focus groups)

(The Charles model was used to explore patient perceptions of shared decision making; the theory of planned behaviour and ecological model were used to investigate patient willingness to engage in SDM, perceived SDM barriers/facilitators and the impact of race on SDM.)

(Topic guides were created to explore patient definitions and perceptions of shared decision making, barriers and facilitators of SDM, and the perceived influence of race/culture on SDM.)

(Interviews and focus groups were audiotaped, transcribed verbatim, and imported into Atlas.ti 4.2 software.)

(Enrolment continued until theme saturation was reached.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(approval from the institutional review board)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(thematic analysis approach

(A codebook was developed using an iterative process where modifications were made to the codes, themes, and concepts that arose from new transcripts.)

(A team of six investigators with experience in medicine, public health, and psychology independently reviewed and coded the first interview transcript, met to discuss codes, and created uniform coding guidelines. Similar process was used for the focus groups.)

(There were quotes for each finding.)

Findings

Is there a clear statement of findings?

Yes

(each interview transcript was independently coded by two randomly assigned reviewers, who then met to discuss coding and address discrepancies. Remaining differences were resolved by the entire group. A multimethod approach enhanced the ability to accurately interpret the data.)

Research value

How valuable is the research?

Yes

(African-Americans' mistrust of physicians may partially be addressed through (1) patient education efforts, (2) physician training in interpersonal skills and cultural competence, and (3) physician efforts to engage patients in the shared decision making process.)

(identifying ways to improve patient trust among African-Americans while simultaneously empowering them to play more active roles in the clinical encounter, with the main goal of improving diabetes outcomes in this population.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Partially applicable

(African-Americans)

1

Peek, 2009

2

Bibliographic Reference

Peek, Monica E.; Wilson, Shannon C.; Gorawara-Bhat, Rita; Odoms-Young, Angela; Quinn, Michael T.; Chin, Marshall H.; Barriers and facilitators to shared decision-making among African-Americans with diabetes; Journal of general internal medicine; 2009; vol. 24 (no. 10); 1135-9

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To explore the barriers and facilitators to SDM among African-Americans with diabetes.)

(Addressing communication disparities will involve understanding the barriers and facilitators to SDM among African-Americans. To date, however, there has been little research in this area.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(but the aim of the research justifies the research design.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(participants were recruited using criterion sampling. Participants were identified by searching administrative databases for diabetes ICD-9-CM codes and patient visit information. Three attempts were made to contact participants.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(semi-structured interviews and focus groups)

(The Charles model was used to explore patient perceptions of shared decision making; the theory of planned behaviour and ecological model were used to investigate patient willingness to engage in SDM, perceived SDM barriers/facilitators and the impact of race on SDM.)

(Topic guides were created using constructs of the Charles SDM model, the theory of planned behaviour and the ecological model. These guides consisted of a list of open-ended questions and follow-up probes, and were pilot tested and modified.)

(Interviews and focus groups were audio-taped, transcribed verbatim and imported into Atlas.ti 4.2 software.)

(Enrolment continued until theme saturation was met.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(approval from the institutional review board)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Concepts and themes were discussed by the research team, and a conceptual framework was created based on predominant themes that emerged from the data.)

(A codebook was developed using an iterative process. Five coders created uniform coding guidelines, and, subsequently, each transcript was independently coded by two randomly assigned reviewers. Outstanding issues were resolved by the group.)

(There were quotes for each finding.)

Findings

Is there a clear statement of findings?

Yes

(this study utilized a multi-method approach that allowed analysis of different data types and enhanced the ability to arrive at valid conclusions.)

Research value

How valuable is the research?

Yes

(The study took place in a single academic medical centre and consequently the findings may not be generalizable to all African-Americans with diabetes.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Partially applicable

(African-Americans)

1

Roodbeen, 2020

2

Bibliographic Reference Roodbeen, R.; Vreke, A.; Boland, G.; Rademakers, J.; van den Muijsenbergh, M.; Noordman, J.; van Dulmen, S.; Communication and shared decision-making with patients with limited health literacy; helpful strategies, barriers and suggestions for improvement reported by hospital-based palliative care providers; PLoS ONE; 2020; vol. 15 (no. 6); e0234926

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(HCPs were interviewed and asked for their strategies, barriers and suggestions for improvement regarding communication and SDM with LHL patients in hospital-based palliative care.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

All participants were selected using convenience sampling. The participating hospitals appointed an employee as a project manager functioning as a 'point of contact' for the researchers—in most cases a specialized nurse working in the department—and this person invited other HCPs face-to-face or via email. The HCPs included were physicians and nurses who regularly conduct consultations with patients with cancer or chronic obstructive pulmonary disease (COPD), and discuss palliative care and treatment options. 21 HCPs were invited to participate, four did not respond to the invitation (no reasons provided). Interviews with 17 HCPs allows for a diversity of perspectives to profoundly assess strategies, barriers or suggestions of LHL in palliative care focusing on communication and SDM.

Data collection

Was the data collected in a way that addressed the research issue?

Yes

The interviews were semi-structured and conducted with a topic list. All interviews were carried out between April and October in 2018. An initial version of the topic list was developed based on literature and experience from previous research with cancer patients [32] (JN). Feedback on this initial version was provided by researchers with ample experience in research focused on LHL (GB, JR & MvdM). After pilot-testing this version in

the field, and after some minor adjustments, the topic list was completed (RR)—it can be found in S2 Appendix. No repeat interviews were conducted, no extensive field notes were recorded during or after the interviews. Informed Consent was signed for by the HCPs. All interviews were audio-recorded and transcribed verbatim by an external transcription service. The interviews took on average 46 minutes, ranging from 33 to 70 minutes. Three were excluded in this calculation, since the duration was accidentally not recorded by the researcher (RR). To increase the credibility of the results, a member check of transcripts was performed—in which the transcripts were given to the participants in order to check the authenticity of the transcripts. Participants did not provide feedback on the results of our study

Researcher and participant relationship

[Has the relationship between researcher and participants been adequately considered?](#)

Yes

The researcher had no profound prior relationship with participants. Furthermore, participants were aware that the researcher was not medically trained or involved in patient care, and participants generally knew the goals and reasons behind the interviews (i.e., investigating their roles as HCPs in palliative care regarding communication, their patients and the organization of their hospital

Ethical Issues

[Have ethical issues been taken into consideration?](#)

Yes

To protect the privacy of the participants, their records were anonymized and all data that could reveal the identity of the participants were deleted from the transcripts. After completing all member checks of the transcripts, the audio recordings were deleted. The study protocol was evaluated by the Medical Ethical committee of the Radboud university medical center, which exempted the study from formal ethical approval (file number CMO: 2017–3623)

Data analysis

[Was the data analysis sufficiently rigorous?](#)

Yes

Transcripts were analysed using thematic analysis following the phases described by Braun and Clarke. For the purpose of the present study, the analyses focused primarily on the data gathered with the questions in the third section of the topic list (see S2 Appendix). Two coders coded the data and, to identify initial and preliminary themes in the material, read the first 10 transcripts, generating, discussing and reviewing initial and

preliminarily codes (RR & AV). These initial themes were all derived from the data and reviewed and named, following an iterative pathway [33]. Subsequently, transcripts were imported in MAXQDA11 and coded by one researcher (AV). To increase reliability, investigator triangulation was applied: ten of the interviews were additionally coded by another researcher (RR). The themes and subthemes that emerged during the analysis were discussed among three researchers (SvD, RR & AV), who then came to an agreement on themes. By analysing segments and codes within themes, one researcher (RR) finalized the naming, positioning and describing of (sub)themes and completed the analyses. A coding scheme was created, in which themes, sub-themes and elements within sub-themes were presented. All (sub)themes that emerged during the thematic analysis are illustrated by multiple quotes in the results section of this study, which were translated into English and edited, increasing readability without the loss of meaning or context.

Findings

Is there a clear statement of findings?

Yes

Split themes with clear explanations and descriptive quotes.

Research value

How valuable is the research?

Yes

First of its kind research, no comparable studies.

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Directly applicable.

1

2

Rose, 2019

1

Bibliographic Reference

Rose, Alice; Soundy, Andy; Rosewilliam, Sheeba; Shared decision-making within goal-setting in rehabilitation: a mixed-methods study; Clinical rehabilitation; 2019; vol. 33 (no. 3); 564-574

2

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To assess extent of Shared Decision Making (SDM) within goal-setting, determine if there are differences between staff and patients' perceptions regarding aspects of SDM adopted and explore patient-reported factors that influenced their SDM ability.)

(experiences of SDM need to be assessed and compared simultaneously using the same tool by the patient, clinician and an observer. There is a need to explore factors which may impact on the SDM interaction which might have resulted in the patient feeling less involved as currently there is limited research considering patient experiences and views.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Yes

(Any patient referred to either team with a frailty syndrome as defined by the British Geriatric Society, was eligible for phase 1 of the study. If patient participants scored 0 or 1, more than once on the MAPPIN'SDM questionnaire, which indicated low involvement in SDM in goal-setting, then these patients were approached for interviews for the second phase.)

(Common reasons for non-participation in interviews included patients not wanting to “tell tales” and “not wanting to get anyone in trouble”.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Researchers described both settings which involved rehabilitation services provided by multi-disciplinary teams and that staff involved in goal-setting from both teams had received a half day course regarding adoption of SDM during patient interaction.)

(quantitative method: a validated questionnaire that assesses competencies relevant to SDM from perspective of patient, clinician and observer. Qualitative method: semi-structured interview.)

(The aim of the research justifies the research design.)

(Quantitative method: the MAPPIN'SDM questionnaire. Qualitative method: an interview guide was used. The guide was developed from a qualitative study on patient-centeredness in goal-setting.)

(the MAPPIN'SDM questionnaire was piloted with 5 patients and the language in some questions was altered to suit the reading age of the population.)

(During quantitative phase, goal-setting meetings with patient participants were observed and SDM within these meetings were scored using the MAPPIN'SDM questionnaire by patient, staff involved in the meeting and by the observer. During qualitative phase, data collected from the interviews was transcribed.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(All participants were provided with participant information sheets along with their consent forms..)

(Ethical approval for the study was granted by the North West NRES Committee.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Quantitative phase: tests were carried out on each question of the questionnaires to find out if there were overall differences in the responses between the three groups. If a significant difference was found, tests were undertaken to identify between which two groups of participants the differences existed. Qualitative phase: the data collected from the interviews was transcribed and analysed using thematic analysis described by Braun and Clarke.)

(The themes were named according to those derived from a recent systematic review of patient-reported barriers to SDM.)

Findings

Is there a clear statement of findings?

Yes

Research value

How valuable is the research?

Yes

(The current research and previous studies have shown that teaching healthcare professionals about SDM can improve involvement of patients in decisions about their goals.)

(Further research could consider developing a goal-setting aid that prepares patients for goal-setting. Further research needs to be carried out across other healthcare settings and teams to measure the extent of SDM and establish whether perceptual differences are present between staff and patients.)

(it is possible that the broader principles from the findings can be applied to wider settings in healthcare such as in a GP practice.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Rosenberg-Yunger, 2018

2

Bibliographic Reference

Rosenberg-Yunger, Zahava R. S.; Verweel, Lee; Gionfriddo, Michael R.; MacCallum, Lori; Dolovich, Lisa; Community pharmacists' perspectives on shared decision-making in diabetes management; The International journal of pharmacy practice; 2018; vol. 26 (no. 5); 414-422

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(to describe community pharmacists' perceptions and awareness of SDM within their provision of general diabetes management [including Ontario's MedsCheck for Diabetes (MCD) programme], and potential challenges of implementing SDM within community pharmacy.)

(The seminal papers on SDM focus on physicians; however, literature exists regarding the consideration of SDM within a team environment and the use of SDM by other clinicians, including pharmacists.)

Appropriateness of methodology

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(A convenience sample of pharmacists were recruited through e-mailing approximately 9000 members of the Ontario Pharmacists Association.)
(certified diabetes educators had a comprehensive knowledge base of diabetes management and patient education.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Telephone interviews were conducted by a research assistant at a mutually agreed upon time.)

(semi structured interviews)

(interview guide)

(Interviews were digitally recorded. Interview recordings were transcribed verbatim.)

(Interviewing continued until no new data emerged, and saturation had occurred.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Participants e-mailed their written informed consent prior to conducting interviews.)

(approved by Ryerson University's Research Ethics Board)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Focused and theoretical codings were used to develop core themes. A coding scheme was created based on these first five transcripts; a list of emerging codes was updated until no unique codes emerged.)

(Analysis was inductive and involved line-by-line coding of the transcripts. Constant comparison was used to examine relationships within and across codes and categories.)

(There were quotes for most of the findings.)

Findings

Is there a clear statement of findings?

Yes

(To triangulate the interpretation of the data, the coding scheme and findings were shared and discussed with all the authors.)

Research value

How valuable is the research?

Yes

(Future research should examine the implementation and effectiveness of SDM and SDM tools with community pharmacists.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Savelberg, 2019

2

Bibliographic Reference

Savelberg, W.; Boersma, L. J.; Smidt, M.; Goossens, M. F. J.; Hermanns, R.; van der Weijden, T.; Does lack of deeper understanding of shared decision making explains the suboptimal performance on crucial parts of it? An example from breast cancer care; European journal of oncology nursing : the official journal of European Oncology Nursing Society; 2019; vol. 38; 92-97

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(to explore the experiences, issues and concerns of professionals in teams that were exposed to the implementation programme, and the specific lessons on the implementation of a PtDA within an oncological clinical pathway.)

(this would provide more knowledge on successful implementation strategies, which can help scale up the use of PtDAs among breast cancer teams also willing to adopt SDM.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(The qualitative design of this study allowed us to learn about the experiences and concerns of dedicated clinicians who recently started to implement SDM in daily clinical practice, as well as about the barriers and facilitators they encountered.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Dedicated breast cancer teams, known for their positive attitude towards SDM and willingness to improve the process of SDM, from eight hospitals in the west and south of the Netherlands were invited to participate in this study.)

(The interviews were held with the clinicians who were still trying to implement SDM.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(semi-structured face-to-face interview)

(The qualitative design of this study allowed us to learn about the experiences and concerns of dedicated clinicians who recently started to implement SDM in daily clinical practice, as well as about the barriers and facilitators they encountered.)

(The interview systematically addressed the following topics: 1. their attitude and behaviour with respect to SDM, 2. their knowledge about SDM and the PtDA, 3. the use of the PtDA within the process of SDM.)

(The interviews were recorded on audiotape, the interviewer also took field notes.

(The sample size of this study (N=27) was sufficient to reach data saturation; no new themes emerged from the data after 23 interviews.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Handling of personal data was in accordance with the Dutch Personal Data Protection Act and Medical Research (Human Subjects) Act.)

(The Maastricht University Medical Centre (MUMC+) ethics committee declared that this study does not fall under the scope of the Medical Research Involving Human Subjects Act (METC 14-5-042).)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(key themes were identified by grouping the codes into larger themes, which were further explored, restructured, refined and reduced in number.)

(Each interview was independently coded by two authors applying thematic content analysis, using NVivo software to organise the data.)

(There quotes for most of the findings.)

Findings

Is there a clear statement of findings?

Yes

(Differences in opinion between the coders were solved by discussion until agreement was reached.)

Research value

How valuable is the research?

Yes

(the more or less forced implementation of PtDAs by patient associations and health insurance companies may also lead to extra costs. The prospect of implementing several of these PtDAs in the future is worrisome for the clinicians in smaller hospitals. The price tags could create serious limitations in the future.)

(The sample consisted of individual surgeons, nurse practitioners and nurses. Therefore, the results do not represent the opinion of the whole breast cancer teams.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Schoenfeld, 2016

2

Bibliographic Reference

Schoenfeld, Elizabeth M.; Goff, Sarah L.; Elia, Tala R.; Khordipour, Errel R.; Poronsky, Kye E.; Nault, Kelly A.; Lindenauer, Peter K.; Mazor, Kathleen M.; The Physician-as-Stakeholder: An Exploratory Qualitative Analysis of Physicians' Motivations for Using Shared Decision Making in the Emergency Department; Academic emergency medicine : official journal of the Society for Academic Emergency Medicine; 2016; vol. 23 (no. 12); 1417-1427

1
2
3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(The purpose of this study was to explore EPs' views on SDM in the emergency department (ED). Specifically, we sought to examine what motivated individual providers to use SDM, what benefits they perceived from the use of SDM, and what effect various research findings might have on providers' motivation to use of SDM.)

(These data may then inform future research seeking to study and implement SDM in the ED by identifying factors and outcomes that EPs find "motivating.")

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

(We then asked participants to discuss scenarios where they used SDM, rather than asking directly, "what motivates you to use SDM?" This allowed further discussion of the motivators in the scenarios the participants provided. They were then asked to discuss scenarios where they could have used SDM but chose not to.)

(Subjective. Based on participant's own experiences)

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(The initial interview guide was developed using an integrative theoretical model that combined the Theory of Planned Behaviour and Social Cognitive Theory. The theoretical framework organizes the factors that potentially influence an individual's performance of a behaviour, such as initiating a SDM conversation.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(We chose a purposeful sample of EP physicians based on sex, years in practice since residency, region (rural/suburban vs. urban) of primary employment, academic versus community practice setting, and location of training (inside versus outside of the state))

(Physicians meeting these predetermined criteria were identified by convenience sampling and by utilization of networks to identify physicians likely to have different perspectives, similar to snowball sampling techniques)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(This was a qualitative study utilizing semi structured interviews with practicing EPs)

(The initial interview guide was developed using an integrative theoretical model that combined the Theory of Planned Behaviour and Social Cognitive Theory. The theoretical framework organizes the factors that potentially influence an individual's performance of a behaviour, such as initiating a SDM conversation.)

(We asked participants to first discuss a scenario where they needed to make a decision, how they made that decision, and who they involved in that decision-making process. We then asked participants if they were familiar with the term "shared decision making" and shared an accepted definition. We then asked participants to discuss scenarios where they used SDM, rather than asking directly, "what motivates you to use SDM?")

This allowed further discussion of the motivators in the scenarios the participants provided. They were then asked to discuss scenarios where they could have used SDM but chose not to)

(All interviews were recorded via audio recording device and transcribed.)

(Initial study design planned for at least 12 interviews, with the option to conduct additional interviews if thematic saturation had not been reached)

Researcher and participant relationship

[Has the relationship between researcher and participants been adequately considered?](#)

Yes

(The interviewers knew many, but not all, of the participants prior to the interviews. Most of the participants did not know the goals of the research prior to the interview, but the goals were stated during the semi structured interview and it was made clear that the interviewers sought honest responses)

Ethical Issues

[Have ethical issues been taken into consideration?](#)

Yes

(Information on informed consent (After agreeing to meet for an interview, participants provided written informed consent) but not on the effects of the study

(The study was granted exempt status by the local institutional review board, but utilized written informed consent due to recording of participants.)

Data analysis

[Was the data analysis sufficiently rigorous?](#)

Yes

(Transcripts were entered into Dedoose qualitative data management and analysis software (Dedoose Version 7.0.18, SocioCultural Research Consultants, LLC). Coding was performed in an iterative fashion by three research team members (EMS, ERK, KEP), all of whom had either

qualitative research experience or recent training pertaining to coding. The codebook was developed using a directed approach to content analysis: that is, we combined a priori codes drawn from previous literature and our theoretical framework with emergent codes that came directly from line by line coding of the transcripts. Iterative coding was done, where transcripts were recoded as the codebook was refined. Each transcript was coded at least twice by at least two coders. We calculated agreement based on excerpt coding as well as by overall codes identified per transcript. Disagreements were discussed until consensus was reached.)

(Themes and subthemes, along with representative quotations, are listed)

(Because we sought to examine the attitudes of the physicians specifically in light of their position as stakeholders in SDM research, our analysis emphasized how the factors identified related to motivation)

(No mention of data saturation)

(While several physicians noted that they attempted to be cognizant of resource utilization issues, many noted that improving resource utilization wasn't a top priority or a motivating factor for using SDM)

(while our research team, including interviewers and coders, attempted to remain unbiased, pre-existing assumptions as well as social desirability bias may have influenced data collection and interpretation. We are optimistic that via rigorous examination of the transcripts and fidelity to the emerging codes, we were able to recognize the effects of our own biases.)

Findings

Is there a clear statement of findings?

Yes

(Themes clearly listed and discussed)

(Discussion about the findings but also lack of consensus between clinicians)

(Two interviewers, 3 analysts and member checking was used)

(particular clinical scenarios. The lack of consensus regarding the importance of any one possible research study outcome is notable and has ramifications for researchers and policy-makers.)

Research value

How valuable is the research?

Yes

(Considers clinicians' views of SDM and how this may impact on policy maker's decisions)

(particular clinical scenarios. The lack of consensus regarding the importance of any one possible research study outcome is notable and has ramifications for researchers and policy-makers.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Seale, 2006

2

Bibliographic Reference

Seale, Clive; Chaplin, Robert; Lelliott, Paul; Quirk, Alan; Sharing decisions in consultations involving anti-psychotic medication: a qualitative study of psychiatrists' experiences; Social science & medicine (1982); 2006; vol. 62 (no. 11); 2861-73

3

4

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To report psychiatrists' perspectives on consultations involving anti-psychotic medication, assessing the extent to which shared decision making is reported in everyday working practice and describing psychiatrists' reported methods for creating a therapeutic alliance that includes negotiation of medication use and consideration of the impact of coercion.)

(The degree to which psychiatrists believe they negotiate decisions with patients about medications, and their perceptions of their success in building therapeutic alliances with patients is undocumented.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(The aim was to find out the kind of things that happen, rather than precisely estimate their prevalence.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(All consultant psychiatrists in the two trusts to be responsible for providing community psychiatric services to adults.)

(Because the degree to which psychiatrists believe they negotiate decisions with patients about medications, and their perceptions of their success in building therapeutic alliances with patients is undocumented.)

(did not volunteer on receiving a general invitation to participate, refused when asked directly, or indicated that their work did not include outpatient appointments.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Qualitative interviews)

(The aim was to find out the kind of things that happen, rather than precisely estimate their prevalence.)

(The interview was loosely structured around key topics.)

(All interviews were audio taped and transcribed in full.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Interview transcripts were indexed with a coding scheme that allocated passages to key themes identified in team discussions.)

(There were quotes for all findings.)

Findings

Is there a clear statement of findings?

Yes

(Codes were also developed by two researchers independently and in team discussions they reconciled or merged these coding categories.)

Research value

How valuable is the research?

Yes

(The present study would be usefully extended by an investigation of the conditions that place psychiatrists in the position of relying to such a large extent on medications to control the symptoms of people felt to be suffering from psychosis, an underlying factor causing such a focus on adverse effects and non-compliance.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Directly applicable

1

Shepherd, 2014

2

Bibliographic Reference

Shepherd, Andrew; Shorthouse, Oliver; Gask, Linda; Consultant psychiatrists' experiences of and attitudes towards shared decision making in antipsychotic prescribing, a qualitative study; BMC psychiatry; 2014; vol. 14; 127

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(to explore the attitudes and experiences of consultant psychiatrists relating to shared decision making in the prescribing of antipsychotic medications.)

(This project sought to build on the previous work of Seale and colleagues assessing the attitudes of consultant psychiatrists towards decision making in the process of antipsychotic prescribing.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

(Qualitative methods of investigation were employed in order that the experiences of participating consultant psychiatrists could be adequately captured.)

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(Qualitative methods of investigation were employed in order that the experiences of participating consultant psychiatrists could be adequately captured.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Participants were recruited from within two NHS Mental Health Foundation Trusts situated within Manchester and the surrounding area.)

(Participants were professionals recruited on the basis of their clinical role.)

(one of whom refused consent to participate. This participant stated they did not feel there was a research question to be answered in the area proposed for discussion and therefore declined to take part.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Interviews were conducted at the participants place of work, generally within a private office space.)

(semi-structured interview)

(Qualitative methods of investigation were employed in order that the experiences of participating consultant psychiatrists could be adequately captured.)

(There were probe questions to elicit attitudes towards shared decision making practices. Participants being invited to draw on clinical cases from their own experience to illustrate their discussion.)

(Interviews were recorded using a digital-audio device.)

(participant recruitment continued until data saturation was reached, this was judged to be the case when no new themes emerged from two subsequent interviews.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(This research project focussed solely on the experience of consultant psychiatrists. Participants were professionals recruited on the basis of their clinical role and no confidential information relating to service user care was discussed.)

(no research ethics committee approval was required in line with guidance from the National Research Ethics service.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Themes identified from analysis of transcripts were subsequently compared with the framework of shared decision making described by Charles and colleagues.)

(Coding was therefore completed in relation to the processes described in the framework with supporting and contradictory themes sought. Themes not represented adequately by the framework were also sought. The overall analysis strategy was therefore consistent with a directed analysis method)

(Comparison of themes between transcripts was made with supporting and contradictory evidence being sought.)

(There were quotes for each finding.)

Findings

Is there a clear statement of findings?

Yes

(Transcript coding and participant recruitment were discussed in supervision with LG with suggestions being made for alternative coding strategies and subsequent focused recruitment to address emergent themes.)

Research value

How valuable is the research?

Yes

(participants in this study supported the principle of shared decision making in the prescribing of antipsychotics, with the caveat that the clinician would adopt a flexible position able to take more control as the situation required.)

(Further work is required to explore more fully the nature of the clinician-client interaction and to identify means to support the shared decision making process.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Siegel, 2015

2

Bibliographic Reference

Siegel, Corey A.; Lofland, Jennifer H.; Naim, Ahmad; Gollins, Jan; Walls, Danielle M.; Rudder, Laura E.; Reynolds, Chuck; Gastroenterologists' Views of Shared Decision Making for Patients with Inflammatory Bowel Disease; Digestive diseases and sciences; 2015; vol. 60 (no. 9); 2636-45

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To examine gastroenterologists' perspectives about SDM with IBD patients, using a novel statistical hybrid approach to analyze qualitative data.)

(there is limited information on gastroenterologists' perspectives of shared decision making or tools used in discussions of therapeutic agents with IBD patients in clinical practice.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(This hybrid research method included moment-to-moment affect trace analyses to evaluate gastroenterologist responses to qualitative audio content.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Qualitative research: physicians were considered experts in their field as having experience with and strong opinions about shared decision making (both positive and reserved). Quantitative research: gastroenterologists from the Research Now (Plano, TX) Physician Panel opted in to take the online survey.)

(Qualitative research: physicians were familiar with shared decision making.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(in-depth telephone interviews and online quantitative survey among gastroenterologists and a moment-to-moment rating of the actor reenacted excerpts from in-depth physician interviews.)

(This hybrid research method included moment-to-moment affect trace analyses to evaluate gastroenterologist responses to qualitative audio content.)

(The content provided from the in-depth interviews with gastroenterologists was based on interviewees' professional opinions)

(in-depth interview transcripts and digital recordings;)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(The in-depth interview transcripts and digital recordings were reviewed and analyzed to identify differing opinions and physician perspectives expressed during the interviewing process. For quantitative data, cluster analysis, segmentations and multiple discriminant analysis were conducted.)

Findings

Is there a clear statement of findings?

Yes

(Qualitative and quantitative data was used.)

Research value

How valuable is the research?

Yes

(These data suggest that the availability of an IBD decision aid may facilitate the practice of shared decision making by gastroenterologists in the IBD clinical setting.)

(Further studies using this hybrid methodology to evaluate gastroenterologists' perceptions and practice of shared decision making with IBD patients are warranted.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Stevenson, 2003

2

Bibliographic Reference

Stevenson, Fiona A.; General practitioners' views on shared decision making: a qualitative analysis; Patient education and counseling; 2003; vol. 50 (no. 3); 291-3

3

Aims of the research

Was there a clear statement of the aims of the research?

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Can't tell

(The paper reports on two focus groups in which GPs were presented with a theoretical model of shared decision making and then asked to reflect on the model using data from their own and others consultations, supplemented with data from interviews with patients and GPs about these consultations.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Can't tell

(Twenty GPs who had participated in a study of doctor– patient communication about drugs were invited to take part in a focus group to discuss the results.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(a focus group)

(The group interaction allowed for a more in-depth understanding of GPs' beliefs about shared decision making than could have been gained from individual interviews with each of the participants.)

(A model of SDM was presented to both groups to provide a focus for discussion.)

(sessions were tape recorded and transcribed verbatim.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(the data were organised into themes by the author. Members of the research team then commented on the analysis.)

(After listening to the tapes and re-reading the transcripts the data were organised into themes by the author. Members of the research team then commented on the analysis.)

Findings

Is there a clear statement of findings?

Can't tell

Research value

How valuable is the research?

Yes

(The data used in the groups related strongly to clinical practice and the meeting was interactive, thus the format is likely to be an effective method for continuing medical education.)

Overall risk of bias and directness

Overall risk of bias

Moderate

(There was not a clear description about why the method was chosen. Recruitment and ethical issues were not well described.)

Directness

Direct

1

Towle, 2006

2

Bibliographic Reference

Towle, Angela; Godolphin, William; Grams, Garry; Lamarre, Amanda; Putting informed and shared decision making into practice; Health expectations : an international journal of public participation in health care and health policy; 2006; vol. 9 (no. 4); 321-32

3

4

5

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To investigate the practice, experiences and views of motivated and trained family physicians as they attempt to implement informed and shared decision making (ISDM) in routine practice and to identify and understand the barriers they encounter.)

(In contrast to studies that have enquired about the barriers that physicians anticipate will be important in practice or that they experienced with a limited set of patients, this qualitative exploratory study investigated the barriers that were reported and independently identified while motivated and trained family physicians attempted to implement ISDM in routine practice with unselected patients.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(qualitative exploratory study investigated the barriers that were reported and independently identified while motivated and trained family physicians attempted to implement ISDM in routine practice with unselected patients.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Family physicians who were 'lead tutors' in the Department of Family Practice at the University of British Columbia, Vancouver, Canada, were invited to participate in the study.)

(Family physicians who were 'lead tutors' were selected as they are experienced preceptors of undergraduate medical students with a known high standard of practice and commitment to patient-centred care.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(identification of barriers was done through analysis of transcripts of actual doctor–patient consultations and through key informant discussion groups with the physicians.)

(Consultations of all consenting patients were audiotaped and transcribed. Each patient completed a short questionnaire after the consultation to collect basic demographic and satisfaction data. The physicians completed a simple log for each patient to assess opportunities for and perceived success of putting ISDM into practice.)

(Transcripts were analysed using the Framework method of analysis developed by the National Centre for Social Research, a method in which themes are developed both from the research questions and from the accounts of research participants.)

(audiotaped and transcribed consultations, patients' questionnaires, and physicians' log.)

Researcher and participant relationship

[Has the relationship between researcher and participants been adequately considered?](#)

Can't tell

Ethical Issues

[Have ethical issues been taken into consideration?](#)

Yes

(Ethics approval for the study was granted by the University of British Columbia Behavioural Research Ethics Board.)

Data analysis

[Was the data analysis sufficiently rigorous?](#)

Yes

(using the Framework method of analysis developed by the National Centre for Social Research, a method in which themes are developed both from the research questions and from the accounts of research participants.)

(The data presented include both key informant and transcribed consultation data organized by the eight ISDM competencies.)

(The key issues emerging from the data are presented with illustrative quotes.)

Findings

Is there a clear statement of findings?

Yes

(physicians' views on questions arising from the analysis of the transcripts and logs to validate or provide explanations for the findings.)

Research value

How valuable is the research?

Yes

(The findings of this study have implications for the design of effective training programmes for ISDM.)

(it seems that an experimental design may have been more efficient with fewer office visits and more frequent discussion of transcripts and experiences.)

(There is not enough data to generalize to the larger community of family physicians.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Upton, 2011

2

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Bibliographic Reference

Upton, Jane; Fletcher, Monica; Madoc-Sutton, Hazel; Sheikh, Aziz; Caress, Ann-Louise; Walker, Samantha; Shared decision making or paternalism in nursing consultations? A qualitative study of primary care asthma nurses' views on sharing decisions with patients regarding inhaler device selection; Health expectations : an international journal of public participation in health care and health policy; 2011; vol. 14 (no. 4); 374-82

1
2
3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

('The aims of the present study were to investigate primary care asthma nurses' views on shared decision making and explore how sharing decisions with patients can be facilitated')

('Much of asthma care is provided by primary care nurses,12 although little is known about their attitudes to and understanding of shared decision making')

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

(Study explored 'the participants clinical experience, the decision making process employed by the participant in asthma consultations and perceived barriers and facilitators to shared decision making')

Research Design

Was the research design appropriate to address the aims of the research?

Yes

('These provided an appropriate focus for the interviews, whilst still affording nurses opportunities to add their own perspectives regarding shared decision making')

Recruitment Strategy

[Was the recruitment strategy appropriate to the aims of the research?](#)

Yes

('post-qualification nurses registered on a distance learning respiratory course and attending a study day at a training centre between June 2007 and February 2008')

(Experienced asthma nurses in the UK. Also included less experienced nurses to determine if they held the same views on SDM)

Data collection

[Was the data collected in a way that addressed the research issue?](#)

Yes

(Semi-structured interviews)

('provided an appropriate focus for the interviews, whilst still affording nurses opportunities to add their own perspectives regarding shared decision making')

(Topic guide)

('This on-going analysis resulted in JU and HMS making minor changes to the topic guide between interviews to ensure that emerging areas of interest were included in the interview')

(Audio recorded and transcribed)

('After 16 interviews, no new themes had emerged. Following completion of 20 interviews, it was agreed by the project team that further interviews were not required to understand participants views of shared decision making')

Researcher and participant relationship

[Has the relationship between researcher and participants been adequately considered?](#)

Can't tell

(Discussed how the selection process could have biased results)

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(Discussed informed consent)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Transcripts analysed using the Framework approach)

(Data analysis continued until no new themes emerged)

Findings

Is there a clear statement of findings?

Yes

(Findings presented in themes and discussed)

(More than one analyst)

Research value

How valuable is the research?

Yes

('there is a fundamental misalignment between the goals of practice nurses and the rhetoric regarding patient empowerment')

(Further testing of shared decision models in asthma)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Van Veenendaal, 2018

2

Bibliographic Reference

van Veenendaal, Haske; van der Weijden, Trudy; Ubbink, Dirk T.; Stiggelbout, Anne M.; van Mierlo, Linda A.; Hilders, Carina G. J. M.; Accelerating implementation of shared decision-making in the Netherlands: An exploratory investigation; Patient education and counseling; 2018; vol. 101 (no. 12); 2097-2104

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(to formulate and prioritize strategies for the implementation of SDM, based on identification of barriers for change, and resulting in an agenda for a nationwide approach.)

(There is a lack of guidance about how to adopt SDM in routine practice)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Researchers used purposeful sampling, for the identification and selection of clinicians from different healthcare areas, researchers, patient advocates and policymakers.)

(all knowledgeable in SDM implementation, i.e. integrating decisions aids locally, training SDM, adapting clinical pathways, or creating (local or national) preconditions for SDM implementation.)

(All participants were either interviewed or participated in focus groups.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Face-to-face or telephone interviews and focus groups.)

(Semi-structured interviews, focus groups, and re-affirmation through written feedback were applied to explore how implementation can be accelerated.)

(Key literature on barriers to and facilitators for implementing SDM was used to prepare the interviews, focus groups and reports, overseen by a six-member steering group.)

(Full verbatim transcripts were not made. Interviews were summarized as field notes and focus groups as written meeting minutes and checked by the participants.)

(Recruitment of participants continued until the investigators concluded that participants no longer provided new insights.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(All participants agreed to participate and to have their opinions and comments used for the research.)

(Ethical approval was not required as no patients were included in the study. All participants agreed to participate and to have their opinions and comments used for the research.)

Data analysis

Was the data analysis sufficiently rigorous?

Can't tell

(After analysing the interviews, two investigators selected discussion themes for the focus groups. The first focus group was geared towards hospital care, the second was expanded to general practice, mental healthcare and long-term care.)

(see tables in appendix)

Findings

Is there a clear statement of findings?

Yes

(This qualitative exploration used different methods to enhance data validity, in line with the Standards for Reporting Qualitative Studies.)

Research value

How valuable is the research?

Yes

(In order to accelerate learning about effective change, research projects should focus on how implementation initiatives perform in different contexts, for different groups of clinicians and patients.)

Overall risk of bias and directness

Overall risk of bias

Moderate

(Type of analysis and theoretical framework were not reported.)

Directness

Direct

1

Walter, 2004

2

Bibliographic Reference

Walter, Fiona M.; Emery, Jon D.; Rogers, Margaret; Britten, Nicky; Women's views of optimal risk communication and decision making in general practice consultations about the menopause and hormone replacement therapy; Patient education and counseling; 2004; vol. 53 (no. 2); 121-8

3

Aims of the research

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

Was there a clear statement of the aims of the research?

Yes

(to examine primary care patients' perspectives of optimal risk communication and decision making, and their views on how to improve its effectiveness.)

(There has been research about peri-menopausal women's understanding of risk and the current research reports their views on risk communication and decision making, using the context of HRT and the menopause.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

(This study's qualitative methodology allows a thorough examination of women's sophisticated and thoughtful views about risk communication and shared decision making relating to the menopause and HRT in general practice consultations.)

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(The analysis was performed within the approach of Ritchie and Spencer's 'Framework analysis' which was used for its systematic and disciplined approach, while allowing meaningful connections between themes to create new meanings and perspectives.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(All women between the ages of 50 and 55 were identified in each practice, and their HRT usage was established, separating them into three groups: Current-Users (CU), Never-Users (NU), and Ex-Users (EU).)

(Practices were purposively chosen in an attempt to sample as broad a range of views as possible across educational levels and occupations, as the gender and age of participants were dictated by the sample group.)

(Dropouts were mainly due to inconvenient times of group meetings.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Researchers only said that focus groups were organised in local settings away from surgeries (e.g. church halls). All women who were unable to attend a group but wished to participate were offered a semi-structured interview in their own home.)

(focus groups and semi-structured interviews)

(The analysis was performed within the approach of Ritchie and Spencer's 'Framework analysis' which was used for its systematic and disciplined approach, while allowing meaningful connections between themes to create new meanings and perspectives.)

(An experienced facilitator ran all groups, asking the questions and facilitating the discussion. In each session, an observer took field notes and observed non-verbal communication, to augment tape recordings. All women who were unable to attend a group but wished to participate were offered a semi-structured interview in their own home.)

(Two groups had patients from both practices: this latter combination resulted in comparing experiences where there had been a dedicated 'HRT clinic' in one practice with those where no explicit times were set aside for consultations specific to menopause.)

(field notes, observation of non-verbal communication, and tape recordings.)

(Groups were convened until saturation of data and no new ideas emerged.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Can't tell

Ethical Issues

Have ethical issues been taken into consideration?

Can't tell

(LREC approval was obtained): No detail on how was explained to patients.

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(Researchers described the coding process, the development of a thematic analysis and that the final stages included bringing data together and the interpretation.)

(The ensuing focus group and interview discussions covered the following themes which had been developed from a literature review and discussions with colleagues.)

(To develop the thematic analysis an iterative process followed, involving identification of key issues, concepts and themes, and then coding using ATLAS Ti software.)

(There were quotes for each finding.)

(The quotations were chosen to reflect a range of both consensual and dissenting views from each HRT user group, and both practices.)

Findings

Is there a clear statement of findings?

Yes

(Measures to enhance reliability and validity were employed, such as using an observer taking field notes to augment the analysis; audio tapes of all participant encounters and verbatim transcripts; and having two coders working together to develop a shared understanding of the codes)

Research value

How valuable is the research?

Yes

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Watson, 2008

2

Bibliographic Reference

Watson, Duika Burges; Thomson, Richard G.; Murtagh, Madeleine J.; Professional centred shared decision making: patient decision aids in practice in primary care; BMC health services research; 2008; vol. 8; 5

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(to explore health care practitioners' perceptions and use of patient decision aids in routine clinical practice as a baseline study prior to an intervention involving the introduction of a suite of patient decision aids including the atrial fibrillation tool.)

(Despite broad acceptance of the use of patient decision aids in improving patient-based outcomes and health, evidence for their successful implementation and use in extending SDM in routine practice remains scarce.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(A framework approach was used. It has been identified as a suitable method for analysing data where the objectives of the research have been set in advance of the analysis, for example where particular themes are deduced as relevant to a research topic.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Five general practice surgeries in northern England were invited to participate in the study. The selection of practices built on the recruitment in our earlier study.)

(Previous studies have limited their studies to practitioners who have an existing interest in and knowledge of SDM.)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(focus groups)

(A framework approach was used. It has been identified as a suitable method for analysing data where the objectives of the research have been set in advance of the analysis, for example where particular themes are deduced as relevant to a research topic.)

(Focus groups (FG1-FG5) were conducted around the themes of SDM and patient decision aids in general practice, exploring potential for further development of SDM in the practice.)

(audio-recorded focus groups)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

Yes

(Reflexivity was used during the analytical phase.)

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(All participants provided written consent to participate in the audio-recorded focus group.)

(The study received ethical approval from Sunderland LREC.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(A 5 stage process of analysis was adopted involving: familiarisation with the data through reading and rereading the transcripts for recurrent themes; identification of a thematic framework based on the objectives of the research; a process of indexing in which transcripts were annotated with codes derived from the thematic framework; summarising and synthesising this data into charts that use representative quotes to demonstrate themes.)

(This is explained in the 5-stage process of analysis.)

(There were quotes for each finding.)

(Reflexivity was used during the analytical phase.)

Findings

Is there a clear statement of findings?

Yes

(Researchers employed a variety of tactics to address concerns about validity in the research involving presenting representative quotes and undertaking a negative case analysis to look for disconfirming cases.)

Research value

How valuable is the research?

Yes

(the implementation of patient decision aids in clinical practice should involve a more explicit recognition of the challenge of this approach and the implicit reordering of power that it may involve.)

(evaluative frameworks and modes of delivering SDM tools into practice may need to address how different institutional settings and cultures modify the introduction of patient decision aids.)

(patient decision aids could be incorporated into routine practice beyond the confines of the consultation.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Wiener, 2018

2

Bibliographic Reference

Wiener, Renda Soylemez; Koppelman, Elisa; Bolton, Rendelle; Lasser, Karen E.; Borrelli, Belinda; Au, David H.; Slatore, Christopher G.; Clark, Jack A.; Kathuria, Hasmeena; Patient and Clinician Perspectives on Shared Decision-making in Early Adopting Lung Cancer Screening Programs: a Qualitative Study; Journal of general internal medicine; 2018; vol. 33 (no. 7); 1035-1042

1

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To characterize patient and clinician impressions of early experiences with communication and decision-making about lung cancer screening and perceived barriers to achieving shared decision making.)

(Little is known about LCS discussions and decision-making in real-world settings, including the degree to which guideline and policy recommendations for SDM have been realized.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(directed content analysis approach)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Researchers recruited patients who were screened in the prior year (randomly selected from each site's LCS registry) and clinicians who refer patients for LCS (primary care providers [PCPs], pulmonologists, screening nurse coordinators.)

(To increase diversity and capture practices in a program governed by CMS policy, researchers collected a second wave of qualitative data at an urban safety net hospital.)

Data collection

[Was the data collected in a way that addressed the research issue?](#)

Yes

(semi-structured interviews)

(To explore the degree to which participants' depictions of LCS discussions reflected SDM, which had been widely recommended by study onset.)

(Informed by the Charles model and recommendations for SDM in LCS, researchers developed interview guides to probe impressions of patient-clinician communication and decision making surrounding LCS, as well as usual practices and barriers to realizing guideline recommendations.)

(All sessions were audio-recorded and professionally transcribed.)

Researcher and participant relationship

[Has the relationship between researcher and participants been adequately considered?](#)

Can't tell

Ethical Issues

[Have ethical issues been taken into consideration?](#)

Can't tell

(The Edith Nourse Rogers Memorial Veterans Affairs (VA) Hospital and Boston University Medical Campus institutional review boards approved this research.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(There is a description about how codes were developed and discussed within the research team to reach a consensus of the categories.)

(Codes were developed to capture attributes of decision-making, working both deductively (specifically looking for recommended SDM elements) and inductively (open to discerning additional attributes that were implicit in participants' accounts).)

(There were quotes for each finding.)

Findings

Is there a clear statement of findings?

Yes

(Through constant comparison and discussion of findings by the team, coding was iteratively revised until they reached consensus on the codes and summary categories of patients' and providers' perceptions.)

Research value

How valuable is the research?

Yes

(Further work is needed to learn how to effectively overcome barriers to implementing this important recommendation.)

(Researchers purposely enrolled participants from diverse sites, but cannot conclude that the findings are generalizable to other settings.)

Overall risk of bias and directness

Overall risk of bias

Moderate

(It is unclear how the research was explained to participants and whether consent was asked.)

Directness

Direct

1

Zeuner, 2015

2

Bibliographic Reference

Zeuner, Rachel; Frosch, Dominick L.; Kuzemchak, Marie D.; Politi, Mary C.; Physicians' perceptions of shared decision-making behaviours: a qualitative study demonstrating the continued chasm between aspirations and clinical practice; Health expectations : an international journal of public participation in health care and health policy; 2015; vol. 18 (no. 6); 2465-76

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(to explore clinicians' attitudes, beliefs and perceived social norms about engaging in SDM behaviours.)

(Although some past studies have examined physicians' barriers and facilitators to adopting SDM, few studies have focused on clinicians' perceptions of specific communication behaviours necessary for SDM and predictors of those.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

Research Design

Was the research design appropriate to address the aims of the research?

Yes

(The questions for the interviews were derived from Fishbein's Integrative Model of Behaviour Prediction and from previous studies that used this theory to guide qualitative exploratory studies about SDM.)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(Researchers recruited clinicians affiliated with an academic medical centre.)

(The goal was to recruit physicians across different practice areas to ensure diversity in clinical experiences.)

(one declined participation and one was unable to participate due to scheduling)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Semi-structured qualitative interviews.)

(semi-structured qualitative interview guide explored physicians' beliefs underlying attitudes, perceived social norms and self-efficacy for engaging in key SDM communication behaviours.)

(the complete Interview Guide was given in appendix S1 and a brief description of further questions in the section of methods)

(audio recordings)

(Recruitment ceased once we reached thematic saturation and no new themes were emerging from the interviews.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(Details about the study and how to schedule an interview were included in the email.)

(The study was approved by the Washington University Human Subjects Research Protection Office.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(The researchers described how codes were developed and categorised into themes.)

(Researchers reviewed the transcripts and developed a preliminary codebook. Research team members then coded five transcripts and discussed revisions to the codebook for the next coding stage. Categories and subcategories within and across interviews were identified.)

(based on both the frequency and emotive force conveyed by the participants when discussing responses to the interview questions.)

(There were quotes for each finding.)

(The findings showed that some clinicians support SDM and others held fundamentally inconsistent beliefs about engaging in key SDM behaviours.)

Findings

Is there a clear statement of findings?

Yes

(At least 2 researchers coded the transcripts and consensus was used either by discussing inconsistencies or by a third member of the team.)

Research value

How valuable is the research?

Yes

(They suggest more training for physicians on how to engage in discussions with patients for SDM and other themes that emerged from the findings)

(More research is needed to explore when and how to incorporate costs into patients' decisions.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

1

Ziebland, 2015

2

Bibliographic Reference

Ziebland, Sue; Chapple, Alison; Evans, Julie; Barriers to shared decisions in the most serious of cancers: a qualitative study of patients with pancreatic cancer treated in the UK; Health expectations : an international journal of public participation in health care and health policy; 2015; vol. 18 (no. 6); 3302-12

3

Aims of the research

Was there a clear statement of the aims of the research?

Yes

(To explore patients' perceptions of barriers to shared decision making in a condition in which shared decision making might be difficult.)

(The researchers recognised that (i) even the realisation that there is anything to make a decision about is not always clear and (ii) communication about treatment options, especially in life-threatening illness, is rarely free of interactional complications.)

Appropriateness of methodology

Is a qualitative methodology appropriate?

Yes

(A qualitative interpretive approach was taken, using modified grounded theory (informed by a detailed literature review) combining thematic analysis with constant comparison)

Research Design

Was the research design appropriate to address the aims of the research?

Can't tell

(A qualitative approach was chosen to examine patients' accounts of the barriers to sharing decisions about their treatment..)

Recruitment Strategy

Was the recruitment strategy appropriate to the aims of the research?

Yes

(purposive sample)

(to capture a diverse range of experiences, including people in different age categories, some who had been diagnosed recently, others who were in remission, and others receiving palliative care)

Data collection

Was the data collected in a way that addressed the research issue?

Yes

(Authors only said that participants were interviewed at a place of their choice)

(people were asked to talk about their experience of pancreatic cancer and when the narrative was finished, a semi-structured interview guide was used to explore any potentially relevant issues that had not already emerged)

(a semi-structured interview guide was used to explore any potentially relevant issues that had not already emerged, such as patients' recollection of information given to them by their doctors or how decisions were made.)

(The interviews were all audio-recorded, fully transcribed, checked and then returned to the participants so that they could read the text if they wished and remove or clarify sections if necessary.)

(After 32 interviews, the researchers felt that they were approaching 'data saturation'.)

Researcher and participant relationship

Has the relationship between researcher and participants been adequately considered?

No

(Not described)

Ethical Issues

Have ethical issues been taken into consideration?

Yes

(The research was explain using packs which included a letter, an information sheet, reply slip and return envelope; those wanting to know more about the study contacted the research team.)

(Researchers only mentioned that pseudonyms were used throughout this paper but they did not mention how they handled effects of the study on participants.)

(With approval from The Berkshire Research Ethics Committee.)

Data analysis

Was the data analysis sufficiently rigorous?

Yes

(The researchers read and re-read the data from all the interviews and constructed a coding frame. They grouped extracts from the interviews with relevance to a number of anticipated and emergent themes; all authors discussed coding and interpretation of results.)

(The researchers mentioned that there were a number of anticipated and emergent themes but the list of anticipated themes is not reported.)

(The researchers used a modified grounded theory (informed by a detailed literature review) combining thematic analysis with constant comparison.)

(There were quotes for each finding.)

(Researchers gave an example of a 'deviant' case and explored the views of this participant.)

Findings

Is there a clear statement of findings?

Yes

(The findings are presented in themes with quotes for each theme.)

(The interviews were returned to the participants so that they could read the text if they wished and remove or clarify sections if necessary. All researchers discussed coding and interpretation of results.)

Research value

How valuable is the research?

Yes

(data suggest that when faced with pancreatic cancer, one of the most life-threatening illnesses, many people want to be involved in at least some of the decisions.)

(Observational approaches may help shed light on the mechanics of these consultations. For example, conversation analysis offers some insight into how doctors might present options in the consultation without appearing either to abandon or direct the patient.)

(Researchers suggest that there is a particularly strong imperative to make sure that the patient is not subject to other people's assumptions about what is best for them. This conclusion could be transferred to people with life-threatening illnesses.)

Overall risk of bias and directness

Overall risk of bias

Low

Directness

Direct

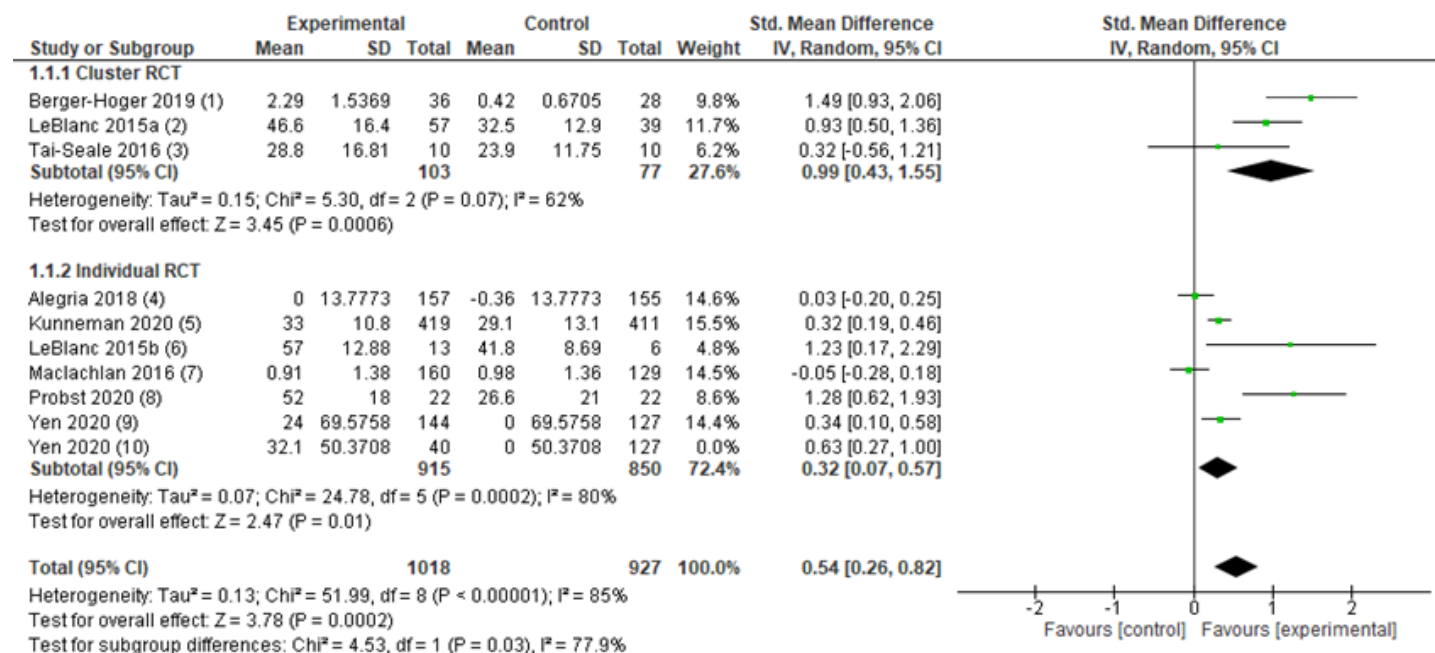
1

2

1 Appendix F – Forest plots

2 Interventions targeting patients using usual care

3 Figure 2: Shared decision making (OBOM, continuous)

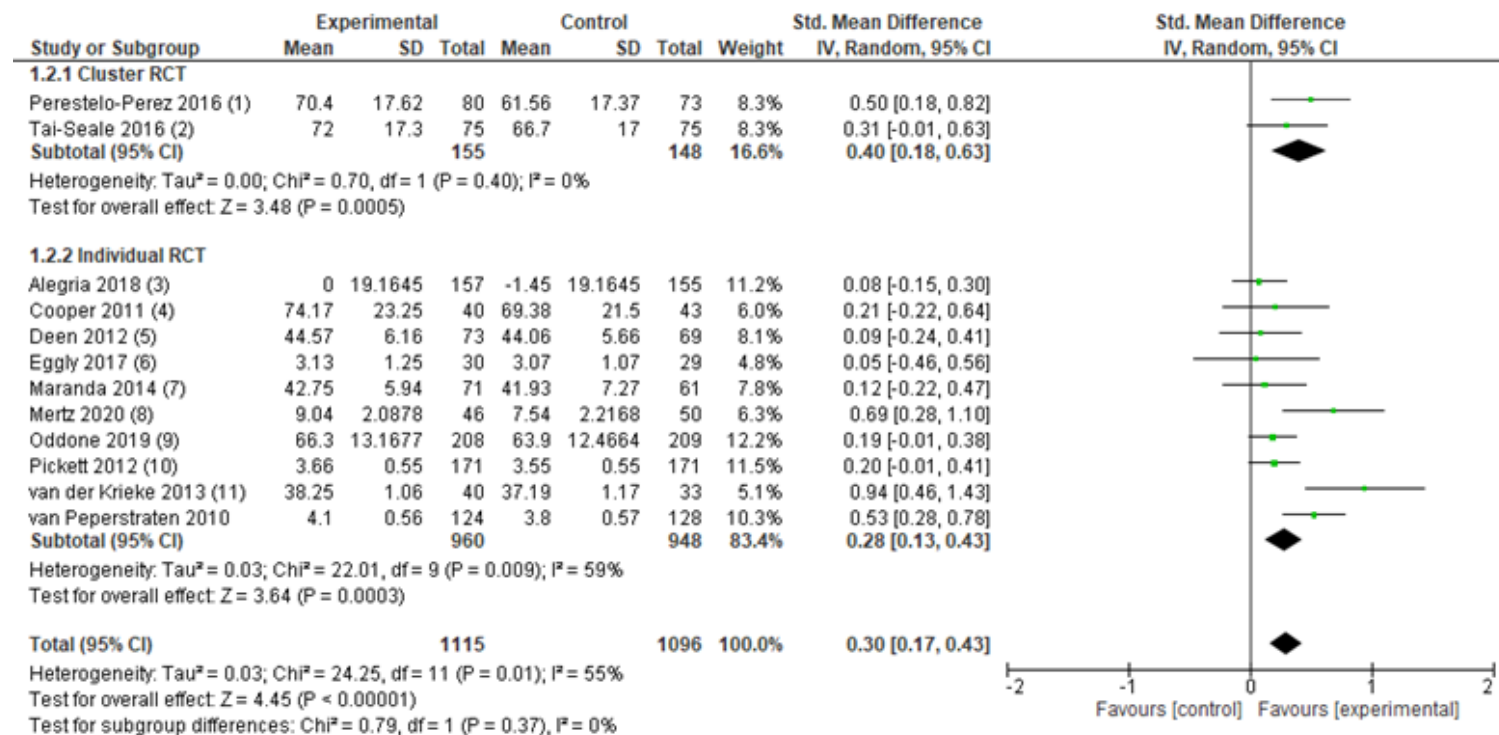


Footnotes

- (1) MAPPIN-O
- (2) OPTION scale
- (3) OPTION-5
- (4) OPTION-12
- (5) OPTION-12
- (6) OPTION
- (7) RIAS for patients
- (8) OPTION-5
- (9) adjusted for clustering, OPTION -5, picture option grid vs UC
- (10) Adjusted for clustering: OPTION-5, OPTION GRID vs UC

4

1 **Figure 3: Shared decision making (PROM, continuous)**



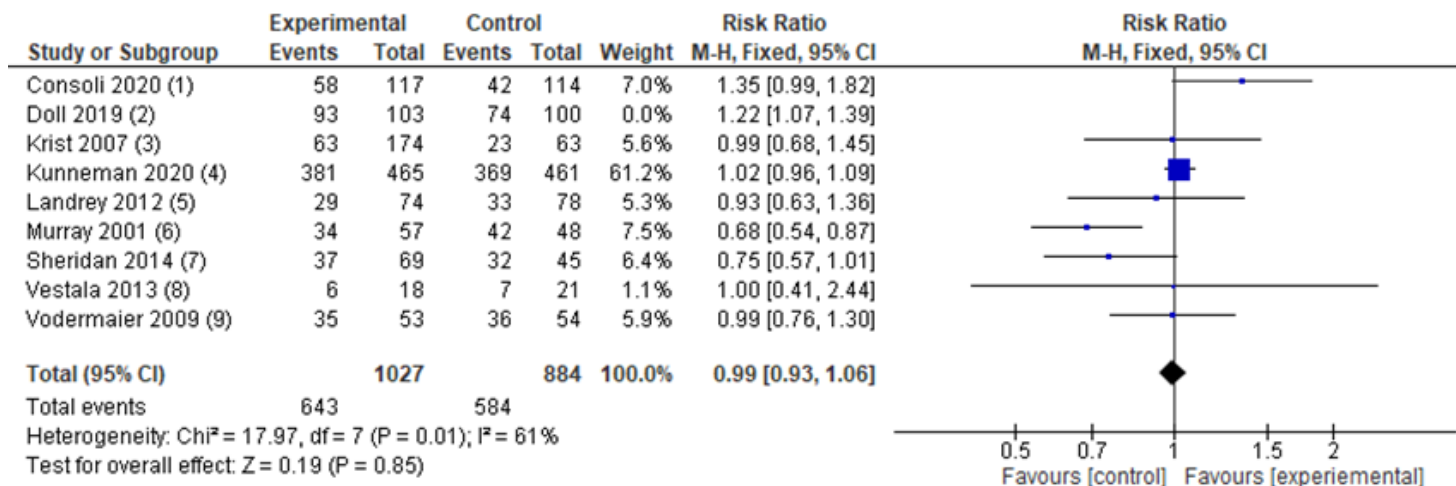
Footnotes

- (1) Satisfaction with Decision making process (SDMP)
- (2) Collabo-RATE (%)
- (3) SDM-9-Q patient
- (4) Participatory Decision making(PDM)
- (5) PAM
- (6) Patient mediated intervention (QPL-only)
- (7) PAM
- (8) PROM SDM: PICS
- (9) PAM
- (10) Patient self-advocacy
- (11) COMRADE (communication)

2

1

2 **Figure 4: Shared decision making (PROM, categorical)**



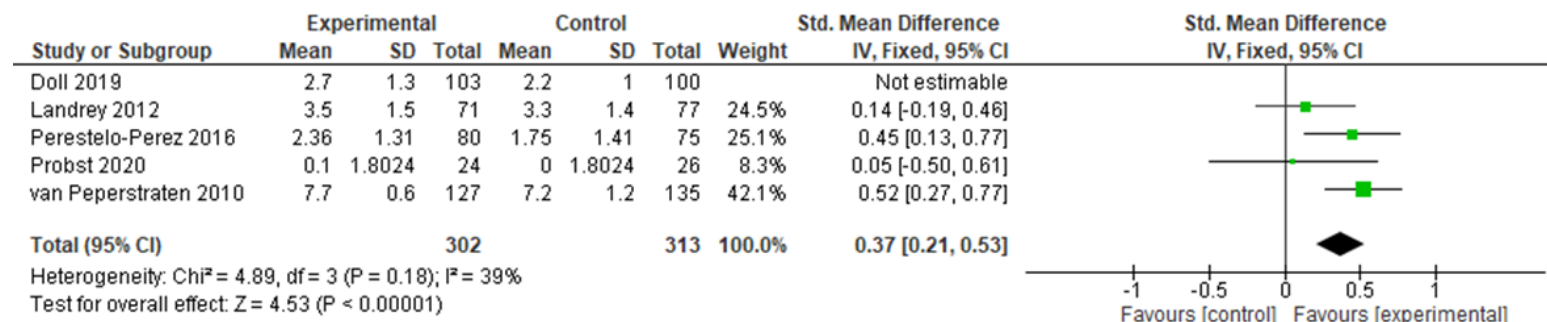
Footnotes

- (1) ENTRED questionnaire - SDM vs clinician-led + patient-led DM
- (2) Control preference scale
- (3) Modified control preference scale
- (4) patient-clinician concordance
- (5) Modified control preference scale
- (6) Modified control preference scale
- (7) Shared decision
- (8) Modified control preference scale
- (9) Modified control preference scale

3

4

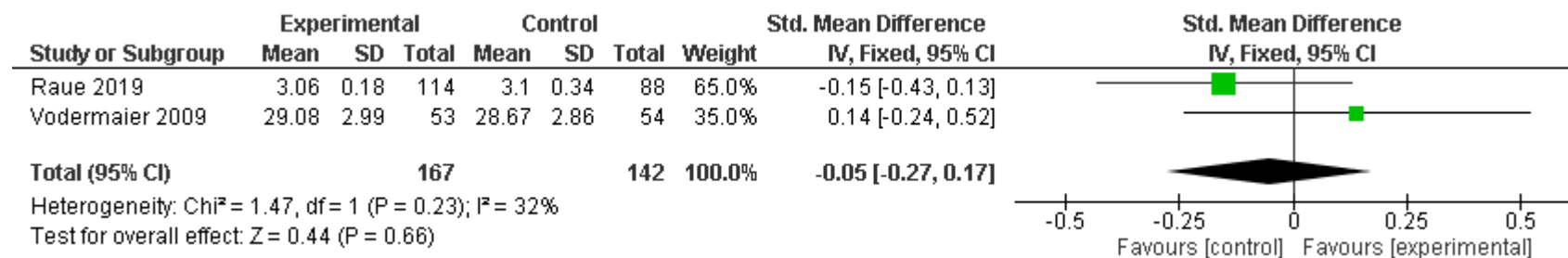
1 **Figure 5: Knowledge**



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3

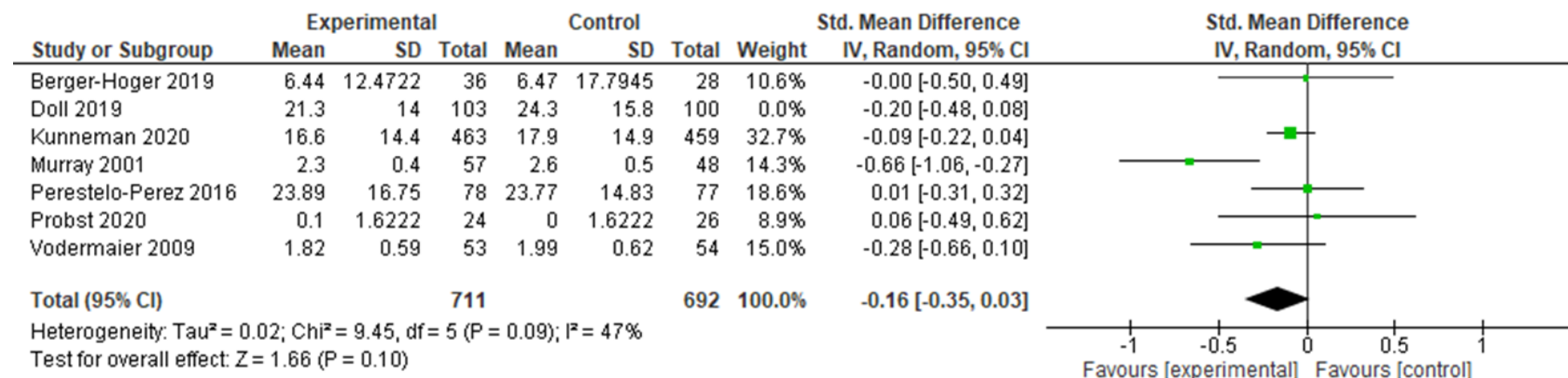
4 **Figure 6: Satisfaction**



5

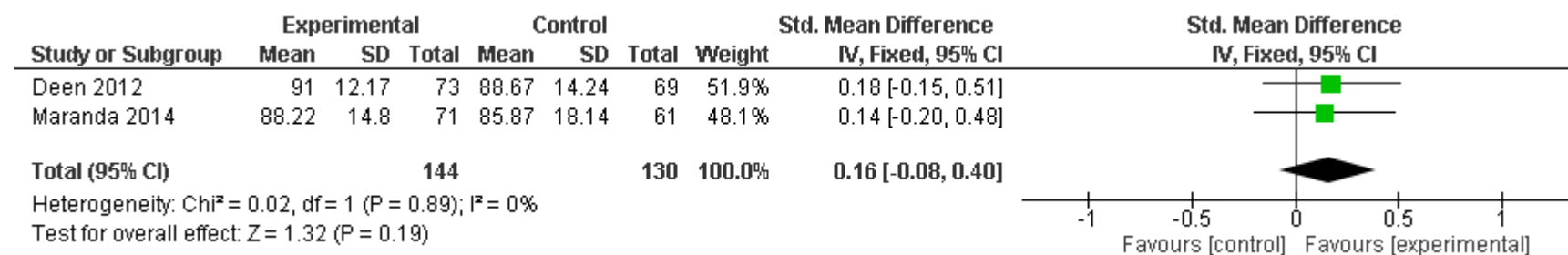
6

1 **Figure 7: Decisional conflict**



2

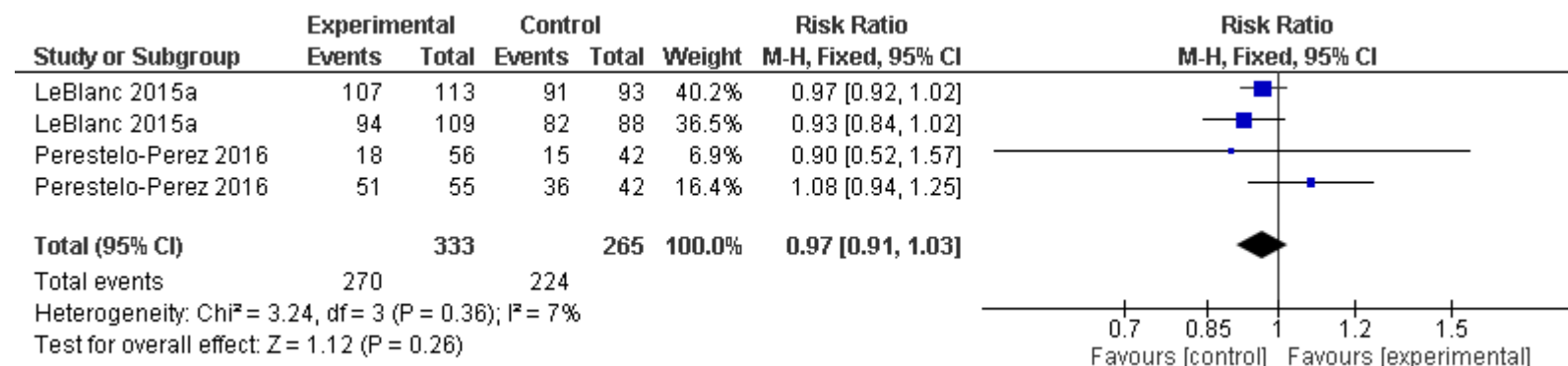
3 **Figure 8: Decision self-efficacy**



4

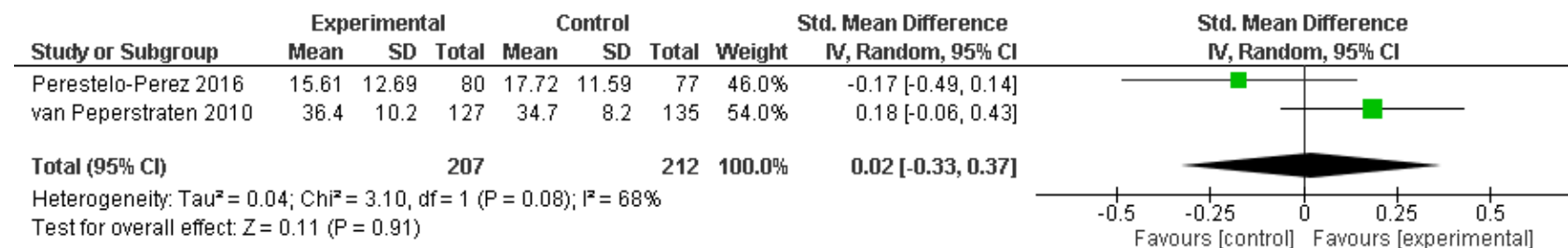
5

1 **Figure 9: Adherence**



2

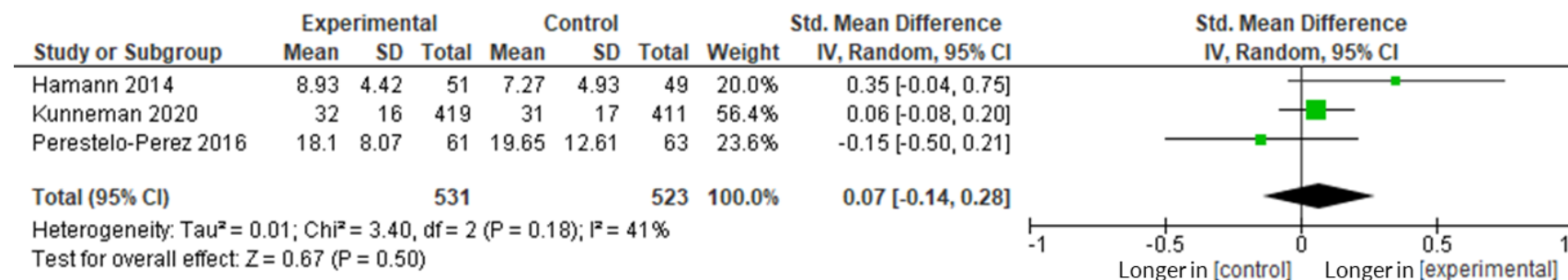
3 **Figure 10: Anxiety**



4

5

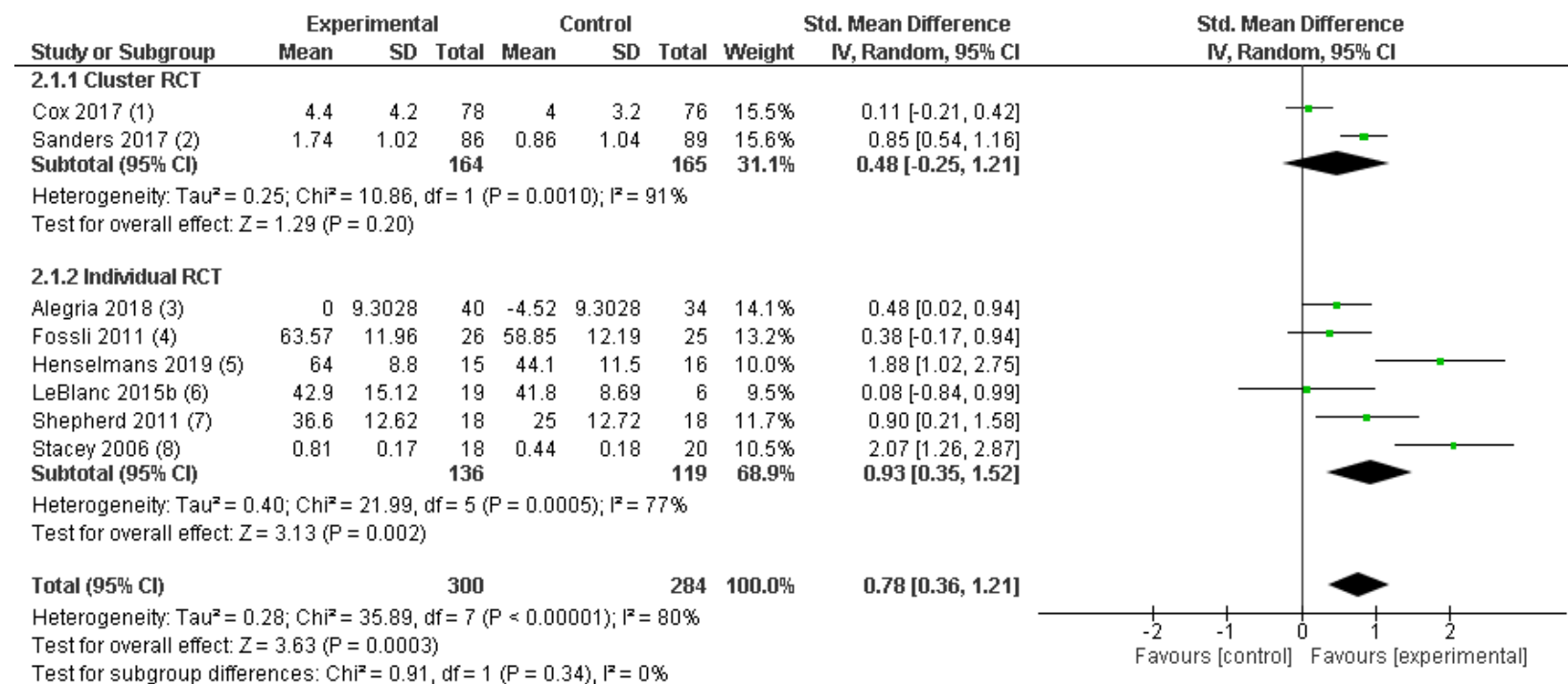
1 **Figure 11: Consultation Length**



2

1 Interventions targeting healthcare professionals compared with usual care

2 Figure 12: Shared decision making (OBOM, continuous)



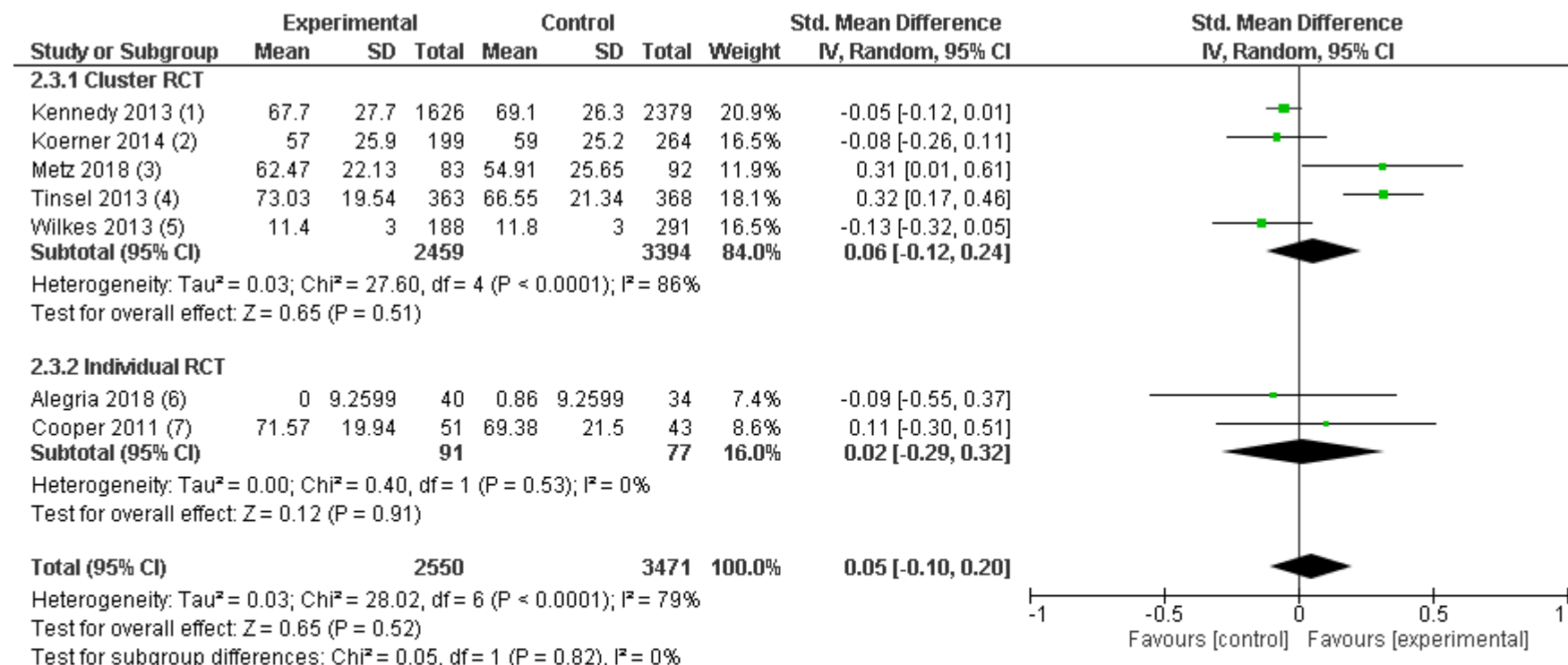
Footnotes

- (1) Family engagement
- (2) Level of autonomy (CPS (2-SDM) [OPTION available])
- (3) OPTION-12
- (4) Four habits coding scheme
- (5) 4SDM
- (6) OPTION (/100)
- (7) OPTION
- (8) Decision support analysis tool (DSAT)

3

4

1 **Figure 13: Shared decision making (PROM, continuous)**



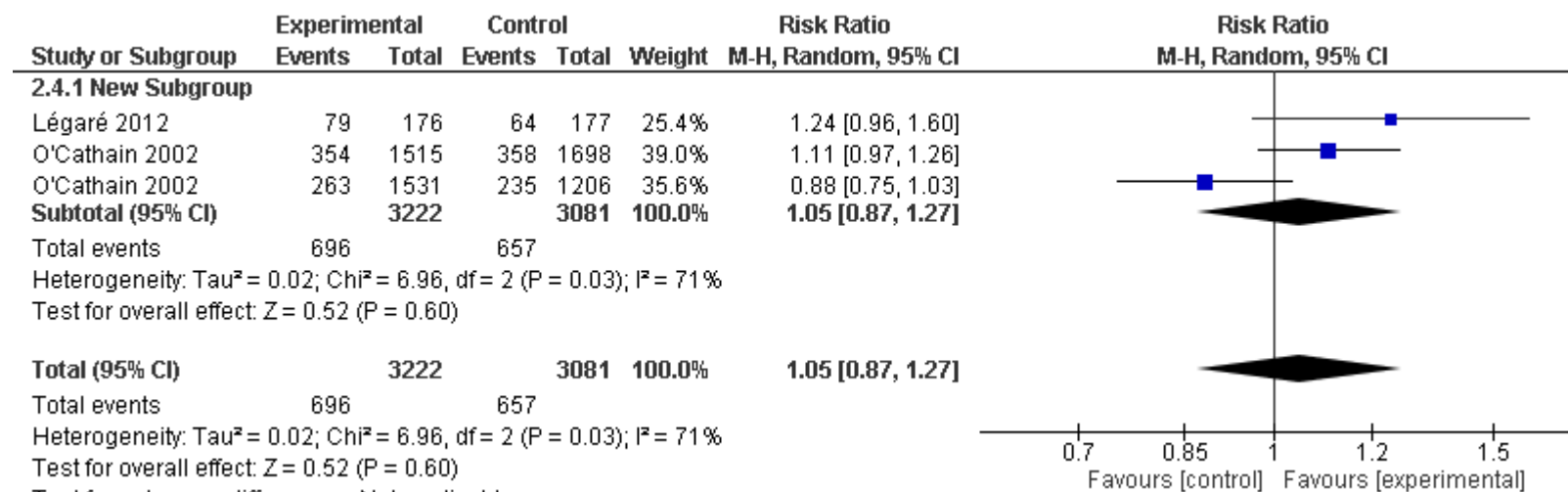
Footnotes

- (1) SDMQ
- (2) SDM-Q-9
- (3) SDM-Q-9 (patient)
- (4) SDM-Q-9
- (5) Overall PSA SDM perception
- (6) SDM-Q-9
- (7) Participatory decision making (PDM)

2

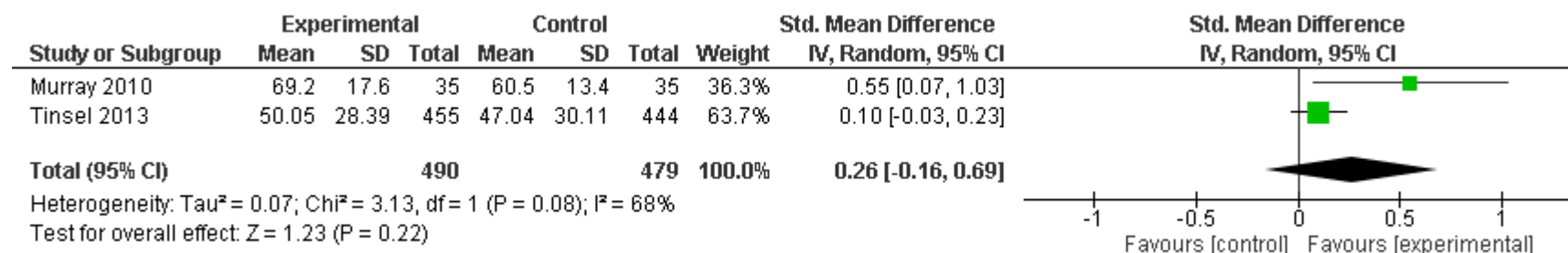
3

1 **Figure 14: Shared decision making (PROM, categorical)**



2 Test for subgroup differences: Not applicable

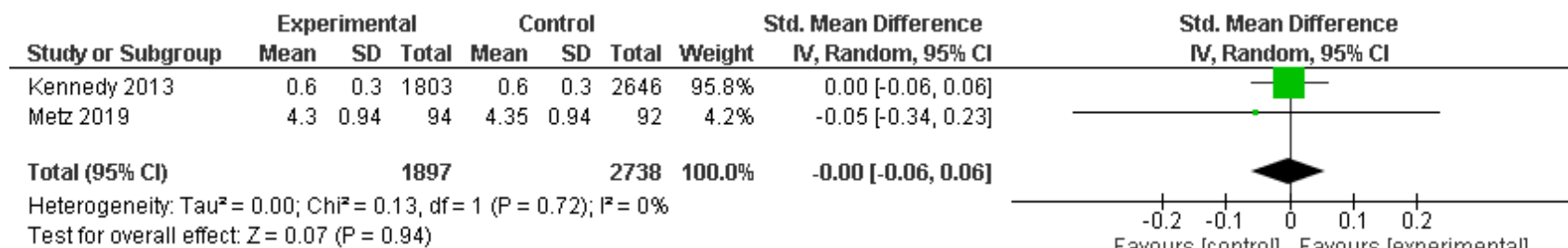
3 **Figure 15: Knowledge**



4

5

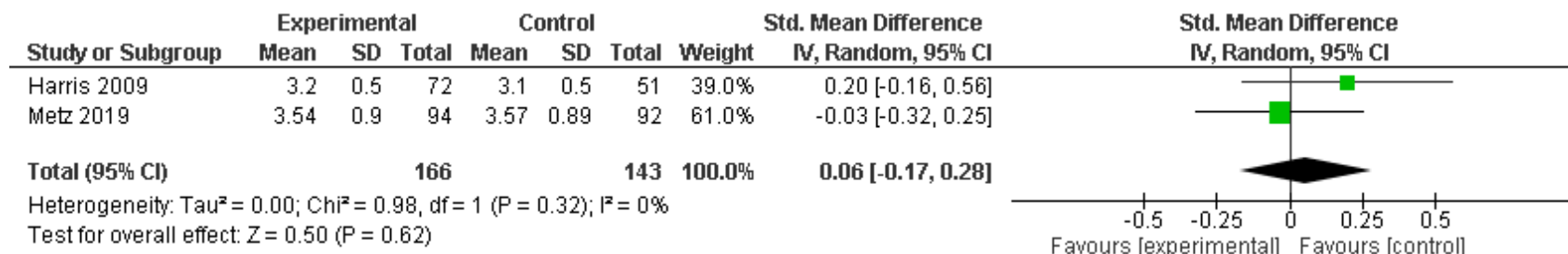
1 **Figure 16: Health-related quality of life**



2

3

4 **Figure 17: Therapeutic alliance**



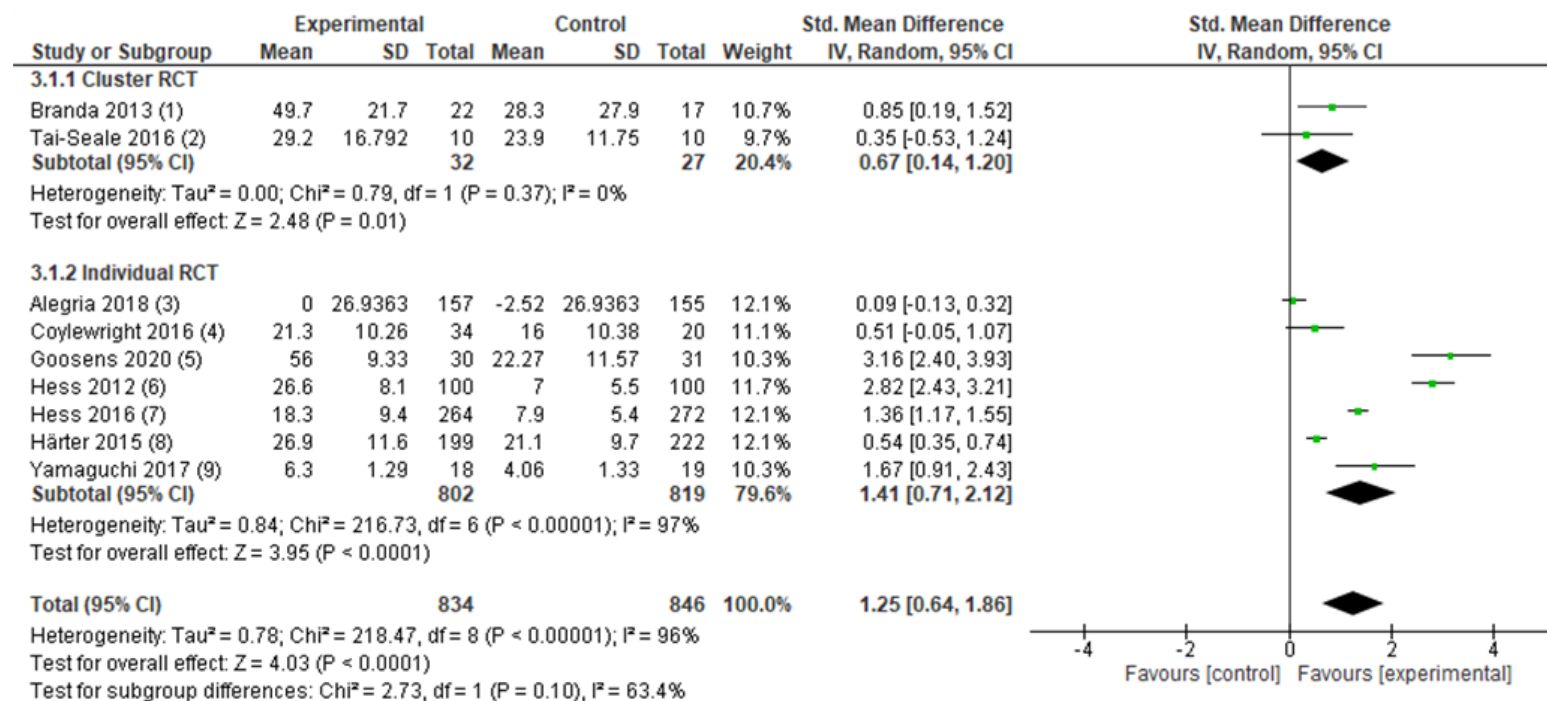
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7

1 Interventions targeting both patients and healthcare professionals

2 Figure 18: Shared decision making (OBOM, Continuous)

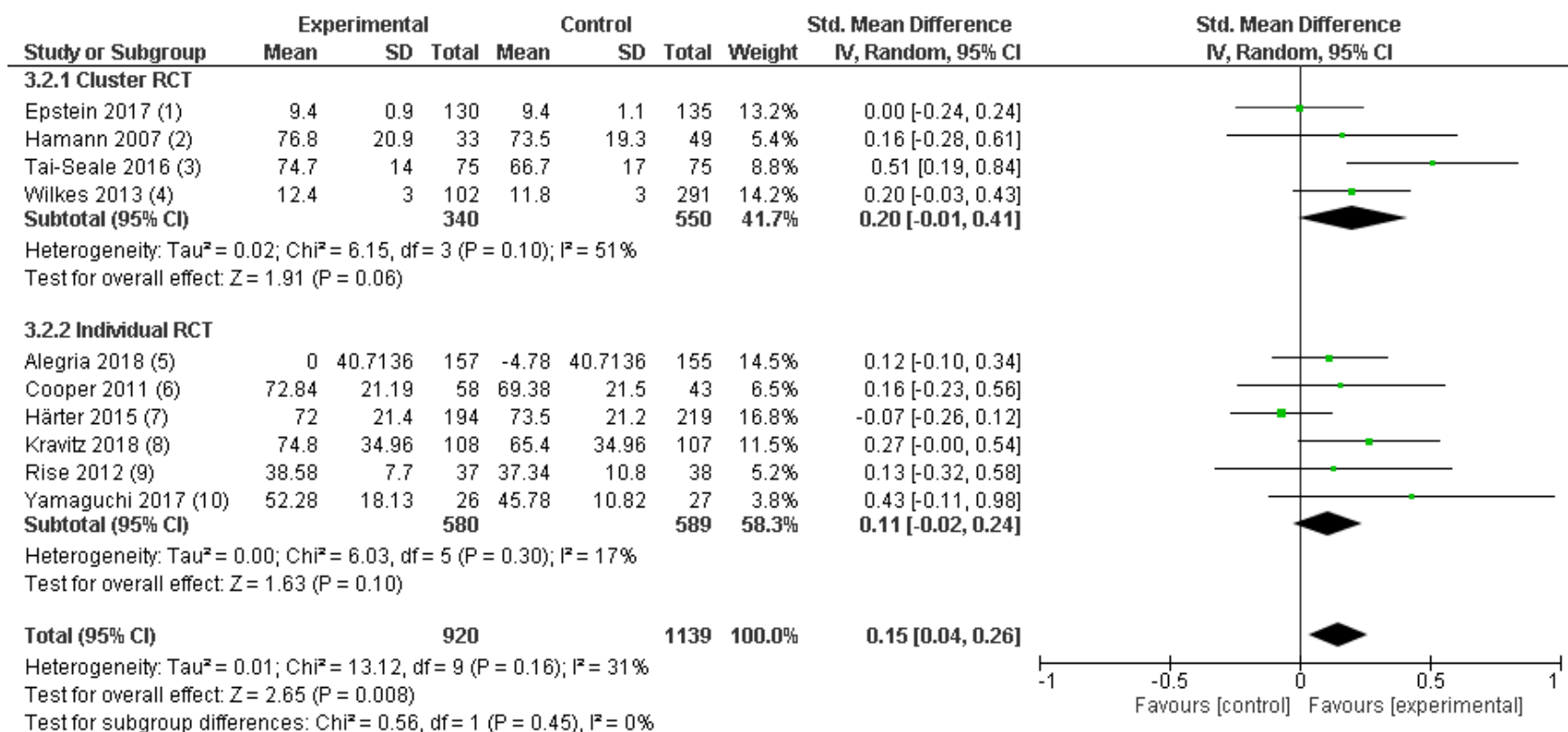


Footnotes

- (1) OPTION (level of patient engagement)
- (2) OPTION5 (/100)
- (3) OPTION-12
- (4) OPTION
- (5) OPTION-12: Cluster RCT but data adjusted in study
- (6) OPTION/100
- (7) OPTION /100
- (8) OPTION
- (9) SDM-18

3

1 **Figure 19: Shared decision making: PROM, continuous**

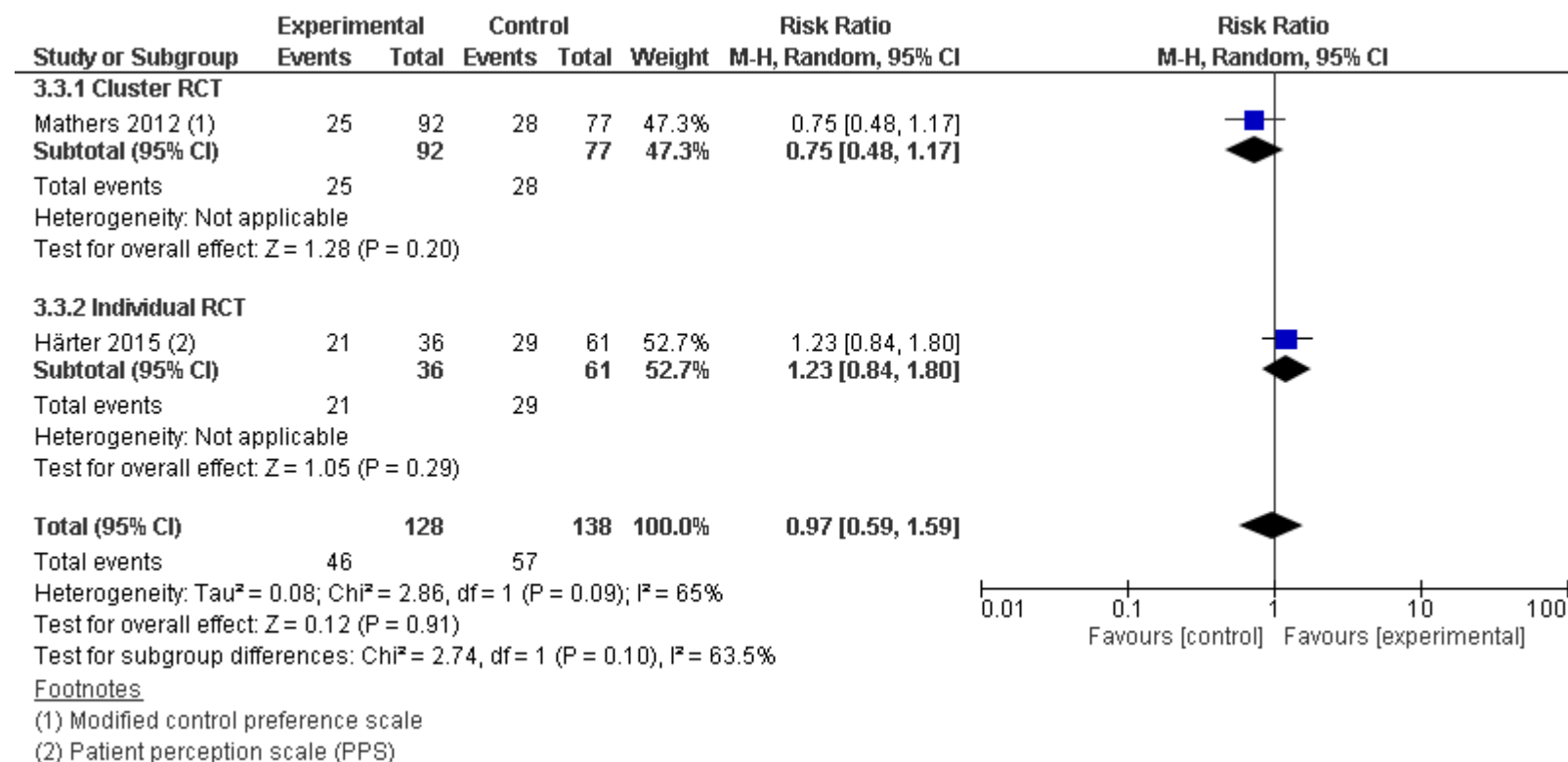


Footnotes

- (1) Healthcare clinical climate questionnaire (HCCQ)
- (2) COMRADE
- (3) Collabo-RATE (/100)
- (4) Overall PSA SDM perception
- (5) SDM-q-9 patient
- (6) Participatory decision making (PDM)
- (7) SDM-Q-9
- (8) medication-related SDM
- (9) Patient activation measure (PAM)
- (10) Patient activation measure (PAM)

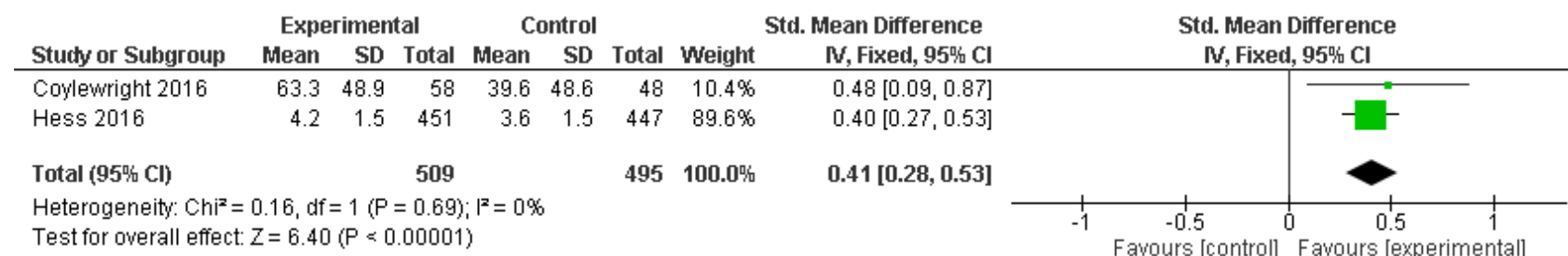
2 Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

1 **Figure 20: Shared decision making (PROM, Categorical)**



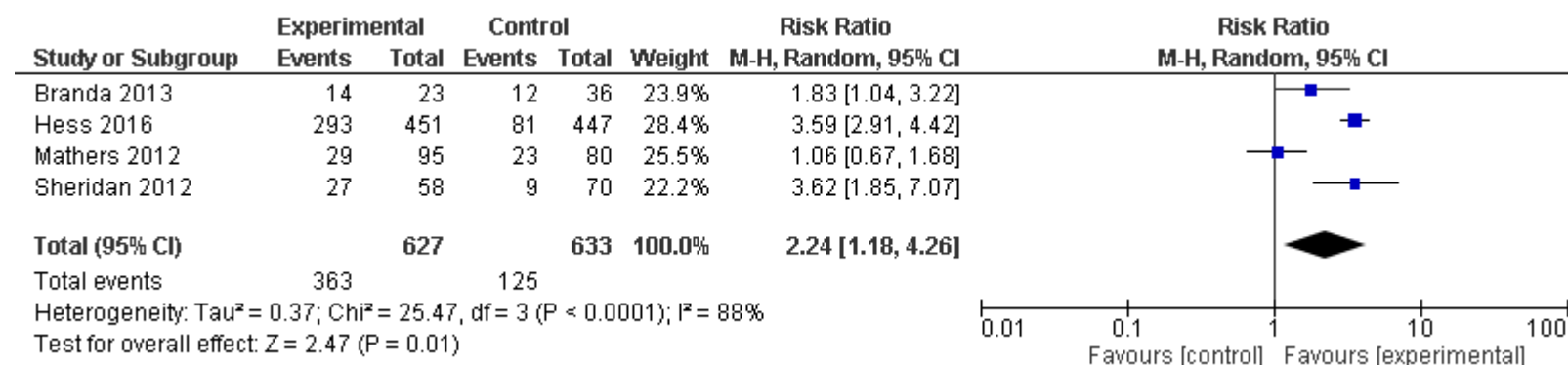
2

3 **Figure 21: Knowledge**



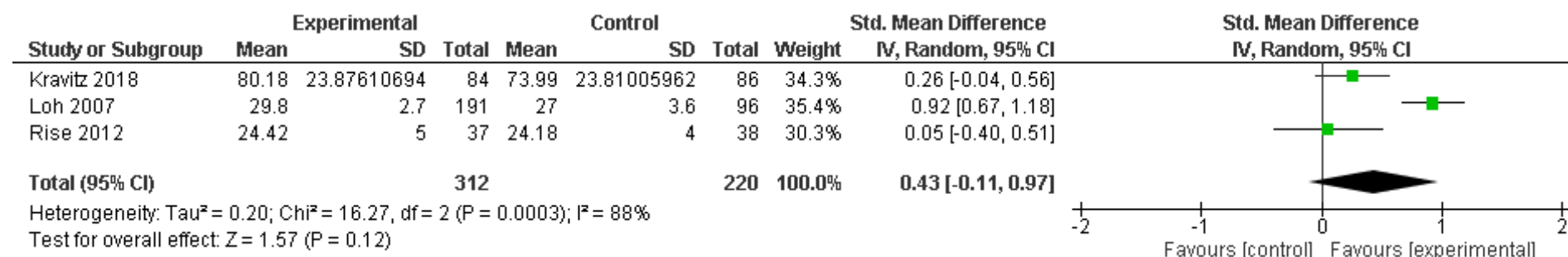
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2 **Figure 22: Knowledge (categorical)**



3

4 **Figure 23: Satisfaction with care**

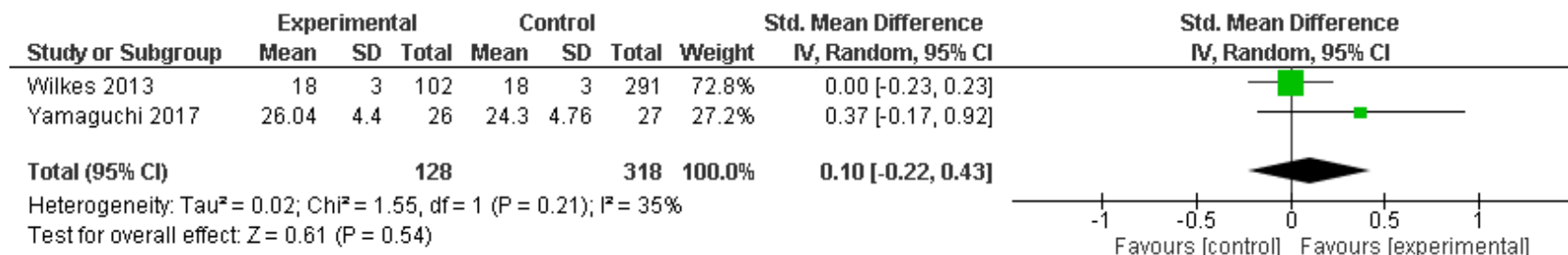


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Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

1

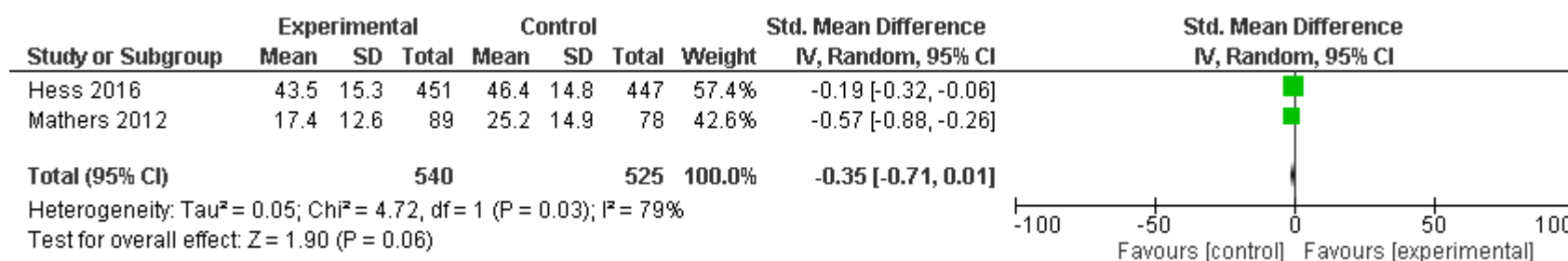
2 **Figure 24: Satisfaction with consultation**



3

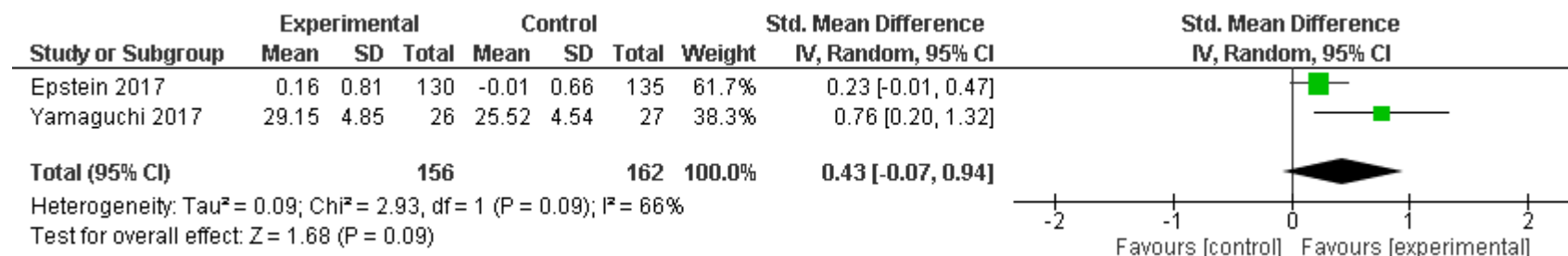
4

5 **Figure 25: Decisional conflict**



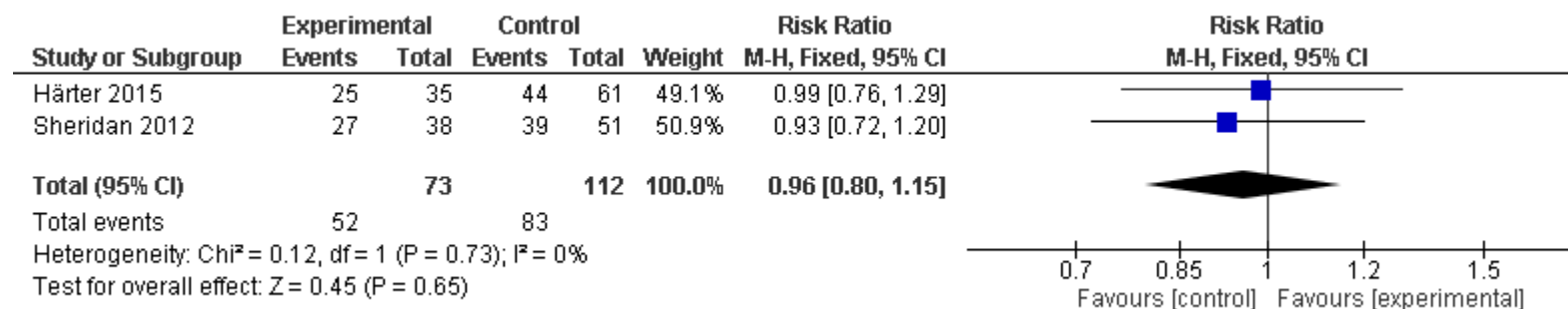
6

1 **Figure 26: patient-physician communication (patient-centred communication)**



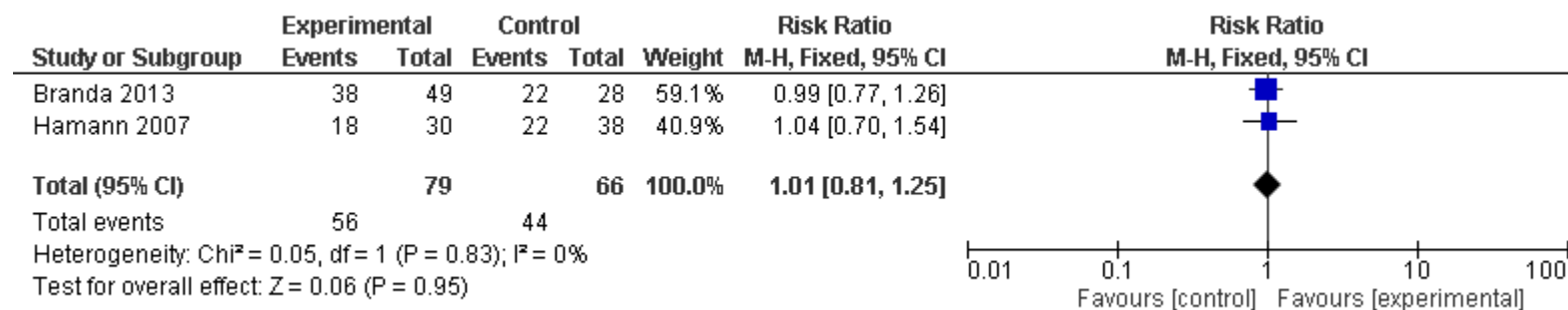
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4 **Figure 27: Match between preferred and actual level of participation in decision making**



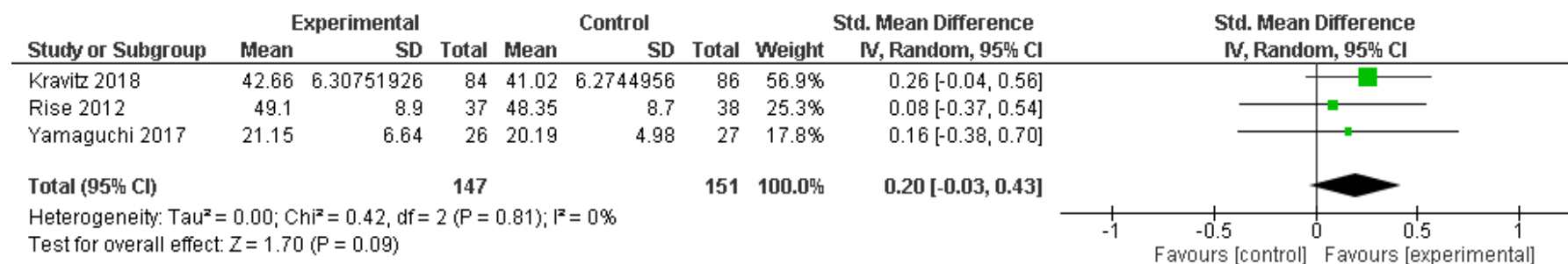
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1 **Figure 28: Adherence (categorical)**



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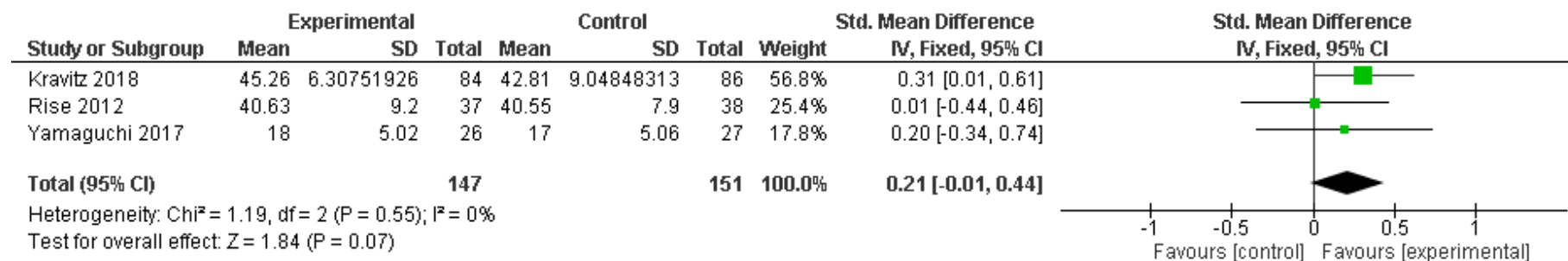
3 **Figure 29: Health related quality of life (Physical)**



4

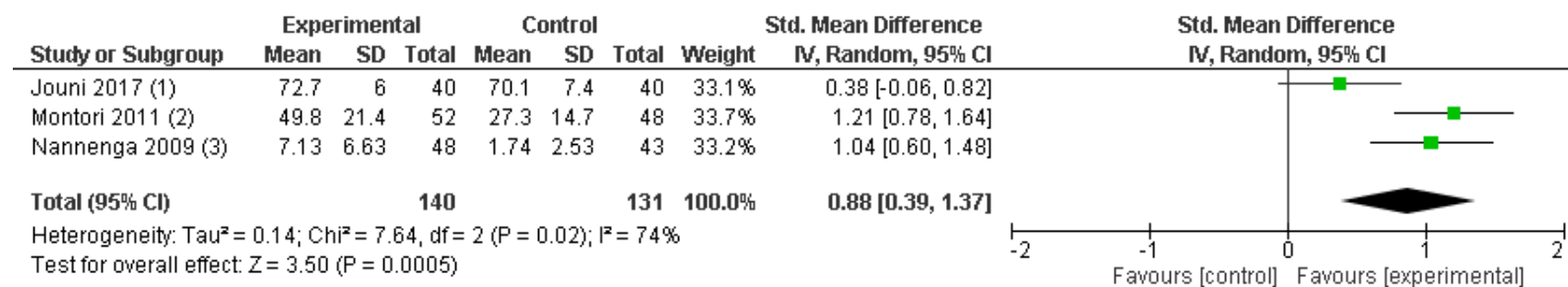
5

1 **Figure 30: Health related quality of life (Mental)**



2
3 **Interventions targeting patients compared to other interventions**

4 **Figure 31: Shared decision making (OBOM, continuous)**

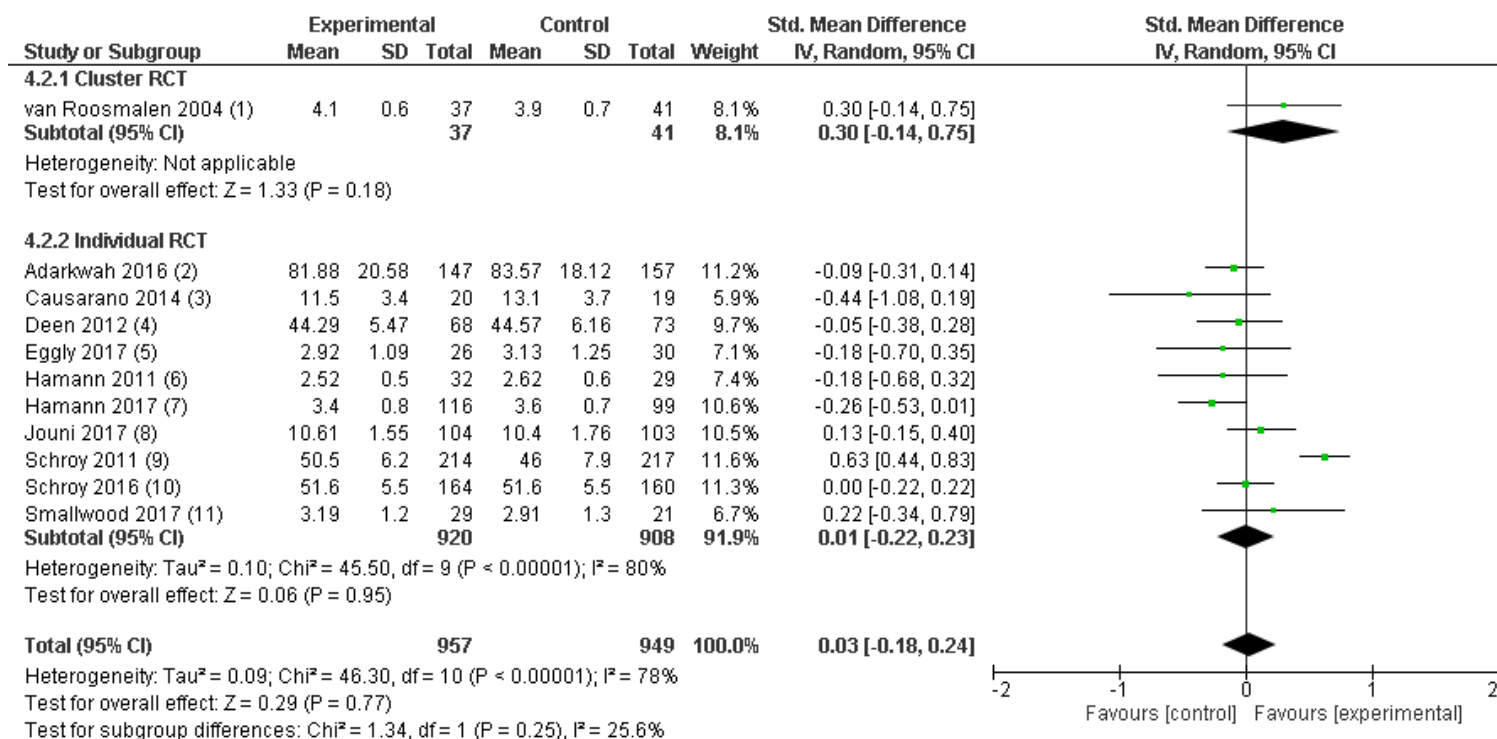


Footnotes

- (1) OPTION5 (/100)
- (2) OPTION
- (3) OPTION

5
6

1 **Figure 32: Shared decision making (PROM, continuous)**



Footnotes

- (1) Perceived participation in decision making
- (2) PEF-FB-9 (SDM-Q-9)
- (3) Decision making subscale (M-PICS)
- (4) Patient activation measure (PAM)
- (5) Patient role in treatment decision
- (6) Who makes important decisions about your medical treatment? (postintervention)
- (7) Who makes important decision about your medical treatment ?
- (8) SDM-Q (0-11)
- (9) Satisfaction with decision making process
- (10) Satisfaction with decision making process (SDMP)
- (11) SDM

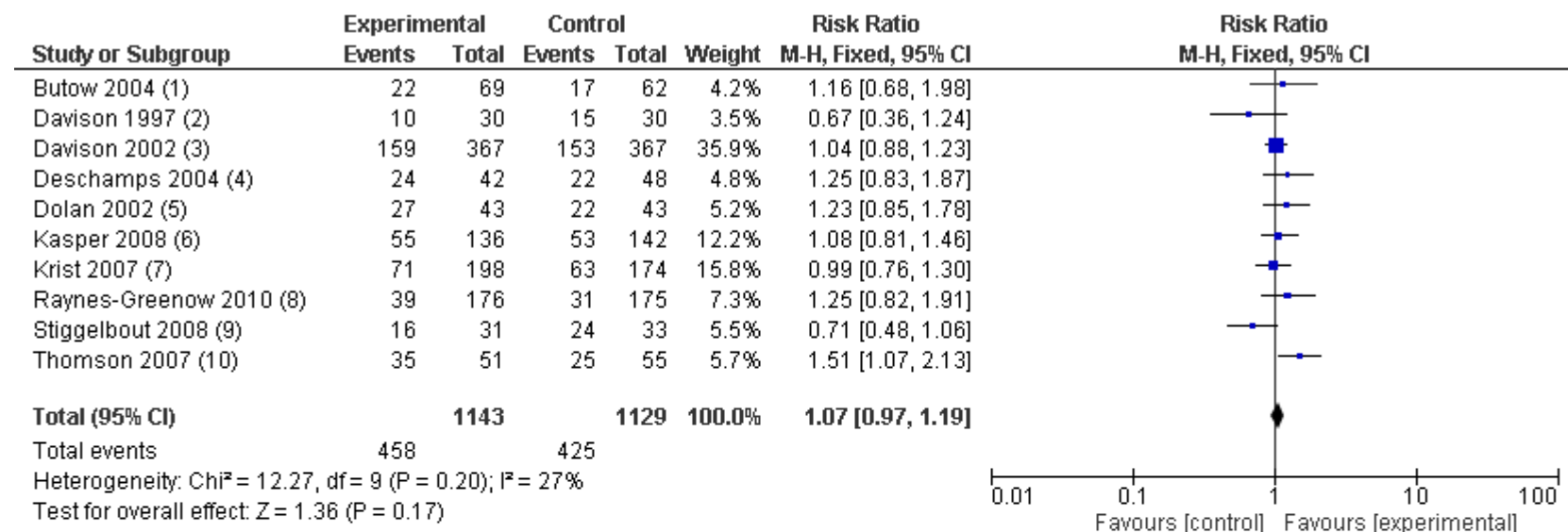
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1 **Figure 33: Shared decision making (PROM, categorical)**

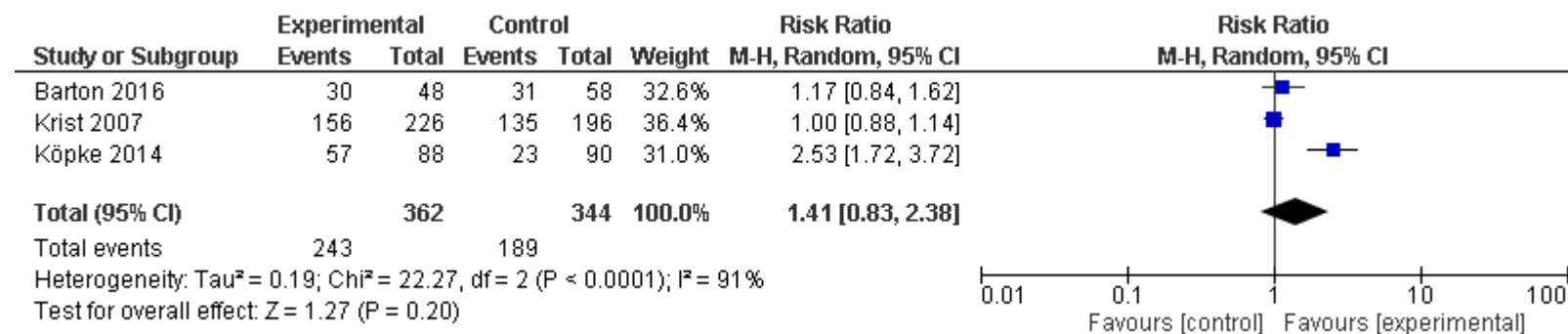


Footnotes

- (1) Modified Control Preference Scale
- (2) Modified Control Preference Scale
- (3) Modified control preference scale
- (4) Modified Control Preference Scale
- (5) Modified Control Preference Scale
- (6) Modified Control Preference Scale
- (7) Modified Control Preference Scale
- (8) Modified Control Preference Scale
- (9) Modified Control Preference Scale
- (10) DM role experiences (patient more important in decision-making)

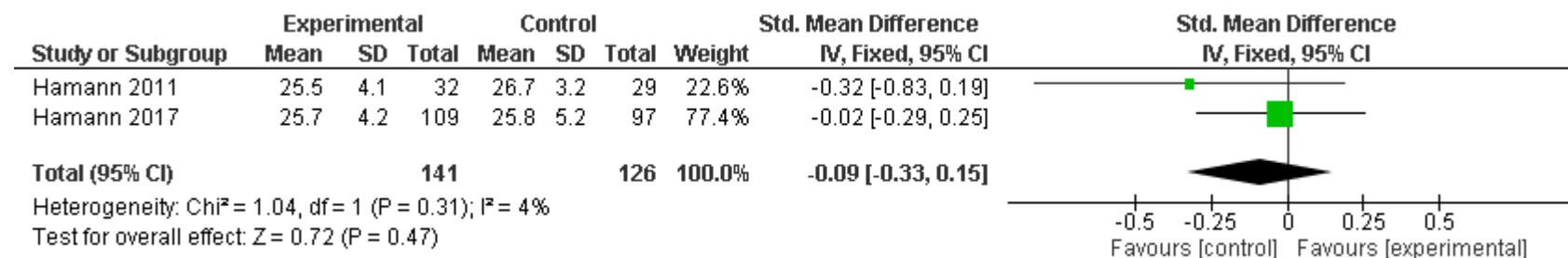
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1 **Figure 34: Knowledge (categorical)**



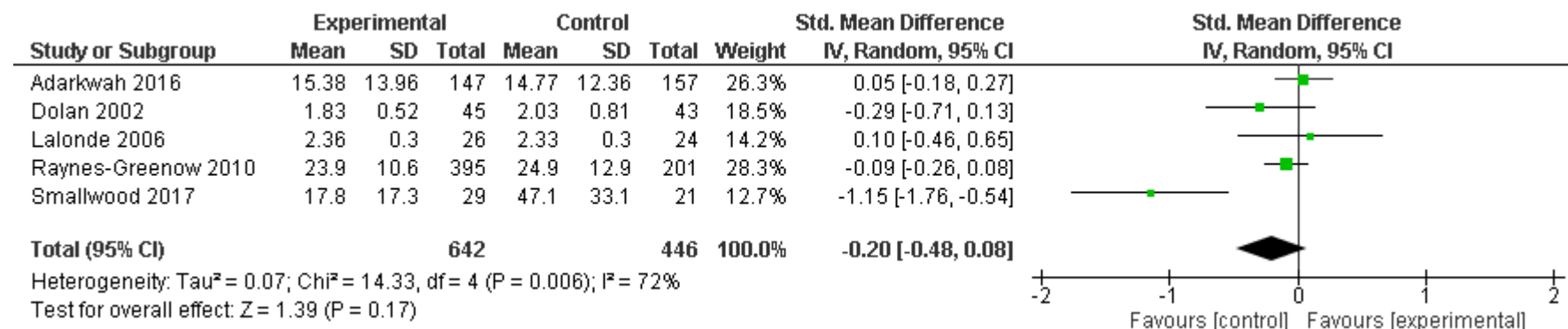
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5 **Figure 35: Satisfaction with treatment**



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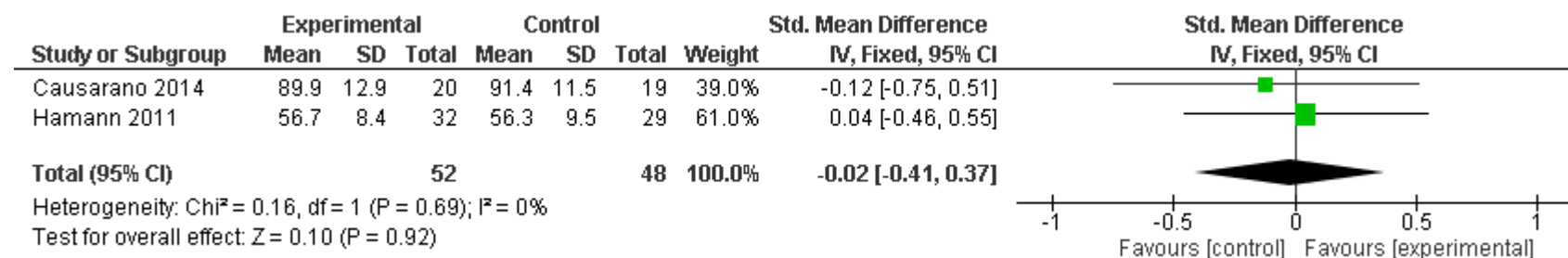
1 **Figure 36: Decisional conflict**



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3

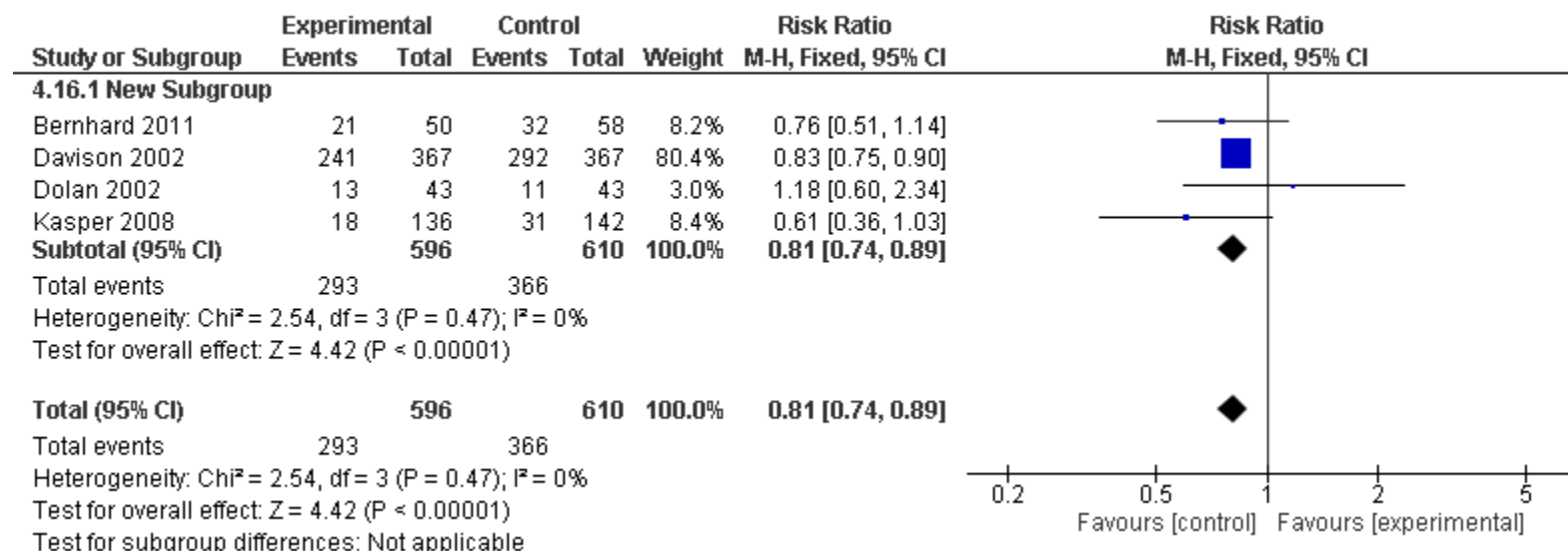
4 **Figure 37: Decision self-efficacy**



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1 **Figure 38: Match between preferred and actual level of participation in decision making**

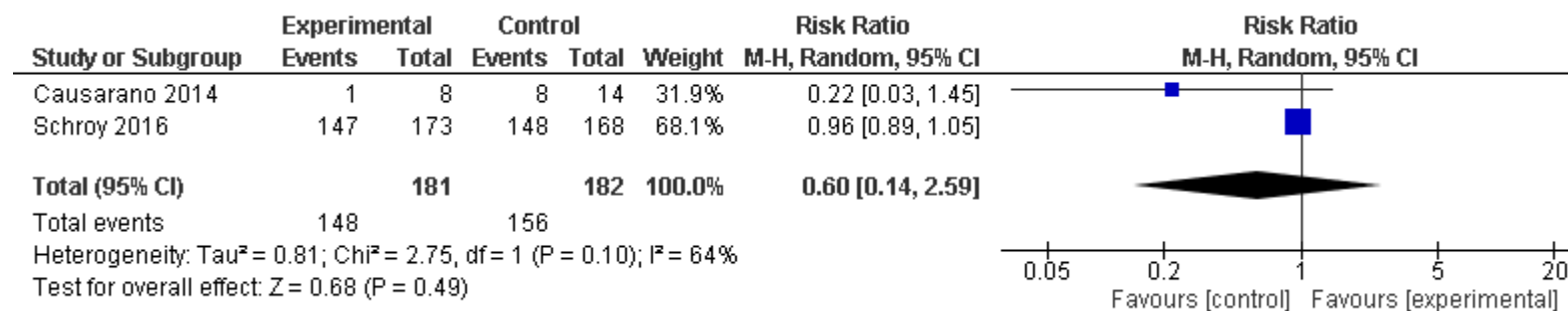


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5 **Figure 39: Match between preferred option and decision made**

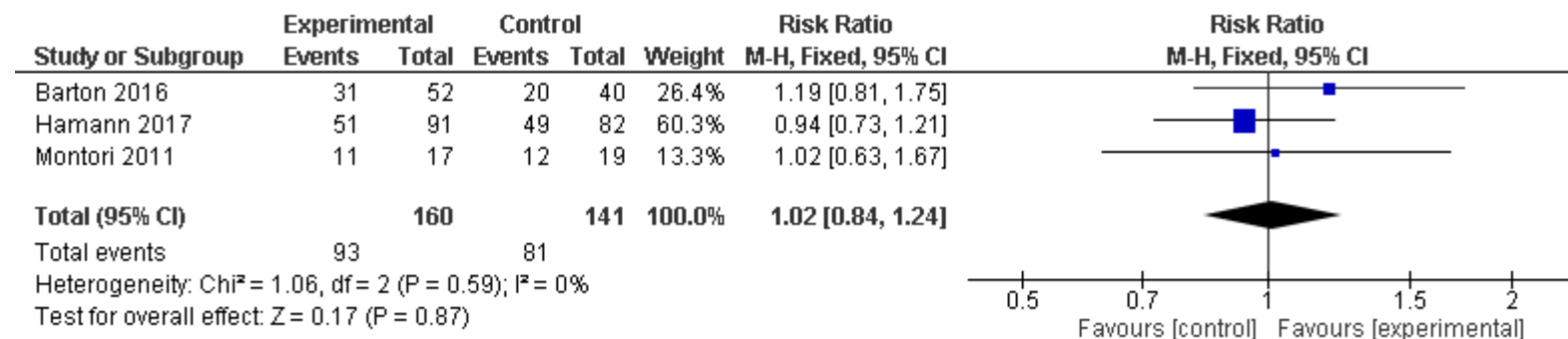


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2 **Figure 40: Adherence (categorical)**

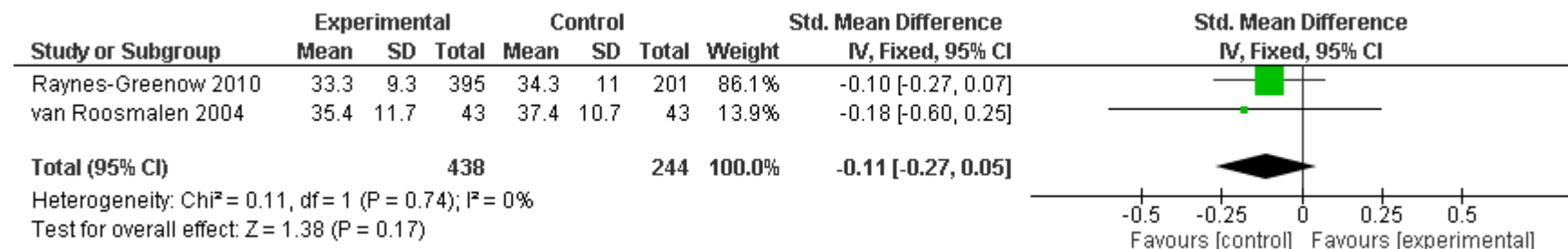


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6 **Figure 41: Anxiety**



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2 Appendix G – Grade tables

3 Table 14: Interventions targeting patients using usual care

| No. of studies | Study design | Sample size | Effect size (95% CI) | Absolute risk: control | Absolute risk: intervention (95% CI) | Risk of bias | Inconsistency | Indirectness | Imprecision | Quality |
|---|---------------------|-------------|-----------------------|------------------------|--------------------------------------|---------------------------|---------------------------|--------------|----------------------|----------|
| Main analysis: Shared decision making (OBOM, continuous) | | | | | | | | | | |
| 9 | RCT and cluster RCT | 1945 | SMD 0.54 (0.26, 0.82) | - | - | Not serious | Very serious ² | Not serious | Serious ⁴ | Very low |
| Subgroup analysis: Shared decision making (OBOM, continuous) – parallel | | | | | | | | | | |
| 6 | RCT | 1765 | SMD 0.32 (0.07, 0.57) | - | - | Not Serious | Very serious ² | Not Serious | Serious ⁴ | Very low |
| Subgroup analysis: Shared decision making (OBOM, continuous) - cluster | | | | | | | | | | |
| 3 | Cluster RCT | 180 | SMD 0.99 (0.43, 1.55) | - | - | Very serious ¹ | Serious ³ | Not Serious | Serious ⁴ | Very low |
| Main analysis: Shared decision making (PROM, continuous) | | | | | | | | | | |
| 12 | RCT and cluster RCT | 2211 | SMD 0.30 (0.17, 0.43) | - | - | Very serious ¹ | Serious ³ | Not Serious | Not Serious | Very low |
| Shared decision making (PROM, continuous) - NRCT | | | | | | | | | | |
| 1 (Almario 2016) | NRCT | 303 | MD 0.30 (-4.05, 4.65) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Shared decision making (PROM, categorical) - Parallel | | | | | | | | | | |
| 9 | RCT | 1911 | RR 0.99 (0.93, 1.06) | 66.1 per 100 | 65.7 per 100 (61.8, 69.8) | Very serious ¹ | Serious ³ | Not Serious | Not Serious | Very low |
| Shared decision making (PROM, categorical) - (Study not included in MA as cluster adjustment not possible) | | | | | | | | | | |
| 1 (Doll 2019) | Cluster RCT | 203 | RR 1.22 (1.07, 1.39) | 74.00 per 100 | 90.28 per 100 (79.18, 102.86) | Very serious ¹ | NA | Not serious | Serious ⁵ | Very low |

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

| | | | | | | | | | | |
|--|---------------------|------|----------------------------|--------------|-------------------------------|---------------------------|----------------------|-------------|----------------------|----------|
| Knowledge | | | | | | | | | | |
| 5 | RCT | 615 | SMD 0.37 (0.21, 0.53) | - | - | Very serious ¹ | Serious ³ | Not Serious | Serious ⁴ | Very low |
| Knowledge - (Study not included in MA as cluster adjustment not possible) | | | | | | | | | | |
| 1 (Doll 2019) | Cluster RCT | 203 | MD 0.50 (0.18, 0.82) | - | - | Very serious ¹ | NA | Not Serious | Serious ⁶ | Very low |
| Knowledge (categorical) | | | | | | | | | | |
| 2 | RCT | 312 | RR 1.33 (1.07, 1.66) | 51.7 per 100 | 68.8 per 100 (55.2, 85.9) | Very serious ¹ | Not Serious | Not Serious | Serious ⁴ | Very low |
| Satisfaction | | | | | | | | | | |
| 2 | RCT | 309 | SMD -0.05 (-0.27, 0.17) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Decisional conflict | | | | | | | | | | |
| 7 | RCT and Cluster RCT | 1403 | SMD -0.16 (-0.35, 0.03) | - | - | Very serious ¹ | Serious ³ | Not serious | Not Serious | Very low |
| Decisional conflict - (Study not included in MA as cluster adjustment not possible) | | | | | | | | | | |
| 1 (Doll 2019) | Cluster RCT | 203 | SMD -0.20 (-0.48, 0.08) | - | - | Very serious ¹ | NA | Not serious | Not serious | Low |
| Decision regret | | | | | | | | | | |
| 1 (van Tol-Geerdink 2016) | RCT | 212 | MD -1.50 (-5.91, 2.91) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Patient-physician communication (number of topics raised by patients) | | | | | | | | | | |
| 1 (Hamann 2014) | RCT | 100 | MD 0.60 (-0.30, 1.50) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁴ | Very low |
| Patient-physician communication (patient raised discussion) | | | | | | | | | | |
| 1 (Sheridan 2014) | RCT | 157 | RR 1.83 (1.29, 2.59) | 34.6 per 100 | 63.3 per 100 (44.7, 89.7) | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Patient-physician communication (patient participation in discussion) | | | | | | | | | | |
| 1 (Sheridan 2014) | RCT | 157 | RR 1.53 (1.20, 1.96) | 51.3 per 100 | 78.5 per 100 (61.4, 100.3) | Very serious ¹ | Not serious | Not Serious | Serious ⁴ | Very low |

| | | | | | | | | | | |
|--|---------------------|-----|---------------------------|--------------|-------------------------------|---------------------------|---------------------------|-------------|---------------------------|----------|
| Decision self-efficacy | | | | | | | | | | |
| 2 | RCT | 274 | SMD 0.16 (-0.08, 0.40) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Empowerment | | | | | | | | | | |
| 1 (Pickett 2012) | RCT | 342 | MD 0.09 (0.02, 0.16) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Empowerment (categorical) | | | | | | | | | | |
| 1 (van Peperstraten 2010) | RCT | 262 | RR 1.25 (1.11, 1.40) | 73.3 per 100 | 91.3 per 100 (81.4, 102.5) | Very serious ¹ | Not serious | Not Serious | Serious ⁴ | Very low |
| Adherence | | | | | | | | | | |
| 2 | RCT and Cluster RCT | 598 | RR 0.97 (0.91, 1.03) | 84.5 per 100 | 81.7 per 100 (76.9, 86.7) | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Health-related quality of life (physical) | | | | | | | | | | |
| 1 (Korteland 2017) | RCT | 116 | MD 0.00 (-3.64, 3.64) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Health-related quality of life (mental) | | | | | | | | | | |
| 1 (Korteland 2017) | RCT | 116 | MD 1.00 (-2.64, 4.64) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Anxiety | | | | | | | | | | |
| 2 | RCT and Cluster RCT | 419 | SMD 0.02 (-0.33, 0.37) | - | - | Very serious ¹ | Very Serious ² | Not Serious | Not Serious | Very low |
| Anxiety (categorical) | | | | | | | | | | |
| 1 (Korteland 2017) | RCT | 127 | RR 1.40 (0.51, 3.80) | 9.2 per 100 | 12.9 per 100 (4.7, 35.1) | Very serious ¹ | Not serious | Not Serious | Very Serious ⁵ | Very low |
| Depression (categorical) | | | | | | | | | | |
| 1 (Korteland 2017) | RCT | 127 | RR 4.54 (1.36, 15.18) | 4.6 per 100 | 21.0 per 100 (6.3, 70.0) | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Consultation length | | | | | | | | | | |

| | | | | | | | | | | |
|--|---------------------|------|----------------------------|---|---|---------------------------|----------------------|-------------|-------------|----------|
| 2 | RCT and Cluster RCT | 1054 | SMD 0.07 (-0.14, 0.28) | - | - | Not serious | Serious ³ | Not Serious | Not serious | Moderate |
| Cost | | | | | | | | | | |
| 1 (Murray 2001) | RCT | 105 | MD 405.30 (227.41, 583.19) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Depression (Continuous) | | | | | | | | | | |
| 1 (Raue 2019) | RCT | 202 | MD 0.90 (0.65, 1.15) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| <ol style="list-style-type: none"> >33.3% of the weight in the meta-analysis came from studies at high risk of bias I² > 66.6% I² > 33.3% 95% confidence interval crosses one end of a defined MID interval (-0.5, 0.5) 95% confidence interval crosses one end of a defined MID interval (0.8, 1.25) 95% confidence interval crosses one end of a defined MID interval (1/2 the median of the sum of the control SD) | | | | | | | | | | |

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2 **Table 15: Interventions targeting healthcare professionals compared with usual care**

| No. of studies | Study design | Sample size | Effect size (95% CI) | Absolute risk: control | Absolute risk: intervention (95% CI) | Risk of bias | Inconsistency | Indirectness | Imprecision | Quality |
|---|---------------------|-------------|-------------------------|------------------------|--------------------------------------|---------------------------|---------------------------|--------------|---------------------------|----------|
| Main analysis: Shared decision making (OBOM, continuous) | | | | | | | | | | |
| 8 | RCT and Cluster RCT | 584 | SMD 0.78 (0.36, 1.21) | - | - | Very serious ¹ | Very serious ³ | Not serious | Serious ⁴ | Very low |
| Shared decision making (OBOM, continuous) - CBAs | | | | | | | | | | |
| 1 | CBA | 21 | MD -1.28 (-11.43, 8.87) | - | - | Very serious ¹ | Not serious | Not Serious | Very Serious ⁵ | Very low |
| Main analysis: Shared decision making (PROM, continuous) | | | | | | | | | | |
| 7 | RCT and Cluster RCT | 6021 | 0.05 (-0.10, 0.20) | - | - | Very serious ¹ | Very serious ³ | Not serious | Not serious | Very low |
| Shared decision making (PROM, categorical) | | | | | | | | | | |
| 2 | Cluster RCT | 6303 | RR 1.05 (0.87, 1.27) | 21.3 per 100 | 22.4 per 100 | Serious ² | Very serious ³ | Not Serious | Serious ⁶ | Very low |

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|--|---------------------|------|------------------------|--------------|---------------------------|---------------------------|-------------|-------------|---------------------------|----------|
| | | | | | | (18.6, 27.0) | | | | |
| Knowledge | | | | | | | | | | |
| 2 | RCT and Cluster RCT | 969 | SMD 0.26 (-0.16, 0.69) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁴ | Very low |
| Knowledge (categorical) | | | | | | | | | | |
| 1 (LeBlanc 2015b) | RCT | 80 | RR 0.69 (0.37, 1.29) | 41.7 per 100 | 28.6 per 100 (15.2, 53.6) | Very serious ¹ | Not Serious | Not Serious | Very Serious ⁷ | Very low |
| Satisfaction with consultation | | | | | | | | | | |
| 1 (Wilkes 2013) | Cluster RCT | 479 | MD 0.00 (-0.45, 0.45) | - | - | Very serious ¹ | NA | Not Serious | Not Serious | Low |
| Satisfaction with information | | | | | | | | | | |
| 1 (O'Cathain 2002) | Cluster RCT | 1492 | RR 1.03 (0.97, 1.10) | 71.9 per 100 | 74.3 per 100 (69.8, 79.1) | Serious ² | NA | Not Serious | Not Serious | Moderate |
| Satisfaction with decision making process | | | | | | | | | | |
| 1 (O'Cathain 2002) | Cluster RCT | 1488 | RR 0.97 (0.92, 1.02) | 79.3 per 100 | 76.7 per 100 (72.7, 81.0) | Serious ² | NA | Not Serious | Not Serious | Moderate |
| Satisfaction with discussion | | | | | | | | | | |
| 1 (O'Cathain 2002) | Cluster RCT | 1483 | RR 0.99 (0.92, 1.07) | 65.1 per 100 | 64.7 per 100 (60.0, 69.8) | Serious ² | NA | Not Serious | Not Serious | Moderate |
| Decision regret | | | | | | | | | | |
| 1 (Legare 2012) | Cluster RCT | 326 | MD 4.80 (1.19, 8.41) | - | - | Serious ² | NA | Not serious | Serious ⁸ | Low |
| Self-efficacy | | | | | | | | | | |
| 1 (Kennedy 2013) | Cluster RCT | 4475 | MD -0.70 (-2.06, 0.66) | - | - | Very serious ¹ | NA | Not Serious | Not Serious | Low |
| Adherence | | | | | | | | | | |

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|--|-------------|------|----------------------------|---------------|---------------|--------------------------------|---------------------------|-------------|----------------------|----------------------|----------|
| 1 (Tinsel 2013) | Cluster RCT | 827 | MD -0.60 (-1.64, 0.44) | - | - | Very serious ¹ | NA | Not Serious | Not Serious | Low | |
| General health | | | | | | | | | | | |
| 1 (Kennedy 2013) | Cluster RCT | 4056 | MD 0.50 (-1.09, 2.09) | - | - | Very serious ¹ | NA | Not Serious | Not Serious | Low | |
| Psychological well-being | | | | | | | | | | | |
| 1 (Kennedy 2013) | Cluster RCT | 4052 | MD 0.00 (-1.39, 1.39) | - | - | Very serious ¹ | NA | Not Serious | Not Serious | Low | |
| Health related quality of life (physical) | | | | | | | | | | | |
| 1 (Legare 2012) | Cluster RCT | 359 | MD 1.20 (-0.38, 2.78) | - | - | Serious ² | NA | Not serious | Not serious | Moderate | |
| Health-related quality of life (mental) | | | | | | | | | | | |
| 1 (Legare 2012) | Cluster RCT | 359 | MD 2.70 (0.71, 4.69) | - | - | Serious ² | NA | Not serious | Not serious | Moderate | |
| Health-related quality of life | | | | | | | | | | | |
| 2 | Cluster RCT | 4635 | SMD -0.00 (-0.06, 0.06) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low | |
| Anxiety | | | | | | | | | | | |
| 1 (O’Cathain 2002) | Cluster RCT | 3003 | RR 1.00 (0.81, 1.22) | 11.15 per 100 | 11.15 per 100 | 11.15 per 100 (9.03, 13.61) | Serious ² | NA | Not Serious | Not Serious | Moderate |
| Consultation length | | | | | | | | | | | |
| 1 (Sanders 2017) | RCT | 175 | MD 2.70 (1.12, 4.28) | - | - | Very serious ¹ | NA | Not Serious | Serious ⁸ | Very low | |
| Consultation length (10-20 min) | | | | | | | | | | | |
| 1 (Wilkes 2013) | Cluster RCT | 479 | RR 0.93 (0.79, 1.09) | 59.1 per 100 | 54.8 per 100 | (46.6, 64.4) | Very serious ¹ | NA | Not Serious | Serious ⁶ | Very low |
| Safety | | | | | | | | | | | |
| 1 (Cox 2017) | Cluster RCT | 154 | MD 0.00 (-0.22, 0.22) | - | - | Serious ² | NA | Not Serious | Not Serious | Moderate | |
| Alliance | | | | | | | | | | | |

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|---|-------------|-----|---------------------------|---|---|---------------------------|-------------|-------------|----------------------|----------|
| 2 | Cluster RCT | 309 | SMD 0.06 (-0.17, 0.28) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Patient - physician communication (doctor responding to emotions) | | | | | | | | | | |
| 1 (Henselmans 2019) | RCT | 31 | MD 0.40 (-0.20, 1.00) | - | - | Not serious | NA | Not Serious | Serious ⁸ | Moderate |
| Patient-physician communication (information provision) | | | | | | | | | | |
| 1 (Henselmans 2019) | RCT | 31 | MD 0.90 (0.44, 1.36) | - | - | Not serious | NA | Not Serious | Not Serious | High |
| Satisfaction (Physician) | | | | | | | | | | |
| 1 (Henselmans 2019) | RCT | 31 | MD -4.00 (-8.78, 0.78) | - | - | Not serious | NA | Not Serious | Serious ⁸ | High |
| Decisional conflict | | | | | | | | | | |
| 1 (Metz 2019) | RCT | 186 | MD -0.15 (-5.31, 5.01) | - | - | Serious ² | NA | Not Serious | Not Serious | Moderate |
| <ol style="list-style-type: none"> 1. >33.3% of the weight in the meta-analysis came from studies at high risk of bias 2. >33.3% of the weight in the meta-analysis came from studies at moderate or high risk of bias 3. I² > 66.6% 4. 95% confidence interval crosses one end of a defined MID interval (-0.5, 0.5) 5. 95% confidence interval crosses both ends of a defined MID interval (1/2 the median of the sum of the control arm SD) 6. 95% confidence interval crosses one end of a defined MID interval (0.8, 1.25) 7. 95% confidence interval crosses both ends of a defined MID interval (0.8, 1.25) 8. 95% confidence interval crosses one end of a defined MID interval (1/2 the median of the sum of the control arm SD) | | | | | | | | | | |

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3 **Table 16: Interventions targeting both patients and healthcare professionals compared to usual care**

| No. of studies | Study design | Sample size | Effect size (95% CI) | Absolute risk: control | Absolute risk: intervention (95% CI) | Risk of bias | Inconsistency | Indirectness | Imprecision | Quality |
|--|---------------------|-------------|--------------------------|------------------------|--------------------------------------|---------------------------|---------------------------|--------------|----------------------|----------|
| Shared decision making (OBOM, continuous) | | | | | | | | | | |
| 9 | RCT and Cluster RCT | 1680 | SMD 1.03 (0.43, 1.63) | - | - | Very serious ¹ | Very Serious ³ | Not Serious | Serious ⁵ | Very low |

| | | | | | | | | | | |
|---|---------------------|------|------------------------|---------------|------------------------------|---------------------------|---------------------------|-------------|---------------------------|----------|
| Shared decision making (PROM, continuous) | | | | | | | | | | |
| 9 | RCT and Cluster RCT | 2059 | SMD 0.15 (0.04, 0.26) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Very low |
| Main analysis: Shared decision making (PROM, categorical) | | | | | | | | | | |
| 2 | RCT and Cluster RCT | 266 | RR 0.97 (0.59, 1.59) | 41.30 per 100 | 40.07 per 100 (24.37, 65.67) | Very serious ¹ | Serious ⁴ | Not serious | Very serious ⁶ | Very low |
| Subgroup analysis: Shared decision making (PROM, categorical) - parallel | | | | | | | | | | |
| 1 (Harter 2015) | RCT | 97 | RR 1.23 (0.84, 1.80) | 47.5 per 100 | 58.3 per 100 (39.8, 85.4) | Very serious ¹ | NA | Not serious | Serious ⁷ | Very low |
| Subgroup analysis: Shared decision making (PROM, categorical) - cluster | | | | | | | | | | |
| 1 (Mathers 2012) | Cluster RCT | 169 | RR 0.75 (0.48, 1.17) | 36.4 per 100 | 27.2 per 100 (17.4, 42.5) | Very serious ¹ | NA | Not Serious | Serious ⁷ | Very low |
| Knowledge | | | | | | | | | | |
| 2 | RCT | 1004 | SMD 0.41 (0.28, 0.53) | - | - | Serious ² | Not Serious | Not Serious | Serious ⁵ | Low |
| Knowledge (categorical) | | | | | | | | | | |
| 4 | RCT and Cluster RCT | 1260 | RR 2.24 (1.18, 4.26) | 19.7 per 100 | 44.3 per 100 (23.3, 84.2) | Very serious ¹ | Very Serious ³ | Not Serious | Not Serious | Very low |
| Satisfaction with care | | | | | | | | | | |
| 3 | RCT and Cluster RCT | 532 | SMD 0.43 (-0.11, 0.97) | - | - | Very serious ¹ | Very Serious ³ | Not Serious | Serious ⁵ | Very low |
| Satisfaction with decision | | | | | | | | | | |
| 1 (Harter 2015) | RCT | 424 | MD 3.60 (0.76, 6.44) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Satisfaction with consultation | | | | | | | | | | |
| 2 | RCT and Cluster RCT | 446 | SMD 0.05 (-0.15, 0.26) | - | - | Very serious ¹ | Serious ⁴ | Not Serious | Not Serious | Very low |
| Decisional conflict | | | | | | | | | | |

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|---|---------------------|------|-------------------------|--------------|---------------------------|---------------------------|---------------------------|-------------|----------------------|----------|
| 2 | RCT and Cluster RCT | 1065 | SMD -0.35 (-0.71, 0.01) | - | - | Very serious ¹ | Very Serious ³ | Not Serious | Serious ⁵ | Very low |
| Confidence in decision | | | | | | | | | | |
| 1 (Harter 2015) | RCT | 414 | MD 0.50 (-2.95, 3.95) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Decision regret | | | | | | | | | | |
| 1 (Harter 2015) | RCT | 369 | MD 2.00 (-1.18, 5.18) | - | - | Very serious ¹ | Not Serious | Not serious | Not Serious | Low |
| Patient-physician communication (patient-centered communication) | | | | | | | | | | |
| 2 | RCT and Cluster RCT | 318 | SMD 0.43 (-0.07, 0.94) | - | - | Very serious ¹ | Serious ⁴ | Not Serious | Serious ⁵ | Very low |
| Match between preferred and actual level of participation in decision making | | | | | | | | | | |
| 2 | RCT and Cluster RCT | 185 | RR 0.96 (0.80, 1.15) | 74.1 per 100 | 71.1 per 100 (59.2, 85.3) | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Adherence | | | | | | | | | | |
| 1 (Loh 2007) | Cluster RCT | 489 | SMD 0.60 (0.36, 0.83) | - | - | Very serious ¹ | Not Serious | Not Serious | Serious ⁵ | Very low |
| Adherence (categorical) | | | | | | | | | | |
| 2 | Cluster RCT | 145 | RR 1.01 (0.81, 1.25) | 66.7 per 100 | 67.1 per 100 (53.9, 83.6) | Very serious ¹ | Not Serious | Not Serious | Serious ⁷ | Very low |
| Health-related quality of life | | | | | | | | | | |
| 1 (Epstein 2017) | Cluster RCT | 265 | MD 0.07 (-0.12, 0.25) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Health-related quality of life (physical) | | | | | | | | | | |
| 3 | RCT | 298 | SMD 0.20 (-0.03, 0.43) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Health-related quality of life (mental) | | | | | | | | | | |
| 3 | RCT | 298 | SMD 0.21 (-0.01, 0.44) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Anxiety | | | | | | | | | | |
| 1 (Harter 2015) | RCT | 419 | MD -0.50 (-1.32, 0.32) | - | - | Very serious ¹ | NA | Not serious | Not Serious | Low |

| Depression | | | | | | | | | | |
|--|-----|-----|---------------------------|-------------|----------------------------|---------------------------|----|-------------|---------------------------|----------|
| 1 (Harter 2015) | RCT | 418 | MD -0.60 (-1.42, 0.22) | - | - | Very serious ¹ | NA | Not serious | Very Serious ⁸ | Very low |
| Consultation length | | | | | | | | | | |
| 1 (Hess 2016) | RCT | 536 | MD 1.30 (1.24, 1.36) | - | - | Serious ² | NA | Not Serious | Not Serious | Moderate |
| Safety | | | | | | | | | | |
| 1 (Hess 2016) | RCT | 898 | RR 0.00 (-0.00, 0.00) | 0.0 per 100 | 0.0 per 100 (-0.0, 0.0) | Serious ² | NA | Not Serious | Not Serious | Moderate |
| <ol style="list-style-type: none"> 1. >33.3% of the weight in the meta-analysis came from studies at high risk of bias 2. >33.3% of the weight in the meta-analysis came from studies at moderate or high risk of bias 3. I² > 66.6% 4. I² > 33.3% 5. 95% confidence interval crosses one end of a defined MID interval (-0.5, 0.5) 6. 95% confidence interval crosses both ends of a defined MID interval (0.8, 1.25) 7. 95% confidence interval crosses one end of a defined MID interval (0.8, 1.25) 8. 95% confidence interval crosses both ends of a defined MID interval (1/2 the median of the sum of the control arm SD) | | | | | | | | | | |

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3 **Table 8: Interventions targeting patients compared to other interventions.**

| No. of studies | Study design | Sample size | Effect size (95% CI) | Absolute risk: control | Absolute risk: intervention (95% CI) | Risk of bias | Inconsistency | Indirectness | Imprecision | Quality |
|--|---------------------|-------------|---------------------------|------------------------|--------------------------------------|---------------------------|---------------------------|--------------|----------------------|----------|
| Shared decision making (OBOM, continuous) | | | | | | | | | | |
| 3 | RCT | 271 | SMD 0.88 (0.39, 1.37) | - | - | Very serious ¹ | Very Serious ² | Not Serious | Serious ⁴ | Very low |
| Shared decision making (PROM, continuous) | | | | | | | | | | |
| 11 | RCT and Cluster RCT | 1906 | SMD 0.03 (-0.18, 0.24) | - | - | Very serious ¹ | Very Serious ² | Not Serious | Not Serious | Very low |
| Shared decision making (PROM, continuous) comp1 - NRCT | | | | | | | | | | |

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|---|------|------|-------------------------------|-----------------|-------------------------------------|------------------------------|------------------------------|----------------|----------------------|-------------|
| 1 (Barton 2016) | NRCT | 97 | MD -8.00 (-22.87, 6.87) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁵ | Very low |
| Shared decision making (PROM, continuous) comp2 - NRCT | | | | | | | | | | |
| 1 (Barton 2016) | NRCT | 110 | MD -7.00 (-20.90, 6.90) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁵ | Very low |
| Shared decision making (PROM, continuous) comp3 - NRCT | | | | | | | | | | |
| 1 (Barton 2016) | NRCT | 99 | MD 1.00 (-12.12, 14.12) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Shared decision making (PROM, categorical) | | | | | | | | | | |
| 10 | RCT | 2272 | RR 1.07 (0.97, 1.19) | 37.6 per 100 | 40.4 per 100 (36.5, 44.7) | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Knowledge | | | | | | | | | | |
| 1 (Raynes-Greenow 2010) | RCT | 596 | MD 8.60 (3.82, 13.38) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Knowledge (categorical) | | | | | | | | | | |
| 3 | RCT | 706 | RR 1.41 (0.83, 2.38) | 54.9 per 100 | 77.2 per 100 (45.6, 130.7) | Very serious ¹ | Very Serious ² | Not Serious | Serious ⁶ | Very low |
| Satisfaction with decision | | | | | | | | | | |
| 1 (Raynes-Greenow 2010) | RCT | 596 | MD 0.80 (-1.11, 2.71) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Satisfaction with treatment | | | | | | | | | | |
| 2 | RCT | 267 | SMD -0.09 (-0.33, 0.15) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Satisfaction with consultation | | | | | | | | | | |
| 1 (Jouni 2017) | RCT | 207 | MD -0.02 (-0.06, 0.02) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁵ | Very low |
| Satisfaction with information provided | | | | | | | | | | |

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|---|-------------|------|----------------------------|--------------|-------------------------------|---------------------------|---------------------------|-------------|---------------------------|----------|
| 1 (Causarano 2014) | RCT | 39 | MD 1.50 (-7.22, 10.22) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁵ | Very low |
| Decisional conflict | | | | | | | | | | |
| 5 | RCT | 1088 | SMD -0.20 (-0.48, 0.08) | - | - | Very serious ¹ | Very Serious ² | Not Serious | Not Serious | Very low |
| Decision uncertainty | | | | | | | | | | |
| 1 (van Roosmalen 2004) | RCT | 80 | MD -0.20 (-0.62, 0.22) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁵ | Very low |
| Decision self-efficacy | | | | | | | | | | |
| 2 | RCT | 100 | SMD -0.02 (-0.41, 0.37) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Match between preferred and actual level of participation in decision making | | | | | | | | | | |
| 4 | RCT | 1206 | RR 0.81 (0.74, 0.89) | 60.0 per 100 | 48.8 per 100 (44.5, 53.5) | Very serious ¹ | Not Serious | Not Serious | Serious ⁵ | Very low |
| Match between preferred option and decision made | | | | | | | | | | |
| 2 | RCT | 363 | RR 0.60 (0.14, 2.59) | 85.7 per 100 | 51.5 per 100 (12.0, 221.9) | Very serious ¹ | Serious ³ | Not Serious | Very Serious ⁷ | Very low |
| Adherence | | | | | | | | | | |
| 1 (Haaman 2017) | RCT | 100 | MD 0.10 (-0.75, 0.95) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Adherence (categorical) | | | | | | | | | | |
| 3 | RCT | 301 | RR 1.02 (0.84, 1.24) | 57.4 per 100 | 58.4 per 100 (48.1, 71.0) | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| General health | | | | | | | | | | |
| 1 (van Roosmalen) | Cluster RCT | 88 | MD -0.30 (-0.99, 0.39) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁵ | Very low |
| Anxiety | | | | | | | | | | |

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|--|---------------------|-----|--------------------------|---|---|---------------------------|-------------|-------------|----------------------|----------|
| 2 | RCT and Cluster RCT | 682 | SMD -0.11 (-0.27, 0.05) | - | - | Very serious ¹ | Not Serious | Not Serious | Not Serious | Low |
| Depression | | | | | | | | | | |
| 1 (van Roosmalen) | Cluster RCT | 86 | MD -2.00 (-5.13, 1.13) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁵ | Very low |
| Consultation length | | | | | | | | | | |
| 1 (Causarano 2014) | RCT | 39 | MD -7.00 (-13.68, -0.32) | - | - | Very serious ¹ | Not serious | Not Serious | Serious ⁵ | Very low |
| <ol style="list-style-type: none"> 1. >33.3% of the weight in the meta-analysis came from studies at high risk of bias 2. I² > 66.6% 3. I² > 66.6% 4. 95% confidence interval crosses one end of a defined MID interval (-0.5, 0.5) 5. 95% confidence interval crosses one end of a defined MID interval (1/2 the median of the sum of the control arm SD) 6. 95% confidence interval crosses one end of a defined MID interval (0.8, 1.25) 7. 95% confidence interval crosses both ends of a defined MID interval (0.8, 1.25) | | | | | | | | | | |

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2 **Table 9: Interventions targeting practitioners compared to other interventions**

| No. of studies | Study design | Sample size | Effect size (95% CI) | Absolute risk: control | Absolute risk: intervention (95% CI) | Risk of bias | Inconsistency | Indirectness | Imprecision | Quality |
|--|---------------------|-------------|-------------------------|------------------------|--------------------------------------|---------------------------|---------------------------|--------------|---------------------------|----------|
| Shared decision making (OBOM, continuous) | | | | | | | | | | |
| 1 (Elwyn 2004) | Cluster RCT | 20 | MD -4.00 (-15.14, 7.14) | - | - | Serious ¹ | Not serious | Not Serious | Very Serious ⁴ | Very low |
| Main analysis: Shared decision making (PROM, continuous) | | | | | | | | | | |
| 2 | RCT and Cluster RCT | 1459 | MD 0.24 (-0.10, 0.58) | - | - | Very serious ² | Very serious ³ | Not serious | Serious ⁵ | Very low |
| Subgroup analysis: Shared decision making (PROM, continuous) - parallel | | | | | | | | | | |
| 1 (Krones 2008 (ARRIBA-Hertz)) | RCT | 1132 | MD 1.72 (1.22, 2.22) | - | - | Very serious ² | Not serious | Not Serious | Not Serious | Low |
| Subgroup analysis: Shared decision making (PROM, continuous) - cluster | | | | | | | | | | |

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|--|-------------|-----|---------------------------|---|---|----------------------|-------------|-------------|-------------|----------|
| 1 (Elwyn 2004) | Cluster RCT | 327 | SMD 0.05 (-0.17, 0.27) | - | - | Serious ¹ | Not serious | Not Serious | Not Serious | Moderate |
| Health status (mental) | | | | | | | | | | |
| 1 (Elwyn 2004) | Cluster RCT | 295 | MD 2.64 (0.08, 5.20) | - | - | Serious ¹ | Not serious | Not Serious | Not Serious | Moderate |
| Health status (physical) | | | | | | | | | | |
| 1 (Elwyn 2004) | Cluster RCT | 295 | MD 0.57 (-2.33, 3.47) | - | - | Serious ¹ | Not serious | Not Serious | Not Serious | Moderate |
| Anxiety | | | | | | | | | | |
| 1 (Elwyn 2004) | Cluster RCT | 843 | SMD 0.14 (0.00, 0.28) | - | - | Serious ¹ | Not Serious | Not Serious | Not Serious | Moderate |
| <ol style="list-style-type: none"> >33.3% of the weight in the meta-analysis came from studies at moderate or high risk of bias >33.3% of the weight in the meta-analysis came from studies at high risk of bias I² > 66.6% 95% confidence interval crosses both ends of a defined MID interval (1/2 the median of the sum of the control arm SD 95% confidence interval crosses one end of a defined MID interval (1/2 the median of the sum of the control arm SD | | | | | | | | | | |

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Table 10: Intervention targeting both patients and practitioners compared to other interventions

| No. of studies | Study design | Sample size | Effect size (95% CI) | Absolute risk: control | Absolute risk: intervention (95% CI) | Risk of bias | Inconsistency | Indirectness | Imprecision | Quality |
|---|--------------|-------------|----------------------------|------------------------|--------------------------------------|---------------------------|---------------|--------------|---------------------------|----------|
| Shared decision making (OBOM; continuous) | | | | | | | | | | |
| 1 (Tai-Seale 2016) | Cluster RCT | 20 | MD -4.70 (-18.47, 9.07) | - | - | Very serious ¹ | Not serious | Not Serious | Very Serious ² | Very low |
| Shared decision making (OBOM; categorical) | | | | | | | | | | |
| 1 (Myers 2011) | RCT | 134 | RR 0.49 (0.12, 1.95) | 8.3 per 100 | 4.1 per 100 (1.0, 16.3) | Very serious ¹ | Not serious | Not Serious | Very Serious ³ | Very low |
| Shared decision making (PROM; continuous) | | | | | | | | | | |

Share decision making evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement DRAFT (Dec 2020)

| | | | | | | | | | | |
|---|-------------|-----|---------------------------|---|---|---------------------------|-------------|-------------|-------------|-----|
| 1 (Tai-Seale 2016) | Cluster RCT | 150 | MD 0.00 (-4.25, 4.25) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| Decisional conflict | | | | | | | | | | |
| 1 (Myers 2011) | RCT | 286 | MD -0.03 (-0.13, 0.07) | - | - | Very serious ¹ | Not serious | Not Serious | Not Serious | Low |
| <ol style="list-style-type: none"> 1. >33.3% of the weight in the meta-analysis came from studies at high risk of bias 2. 95% confidence interval crosses both ends of a defined MID interval (1/2 the median of the sum of the control arm SD 3. 95% confidence interval crosses both ends of a defined MID interval (0.8, 1.25) | | | | | | | | | | |

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2 Appendix H – CERQual tables

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|---|---------|--|--|-------------|-------------|------------|
| <p>Patient empowerment</p> <p>Low health literacy and lack of knowledge around uncertainty in medicine and medical history can make SDM difficult.</p> <p>Overcoming this information asymmetry through self-driven or administered education and behaviour including list-making and understanding personal health preferences.</p> | 41 | <p>Minor concerns</p> <p>Four studies with high methodological concerns: 3 with limited information on participant recruitment/ recruitment strategy not appropriate, 1 with no clear aim or information on how focus groups were conducted</p> | <p>Minor concerns</p> <p>(Many sub-themes under one banner – may be difficult to make a single recommendation. A lot of different facets to patient knowledge.)</p> | No concerns | No concerns | Moderate |
| <p>Patient’s capability to participate</p> <p>Some service users experience anxiety, a lack of confidence in expressing own preferences and preconceived notions about how practice should occur, leading to reduced motivation to participate in SDM.</p> <p>Patient willingness to participate in SDM beyond just “being friendly” was said to facilitate a more open discussion and a healthcare. This includes expressing treatment preferences, suggesting treatment options, taking the time necessary to deliberate about treatment decisions, and asking for</p> | 38 | <p>Minor concerns</p> <p>Five studies with methodological concerns: 3 with limited information on participant recruitment/ recruitment strategy not appropriate, 1 with no clear aim or information on how focus groups were conducted, 1 with inappropriate explanation of adaptation of questionnaire tool.</p> | <p>Minor concerns</p> <p>(Many sub-themes under one banner – may be difficult to make a single recommendation.)</p> | No concerns | No concerns | Moderate |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|---|---------|---|---|-------------|-------------|------------|
| explanations required to make informed decisions. | | | | | | |
| <p>Paternalistic practice versus shared practice</p> <p>Practitioners felt that some patients did not have enough information to participate in the decision, and giving them too much information overwhelming, resulting in a more 'traditional' paternalistic style of care, where patients may feel coerced towards certain treatments.</p> <p>Showing a genuine interest in consumer perspectives can facilitate SDM and practitioners can feel more protected from negative outcomes. Patients see practitioners as a guide to the SDM process, with the patient stepping in to stand up for themselves.</p> | 39 | <p>Minor concerns Three studies with methodological limitations: 2 with limited information on recruitment/ recruitment strategy not appropriate, 1 with inappropriate explanation of adaptation of questionnaire tool.</p> | <p>Minor concerns Many sub-themes under one banner – may be difficult to make a single recommendation.)</p> | No concerns | No concerns | Moderate |
| <p>Time</p> <p>Pressure to finish consultations quickly can prevent SDM and reduce time available for patients and practitioners to come to a joint decision.</p> <p>Allowing more time for consultations can lead to better two-way communication and lead to more SDM.</p> | 32 | <p>Minor concerns Two studies with methodological concerns: 1 with inappropriate explanation of adaptation of questionnaire tool, 1 with limited information on participant recruitment.</p> | No concerns | No concerns | No concerns | High |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|---|---------|---|---|-------------|-------------|------------|
| <p>Clinician attitudes and skills Good communication and interpersonal skills are seen as vital for patient engagement. These allow practitioners to elicit patient preferences by exploring their thoughts, feelings and fears around care.</p> <p>Poor physician communication style can include providing sparse or incomplete information, a lack of explanation about care trajectory. Not effectively eliciting input from the patient, rushed discussion, brief rushed discussion and using language that is too technical for the patient.</p> | 31 | <p>Minor concerns One study with methodological concerns: limited information on participant recruitment</p> | No concerns | No concerns | No concerns | High |
| <p>Trust Trust makes patients feel more comfortable in engaging in SDM. This trust goes beyond primary practitioner to include all members of the MDT healthcare team, it helps the patient feel like they are being listened to and allows them to speak more openly will give practitioners better idea of their true concerns and preferences.</p> <p>If there is a low level of trust patient participation is reduced. Low level of trust also results in poor communication between patient and</p> | 22 | <p>Minor concerns Two studies with methodological concerns: 1 with self-selected participants and 1 with limited information on participant recruitment.</p> | <p>Minor concerns Difficult to quantify specific aspects of this relationship leading to broad theme</p> | No concerns | No concerns | Moderate |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|---|---------|--|---|-------------|-------------|------------|
| practitioner and can lead to misunderstandings. | | | | | | |
| <p>Applying SDM where there is a high risk of harm.</p> <p>Both patients and practitioners showed an apprehension to engaging in SDM practices when the results of an incorrect decision were seen to be severe, or where a decision must be made quickly to avoid severe health consequences.</p> <p>Facilitators for overcoming this barrier included patient/practitioner experience and a high level of trust between patients and practitioners.</p> | 18 | <p>Moderate concerns Four studies with methodological concerns: 3 with limited information on participant recruitment/ recruitment strategy not appropriate, 1 with no clear aim or information on how focus groups were conducted.</p> | No concerns | No concerns | No concerns | Moderate |
| <p>Continuity of, and access to, care As a patient accesses many different practitioners across a multi-disciplinary team, they can encounter contradicting recommendations which may impede the SDM process due to different teams operating in 'silos', using different models that prevent convergence.</p> <p>It is important to have the whole multidisciplinary team involved in the SDM process and aligned on their messaging to the patient, possibly through team meetings and sharing medical data.</p> | 18 | <p>Minor concerns 1 study with methodological concerns: No aim or description of how focus groups were conducted.</p> | <p>Minor concerns Many different subjects surrounding multidisciplinary teams under one theme.</p> | No concerns | No concerns | Moderate |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|---|---------|---|---|-------------|-------------|------------|
| <p>Disadvantaged/Marginalised groups The wider social and cultural environment around patients was thought to have a large and varied effect on the practice of SDM.</p> <p>Ethnicity, gender, sexuality and socioeconomic factors are commonly cited barriers to shared decision making, and consideration must be given to how these characteristics could shape an individual person's experience of SDM.</p> | 17 | <p>Minor concerns 2 studies with methodological concerns: 1 with inappropriate explanation of adaptation of questionnaire tool, 1 with limited information on participant recruitment.</p> | <p>Minor concerns Many different cultural factors under one theme – may be difficult to make a single recommendation</p> | No concerns | No concerns | Moderate |
| <p>Family, carer & other health advocate engagement People who accompany healthcare users in the healthcare setting can feel excluded from the SDM process, and their inclusion creates a three-way conversation.</p> <p>Including accompanying individuals can be a key facilitator to SDM, helping to elicit healthcare user preferences and opinions on care, and retain information from appointments.</p> | 15 | <p>Minor concerns 1 study with methodological concerns: missing information on data collection</p> | No concerns | No concerns | No concerns | High |
| <p>Practitioner development Continued practitioner development is an important facilitator to SDM,</p> | 15 | <p>Minor concerns Two studies with methodological concerns: 1 with limited information on</p> | No concerns | No concerns | No concerns | High |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|---|---------|---|-------------|-------------|--|------------|
| <p>particularly practitioners becoming more adept at patient engagement.</p> <p>Specific training involves both communication skills and increasing experience with practicing SDM.</p> | | <p>patient recruitment and 1 with no aim or description of how focus groups were conducted.</p> | | | | |
| <p>Patient capacity Issues regarding cognitive capacity, whether ongoing or temporary can be a barrier as cognitive problems can affect insight and communication and thus made it difficult to operate in an SDM space</p> <p>People should not be disregarded as being able to participate in SDM just because of a mental health condition, ability to engage varied.</p> | 11 | <p>Minor concerns Two studies with methodological concerns: 1 with limited information on patient recruitment and 1 with no aim or description of how focus groups were conducted.</p> | No concerns | No concerns | <p>Moderate concerns patients who lack mental capacity to make decisions are excluded from our review, but reduced mental capacity as a barrier still retains some relevance in more minor cases.</p> | Moderate |
| <p>Ongoing SDM</p> <p>SDM is not a one-off activity, but an ongoing process that should start as early as possible. A decision may take several appointments, and that decision could change over time.</p> <p>This can be an issue if follow-up on a healthcare service users' decision is not appropriately planned for, or if</p> | 12 | <p>Minor concerns 1 study with methodological limitations: limited information on patient recruitment</p> | No concerns | No concerns | No concerns | High |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|---|---------|--|--|-------------|---|------------|
| previous decision states are lost due to a change in healthcare provider. | | | | | | |
| <p>SDM tools</p> <p>Certain tools can facilitate SDM, such as care plans, patient decision aids and other forms of patient information.</p> <p>Access to computer based information was cited as a facilitator, including online resources for patients outside of the healthcare setting, and access to computerised medical records and decision aids for practitioners.</p> | 12 | <p>Minor concerns</p> <p>Two studies with methodological limitations: limited information on patient recruitment</p> | No concerns | No concerns | <p>Moderate concerns</p> <p>only one UK study (Upton 2011). Provision of SDM tools can also vary depending on country study is conducted in.</p> | Moderate |
| <p>Healthcare system resource limits</p> <p>Larger patient numbers, longer waiting lists and larger staff workloads mean people must be moved through healthcare settings quickly. SDM is rarely the quickest and easiest way to do this, and therefore in these high-pressure scenarios SDM may not be performed.</p> <p>High staff turnover, high staff stress and fatigue, and less time for staff communication, mean communication between professionals will occur less.</p> | 10 | <p>Minor concerns</p> <p>1 study with methodological limitations: inappropriate explanation of adaptation of questionnaire tool</p> | <p>Minor concerns</p> <p>Many different types of resource limits under one theme.</p> | No concerns | <p>Minor concerns:</p> <p>two UK studies quite small (Shepherd, Stevenson)</p> | Moderate |
| Space for SDM | 8 | No concerns | No concerns | No concerns | No concerns | High |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|---|---------|----------------------------|-------------|-------------|---|------------|
| <p>Lack of a designated space within which to practice SDM was a barrier identified particularly in hospital settings, where conversations take place with patients in hallways and wards with a lack of privacy, interruptions, and lots of background noise, which led to stress and an unwillingness to talk candidly.</p> <p>A good place for practicing SDM was thought to be in a private, quiet space, where the patient is comfortable and able to sit.</p> | | | | | | |
| <p>Patients being informed that choice is available</p> <p>Some healthcare events can lead a service user feeling they are in a situation where there is not a decision to be made.</p> <p>This included life threatening cancer diagnosis requiring surgery and dialysis, where the severity of the condition affected the patients perceived lack of choice. Presenting the patient with a choice, even if that choice is variation within a specific treatment, or the choice is to do nothing, is a facilitator for SDM.</p> | 7 | No concerns | No concerns | No concerns | Moderate concerns only 1 UK study (Ziebland 2014), however, Patients being informed of choice could be transferable across countries. | Moderate |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|--|---------|----------------------------|-------------|---|---|------------|
| <p>Countries where patients pay for care through insurance</p> <p>If the patient was not paying for care they felt like they had less right to participate in healthcare decisions, whereas when people felt they were spending money on a service. However, where healthcare was not covered financially by insurers, there was less SDM possible, due to the cost barrier for certain treatments.</p> | 7 | No concerns | No concerns | Minor concerns Only 7 studies. | Serious concerns Healthcare system in UK differs greatly from settings that describe this theme. | Very low |
| <p>Guidelines and regulations</p> <p>Some practitioners said there were too many national regulations, making it difficult to balance limitations imposed by them with provision of patient care, and that sometimes guidelines limited options for the service used. Some said that more regulations would facilitate the implementation of quality improvement projects.</p> | 5 | No concerns | No concerns | Minor concerns Only 5 studies. | Serious concerns Contribution of the 1 UK based study (Shepherd 2014) minor and guidelines regulations very country specific. | Low |
| <p>Financial concerns of healthcare settings</p> <p>Practitioners stated that SDM was sometimes not possible due to the risk of not matching reimbursement in high cost environments such as surgery, this was also the case for</p> | 4 | No concerns | No concerns | Moderate concerns Only 4 studies. | Moderate concerns Only 1 UK study (Upton). Other studies from other EU countries. | Moderate |

| Theme | Studies | Methodological limitations | Coherence | Adequacy | Relevance | Confidence |
|--|---------|----------------------------|-------------|--|---|---------------------|
| <p>taking time to engage in multidisciplinary deliberation.</p> <p>Another barrier was quality assurance/quality outcome frameworks not being set up in a way that encourages SDM, with practitioners stating they prioritised increasing efficiency rather than focusing on patient care.</p> | | | | | | |
| <p>Concept of SDM Some professionals mentioned that the concept of what SDM itself entailed was not clear, this was seen as a barrier as then professionals were not sure if they were actually meeting all the conditions for practising SDM.</p> | 3 | No concerns | No concerns | Serious concerns Only 3 studies. | Serious concerns No UK studies, studies from Netherlands and Canada | Very low confidence |
| <p>Other legal concerns Some practitioners highlighted that local laws prevented some practitioners from practicing SDM, and some feared SDM could increase risk of legal liability.</p> | 2 | No concerns | No concerns | Serious concerns Only 2 studies. | Serious concerns No UK studies, both studies from USA | Very low confidence |

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1 Appendix I – Excluded studies

2 Quantitative review

| Study | Code [Reason] |
|---|---|
| (2019) Correction: informed shared decision-making programme for patients with type 2 diabetes in primary care: cluster randomised controlled trial (BMJ Open (2018) 8 (e024004) DOI: 10.1136/bmjopen-2018-024004). BMJ open 9(1) | - Duplicate reference |
| Adarkwah, Charles Christian, Jegan, Nikita, Heinzl-Gutenbrunner, Monika et al. (2016) Time-to-event versus ten-year-absolute-risk in cardiovascular risk prevention - does it make a difference? Results from the Optimizing-Risk-Communication (OptRisk) randomized-controlled trial. BMC medical informatics and decision making 16(1): 152 | - Duplicate reference from Cochrane review |
| Adarkwah, Charles Christian, Jegan, Nikita, Heinzl-Gutenbrunner, Monika et al. (2019) The Optimizing-Risk-Communication (OptRisk) randomized trial - impact of decision-aid-based consultation on adherence and perception of cardiovascular risk. Patient preference and adherence 13: 441-452 | - No outcomes related to adoption of SDM <i>outcomes for treatment adherence and patient knowledge.</i> |
| Adepedjou, Rheda, Stacey, Dawn, Briere, Nathalie et al. (2019) Engaging Caregivers in Health-Related Housing Decisions for Older Adults With Cognitive Impairment: A Cluster Randomized Trial. The Gerontologist | - Not a relevant study design <i>Not RCT or CBA study (same population not followed from baseline through to post-intervention).</i> |
| 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 | - Unclear which control preference scale used and no baseline measures available. |
| Almario, C. V., Chey, W. D., 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 | - Duplicate reference from Cochrane review |
| Angela Fagerlin, PhD and Mandy Pershing, MS (0029) Improving Patient and Family Health | - unfinished trial |

| Study | Code [Reason] |
|---|---|
| Using Family-Centered Outcomes and Shared Decision-Making. | |
| Aoki, Yumi, Takaesu, Yoshikazu, Inoue, Masato et al. (2019) Seven-day shared decision making for outpatients with first episode of mood disorders among university students: A randomized controlled trial. <i>Psychiatry research</i> 281: 112531 | - Duplicate reference <i>excluded 1.3 - no extractable data</i> |
| Author not, found (0027) A novel approach to clinical practice by using a shared decision-making model to target cardiovascular risk: The YANKEES (Your demographics, Adherence, Nutrition, Knowledge, Environment, E-EtOH [alcohol], Smoking, Sleep-quality) study. | - unfinished trial |
| Author not, found (0018) A randomised controlled trial to evaluate the effects of shared decision making within a multidisciplinary team on decision making in the older adult population considering surgery. | - unfinished trial |
| Author not, found (0014) Evaluating a train-the-trainer program to facilitate implementation of shared decision making in Norway. | - unfinished trial |
| Author not, found (0003) The Effects of Family-Clinician Shared Decision-Making Model on Patient-Centered Care in Advanced Critical Illness: A Multicenter Randomized Control Trial. | - unfinished trial |
| Author not, found (0006) A Clinical Trial of Decision Aid for Continuous Renal Replacement Therapy (CRRT) Decision Making Among Surrogate Decision Makers of Patients with Acute Kidney Injury in ICU. | - unfinished trial |
| Author not, found (0003) Comparing the use of an Arabic decision aid to the usual care: a multicenter randomized controlled trial for Arabic-speaking metastatic colorectal cancer patients in Saudi Arabia. | - unfinished trial |
| Bailey, Robert A., Shillington, Alicia C., Harshaw, Qing et al. (2018) Changing Patients' Treatment Preferences and Values with a Decision Aid for Type 2 Diabetes Mellitus: Results from the Treatment Arm of a Randomized Controlled Trial. <i>Diabetes therapy : research, treatment and education of diabetes and related disorders</i> 9(2): 803-814 | - Not a relevant study design <i>Data only reported at baseline or follow-up, no measure reported at both.</i> |

| Study | Code [Reason] |
|---|---|
| Barreto, Tyler and Lin, Kenneth W. (2017) Interventions to Facilitate Shared Decision Making to Address Antibiotic Use for Acute Respiratory Tract Infections in Primary Care. American family physician 95(1): 11-12 | - Not a relevant study design <i>not a trial</i> |
| Barton, J. L., Trupin, L., Schillinger, D. et al. (2016) Use of Low-Literacy Decision Aid to Enhance Knowledge and Reduce Decisional Conflict Among a Diverse Population of Adults With Rheumatoid Arthritis: results of a Pilot Study. Arthritis care & research 68(7): 889-898 | - Duplicate reference from cochrane review |
| Berger-Hoger, Birte, Liethmann, Katrin, Muhlhauser, Ingrid et al. (2017) Implementation of shared decision-making in oncology: development and pilot study of a nurse-led decision-coaching programme for women with ductal carcinoma in situ. BMC medical informatics and decision making 17(1): 160 | - Not a relevant study design <i>systematic review and focus groups</i> |
| Bergeron, Mathieu, Duggins, Angela L., Cohen, Aliza P. et al. (2018) A shared decision-making tool for obstructive sleep apnea without tonsillar hypertrophy: A randomized controlled trial. The Laryngoscope 128(4): 1007-1015 | - Not the relevant population <i>Paediatric population.</i> |
| 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 | - Secondary outcomes of study only <i>Decisional conflict.</i> |
| Bieber, Christiane, Nicolai, Jennifer, Gschwendtner, Kathrin et al. (2018) How does a shared decision-making (SDM) intervention for oncologists affect participation style and preference matching in patients with breast and colon cancer?. Journal of Cancer Education 33(3): 708-715 | - Secondary publication of an included study that does not provide any additional relevant information <i>Include-like CPS and PPS, but post-hoc of Harter 2015.</i> |
| Brown, Leanne; Gardner, Glenn; Bonner, Ann (2019) A randomized controlled trial testing a decision support intervention for older patients with advanced kidney disease. Journal of advanced nursing | - Secondary outcomes of study only <i>Decisional conflict, Decisional regret, Knowledge</i> |
| Chhatriwalla, Adnan K., Decker, Carole, Gialde, Elizabeth et al. (2019) Developing and Testing a Personalized, Evidence-Based, Shared Decision-Making Tool for Stent Selection in Percutaneous Coronary Intervention Using a | - Outcome not an objective measure of SDM adoption <i>Methodology not provided thus cannot certify this is an objective measure</i> |

| Study | Code [Reason] |
|---|---|
| Pre-Post Study Design. Circulation. Cardiovascular quality and outcomes 12(2): e005139 | |
| Clark, Brendan J, Sorrell, Tanya, Hodapp, Rachel M et al. (2019) Pilot Randomized Trial of a Recovery Navigator Program for Survivors of Critical Illness With Problematic Alcohol Use. Critical care explorations 1(10): e0051 | - Outcome not an objective measure of SDM adoption |
| Coylewright, Megan, Dick, Sara, Zmolek, Becky et al. (2016) PCI Choice Decision Aid for Stable Coronary Artery Disease: A Randomized Trial. Circulation. Cardiovascular quality and outcomes 9(6): 767-776 | - Duplicate reference from Cochrane review |
| Cuevas, A. G.; O'Brien, K.; Saha, S. (2019) Can patient-centered communication reduce the effects of medical mistrust on patients' decision making?. Health Psychology 38(4): 325-333 | - Outcome not an objective measure of SDM adoption <i>Two items were used to assess study participants' decision making. The items asked participants to imagine themselves as the patient in the video and to rate their hypothetical likelihood of undergoing the recommended coronary artery bypass graft surgery, and of obtaining a second opinion. Each item employed four Likert-type response options ranging from definitely to definitely not.</i> |
| Den Ouden, Henk; Vos, Rimke C.; Rutten, Guy E. H. M. (2017) Effectiveness of shared goal setting and decision making to achieve treatment targets in type 2 diabetes patients: A cluster-randomized trial (OPTIMAL). Health expectations : an international journal of public participation in health care and health policy 20(5): 1172-1180 | - No outcomes related to adoption of SDM |
| Diefenbach, Michael A., Benedict, Catherine, Miller, Suzanne M. et al. (2018) Examining the impact of a multimedia intervention on treatment decision-making among newly diagnosed prostate cancer patients: results from a nationwide RCT. Translational behavioral medicine 8(6): 876-886 | - Secondary outcomes of study only <i>Decisional Conflict Scale only. 2ndary outcome in CR</i> |
| Elissa Ozanne, PhD and Maddie McCarty, BS (0016) Randomized Evaluation of Decision Support Interventions for Atrial Fibrillation. | - unfinished trial |
| Epstein RM, Duberstein PR, Fenton JJ et al. (2017) Effect of a Patient-Centered Communication Intervention on Oncologist- | - Duplicate reference from Cochrane review |

| Study | Code [Reason] |
|--|---|
| Patient Communication, Quality of Life, and Health Care Utilization in Advanced Cancer: The VOICE Randomized Clinical Trial. JAMA oncology 3(1): 92-100 | <i>NOT REALLY SDM AND NOT REALLY SDM SECONDARY OUTCOMES.</i> |
| Eslami, S., Aslani, A., Tara, F. et al. (2015) The impact of a computerized decision aid on empowering pregnant women for choosing vaginal versus cesarean section delivery: study protocol for a randomized controlled trial. Trials 16: 549 | - Not yet published <i>Trial does not seem to be published, trial registry no extra information.</i> |
| Finderup, Jeanette; Jensen, Jens K. D.; Lomborg, Kirsten (2018) Developing and pilot testing a shared decision-making intervention for dialysis choice. Journal of renal care | - No intervention designed to increase adoption of SDM by healthcare professionals <i>Single arm</i> |
| Furumaya (0010) Shared decision making in Perihilar Cholangiocarcinoma and Hepatocellular Adenoma: The SAPACHA study. | - unfinished trial |
| Gagne, Myriam E., Legare, France, Moisan, Jocelyne et al. (2017) Impact of Adding a Decision Aid to Patient Education in Adults with Asthma: A Randomized Clinical Trial. PloS one 12(1): e0170055 | - Secondary outcomes of study only <i>Decisional conflict scale only 2ndary outcome in CR</i> |
| Gilbar, P. (2019) Shared decision making can aid the informed consent process for end-of-life chemotherapy in cancer patients. Journal of Oncology Pharmacy Practice 25(1): 249-250 | - Not a relevant study design |
| Gionfriddo, Michael R., Branda, Megan E., Fernandez, Cara et al. (2018) Comparison of audio vs. audio + video for the rating of shared decision making in oncology using the observer OPTION5 instrument: an exploratory analysis. BMC health services research 18(1): 522 | - No intervention designed to increase adoption of SDM by healthcare professionals <i>Comparison is between different ways of assessing the OPTION score, not the intervention itself.</i> |
| Graham, M. E., Westerberg, B. D., Lea, J. et al. (2018) Shared decision making and decisional conflict in the Management of Vestibular Schwannoma: A prospective cohort study. Journal of Otolaryngology - Head and Neck Surgery 47(1): 52 | - No intervention designed to increase adoption of SDM by healthcare professionals <i>cohort study single arm</i> |
| Granados-Santiago, M., Valenza, M.C., Lopez-Lopez, L. et al. (2020) Shared decision-making and patient engagement program during acute exacerbation of COPD hospitalization: A randomized control trial. Patient Education and Counseling 103(4): 702-708 | - No intervention designed to increase adoption of SDM by healthcare professionals <i>2ndary outcomes only</i> |

| Study | Code [Reason] |
|--|---|
| Hackert (0010) Implementation and evaluation of shared decision-making, supported by outcome measures, for treatment modality decisions in advanced kidney disease. | - unfinished trial |
| Hackert (0010) Implementation and evaluation of shared decision-making, supported by outcome measures, regarding the organisation of follow-up care in breast cancer. | - unfinished trial |
| Hackert (0010) Implementation and evaluation of shared decision-making, supported by outcome measures, with stroke patients regarding discharge location and type of care after discharge from hospital. | - unfinished trial |
| Hahlweg, P., Kriston, L., Scholl, I. et al. (2020) Cancer patients' preferred and perceived level of involvement in treatment decision-making: an epidemiological study. <i>Acta Oncologica</i> 59(8): 967-974 | - Not a relevant study design |
| Hamann, J., Parchmann, A., Sassenberg, N. et al. (2017) Training patients with schizophrenia to share decisions with their psychiatrists: a randomized-controlled trial. <i>Social psychiatry and psychiatric epidemiology</i> 52(2): 175-182 | - Duplicate reference from Cochrane review |
| Harman, Stephanie M., Blankenburg, Rebecca, Satterfield, Jason M. et al. (2019) Promoting Shared Decision-Making Behaviors During Inpatient Rounds: A Multimodal Educational Intervention. <i>Academic medicine : journal of the Association of American Medical Colleges</i> 94(7): 1010-1018 | - Not a relevant study design <i>Uncontrolled before-after study</i> |
| Harter, M., Buchholz, A., Nicolai, J. et al. (2015) Shared decision making and the use of decision AIDS-a cluster-randomized study on the efficacy of a training in an oncology setting. <i>Deutsches arzteblatt international</i> 112(40): 672-679 | - Duplicate reference from Cochrane review |
| Henselmans, I., van Laarhoven, H.W.M., van Maarschalkerweerd, P. et al. (2020) Effect of a Skills Training for Oncologists and a Patient Communication Aid on Shared Decision Making About Palliative Systemic Treatment: A Randomized Clinical Trial. <i>The oncologist</i> 25(3): e578-e588 | - Duplicate reference <i>Same cohort as Henselmans 2019</i> |

| Study | Code [Reason] |
|--|--|
| Holzhüter (0010) Nocebo effects by providing informed consent in shared decision making? Not necessarily: A randomized pilot-trial. | - unfinished trial |
| Huang, E. S., Nathan, A. G., Cooper, J. M. et al. (2017) Impact and Feasibility of Personalized Decision Support for Older Patients with Diabetes: a Pilot Randomized Trial. Medical decision making 37(5): 611-617 | - Secondary outcomes of study only <i>Patient and Physician Communication about A1C Goals, Decisional conflict, Changes in physician identified goals - 2ndary outcomes in CR</i> |
| 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 | - No outcomes related to adoption of SDM |
| ISRCTN14184328 (2018) Ready for SDM - evaluation of a multidisciplinary training module in Shared Decision Making. | - Not yet published |
| ISRCTN98108615 (2018) A decision aid for helping people to decide about colorectal cancer screening. | - Duplicate reference <i>perestelo-perez 2019</i> |
| Jennifer Ridgeway, PhD and Victor Montori, MD (0003) Implementing Shared Decision Making (SDM) For Individualized CV Prevention (SDM4IP). | - unfinished trial |
| Jouni, Hayan, Haddad, Raad A., Marroush, Tariq S. et al. (2017) Shared decision-making following disclosure of coronary heart disease genetic risk: results from a randomized clinical trial. Journal of investigative medicine : the official publication of the American Federation for Clinical Research 65(3): 681-688 | - Duplicate reference from Cochrane review |
| Karagiannis, Thomas, Liakos, Aris, Branda, Megan E. et al. (2016) Use of the Diabetes Medication Choice Decision Aid in patients with type 2 diabetes in Greece: a cluster randomised trial. BMJ open 6(11): e012185 | - Secondary outcomes of study only <i>Decisional Conflict Scale: 2ndary outcome in CR only</i> |
| Karen Sepucha, PhD (0020) Online Trial Examining Validity and Reliability of the Shared Decision Making Process Survey. | - unfinished trial |
| Karen Sepucha, PhD (0020) Online Trial Examining Validity of the Shared Decision Making Process Survey With Video Vignettes. | - unfinished trial |

| Study | Code [Reason] |
|--|---|
| Kearing (2016) Can decision support help patients with spinal stenosis make a treatment choice?: a prospective study assessing the impact of a patient decision aid and health coaching. Spine 41: 563-567 | - Duplicate reference |
| Koch, C., Dreimuller, N., Weisskircher, J. et al. (2020) Teaching Conflicts of Interest and Shared Decision-Making to Improve Risk Communication: a Randomized Controlled Trial. Journal of General Internal Medicine 35(2): 473-480 | - No intervention designed to increase adoption of SDM by healthcare professionals <i>Moved to question 1.3c regarding risk communication</i> |
| Korteland, Nelleke M., Ahmed, Yunus, Koolbergen, David R. et al. (2017) Does the Use of a Decision Aid Improve Decision Making in Prosthetic Heart Valve Selection? A Multicenter Randomized Trial. Circulation. Cardiovascular quality and outcomes 10(2) | - Duplicate reference from Cochrane review |
| Kunneman, M., Branda, M. E., Hargraves, I. et al. (2018) Fostering Choice Awareness for Shared Decision Making: A Secondary Analysis of Video-Recorded Clinical Encounters. Mayo Clinic Proceedings: Innovations, Quality and Outcomes 2(1): 60-68 | - Not a relevant study design <i>Takes a random sample of records from 10 other clinical trials</i> |
| Lam, W. W. T., Chan, M., Or, A. et al. (2013) Reducing treatment decision conflict difficulties in breast cancer surgery: A randomized controlled trial. Journal of Clinical Oncology 31(23): 2879-2885 | - Secondary outcomes of study only <i>satisfaction with decision making not verified scale put composite outcome of decisional conflict and treatment decision making difficulties</i> |
| Lilisbeth Perestelo Perez, PhD; Lilisbeth Perestelo PÃ©rez, PhD; Lilisbeth G Perestelo-PÃ©rez, PhD (0011) The Effectiveness of a Web-based Decision Aid for Patients With Generalized Anxiety Disorder: Protocol for a Randomized Controlled Trial. | - unfinished trial |
| Lord, Kathryn; Livingston, Gill; Cooper, Claudia (2017) A feasibility randomised controlled trial of the DECIDE intervention: Dementia carers making informed decisions. BJPsych Open 3(1): 12-14 | - Not a relevant study design <i>Short report</i> |
| Ludden, Thomas, Shade, Lindsay, Reeves, Kelly et al. (2018) Asthma dissemination around patient-centered treatments in North Carolina (ADAPT-NC): a cluster randomized control trial evaluating dissemination of an evidence-based | - Not the relevant population <i>"All patients over the age of 2: 95% of patients in some cases under 21</i> |

| Study | Code [Reason] |
|---|--|
| shared decision-making intervention for asthma management. The Journal of asthma : official journal of the Association for the Care of Asthma: 1-12 | |
| McAlpine, Kristen, Lewis, Krystina B., Trevena, Lyndal J. et al. (2018) What Is the Effectiveness of Patient Decision Aids for Cancer-Related Decisions? A Systematic Review Subanalysis. JCO clinical cancer informatics 2: 1-13 | - Not a relevant study design |
| 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 | - Secondary outcomes of study only <i>Decisional self-efficacy, Decisional conflict, Decisional regret</i> |
| McCabe, Rose, Pavlickova, Hana, Xanthopoulou, Penny et al. (2019) Patient and companion shared decision making and satisfaction with decisions about starting cholinesterase medication at dementia diagnosis. Age and ageing 48(5): 711-718 | - Not a relevant study design <i>No comparison arm</i> |
| McGrath, Amanda, Sharpe, Louise, Lah, Suncica et al. (2017) Evaluation of a Decision Aid for Women with Epilepsy Who Are Considering Pregnancy: A Randomized Controlled Trial. Medical decision making : an international journal of the Society for Medical Decision Making 37(5): 589-599 | - Secondary outcomes of study only <i>Knowledge, Decisional conflict, Ptnt/Prac communication</i> |
| 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 | - Secondary outcomes of study only |
| Meijers, M. C., Noordman, J., Spreeuwenberg, P. et al. (2019) Shared decision-making in general practice: an observational study comparing 2007 with 2015. Family practice 36(3): 357-364 | - Not a relevant study design <i>Comparing 1 intervention across two timepoints (not a relevant comparator....)</i> |
| Mikael Sandlund, Professor and Mikael Sandlund, Professor (0006) Shared Decision Making in Psychiatric Inpatient Care to Enhance Patient Participation. | - unfinished trial |

| Study | Code [Reason] |
|--|--|
| <p>Moin, T., Duru, O.K., Turk, N. et al. (2019) Effectiveness of Shared Decision-making for Diabetes Prevention: 12-Month Results from the Prediabetes Informed Decision and Education (PRIDE) Trial. <i>Journal of General Internal Medicine</i> 34(11): 2652-2659</p> | <p>- No outcomes related to adoption of SDM <i>Uptake and weight gain</i></p> |
| <p>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. <i>Health literacy research and practice</i> 3(3suppl): 58-s74</p> | <p>- Duplicate reference <i>Included in 1.3</i></p> |
| <p>Myers, Ronald E., Leader, Amy E., Censits, Jean Hoffman et al. (2018) Decision Support and Shared Decision Making About Active Surveillance Versus Active Treatment Among Men Diagnosed with Low-Risk Prostate Cancer: a Pilot Study. <i>Journal of cancer education : the official journal of the American Association for Cancer Education</i> 33(1): 180-185</p> | <p>- Secondary outcomes of study only <i>Decisional Conflict, Patient knowledge</i></p> |
| <p>Naykky Singh, Ospina (0003) Adequate Selection of Patients for Thyroid Biopsy: Evaluation of a Shared Decision Making Conversation Aid.</p> | <p>- unfinished trial</p> |
| <p>NCT03766256 (2018) Shared Decision Making in Diabetes Prevention for Women With a History of GDM.</p> | <p>- Not yet published</p> |
| <p>Nouri SS, Damschroder LJ, Olsen MK et al. (2019) Health Coaching Has Differential Effects on Veterans with Limited Health Literacy and Numeracy: a Secondary Analysis of ACTIVATE. <i>Journal of general internal medicine</i> 34(4): 552-558</p> | <p>- Secondary publication of an included study that does not provide any additional relevant information <i>Oddone 2019</i></p> |
| <p>O'Donnell, Maryanne, Parker, Gordon, Proberts, Miriam et al. (1999) A Study of Client-Focused Case Management and Consumer Advocacy: The Community and Consumer Service Project. <i>Australian & New Zealand Journal of Psychiatry</i> 33(5): 684-693</p> | <p>- No outcomes related to adoption of SDM <i>No outcomes that specifically measure the adoption of SDM practices</i></p> |
| <p>Parkinson, Bonny, Sherman, Kerry A., Brown, Paul et al. (2018) Cost-effectiveness of the BRECONDA decision aid for women with breast cancer: Results from a randomized controlled trial. <i>Psycho-oncology</i> 27(6): 1589-1596</p> | <p>- Not a relevant study design</p> |

| Study | Code [Reason] |
|---|--|
| <p>Patzer, Rachel E., McPherson, Laura, Basu, Mohua et al. (2018) Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons 18(8): 1954-1965</p> | <p>- Secondary outcomes of study only <i>Decisional conflict, patient preferences, provider opinions.</i></p> |
| <p>Perestelo-Perez, Lilisbeth, Rivero-Santana, Amado, Sanchez-Afonso, Juan Antonio et al. (2017) Effectiveness of a decision aid for patients with depression: A randomized controlled trial. Health expectations : an international journal of public participation in health care and health policy 20(5): 1096-1105</p> | <p>- Secondary outcomes of study only <i>Decisional conflict, Decisional control preference, Knowledge, Treatment intention, Goals and concerns</i></p> |
| <p>Perestelo-Perez, Lilisbeth, Rivero-Santana, Amado, Torres-Castano, Alezandra et al. (2019) Effectiveness of a decision aid for promoting colorectal cancer screening in Spain: a randomized trial. BMC medical informatics and decision making 19(1): 8</p> | <p>- Secondary outcomes of study only <i>Decisional conflict, Patient knowledge</i></p> |
| <p>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</p> | <p>- Secondary publication of an included study that does not provide any additional relevant information <i>No cross arm comparisons in this compared to HEss 2016</i></p> |
| <p>Reder, Maren and Kolip, Petra (2017) Does a decision aid improve informed choice in mammography screening? Results from a randomised controlled trial. PloS one 12(12): e0189148</p> | <p>- No intervention designed to increase adoption of SDM by healthcare professionals <i>DOESNT LOOK LIKE THIS WAS ABOUT SDM AT ALL, BUT RATHER ABOUT INFORMED CHOICE</i></p> |
| <p>Reder, Maren; Soellner, Renate; Kolip, Petra (2019) Do Women With High eHealth Literacy Profit More From a Decision Aid on Mammography Screening? Testing the Moderation Effect of the eHEALS in a Randomized Controlled Trial. Frontiers in public health 7: 46</p> | <p>- No outcomes related to adoption of SDM</p> |
| <p>Reeves MJ, Fritz MC, Woodward AT et al. (2019) Michigan Stroke Transitions Trial. Circulation. Cardiovascular quality and outcomes 12(7): e005493</p> | <p>- No intervention designed to increase adoption of SDM by healthcare professionals <i>not SDM related</i></p> |

| Study | Code [Reason] |
|--|--|
| <p>Rising, Kristin L., Hollander, Judd E., Schaffer, Jason T. et al. (2018) Effectiveness of a Decision Aid in Potentially Vulnerable Patients: A Secondary Analysis of the Chest Pain Choice Multicenter Randomized Trial. <i>Medical decision making : an international journal of the Society for Medical Decision Making</i> 38(1): 69-78</p> | <p>- Secondary publication of an included study that does not provide any additional relevant information <i>secondary analysis of Hess 2016</i></p> |
| <p>Ritter, Simon, Stirnemann, Jerome, Breckwolddt, Jan et al. (2019) Shared Decision-Making Training in Internal Medicine: A Multisite Intervention Study. <i>Journal of graduate medical education</i> 11(4suppl): 146-151</p> | <p>- Not a relevant study design <i>Signle arm pre post study and we have minimum required number of RCTs</i></p> |
| <p>Sanders, A. R. J., Bensing, J. M., Essed, M. A. L. U. et al. (2017) Does training general practitioners result in more shared decision making during consultations?. <i>Patient education and counseling</i> 100(3): 563-574</p> | <p>- Duplicate reference from Cochrane review</p> |
| <p>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. <i>BMC family practice</i> 19(1): 102</p> | <p>- No outcomes related to adoption of SDM</p> |
| <p>Sarai, Michael; Ray, Charles E., Jr.; Duszak, Richard, Jr. (2017) An Ideal Opportunity for Interventional Radiologists to Advance Shared Decision Making. <i>Journal of vascular and interventional radiology : JVIR</i> 28(7): 1022-1024</p> | <p>- Not a relevant study design</p> |
| <p>Scalia, Peter, Durand, Marie-Anne, Kremer, Jan et al. (2018) Online, Interactive Option Grid Patient Decision Aids and their Effect on User Preferences. <i>Medical decision making : an international journal of the Society for Medical Decision Making</i> 38(1): 56-68</p> | <p>- Not a relevant study design</p> |
| <p>Schaffer, Jason T., Hess, Erik P., Hollander, Judd E. et al. (2018) Impact of a Shared Decision Making Intervention on Health Care Utilization: A Secondary Analysis of the Chest Pain Choice Multicenter Randomized Trial. <i>Academic emergency medicine : official journal of the Society for Academic Emergency Medicine</i> 25(3): 293-300</p> | <p>- Outcome not an objective measure of SDM adoption <i>No primary outcome</i></p> |

| Study | Code [Reason] |
|--|---|
| Schwartz, Peter H., Perkins, Susan M., Schmidt, Karen K. et al. (2017) Providing Quantitative Information and a Nudge to Undergo Stool Testing in a Colorectal Cancer Screening Decision Aid: A Randomized Clinical Trial. Medical decision making : an international journal of the Society for Medical Decision Making 37(6): 688-702 | - No intervention designed to increase adoption of SDM by healthcare professionals |
| Seal, Karen H., Borsari, Brian, Tighe, Jennifer 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 outcomes related to adoption of SDM |
| Sepucha, Karen, Atlas, Steven J., Chang, Yuchiao et al. (2017) Patient Decision Aids Improve Decision Quality and Patient Experience and Reduce Surgical Rates in Routine Orthopaedic Care: A Prospective Cohort Study. The Journal of bone and joint surgery. American volume 99(15): 1253-1260 | - Not a relevant study design <i>No baseline data, only post-study data.</i> |
| 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 intervention designed to increase adoption of SDM by healthcare professionals <i>PDA vs PDA</i> |
| Sferra, S.R., Cheng, J.S., Boynton, Z. et al. (2020) Aiding shared decision making in lung cancer screening: two decision tools. Journal of public health (Oxford, England) | - No outcomes related to adoption of SDM <i>Cannot extract SDM outcomes as no variance is reported</i> |
| Shepherd, Heather L., Barratt, Alexandra, Jones, Anna et al. (2016) Can consumers learn to ask three questions to improve shared decision making? A feasibility study of the ASK (AskShareKnow) Patient-Clinician Communication Model() intervention in a primary health-care setting. Health expectations : an international journal of public participation in health care and health policy 19(5): 1160-8 | - Not a relevant study design |
| Shum, Jennifer W. H., Lam, Wendy W. T., Choy, Bonnie N. K. et al. (2017) Development and pilot-testing of patient decision aid for use among Chinese patients with primary open- | - Not a relevant study design |

| Study | Code [Reason] |
|---|--|
| angle glaucoma. BMJ open ophthalmology 2(1): e000100 | |
| 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 | - No intervention designed to increase adoption of SDM by healthcare professionals <i>NOT AN SDM INTERVENTION</i> |
| Simmons, Magenta Bender, Batchelor, Samantha, Dimopoulos-Bick, Tara et al. (2017) The Choice Project: Peer Workers Promoting Shared Decision Making at a Youth Mental Health Service. Psychiatric services (Washington, D.C.) 68(8): 764-770 | - Not the relevant population <i>NOT SURE INTAKE WORKERS WERE HCP. NO MENTION OF AN OBJECTIVE OUTCOME.</i> |
| Simmons, Vani N., Gray, Jhanelle E., Schabath, Matthew B. et al. (2017) High-risk community and primary care providers knowledge about and barriers to low-dose computed topography lung cancer screening. Lung cancer (Amsterdam, Netherlands) 106: 42-49 | - Not a relevant study design <i>Qualitative</i> |
| 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 | - No intervention designed to increase adoption of SDM by healthcare professionals <i>only 1 arm of data</i> |
| Skains, R.M., Kuppermann, N., Homme, J.L. et al. (2020) What is the effect of a decision aid in potentially vulnerable parents? Insights from the head CT choice randomized trial. Health expectations : an international journal of public participation in health care and health policy 23(1): 63-74 | - Outcome not an objective measure of SDM adoption <i>2ndary SDM outcomes only</i> |
| Smallwood, A. J., Schapira, M. M., Fedders, M. et al. (2017) A pilot randomized controlled trial of a decision aid with tailored fracture risk tool delivered via a patient portal. Osteoporosis international : a journal established as result of cooperation between the European Foundation for Osteoporosis and the National Osteoporosis Foundation of the USA 28(2): 567-576 | - Duplicate reference from Cochrane review |
| Smith, S.K., Westbrook, K., MacDermott, K. et al. (2020) Four Conversations: A Randomized Controlled Trial of an Online, Personalized Coping and Decision Aid for Metastatic Breast Cancer Patients. Journal of Palliative Medicine 23(3): 353-358 | - Outcome not an objective measure of SDM adoption <i>2ndary outcomes only</i> |

| Study | Code [Reason] |
|--|---|
| Smith, Sian K., Simpson, Judy M., Trevena, Lyndal J. et al. (2014) Factors Associated with Informed Decisions and Participation in Bowel Cancer Screening among Adults with Lower Education and Literacy. <i>Medical decision making : an international journal of the Society for Medical Decision Making</i> 34(6): 756-72 | <p>- No intervention designed to increase adoption of SDM by healthcare professionals</p> <p><i>Screening decision, does not stratify between Shared decision and solitary patient informed decision, even though its uses CPS.</i></p> |
| 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. <i>The Canadian journal of urology</i> 24(4): 8910-8917 | <p>- No intervention designed to increase adoption of SDM by healthcare professionals</p> <p><i>compares decision aid vs decision aid and SDM, not something we're looking at as assessing effectiveness of SDM</i></p> |
| Stegmann, M.E., Brandenburg, 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. <i>British Journal of General Practice</i> 70(696): e450-e456 | <p>- Outcome not an objective measure of SDM adoption</p> <p><i>DSE and secondary outcomes only</i></p> |
| Steinwachs, Donald M, Roter, Debra L, Skinner, Elizabeth A et al. (2011) A web-based program to empower patients who have schizophrenia to discuss quality of care with mental health providers. <i>Psychiatric services (Washington, D.C.)</i> 62(11): 1296-1302 | <p>- No intervention designed to increase adoption of SDM by healthcare professionals</p> <p><i>No mention of concept of SDM, patient communication only.</i></p> |
| Stubenrouch, Fabienne E., Pieterse, Arwen H., Falkenberg, Rijn et al. (2016) OPTION(5) versus OPTION(12) instruments to appreciate the extent to which healthcare providers involve patients in decision-making. <i>Patient education and counseling</i> 99(6): 1062-8 | <p>- No intervention designed to increase adoption of SDM by healthcare professionals</p> <p><i>Comparing different option scores using secondary data</i></p> |
| Tates, Kiek, Antheunis, Marjolijn L., Kanters, Saskia et al. (2017) The Effect of Screen-to-Screen Versus Face-to-Face Consultation on Doctor-Patient Communication: An Experimental Study with Simulated Patients. <i>Journal of medical Internet research</i> 19(12): e421 | <p>- Outcome not an objective measure of SDM adoption</p> <p><i>not objective outcomes and simulated patients.</i></p> |
| Thomson, Carrie Louise; Maskrey, Neal; Vlaev, Ivo (2017) Making Decisions Better: an evaluation of an educational intervention. <i>Journal of evaluation in clinical practice</i> 23(2): 251-256 | <p>- No outcomes related to adoption of SDM</p> <p><i>Think this is exclude as not looking at action of practitioners in a consultation but rather their understanding of SDM in general?</i></p> |
| Tomko, C., Davis, K. M., Luta, G. et al. (2014) A Comparison of Web-Based Versus Print-Based Decision Aids for Prostate Cancer Screening: | <p>- Secondary outcomes of study only</p> |

| Study | Code [Reason] |
|--|--|
| participants' Evaluation and Utilization. Journal of general internal medicine | <i>Physician-patient communication - listed as 2ndary outcome in CR</i> |
| van Laarhoven, H.W.M., Henselmans, I., van Maarschalkerweerd, P. et al. (2018) Training oncologists and preparing patients for shared decision making about palliative systemic treatment: Results from the randomized controlled CHOICE study. Annals of oncology : official journal of the European Society for Medical Oncology 29(supplement8) | - Conference abstract |
| Van Os, Jim, Altamura, A. Carlo, Bobes, Julio et al. (2004) Evaluation of the Two-Way Communication Checklist as a clinical intervention: Results of a multinational, randomised controlled trial. British Journal of Psychiatry 184(1): 79-83 | - Outcome not an objective measure of SDM adoption <i>Change in behaviour scale does not include an SDM element, also no mention of SDM in the paper.</i> |
| Vigod, Simone N., Hussain-Shamsy, Neesha, Stewart, Donna E. et al. (2019) A patient decision aid for antidepressant use in pregnancy: Pilot randomized controlled trial. Journal of affective disorders 251: 91-99 | - Secondary outcomes of study only <i>Decisional conflict scale</i> |
| Vitger, Tobias, Austin, Stephen F., Petersen, Lone 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 outpatient treatment settings: a randomized controlled single-blind trial. BMC psychiatry 19(1): 185 | - Not yet published <i>Recruiting til 2020</i> |
| Wanda K Nicholson, MD (0003) Pilot Study to Assess the Effectiveness of a Decision Tool for Cesarean Delivery vs. Trial of Labor. | - unfinished trial |
| WEN-HSUAN, HOU; YI-HSUAN, LAN; YI-HSUAN, LAN (0018) A Patient-centered Continuous and Interdisciplinary Shared Decision Making Approach for Breast Cancer Rehabilitation. | - unfinished trial |
| Woltz, Sarah, Krijnen, Pieta, Meylaerts, Sven A. G. et al. (2017) Shared decision making in the management of midshaft clavicular fractures: Nonoperative treatment or plate fixation. Injury 48(4): 920-924 | - Not a relevant study design <i>single arm cross-sectional study</i> |

| Study | Code [Reason] |
|--|--|
| Wysocki, Tim, James, Lauren, Milkes, Amy et al. (2018) Electronically Verified Use of Internet-Based, Multimedia Decision Aids by Adolescents With Type 1 Diabetes and Their Caregivers. <i>MDM policy & practice</i> 3(1): 2381468318769857 | - Not the relevant population <i>Adolescents</i> |
| Zisman-Ilani, Yaara, Roe, David, Elwyn, Glyn et al. (2019) Shared Decision Making for Psychiatric Rehabilitation Services Before Discharge from Psychiatric Hospitals. <i>Health communication</i> 34(6): 631-637 | - Not a relevant study design <i>Only 1 time point. No primary outcome at baseline/</i> |

1

2 Qualitative review

| Study | Code [Reason] |
|---|--|
| Allaire, Anne-Sophie, Labrecque, Michel, Giguere, Anik et al. (2011) Barriers and facilitators to the dissemination of DECISION+, a continuing medical education program for optimizing decisions about antibiotics for acute respiratory infections in primary care: a study protocol. <i>Implementation science : IS</i> 6: 3 | - Study does not report any of the factors of interest specified in the protocol <i>Protocol for DECISION+ study, actual study about a specific PDA so not an include</i> |
| Brooks, Helen, Lovell, Karina, Bee, Penny et al. (2019) Implementing an intervention designed to enhance service user involvement in mental health care planning: a qualitative process evaluation. <i>Social psychiatry and psychiatric epidemiology</i> 54(2): 221-233 | - Study does not report any of the factors of interest specified in the protocol <i>Regarding a specific SDM intervention and the barriers/facilitators for that</i> |
| Coylewright, M., O'Neill, E., Sherman, A. et al. (2020) The Learning Curve for Shared Decision-making in Symptomatic Aortic Stenosis. <i>JAMA Cardiology</i> 5(4): 442-448 | - Study does not report any of the factors of interest specified in the protocol <i>PDA's not SDM</i> |
| Lynch, R., Toozs-Hobson, P., Duckett, J. et al. (2020) Making a decision about surgery for female urinary incontinence: a qualitative study of women's views. <i>International Urogynecology Journal</i> | - Study does not report any of the factors of interest specified in the protocol <i>Not about SDM barriers and facilitators, general UI barriers</i> |
| Munro, Sarah, Manski, Ruth, Donnelly, Kyla Z et al. (2019) Investigation of factors influencing the implementation of two shared decision-making interventions in contraceptive care: a qualitative interview study among clinical and | - Study does not report any of the factors of interest specified in the protocol <i>Acceptability study of particular intervention not SDM in general.</i> |

| Study | Code [Reason] |
|--|--|
| administrative staff. Implementation science : IS 14(1): 95 | |
| Saba, George W., Wong, Sabrina T., Schillinger, Dean et al. (2006) Shared decision making and the experience of partnership in primary care. Annals of family medicine 4(1): 54-62 | - Study does not report any of the factors of interest specified in the protocol <i>no barrier discussion.</i> |
| van der Weijden, Trudy, Pieterse, Arwen H., Koelewijn-van Loon, Marije S. et al. (2013) How can clinical practice guidelines be adapted to facilitate shared decision making? A qualitative key-informant study. BMJ quality & safety 22(10): 855-63 | - Study does not report any of the factors of interest specified in the protocol <i>"How guidelines could be used to facilitate shared decision making" not barriers and facilitators themselves!</i> |
| Williams, D., Edwards, A., Wood, F. et al. (2019) Ability of observer and self-report measures to capture shared decision-making in clinical practice in the UK: A mixed-methods study. BMJ Open 9(8): e029485 | - Not a relevant study design <i>Not a qualitative analysis of SDM</i> |

1
2

1 Appendix J – Research recommendations

| Question | What is the best objective tool for measuring SDM, and how well do other objective measures of SDM match it? |
|---|--|
| Population | Adults (aged 18 years and over) using healthcare services (and their families, carers and advocates if they choose to involve them). |
| Intervention | SDM intervention |
| Comparator | <ul style="list-style-type: none"> • Each other • No intervention • Sham intervention • Different intensity of same intervention |
| Outcomes | Any validated objective outcome of SDM. [Study must use/compare two different objective outcome measures of SDM] |
| Study design | RCT / nRCT |
| Potential criterion | Explanation |
| Importance to patients, service users or the population | There is currently a wide range of objective measures of SDM and it is unclear whether all are equally valid, or if all of them measure the same thing, since shared decision making is poorly defined and nebulous. A standardised measure of SDM would enable reviewers to compare research studies more easily to identify effective shared decision making interventions |
| Relevance to NICE guidance | The guideline committee had difficulty comparing different interventions to increase the use of SDM because it was unable to make head to head comparisons for many of the studies, which used different outcome measures. |
| Current evidence base | None found. |
| Equality | It may be that different measures of SDM are affected by some of the protected characteristics and studies should perform sub-group analyses to explore this. |
| Feasibility | RCTs looking at shared decision making are already underway and many have been done, therefore there are no obvious barriers to this research |

2

3

| How does the same SDM intervention differ in effectiveness between different patient populations | |
|---|---|
| Question | |
| Population | Adults (aged 18 years and over) using healthcare services (and their families, carers and advocates if they choose to involve them) stratified into two or more sub-populations by specified characteristics (e.g gender, family background) |
| Intervention | The same SDM intervention in each population group |
| Comparator | Each other |
| Outcomes | Measurement of use of SDM |
| Study design | RCT /nRCT |
| Potential criterion | Explanation |
| Importance to patients, service users or the population | SDM tools are complex interventions that can have significantly differing effects between different populations. Many studies cannot be easily compared as both population and type of SDM intervention are both different. Studies looking at identical or similar interventions in differing population would enable observation of the differing effects of SDM across these groups. |
| Relevance to NICE guidance | The guideline committee had difficulty comparing different interventions to increase the use of SDM because of the heterogeneity between population and variation in SDM interventions used. |
| Current evidence base | None found |
| Equality | The purpose of this study is to highlight the effects of SDM on different populations |
| Feasibility | There are many SDM RCTs so this is feasible. |

1

| Research question | What influences the acceptability of shared decision making in populations where belief in the authority of the healthcare professional is still prevalent? |
|--------------------------|--|
| Population | Healthcare users in populations where authority of healthcare professional is prevalent |
| Intervention | Shared decision making interventions |
| Comparators | <ul style="list-style-type: none"> • Each other • No intervention • Sham intervention • Different intensity |
| Outcome measures | <p>Acceptability of SDM: This could be measured by</p> <ul style="list-style-type: none"> • 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 <p>More likely, this will be qualitative evidence identified from focus groups and interviews.</p> |
| Study designs | <ul style="list-style-type: none"> • Randomised controlled studies • Systematic reviews of randomised controlled studies • Mixed methods studies • Qualitative primary studies • Qualitative syntheses |
| Subgroups of interest | <ul style="list-style-type: none"> • Ethnicity • Age |

1

| Potential criterion | Explanation |
|---|--|
| Importance to patients, service users or the population | Certain populations have more embedded beliefs about the idea of paternalistic care, and different approaches to shared decision making may be required to accommodate these beliefs. |
| Relevance to NICE guidance | Moderate priority: Addresses a significant subgroup of healthcare service users identified in the barriers and facilitators review of this guideline. No clear quantitative evidence was located for these groups. (This will help future committees ensure all populations are accounted for in SDM interventions) |
| Current evidence base | Qualitative evidence in this guideline (RQ 1.2) |
| Equality | This question is to specifically address an equalities gap identified in RQ 1.2 of this guideline. |
| Feasibility | Would require identification of trials in these specific groups and identification of any more subgroups with beliefs about paternalistic care. Capturing of SDM acceptability may require a mixed methods approach to capture both acceptability from a patient value perspective and an objective outcome perspective. |

2

| Research question | What are the best ways to measure shared decision making in different contexts with different populations and which reflect the complexity across encounters and people involved? |
|--------------------------|--|
| Population | Populations where SDM is taking place. |
| Intervention | SDM intervention |

| Research question | What are the best ways to measure shared decision making in different contexts with different populations and which reflect the complexity across encounters and people involved? |
|-----------------------|---|
| Comparators | The same SDM intervention with different SDM outcome measures, both objective and subjective |
| Outcome measures | Difference in SDM measure results. |
| Study designs | RCTs Systematic reviews of RCTs |
| Subgroups of interest | N/A |

1

| Potential criterion | Explanation |
|---|--|
| Importance to patients, service users or the population | Better measures of SDM will better capture the effects of SDM for patients and practitioners and help ascertain which SDM interventions are effective and how. |
| Relevance to NICE guidance | High priority: Committee highlighted that there is a lot of disagreement currently about the best ways to measure SDM and what each SDM measure is actually capturing. Appraising these measures will allow SDM to be measured more consistently and accurately, leading to more reliable data and thus a larger evidence base to make better recommendations. |
| Current evidence base | There is a lack of evidence comparing different SDM measures to each other. |
| Equality | No obvious equality issues. |
| Feasibility | Possible in any setting where SDM is taking place, but objective measures require recording of appointments which has a resource implication. |

2

3 Appendix K – References to included studies

4 Quantitative review

5 Original Cochrane review

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10 Primary studies

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1

2 Qualitative review

3 Systematic reviews

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16

17 Primary studies

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