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Shared decision-making interventions for people with mental health conditions (Review)

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[Intervention Review]

Shared decision-making interventions for people with mental health conditions

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ABSTRACT

Background

One person in every four will suffer from a diagnosable mental health condition during their life. Such conditions can have a devastating impact on the lives of the individual and their family, as well as society.

International healthcare policy makers have increasingly advocated and enshrined partnership models of mental health care. Shared decision-making (SDM) is one such partnership approach. Shared decision-making is a form of service user-provider communication where both parties are acknowledged to bring expertise to the process and work in partnership to make a decision.

This review assesses whether SDM interventions improve a range of outcomes. This is the first update of this Cochrane Review, first published in 2010.

Objectives

To assess the effects of SDM interventions for people of all ages with mental health conditions, directed at people with mental health conditions, carers, or healthcare professionals, on a range of outcomes including: clinical outcomes, participation/involvement in decision-making process (observations on the process of SDM; user-reported, SDM-specific outcomes of encounters), recovery, satisfaction, knowledge, treatment/medication continuation, health service outcomes, and adverse outcomes.

Search methods

We ran searches in January 2020 in CENTRAL, MEDLINE, Embase, and PsycINFO (2009 to January 2020). We also searched trial registers and the bibliographies of relevant papers, and contacted authors of included studies.

We updated the searches in February 2022. When we identified studies as potentially relevant, we labelled these as studies awaiting classification.

Selection criteria

Randomised controlled trials (RCTs), including cluster-randomised controlled trials, of SDM interventions in people with mental health conditions (by Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD) criteria).

Data collection and analysis

We used standard methodological procedures expected by Cochrane. Two review authors independently screened citations for inclusion, extracted data, and assessed risk of bias. We used GRADE to assess the certainty of the evidence.

Main results

This updated review included 13 new studies, for a total of 15 RCTs. Most participants were adults with severe mental illnesses such as schizophrenia, depression, and bipolar disorder, in higher-income countries. None of the studies included children or adolescents.

Primary outcomes

We are uncertain whether SDM interventions improve clinical outcomes, such as psychiatric symptoms, depression, anxiety, and readmission, compared with control due to very low-certainty evidence.

For readmission, we conducted subgroup analysis between studies that used usual care and those that used cognitive training in the control group. There were no subgroup differences.

Regarding participation (by the person with the mental health condition) or level of involvement in the decision-making process, we are uncertain if SDM interventions improve observations on the process of SDM compared with no intervention due to very low-certainty evidence. On the other hand, SDM interventions may improve SDM-specific user-reported outcomes from encounters immediately after intervention compared with no intervention (standardised mean difference (SMD) 0.63, 95% confidence interval (CI) 0.26 to 1.01; 3 studies, 534 participants; low-certainty evidence). However, there was insufficient evidence for sustained participation or involvement in the decision-making processes.

Secondary outcomes

We are uncertain whether SDM interventions improve recovery compared with no intervention due to very low-certainty evidence.

We are uncertain if SDM interventions improve users' overall satisfaction. However, one study (241 participants) showed that SDM interventions probably improve some aspects of users' satisfaction with received information compared with no intervention: information given was rated as helpful (risk ratio (RR) 1.33, 95% CI 1.08 to 1.65); participants expressed a strong desire to receive information this way for other treatment decisions (RR 1.35, 95% CI 1.08 to 1.68); and strongly recommended the information be shared with others in this way (RR 1.32, 95% CI 1.11 to 1.58). The evidence was of moderate certainty for these outcomes. However, this same study reported there may be little or no effect on amount or clarity of information, while another small study reported there may be little or no change in carer satisfaction with the SDM intervention. The effects of healthcare professional satisfaction were mixed: SDM interventions may have little or no effect on healthcare professional satisfaction when measured continuously, but probably improve healthcare professional satisfaction when assessed categorically.

We are uncertain whether SDM interventions improve knowledge, treatment continuation assessed through clinic visits, medication continuation, carer participation, and the relationship between users and healthcare professionals because of very low-certainty evidence.

Regarding length of consultation, SDM interventions probably have little or no effect compared with no intervention (SDM 0.09, 95% CI -0.24 to 0.41; 2 studies, 282 participants; moderate-certainty evidence). On the other hand, we are uncertain whether SDM interventions improve length of hospital stay due to very low-certainty evidence.

There were no adverse effects on health outcomes and no other adverse events reported.

Authors' conclusions

This review update suggests that people exposed to SDM interventions may perceive greater levels of involvement immediately after an encounter compared with those in control groups. Moreover, SDM interventions probably have little or no effect on the length of consultations.

Overall we found that most evidence was of low or very low certainty, meaning there is a generally low level of certainty about the effects of SDM interventions based on the studies assembled thus far. There is a need for further research in this area.

PLAIN LANGUAGE SUMMARY

Shared decision-making interventions for people with mental health conditions

Shared decision-making interventions or care as usual: which works better for people with mental health conditions?

What are mental health conditions?

There are many mental health conditions. They are generally characterised by a combination of abnormal thoughts, perceptions, emotions, behaviour, and relationships with others. Access to health care and social services capable of providing treatment and social support is key.

What did we want to find out?

Shared decision-making is an approach to consumer-professional communication where both parties (e.g. patients or their carers, or both, together with their clinician) are acknowledged to bring equally important experience and expertise to the process. In this approach, both parties work in partnership to make treatment recommendations and decisions.

This approach is considered part of a broader recovery and person-centred movement within the behavioural health field. The focus on recovery and individual responsibility for understanding and managing symptoms in collaboration with professionals, caregivers, peers, and family members is also fundamental to this approach.

Sometimes it also involves a 'decision aid', such as videos, booklets, or online tools, presenting information about treatments, benefits and risks of different options, and identifying ways to make the decision that reflects what is most important to the person. The process of shared decision-making may often also involve decision coaching by someone who is non-directive and provides decision support that aims to prepare people for discussion and the decision in the encounter with their practitioner.

We wanted to find out if shared decision-making interventions were better than care as usual for people with mental health conditions to improve:

• clinical outcomes, such as psychotic symptoms, depression, anxiety, and readmission;

• participation or level of involvement in the decision-making process.

We also wanted to find out if shared decision-making interventions were associated with any unwanted (harmful) effects.

What did we do?

We searched for studies that examined shared decision-making interventions compared with care as usual in people with mental health conditions. We compared and summarised the results of the studies and rated our confidence in the evidence, based on factors such as study methods and sizes.

What did we find?

We found 15 studies involving 3141 adults, from seven countries: Germany, Italy, Japan, Saudi Arabia, the Netherlands, the UK, and the USA.

Care settings included primary care, community mental health services, outpatient psychiatric services, specialised outpatient services such as post-traumatic stress disorder clinics, forensic psychiatric services, and nursing home wards.

The mental health conditions studied were schizophrenia, depression, bipolar disorder, post-traumatic stress disorder, dementia, substance-related disorders and multiple clinical conditions, including personality disorder. Care providers included family carers, clinicians, case managers, nurses, pharmacists, and peer supporters. Three studies used an interprofessional collaboration.

When people with mental health conditions receive shared decision-making interventions, we do not know if their clinical conditions change. They may feel that they participated more in decision-making processes compared with those receiving usual care, although we are uncertain about this when participation was measured in other ways or at later time points after the consultation.

People who take this approach probably improve some, but not all, aspects of their satisfaction with received information compared with those receiving usual care.

Although it is often suggested that shared decision-making takes a lot of time, we found that there is probably little or no difference compared with usual care in the length of consultation.

We are uncertain about whether shared decision making-interventions change outcomes such as recovery, carer satisfaction, healthcare professional satisfaction, knowledge, treatment/medication continuation, carer participation, relationship with healthcare professionals, length of hospital stay, or possible harmful effects.

Further research is needed in this area. Longer term follow-up is also needed to better determine the impact of shared decision-making on: perceptions of quality of life; impact on frequency and severity of crises, hospitalisations, or both; stability of key functions of life, work, housing and overall health; and satisfaction with decision-making.

The review is up to date as of January 2020.

SUMMARY OF FINDINGS

Summary of findings 1. Shared decision-making interventions compared with usual care for people with mental health conditions

Shared decision-making interventions compared with usual care for people with mental health conditions

Patient or population: people with mental health conditions
Setting: various
Intervention: shared decision-making
Comparison: usual care, cognitive training, placebo session

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with usual care	Risk with SDM intervention				
Psychiatric symptoms Brief Psychiatric Rating Scale (BPRS; Overall 1988): 16 items with 7-item Likert scale ('not present' to 'extremely severe') measured 6 months after intervention (Yamaguchi 2017).		MD -1.10 lower (-5.54 lower to 3.34 higher)	-	53 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	Higher scores indicate more severe psychiatric symptoms; the results indicate little or no difference between groups. One further study that could not be pooled reported no statistically significant difference in PANSS scores between the groups when they were discharged from hospital (Hamann 2006).
Depression (1 to 6 months) Montgomery–Åsberg Depression Rating Scale (MADRS; Montgomery 1979): measured 3 months after intervention (Aljumah 2015). Patient Health Questionnaire-9 (PHQ-9; Kroenke 2001): measured 6 to 8 weeks after intervention (Loh 2007) or 3 months after intervention (LeBlanc 2015). Quick Inventory of Depressive Symptomatology Self-Report (QIDS-J; Rush 2003): mea-		SMD -0.03 lower (-0.17 lower to 0.12 higher)	-	717 (4 RCTs)	⊕⊕⊖⊖ Low[c,d]	Higher scores indicate more severe depression symptoms; the results indicate little or no difference between groups.

sured 3 months after intervention (Aoki 2019a).						
Depression (6 months or more) MADRS measured 6 months after intervention (Aljumah 2015). PHQ-9 measured 6 months after intervention (LeBlanc 2015). QIDS-J measured 6 months after intervention (Aoki 2019a). Hospital Anxiety and Depression Scale (HADS-D; Zigmond 1983) measured 6 months after intervention (Lovell 2018).		SMD 0.03 higher (-0.10 lower to 0.17 higher)	-	898 (4 RCTs)	⊕⊕⊖⊖ Low[c,d]	Higher scores indicate more severe depression symptoms; the results indicate little or no difference between groups.
Readmission (6 months or more) Rehospitalisation at 8 months after discharge (Hamann 2006) or 12 months after discharge (Hamann 2017).	Study population 362 per 1000[i]	384 per 1000 (279 to 529)	RR 1.06 (0.77 to 1.46)	249 (2 RCTs)	⊕⊖⊖⊖ Very low[c-e]	-
Participation (observations on the process of SDM) Observing Patient Involvement in shared decisiON-making (OPTION; Elwyn 2005) assessed from video recording on the encounter (LeBlanc 2015). Core components of SDM: scoring the transcripts of conversations between participants and doctors during consultation (SDM-18; Salyers 2012) during consultation (Yamaguchi 2017).		SMD 1.14 higher (0.63 higher to 1.66 higher)	-	133 (2 RCTs)	⊕⊖⊖⊖ Very low[c,f,g]	Higher scores indicate more involvement in decision-making; the results indicate an increase in involvement for the SDM group.
Participation (SDM-specific-reported outcomes, immediately after intervention)		SMD 0.63 higher (0.26 higher to 1.01 higher)	-	534 (3 RCTs)	⊕⊕⊖⊖ Low[c,h]	COMRADE, Man-Song-Hing Scale: higher scores indicate more involvement in decision-making;

Combined Outcome Measure for Risk Communication and Treatment Decision-making Effectiveness (COMRADE; Edwards 2003) measured immediately after decision-making (Aoki 2019a). Decisional Conflict Scale (DCS; O'Connor 1995a) measured immediately after the clinical encounter (LeBlanc 2015). Man-Song-Hing Scale (Man-Song-Hing 1999) measured after intervention (Loh 2007).					DCS: lower scores indicate less decisional conflict; the results indicate an increase in involvement for the SDM group. In one further study that could not be pooled, participants in the intervention group reported significantly greater perceived involvement than those in the control group (Hamann 2006).
Adverse events - not reported	There were no adverse effects reported.	-	-	-	-

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).
CI: confidence interval; **PANSS:** Positive and Negative Syndrome Scale; **RR:** risk ratio; **SDM:** shared decision-making

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded by one level: for risk of bias (high risk of bias for blinding of participants and outcome assessment)
[b]Downgraded by two levels: for imprecision (insufficient number of participants for one study and large confidence interval)
[c]Downgraded by one level: for indirectness (the outcome was measured using various approaches)
[d]Downgraded by one level: for imprecision (large confidence interval)
[e]Downgraded by two levels: for risk of bias (1 of 2 studies were at high risk of bias for randomisation and allocation concealment, and 2 of 2 studies were at high risk of bias for blinding of participants and outcome assessment)
[f]Downgraded by two levels: for imprecision (small sample size)
[g]Downgraded by one level: for risk of bias (2 of 2 studies were at high risk for blinding of participants and outcome assessment)
[h]Downgraded by one level: for inconsistency ($I^2 \geq 50\%$; P value for heterogeneity ≤ 0.05)
[i]Control event rate calculated from means of usual care groups used in this analysis (Hamann 2006; Hamann 2017)

BACKGROUND

Description of the condition

Mental health conditions

Mental health conditions comprise a wide range of problems, with different symptoms, including: neurodevelopmental disorders, schizophrenia spectrum and other psychotic disorders, bipolar and related disorders, depressive disorders, anxiety disorders, obsessive-compulsive and related disorders, trauma and stressor-related disorders, eating disorders, and personality disorders (APA 2013). A World Health Organization (WHO) survey estimated that 18.1% to 36.1% of the world's population suffer from a diagnosable mental health condition during their life course (Kessler 2007). Hence, mental health conditions are globally prevalent and have a devastating impact on the lives of the people who experience them, their families, and communities (Whiteford 2015; WHO 2017). Mental health conditions affect people's health and productivity both at home and in the workplace. This can lead to economic burdens for the person and their families. As more people experience mental health conditions, the more societal costs also rise. In Japan, the economic cost due to schizophrenia in 2008 has been estimated as 2.8 trillion Japanese yen (JPY) (USD 25.7 billion or USD 25,700 million) (Sado 2013), and depression in 2005 was JPY 2 trillion (USD 18 billion or USD 18,000 million) (Sado 2011). In Europe, the societal costs due to brain disorders, including mental health conditions, was estimated to be 800 billion euros (EUR) (USD 1 trillion or USD 1,000,000 million) a year, more than cancer, cardiovascular disease, and diabetes put together (Smith 2011). Moreover, the relative share and impact of the health burden caused by mental health conditions is increased due to stigma and lack of adequate support for treatment or care (Rehm 2019). Most notably, many low-income countries invest less than 1% of their health budgets in mental health services (WHO 2015). Given this situation, WHO has a comprehensive mental health action plan (2013-2020) under the catchphrase "no health without mental health" (Saxena 2013). Thus, mental health conditions are a worldwide health priority topic.

The recovery movement

The treatment of people with mental health conditions has evolved towards more comprehensive care in this century, where people are recognised as being at the centre, and health improvement is viewed in terms of *recovery*, rather than simply symptom relief. Recovery is a way of living a meaningful life even with limitations caused by mental illness, accepting and overcoming the challenge of the disability (Deegan 1988; Anthony 1993). Recovery is not a uniform process but varies from person to person. Recently, the term 'personal recovery' has been widely used to describe patient-based recovery, which consists of elements such as re-establishment of identity, finding meaning in life, empowerment, and taking responsibility for recovery (Van Eck 2018). The recovery process emphasises control being placed in the hands of the individual and not the professional (Jacobson 2001). In this regard, recovery-oriented mental health care requires greater emphasis on the collaborative nature of interactions among health professionals, people with mental health conditions and their families (Duncan 2010). This concept has now been adopted at a national policy level in many Western countries (Perkin 2012; Van Hoof 2015; National Alliance on Mental Illness 2016), and has extended to Asian and African countries (Stein 2014; Singh 2015).

Shared decision-making

The dominant paradigms in modern health care today are those of evidence-based and person-centred care. Thus, medical decision-making has moved away from traditional, paternalistic approaches, where physicians drive the decision-making process (Charles 1997). Increasingly, shared decision-making (SDM) is advocated as an ideal model of treatment decision-making in various medical fields, including mental health (Storm 2013). Charles and colleagues proposed an SDM model that encapsulates the most widely recognised core features (Charles 1997):

- at least two participants - physician and patient - are involved;
- both parties share information;
- both parties take steps to build a consensus about the preferred treatment (that is, both participate in the decision-making process); and
- an agreement is reached on the treatment to implement (that is, a decision is made or is actively deferred).

Shared decision-making emphasises the involvement of both parties in the collaborative process of understanding and deliberating the best available evidence about the risks and benefits across all available options, while ensuring that the patient's values and preferences are fully clarified (Charles 1997; Elwyn 1999; Towle 1999). Shared decision-making is an ethical imperative (Drake 2009; Elwyn 2017), and has been gaining support as a key principle of the delivery of person-centred care (Barry 2012). Especially in the mental health field, it is a central part of the recovery paradigm described above, which derives from the patient's right to autonomy and self-determination (Storm 2013; Slade 2017).

Makoul and Clayman conducted a systematic review of 161 articles that specifically addressed SDM in health care to determine the range of conceptual definitions (Makoul 2006). They proposed nine essential elements as an *integrative model of SDM* during consultations with patients (Makoul 2006):

- define and explain the healthcare problem;
- present options;
- discuss pros and cons (benefits, risks, costs);
- clarify patient values and preferences;
- discuss patient ability and self-efficacy;
- present what is known and make recommendations;
- check and clarify the patient's understanding;
- make or explicitly defer a decision; and
- arrange follow-up.

Accordingly, for a decision to be a truly 'shared' decision it must have certain characteristics. It must involve at least two participants, and the sharing of information. The decision (which may be to do nothing) must be made and agreed upon by all parties (Charles 1997). Once a decision is made, there must be opportunities to review the decision (Edwards 2005).

Unsurprisingly, SDM does not mean the same thing in all cases. Trevena and Barratt proposed that the suitability of a decision for SDM depends upon the clinical context, patient preferences, and practitioner responsibilities (Trevena 2003). Kon suggested that SDM can best be understood as a continuum, at one end of which

is patient-driven decision-making, at the opposite is physician-driven decision-making, and in the middle are many possible SDM approaches (Kon 2010).

Montori and colleagues examined the Charles 1997 SDM model in relation to long-term conditions (Montori 2017). They concluded that for SDM to work in these conditions, it was necessary to add another component to the model: ongoing partnership between the clinical team (not just the clinician) and the patient (Montori 2017). SDM often evolves over multiple encounters because decision-making is never just a single event or activity but rather is distributed over a range of people and times or episodes (Rapley 2008). Furthermore, especially in the public sector, SDM requires the active involvement of other parties, such as family members (Aoki 2019b) or peer-support staff (Goscha 2015). In the case of long-term conditions, 'planning' may be as much a feature as actually making decisions (Joseph-Williams 2019).

Description of the intervention

This review is an update of an existing review of SDM for people with diagnosable mental health conditions published in 2010 (Duncan 2010), which included two cluster-randomised trials. One was an SDM intervention for inpatients with schizophrenia, which consisted of a decision aid, decision support by nurses, and planning talk with their physicians (Hamann 2006). The other SDM intervention was for primary care patients with depression using a decision board during consultation with physicians (Loh 2007). To our knowledge, several articles about SDM interventions in mental health settings which could be incorporated into the updated version of the review had been reported since 2010 (Hamann 2011; Aljumah 2015; LeBlanc 2015). We have therefore identified an increasing number of recent trials in this area and have used these to inform the features of the interventions to be included in this review update.

We also recognise in this update that chronic or long-term conditions require treatment decision-making but that collaborative goal setting (between individual patients and clinicians) and action planning are also important (Coulter 2015).

Interventions eligible for inclusion in this review therefore include:

- psychiatric ward-based interventions for inpatients with mental health conditions, such as sharing treatment decision-making between patient and clinician, perhaps also using decision support tools, or sharing ‘care planning’ between the patient and the interprofessional team as a role in decision coaching;
- primary care-based interventions for newly diagnosed or regular outpatients with mental disorders, such as sharing treatment decision-making during initial or routine consultations, perhaps also using decision support tools, or sharing care planning between service users and their interprofessional team and/or peer support staff as a role in decision coaching; and
- community-based interventions, such as sharing care planning using telecommunication tools, web-based tools, or home-visiting care services.

In addition, studies of SDM educational or training programmes have been reported in recent years (Hamann 2011; Hamann 2017). Therefore, eligible interventions also include:

- SDM educational or training programmes targeting patients or healthcare professionals, or both, in psychiatric ward-based, primary-care based, or community-care based settings.

In this review update, we identify three overarching categories of intervention implementation in the context of both SDM interventions and interventions based on SDM educational or training programmes:

- interventions targeting patients or carers such as family members, or both;
- interventions targeting healthcare professionals; and
- interventions targeting both.

Regarding patients, although the original review included only people with severe mental illnesses (schizophrenia and depression), despite no diagnostic restrictions (Duncan 2010), recent trials seem to include not only people with severe mental illnesses, such as schizophrenia, bipolar disorder, and depression, but also other mental illnesses such as neurodevelopmental disorder, anxiety disorder, personality disorder, and post-traumatic stress disorder (Woltmann 2011; Westermann 2013; Metz 2018).

In short, as described above, there are several types of environmental settings, various types of interventions, and different diagnoses in this area. This situation allowed us to plan to conduct subgroup analyses for environmental setting, intervention types, participant diagnosis, and intervention elements as potential effect modifiers.

The main comparison sought for this review was between SDM interventions and usual care or control groups, which do not explicitly intend to involve patients. So far, we have found no adverse effects of SDM interventions in the mental health field, but the review sought to identify any harms reported by included studies.

How the intervention might work

Shared decision-making includes collaboration and deliberation between patients and healthcare professionals, leading to well-informed, preference-based patient decisions and more cost-effective health care. This, in turn, results in improved health outcomes (Elwyn 2016).

Information exchange during consultation is a central element of the identified SDM studies in various medical fields (Légaré 2018). There are also additional important elements, other than information exchange, such as sufficient rapport and trusting relationships between patient and healthcare professional in interventions of SDM in mental health (Zisman-Ilani 2017; Aoki 2020). Shared decision-making in mental health can foster and strengthen a therapeutic relationship between patient and healthcare professional, developing empathy, genuineness, trust, and mutual understanding between two parties (Corrigan 2012; Aoki 2020).

Moreover, in the SDM model, people can challenge existing barriers associated with mental health conditions, such as abuse of power, power asymmetry, assumptions of decisional incapacity, and stigma, while empowering patients through the decision-making process (James 2017; Aoki 2020). Contrary to conventional assumptions of cognitive dysfunction, there is evidence that most

people who access mental health services want to be involved in decisions about their care (Patel 2010; De las Cuevas 2012; Park 2014).

Shared decision-making interventions in mental health seem to have an effect on both patients and healthcare professionals. For example, for patient outcomes, some trials indicate that SDM can have an impact on affective-cognitive outcomes, such as knowledge, satisfaction, decision conflict, responsibility in decision-making, beliefs towards treatment (Woltmann 2011; LeBlanc 2015; Ishii 2017), and behavioural outcomes, such as participation in decision-making and communication improvements (Yamaguchi 2017; Aoki 2019a).

Shared decision-making interventions can also change the behaviour of healthcare professionals to facilitate a patient's active engagement in decision-making during the consultation (Hamann 2011; Aoki 2020).

From a few trials, limited evidence suggests that SDM for people with mental health conditions may be able to improve long-term outcomes, such as medication adherence, treatment adherence, and clinical symptoms (Aljumah 2015). This is largely centred around engagement with psychopharmacology, and the idea that SDM may be able to improve concordance between the expectations of patients and healthcare professionals (McKinnon 2014).

Why it is important to do this review

The original review included only two eligible studies: one undertaken in inpatients with schizophrenia and the other in outpatients newly diagnosed with depression. No definite conclusions could be drawn (Duncan 2010). However, recent further empirical evidence about SDM interventions in mental health warranted an update of the original review.

Shared decision-making as a high-priority interest in mental health care

Patient participation in treatment decision-making has become a high priority in mental health care systems in recent years around the world (Thompson 2007). In many countries, mental health clinicians and policy makers advocate shared decision-making as an important component of national mental health policies (Härter 2017).

Shared decision-making is not only an ideal; it is also essential to focus on its effectiveness and implementation in practice (Adshead 2018). For example, guidance from the National Institute for Health and Care Excellence (NICE, UK) recommends that healthcare professionals should involve people with mental health conditions in decisions about prescribed medicines (NICE 2009; NICE 2015). World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for biological treatment of schizophrenia also specify that the goals of long-term treatment have to be discussed with the patient and, if she/he agrees, with family members, relatives, carers and, in some cases, advocates, with the aims of providing adequate information and understanding the patient's personal goals (Hasan 2013).

Moreover, the cost-effectiveness of SDM in mental health care has been drawing increasing attention. Cosh and colleagues have argued that SDM could reduce medical care costs by reducing admissions of inpatients with severe mental illness (Cosh 2017). This approach may also decrease the costs associated with the use of unnecessary, or unwanted, prescriptions (Latimer 2011; De las Cuevas 2012).

Originality of this review update

There are some systematic and narrative reviews related to this topic. A review and synthesis by James and Quirk identified a "rationale for SDM" as any argument or reason for SDM in mental health care outlined by authors in a journal paper and which described the rationales of SDM (James 2017). Their review excluded raw data or findings from experimental trials. Therefore, they did not draw conclusions on the effects of SDM interventions in mental health settings. A review by Zisman-Ilani and colleagues indicated unique elements of SDM in mental health, such as facilitating patient motivation and providing patient communication skills training, which were rarely seen in other medical fields (Zisman-Ilani 2017). However, this review was also descriptive and did not attempt statistical synthesis of the outcomes nor draw conclusions about effectiveness.

Stovell and colleagues conducted a systematic review of shared treatment decision-making for psychosis, which identified 11 RCTs and showed small beneficial effects on indices of treatment-related empowerment (Stovell 2016). However, given its focus on treatment decisions concerning psychosis, this review did not consider other mental health conditions and rehabilitation or care plan decisions beyond medical treatments.

As described above, an increasing number of systematic reviews of studies of SDM interventions have been reported in the mental health field thus far. However, there are few reviews examining the effects of SDM interventions on different types of decisions regarding treatment and care and addressing the broad range of mental health conditions since the original review conducted in 2010 (Duncan 2010).

In 2010, Légaré and colleagues first published a Cochrane Review entitled "Interventions for increasing the use of shared decision-making by healthcare professionals" and have updated it periodically (Légaré 2018). The review has not restricted the 'types of participants' to any specific health condition; instead, it has targeted a broad range of conditions. As the review title indicates, Légaré and colleagues have focused on interventions aimed at improving uptake of SDM by healthcare professionals, with a primary focus on how well this is adopted in practice (Légaré 2018). Légaré and colleagues have focused on healthcare professionals, whereas this review update focuses on service users and their carers, as well as healthcare professionals. Thus, this review has updated the available evidence for SDM in mental health settings and allowed us to conduct wider searches of the psychiatric and mental health literature to find additional studies and to focus on crucial psychiatric-specific outcomes, which are not covered in the Légaré 2018 review. It is particularly important to focus on clinical symptoms (e.g. severity of psychotic symptoms), stages of recovery, and treatment/medication continuation because such outcomes form a link with personal recovery for people with mental health conditions.

For this review update, we also carefully considered recent research on outcome measurement tools used for assessing the effects of SDM interventions in the mental health field. Perestelo-

Perez and colleagues reviewed existing instruments used in SDM-related studies in mental health (Perestelo-Perez 2017b). The review revealed that there are three types of measurements: SDM antecedent measurements, such as the Autonomy Preference Index and Control Preference Scale (API, Ende 1989; CPS, Denger 1992); SDM process measurements, such as Observation Patient Involvement in Decision-Making (OPTION, Edwards 2003; Edwards 2005; Elwyn 2013) and Shared Decision-Making Questionnaire-9 (SDM-Q-9, Kriston 2010); and SDM outcome measurements, such as the Decisional Conflict Scale and the Decision Regret Scale (DCS, O'Connor 1995a; DRS, Brehaut 2003). Information about the measurements used in previous trials informed our planning and decisions about which outcomes to assess in this review update.

It is over 10 years since the original Duncan 2010 review was published. Due to the growth of trials in this area, and a lack of systematic reviews with the same focus, an update of the systematic review is timely.

OBJECTIVES

To assess the effects of SDM interventions for people of all ages with mental health conditions, directed at people with mental health conditions, carers, or healthcare professionals, on a range of outcomes including: clinical outcomes, participation/involvement in decision-making process (observations on the process of SDM; user-reported, SDM-specific outcomes of encounters), recovery, satisfaction, knowledge, treatment/medication continuation, health service outcomes, and adverse outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) and cluster-RCTs (trials in which groups of participants are randomised). Although the original review's inclusion criteria allowed for controlled before-and-after (CBA) studies, interrupted time series (ITS) studies, and quasi-RCTs, these study designs are at greater risk of bias than RCTs or cluster-RCTs in evaluating the effectiveness of the interventions. Furthermore, we were aware that more literature in this area existed for this update, rather than only the two eligible studies identified in the original 2010 review. Therefore, we excluded study designs other than RCTs and cluster-RCTs.

Types of participants

The people receiving the healthcare service within studies were those diagnosed with a mental health condition by any defined criteria, such as the International Classification of Diseases (ICD) (WHO 1992; WHO 2018), or the Diagnostic and Statistical Manual of Mental Disorders (DSM) (APA 2000; APA 2013). We included studies enrolling individuals of all ages. We included both public and private healthcare patients. We excluded simulated patients and those without any psychiatric diagnosis. We also excluded people who were making hypothetical decisions or advanced directive decisions.

The participants (those receiving the intervention) were people with mental health conditions or service users, informal carers such as family members, or healthcare professionals for people with mental health conditions (including general practitioners, psychiatrists, psychologists, nurses, social workers, occupational therapists, other allied health professionals, and lay support staff including peer support staff).

Types of interventions

The descriptions of the interventions were consistent with the SDM definition articulated by Charles 1997:

- at least two participants, patient and physician, should be involved;
- both parties share information;
- both parties take steps to build a consensus about the preferred treatment; and
- an agreement is reached on the treatment to implement.

Therefore, we included any intervention which:

- met the four criteria identified by Charles 1997, above; and/or
- consisted of SDM educational or training programmes targeted at people with mental health conditions (such as training in asking questions, discussion, clarifying own preferences, and reaching a decision) or healthcare professionals (such as training in problem definition, presenting options, communication skills, providing recommendations based on their expertise and previous experiences, and reaching a consensus), or both.

We excluded any intervention which:

- did not meet the Charles 1997 criteria;
- made the SDM element a secondary focus of the intervention (e.g. anxiety management);
- consisted solely of information provided to people with mental health conditions about a condition (e.g. patient education without the two-way sharing of information necessary for SDM);
- aimed at enhancing communication between people with mental health conditions and healthcare professional, without focusing on a particular choice or decision;
- targeted future care; that is, advanced directives - also known as Ulysses contracts - that set out how a person who is periodically mentally unwell wishes to be treated at those times; or
- consisted exclusively of decision support interventions, such as decision coaching, patient decision aids, and question prompt sheets, and did not meet the Charles 1997 criteria.

We included interventions with decision support, such as decision coaching, patient decision aids, and question prompt sheets, if this formed a part of SDM.

Interventions took place in any care setting and were not restricted by the mode or intensity of delivery.

Included studies assessed a single intervention or a combination of interventions, and compared them with another type of intervention, with usual or standard care, or with no intervention.

Types of outcome measures

We have made changes from the original review for several outcomes. First, for the primary outcome, the level of patient involvement replaced satisfaction because patient involvement in decision-making is crucial in the SDM process. In addition, since

the concept of recovery has been gaining attention in this area in recent years, we decided to adopt recovery as one of the secondary outcomes in this review. We describe the primary and secondary outcomes below.

Primary outcomes

Clinical outcomes assessed using measurement tools such as psychiatric scales, depression scales, and anxiety scales

- Psychiatric symptoms (for severe mental health conditions; e.g. Brief Psychiatric Rating Scale (BPRS; Overall 1988); Positive and Negative Syndrome Scale (PANSS; Kay 1988); or 48-item Symptom Questionnaire (SQ-48; Carlier 2012))
- Depression (e.g. the Hospital Anxiety and Depression Scale (HADS; Zigmond 1983); Montgomery–Åsberg Depression Rating Scale (MADRS; Montgomery 1979); Beck Depression Inventory (BDI II; Beck 1996); or Patient Health Questionnaire-9 (PHQ-9; Kroenke 2001))
- Anxiety (e.g. State-Trait Anxiety Inventory (STAI; Spielberger 1983); or Hospital Anxiety and Depression Scale (HADS-A; Zigmond 1983))
- Readmission rates

Participation (by the person with the mental health condition) or level of involvement in the decision-making process

- Observations on the process of SDM (e.g. Observing Patient Involvement in Decision-Making Scale for measuring patient involvement: OPTION (Elwyn 2003; Elwyn 2005); OPTION 5 Item (Elwyn 2013); Coding System to Measure Elements of Shared Decision-Making During Psychiatric Visits (Salyers 2012))
- Shared decision-making-specific user-reported outcomes from encounters (e.g. Client Decision Conflict Scale (DCS; O'Connor 1995a); decision regret scale (DRS; Brehaut 2003); the 9-item Shared Decision-Making Questionnaire (SDMQ-9; Kriston 2010); Combined Outcome Measure for Risk Communication and Treatment Decision-Making (COMRADE; Edwards 2003); Clinical Decision-Making Involvement and Satisfaction (CDIS-P Involvement subscale; Slade 2014); Control Preferences Scale (CPS; Denger 1992); or Evaluating and Quantifying User and Carer Involvement in Mental Health Care Planning Patient-Reported Outcome Measure (EQUIP ROPM; Bee 2016))

Assessing effects on clinical outcomes can be challenging because the effects of SDM interventions can depend on which treatment option is chosen. However, individuals wish not only to be involved in decision-making but for their symptoms to improve, and this review therefore regards clinical outcomes as key outcomes alongside those measuring the degree of involvement in decision-making.

Secondary outcomes

Recovery

e.g. Recovery Assessment Scale (Corrigan 2004); Developing Recovery Enhancing Environments Measure (DREEM; Ridgway 2004); Stages of Recovery Instrument (STORI; Andresen 2006); or Self-Identified Stage of Recovery Parts A and B (SISR-A and B; Andresen 2006)

Satisfaction

- Overall satisfaction (with care) of person with mental health condition (e.g. Client Satisfaction Questionnaire-8 (CSQ-8; Attkisson 1982); Verona Service Satisfaction Scale (VSSS; Ruggeri 1993))
- Users' satisfaction concerning decision-making (e.g. the satisfaction with decision scale (Holmes-Rovner 1996); or Clinical Decision-Making Involvement and Satisfaction (CDIS-P Satisfaction subscale; Slade 2014))
- Users' satisfaction with received information
- Carer satisfaction (e.g. Carer satisfaction measured via the Carers and Users' Expectations of Services—carer version (CUES-C; Lelliott 2003))
- Healthcare professional satisfaction

Knowledge

e.g. Patient/carer knowledge about disease, condition, or treatment options, provider knowledge

Treatment or medication continuation

e.g. Morisky Medication Adherence (MMAS; Morisky 1986; Morisky 2008)

Relationship or interaction between service users and health professionals

e.g. therapeutic alliance, concordance

Health service use outcomes

e.g. resource use; length of consultation; costs

Adverse outcomes

Any potential harms associated with interventions, including potential worsening of mental health condition

Timing of outcome assessment

We included all time points of outcome assessment in this review. We prespecified three categories: short-term (until one month after decision-making), medium-term (one to six months after), and long-term time points (six months or more), if applicable.

Main outcomes for the summary of findings tables

We reported the following outcomes in the summary of findings tables:

- clinical outcomes, such as psychiatric scales and depression scales;
- participation or involvement during the SDM process; and
- adverse outcomes associated with interventions.

Search methods for identification of studies

We:

- searched electronic bibliographic databases for published work;
- searched trial registers and contacted authors for information on ongoing and recently completed studies;
- searched the reference lists of relevant published studies; and
- contacted authors of relevant studies to check for additional studies.

There were no language restrictions.

Electronic searches

We used an explicit search strategy, developed in collaboration with the Cochrane Consumer and Communication Group, to search the following bibliographic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL, the latest issue) in the Cochrane Library (2009 to 13 January 2020);
- MEDLINE (OvidSP) (2009 to 14 January 2020);
- Embase (OvidSP) (2009 to 14 January 2020); and
- PsycINFO (OvidSP) (2009 to 14 January 2020).

We structured the search strategy according to a study design filter, mental illness search terms (based on advice from the Cochrane Common Mental Disorders Group), and shared decision-making terms (Makoul 2006).

We updated and re-ran the searches in February 2022.

We present the search strategy for CENTRAL in Appendix 1; Embase in Appendix 2; MEDLINE in Appendix 3; and PsycINFO in Appendix 4.

Searching other resources

We searched online trial registers for ongoing and recently completed studies using the following databases with the terms (shared decision-making) OR SDM | psychiatry OR psychiatric OR psychology OR psychologic:

- ClinicalTrials.gov, US National Institutes of Health (NIH) at clinicaltrials.gov/ (all dates);
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) at apps.who.int/trialsearch/ (all dates); and
- Web of Science (all dates).

We also searched reference lists of included studies and relevant systematic reviews, and primary studies.

Data collection and analysis

Selection of studies

We used the Cochrane RCT Classifier, which classifies records into two groups: 1) records with a low probability of being RCTs; and 2) records that have a high probability of being RCTs.

For the records with a low probability of being RCTs, one review author (TU) screened all titles and abstracts and confirmed that there were no RCTs.

For the records with a high probability of being RCTs, two review authors (YA, YY or MS, LS) independently screened all titles and abstracts to determine which studies met the inclusion criteria.

We retrieved in full text any papers identified as potentially relevant by at least one review author. Two review authors (YA, YY or MS, LS) independently screened full-text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting a third review author (TU or AE), if necessary, to reach consensus. We listed as excluded studies all the potentially relevant papers excluded from the review at this stage, with reasons provided.

We also provided citation details and any available information about ongoing studies. We collated and reported details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review.

On 8 February 2022, we updated the searches. We searched references since January 2020 using the same bibliographic databases and resources described above. We also used the Cochrane RCT Classifier.

One review author (YY) screened all titles and abstracts for the records with a low probability of being RCTs, according to the RCT Classifier, and confirmed that there were no RCTs.

Two review authors (YA, UT) screened all titles and abstracts for the records that had a high probability of being RCTs. We retrieved in full text any papers identified as potentially relevant by at least one review author. Two review authors (YA, UT) independently screened full-text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting a third author (YY) if necessary, to reach consensus. All potentially-relevant papers excluded from the review at this stage were listed as excluded studies, with reasons provided.

We then listed the studies which met the inclusion criteria as studies awaiting classification.

We also provided citation details and any available information about ongoing studies. We collated and reported details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review.

We reported the screening and selection process in an adapted PRISMA flow chart (Liberati 2009).

Data extraction and management

Two review author pairs (YA, YY or MS, LS) independently extracted data from included studies. For any studies involving the review authors, different members of the review author team assessed and extracted data from those studies. We resolved any discrepancies through discussion until consensus was reached, or through consultation with a third review author (TU or AE), where necessary. We developed and piloted a data extraction form using the Cochrane Consumers and Communication Review Group Data Extraction Template (available at: cccrg.cochrane.org/author-resources). We pilot tested the data extraction form with the first five included studies and refined it as necessary.

We extracted the following study data.

- General information: title, source, publication date, country, language, author contact details, study design, aim, number of arms, consumer involvement, if informed consent was obtained, whether ethical approval was obtained.
- Characteristics of participants: description of participants, geographic location, setting, methods of recruitment of participants, inclusion/exclusion criteria for participation in study, age (range, mean (standard deviation)), gender, ethnicity, principal diagnosis, other health problem/s, severity of illness, treatment receiving.
- Characteristics of interventions: intervention description, whether SDM criteria were completely met (Charles 1997), aims of intervention, what was done, who delivered intervention,

where/when/how often/how much was intervention provided, how people with mental health conditions accessed the intervention; whether the intervention was tailored/modified, how well the intervention was delivered.

- Characteristics of outcomes and comparison groups: method of assessing outcome measures, method of follow-up of non-respondents, and timing of outcome assessment; loss-to-follow-up rates, and characteristics of those lost to follow-up. When two or more relevant measures were reported for each outcome, the scale of the validated assessment tool was chosen in the pooled statistical analysis.
- Data and results: timing of outcome assessment, observed/total number (for dichotomous outcomes), mean change/standard deviation/number (for continuous outcomes), whether validated assessment tools were used.
- Assessment of risk of bias: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, other sources of bias (e.g. baseline differences).
- Funding source: details of the funding source, declaration of interests for the primary investigators.

One review author (YA) entered all extracted data into Review Manager 5 (RevMan 5) (Review Manager 2014). A second review (YY) author, working independently, checked for accuracy against the data extraction sheets. We contacted authors of individual studies to ask for additional information if required.

Assessment of risk of bias in included studies

We assessed and reported on the methodological risk of bias of included studies in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2019), which recommends the explicit reporting of the following: individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; and other sources of bias, such as baseline comparability.

We considered blinding separately for different outcomes where appropriate (for example, blinding may have the potential to differently affect subjective versus objective outcome measures).

For cluster-RCTs, we assessed the adequacy of adjustment for clustering, and assessed and reported the risk of bias associated with an additional domain: selective recruitment of cluster participants.

We judged each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provided a quote from the study report and a justification for our judgement for each item in the risk of bias table.

We deemed studies to be at the highest risk of bias if we scored them as at high or unclear risk of bias for either the sequence generation or allocation concealment domains, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011).

In all cases, two review authors independently assessed the risk of bias of included studies (YA, YY or MS, LS), with any disagreements resolved by discussion to reach consensus. We contacted study authors for additional information about the included studies, or for clarification of the study methods, as required.

We incorporated the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the domains, leading to an overall assessment of the risk of bias of included studies and a judgment about the internal validity of the review's results.

Measures of treatment effect

For dichotomous outcomes, we analysed data based on the number of events and the number of people assessed in the intervention and comparison groups. We used these to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we analysed data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD was reported without individual group data, we used this to report the study results. If more than one study measured the same outcome using different tools, we calculated the standardised mean difference (SMD) and 95% CI using the inverse variance method in Review Manager 5.

Unit of analysis issues

For cluster-RCTs, we checked for unit-of-analysis errors. If errors were found, and sufficient information was available, we reanalysed the data using the appropriate unit of analysis, by taking account of the intra-cluster correlation (ICC). We obtained estimates of the ICC by contacting authors of included studies or imputed them using estimates from external sources. If it was not possible to obtain sufficient information to reanalyse the data, we reported only the point estimate, and identified those studies as being high risk for 'other' bias based on the 'unit-of-analysis error'.

Dealing with missing data

We contacted study authors to obtain missing data (participant, outcome, or summary data). For participant data, where possible, we conducted analysis on an intention-to-treat basis; otherwise, we analysed data as reported. We reported on the levels of loss to follow-up and assessed this as a source of potential bias. For missing outcome or summary data, we imputed missing data where possible and reported any assumptions in the review.

Assessment of heterogeneity

Where studies were considered similar enough (based on consideration of populations, interventions, and other factors) to allow pooling of data using meta-analysis, we assessed the degree of heterogeneity by visual inspection of forest plots and by examining the Chi^2 test for heterogeneity. A significance level of P = 0.1 was used in view of the low power of such tests.

We reported our reasons for deciding that studies were similar enough to pool statistically. We quantified heterogeneity using the I^2 statistic. We considered an I^2 value of 50% or more to represent substantial levels of heterogeneity, but we interpreted this value in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi^2 test (Higgins 2011). Where heterogeneity was present in pooled

effect estimates, we explored possible reasons for variability by conducting subgroup analyses.

Where we detected substantial clinical, methodological, or statistical heterogeneity across included studies, we did not report pooled results from meta-analysis but instead tried to use a narrative approach to data synthesis. In this event, we reported our reasons for deciding that studies were too dissimilar to meta-analyse. We also explored possible clinical or methodological reasons for this variation by grouping studies that were similar in terms of populations, intervention features, methodological features, or other factors, to explore differences in intervention effects.

Assessment of reporting biases

We assessed reporting bias qualitatively based on the characteristics of the included studies (e.g. if only small studies indicating positive findings were identified for inclusion), or if information that we obtained from contacting experts and authors of studies suggested that there were relevant unpublished studies. If we could identify sufficient studies for inclusion in the review, we planned to construct a funnel plot to investigate small study effects, which can indicate the presence of publication bias. We planned to test for funnel plot asymmetry, with the choice of test made based on advice in Higgins 2011, and bearing in mind that there may be several reasons for funnel plot asymmetry when interpreting the results. However, we did not include sufficient studies to construct a funnel plot.

Data synthesis

We assessed suitability for meta-analysis based upon whether the interventions in the included trials were similar enough in terms of participants, settings, intervention, comparison, and outcome measures to ensure meaningful conclusions from a statistically pooled result (see Assessment of heterogeneity). Due to the anticipated variability in the populations and interventions, and possibly other factors, of included studies, we used a random-effects model for meta-analysis.

When we were unable to pool the data statistically using meta-analysis, we provided clear reasons for this decision, and conducted a narrative synthesis of results.

We planned to explore the main comparisons of the review as follows: intervention versus no intervention; intervention versus usual care; and one form of intervention versus another. However, the majority of studies were 'intervention versus usual care'. The exceptions were two studies that compared SDM interventions with cognitive training (Hamann 2011; Hamann 2017), and one study that included a placebo attention control comparison group (Mott 2014). We therefore analysed studies together but conducted subgroup analysis of SDM versus usual care and SDM versus cognitive training for the primary outcomes.

We planned to analyse the effects of interventions from studies comparing more than one intervention separately against the control, but no studies compared multiple interventions.

Subgroup analysis and investigation of heterogeneity

The potential subgroups for analysis included:

- care setting (inpatient, outpatient, primary care, community secure environment);
- types of intervention target population (directed to people with mental health conditions (and children versus older persons with mental health conditions), health professional, carers such as family members);
- mental illness severity of people with mental health conditions (severe mental illness including schizophrenia, bipolar disorder, and depression versus non-severe mental illness);
- intervention types (SDM with or without decision support tools versus none, SDM training to health professionals or people with mental health conditions /carers).

If substantial heterogeneity was found, we determined potential reasons for heterogeneity by examining individual study characteristics and those of subgroups of the main body of evidence.

Sensitivity analysis

We conducted a sensitivity analysis on the risk of bias assessment, comparing the results of studies at higher and lower risk of bias. In these cases, we removed lower-certainty studies (high overall risk of bias) from the analysis and examined how robust the results were when based only on higher-certainty studies (overall low risk of bias or some concerns).

Summary of findings and assessment of the certainty of the evidence

We developed a summary of findings table to present the results of the meta-analysis or narrative synthesis, or both, for the primary outcomes, including potential harms. We provided a source and rationale for each assumed risk cited in the table, and used the GRADE criteria to rank the certainty of the evidence based on the methods described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions*, using the GRADEprofiler (GRADEpro) software (Schünemann 2011). We ranked the certainty of the evidence for each outcome, downgrading the rating if one or more of the following criteria were present: risk of bias, inconsistency, imprecision of the observed effect, indirect evidence, and publication bias. We used footnotes to justify our decisions to downgrade the certainty of the evidence to aid the reader's understanding of the review.

Two review authors independently assessed each outcome against the GRADE criteria.

Where meta-analysis was not possible, or possible for only some data for an outcome, we presented these findings descriptively alongside any pooled effect estimates from meta-analysis.

No review authors selected, extracted data, or appraised the risk of bias for the study on which they were an author (Aoki 2019a). Members of the review author team other than YA, TY, and KW (authors on the Aoki 2019a trial) led the GRADE ratings for assessment of overall certainty of evidence for each outcome.

RESULTS

Description of studies

See: Included studies; Studies awaiting classification; Ongoing studies

Results of the search

We conducted the initial database searches on 14 January 2020.

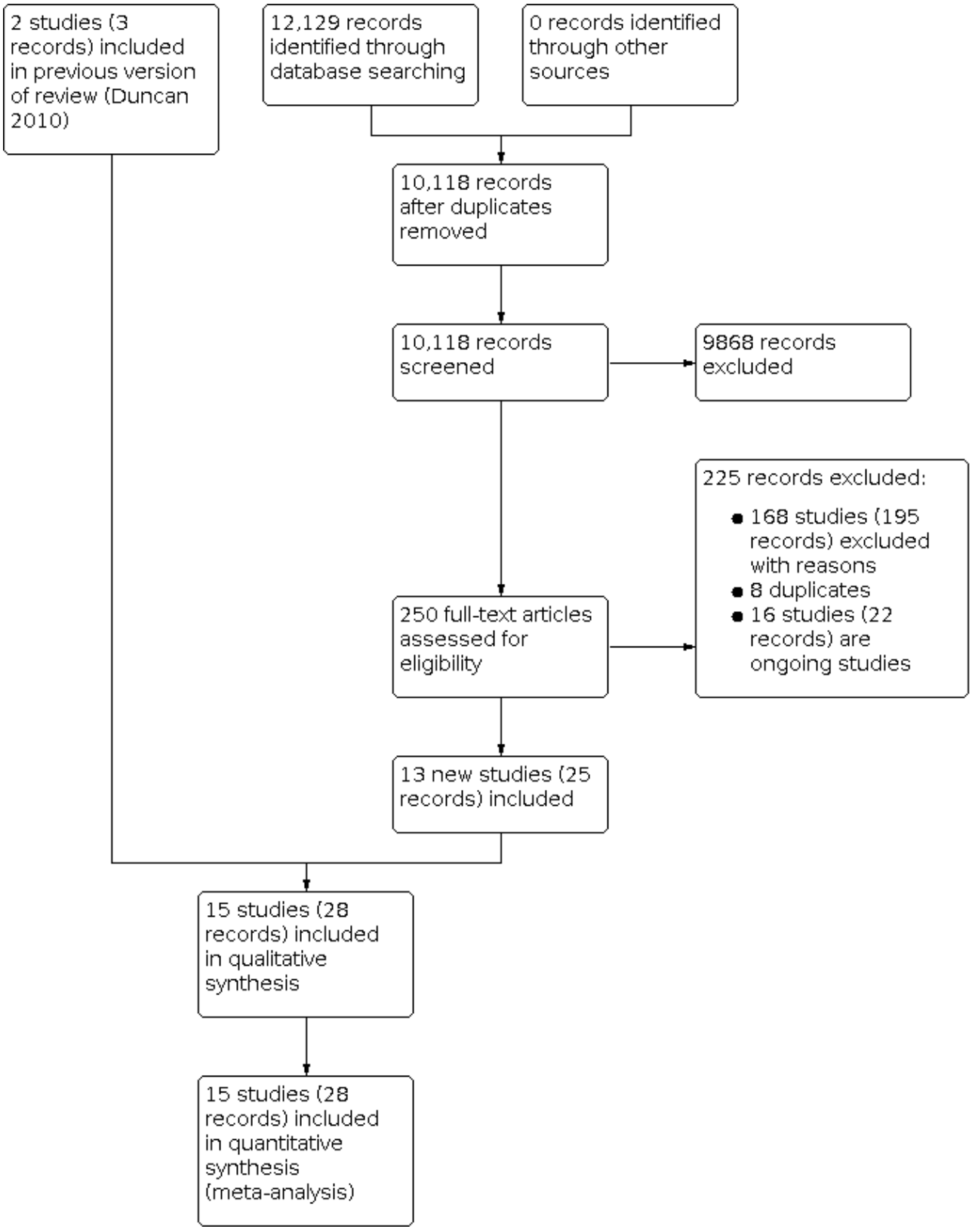
We generated 10,118 references (6935 references from MEDLINE, Embase, PsychINFO, and Web of Science plus 3183 references from CENTRAL, ClinicalTrials.gov, and WHO ICTRP) after removing duplicates from 12,129 references identified through database searching.

For the 6935 references from MEDLINE, Embase, PsychINFO, and Web of Science, we used the Cochrane RCT Classifier and classified two groups: 2956 references with a low probability of being RCTs; and 3976 references that had a high probability of being RCTs. For the 2956 references screened out based on the low probability of their being RCTs by the RCT Classifier, TU screened all titles and abstracts and checked there had been no RCT among them.

For 7162 references (3183 from CENTRAL, ClinicalTrials.gov, and WHO ICTRP plus the 3976 classified as having a high possibility of being RCTs by the RCT Classifier), two review authors independently screened all titles and abstracts of these references to determine which met the inclusion criteria. YA and YY screened half of them and LS and MS screened the other half. We identified and retrieved a total of 250 articles for appraisal in full-text screening. Of the 250 full-text articles, YA and YY independently screened 103 full-text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting TU to reach consensus. LS and MS independently screened the remaining 147 full-text articles, with discrepancies resolved by discussion and by consulting AE. We ultimately identified 13 studies (25 articles) that met the inclusion criteria.

Thus, in this update, we have included 15 studies (28 articles) in the review: two studies (3 articles) were previously included studies in the 2010 version of the review (Duncan 2010) (see Figure 1).

Figure 1. PRISMA study flow diagram for initial search in January 2020



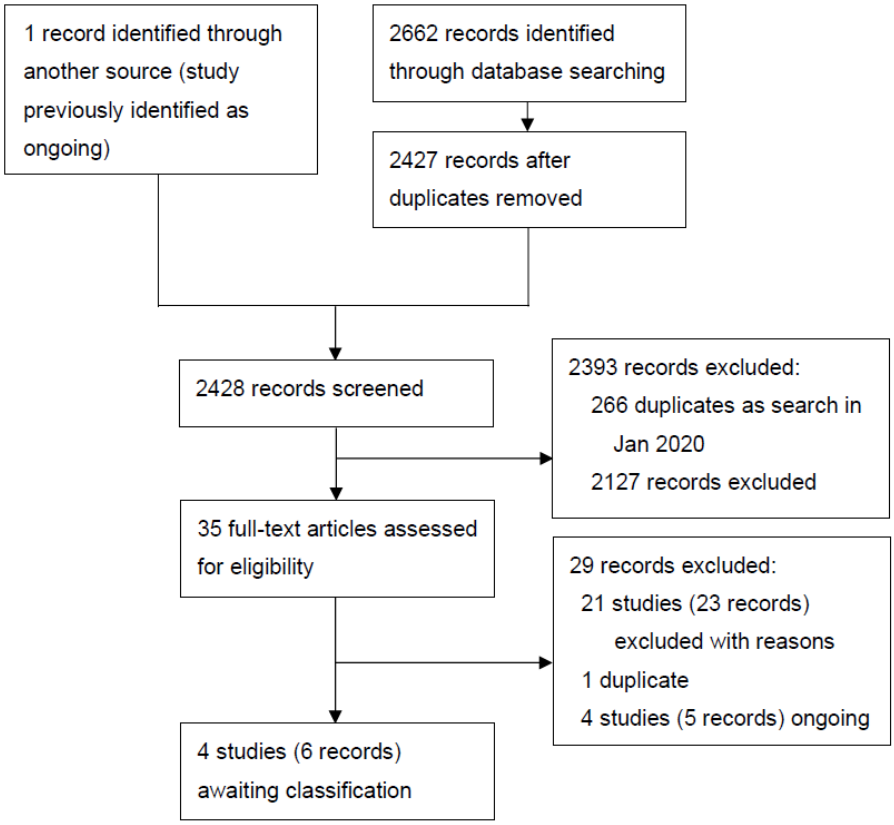
Search update

We updated the searches on 16 February 2022. We generated 2427 references (1636 references from MEDLINE, Embase, PsychINFO, and Web of Science plus 791 references from CENTRAL and ClinicalTrials.gov) after removing duplicates from 2662 references identified through database searching.

For the 1636 references from MEDLINE, Embase, PsychINFO, and Web of Science, we used the Cochrane RCT Classifier and classified two groups: 708 references with a low probability of being RCTs; and 928 references that had a high probability of being RCTs. For the 708 references screened out based on the low probability of their being RCTs by the RCT Classifier, YY screened all titles and abstracts and confirmed there had been no RCT among them.

For 1719 references (791 from CENTRAL and ClinicalTrials.gov plus the 928 references classified as having a high probability of being RCTs by the RCT Classifier), YA and TU independently screened all titles and abstracts of these references to determine which met the inclusion criteria. We identified and retrieved a total of 35 articles for appraisal in full-text screening. From these, we identified four studies which met the inclusion criteria; we have listed these as studies awaiting classification (see Figure 2).

Figure 2. PRISMA study flow diagram for update search in February 2022



Included studies

This update search added 13 new studies (Aljumah 2015; Aoki 2019a; Hamann 2011; Hamann 2017; Ishii 2017; LeBlanc 2015; Lovell 2018; Mariani 2018; Mott 2014; Raue 2019; Troquete 2013; Woltmann 2011; Yamaguchi 2017), to the two previously included studies (Hamann 2006; Loh 2007), for a total of 15 studies.

Unit of randomisation

All the studies were randomised controlled trials. Of these, eight studies randomised individual participants, and seven randomised clusters (Hamann 2006; Loh 2007; LeBlanc 2015; Lovell 2018; Mariani 2018; Troquete 2013; Woltmann 2011). Four of seven trials accounted for the cluster effect in the published outcome data (Loh 2007; LeBlanc 2015; Lovell 2018; Woltmann 2011), and our meta-analysis used the published data. However, the three remaining studies did not account for the cluster effect in the published data (Hamann 2006; Mariani 2018; Troquete 2013). Troquete 2013 did not report any of the primary or secondary outcomes of this systematic review. For Hamann 2006 and Mariani 2018, we did not reanalyse the data and we report these studies separately.

Settings and participants

The 15 RCTs, involving 3141 adults with mental health conditions, presented results from seven countries: Germany (four studies: Hamann 2006; Hamann 2011; Hamann 2017; Loh 2007), Japan (three studies: Aoki 2019a; Ishii 2017; Yamaguchi 2017), the Netherlands (one study: Troquete 2013), the UK (one study: Lovell

2018), the USA (four studies: LeBlanc 2015; Mott 2014; Raue 2019; Woltmann 2011), Saudi Arabia (one study: Aljumah 2015), and the Netherlands and Italy (one study: Mariani 2018). We did not find any trials which studied children.

The level of care was primary care in two studies (LeBlanc 2015; Loh 2007); community mental health service in two studies (Lovell 2018; Woltmann 2011); outpatient psychiatric service in four studies (Aljumah 2015; Aoki 2019a; Raue 2019; Yamaguchi 2017); specialised outpatient service in two studies such as a PTSD clinic (Mott 2014) and a forensic psychiatric service (Troquete 2013); acute wards in psychiatric hospital in four studies (Hamann 2006; Hamann 2011; Hamann 2017; Ishii 2017); and nursing home wards in one study (Mariani 2018).

The mental health conditions studied were schizophrenia in four studies (Hamann 2006; Hamann 2011; Hamann 2017; Ishii 2017); depression in four studies (Aljumah 2015; LeBlanc 2015; Loh 2007; Raue 2019); post-traumatic stress disorder (PTSD) in one study (Mott 2014); and dementia in one study (Mariani 2018). Five studies included multiple clinical conditions: Aoki 2019a, depression and bipolar disorder; Lovell 2018, severe mental illness such as schizophrenia and bipolar disorder; Troquete 2013, substance-related disorder, personality disorder, psychotic disorder, and others; Woltmann 2011, schizophrenia, bipolar disorder, depression, PTSD, and others; Yamaguchi 2017, schizophrenia, bipolar disorder, depression, and developmental disorder.

The care providers were physicians in five studies (Hamann 2011; Hamann 2017; LeBlanc 2015; Loh 2007; Mott 2014); case managers in two studies (Troquete 2013; Woltmann 2011); nurses in one study (Raue 2019); and pharmacists in one study (Aljumah 2015). Three studies included an interprofessional approach: Aoki 2019a and Hamann 2006, nurses and clinicians; Lovell 2018, nurses, occupational therapists, social workers, and others. Mariani 2018 included family carers and professionals, and Yamaguchi 2017 included peer supporters and clinicians.

Interventions

Of the 15 studies, nine studies used a decision support tool during consultation or decision coaching sessions. Of the nine studies, seven studies used a printed decision aid (Aljumah 2015; Aoki 2019a; Hamann 2006; LeBlanc 2015; Loh 2007; Mott 2014; Raue 2019), and two used electronic decision support systems (Woltmann 2011; Yamaguchi 2017). Among those that did not use decision support tools, Ishii 2017 used a question prompt sheet about treatment and Troquete 2013 used the assessment tool for risks and treatability.

Nurse interventions with decision aids before or after physician consultation were provided in three studies (Aoki 2019a; Hamann 2006; Raue 2019). Interventions by other care providers before or after physician consultation were pharmacists in one study (Aljumah 2015), case managers in one study (Woltmann 2011), and peer support specialists in one study (Yamaguchi 2017).

Almost all studies provided SDM training sessions to healthcare providers, and two of the 15 studies provided SDM training sessions to participants (Hamann 2011; Hamann 2017).

For details, see Characteristics of included studies.

Comparisons

Of the 15 studies, 12 studies provided people in the control group with usual care, such as usual physician consultation (Aoki 2019a; Hamann 2006; Ishii 2017; LeBlanc 2015; Loh 2007; Lovell 2018; Raue 2019; Yamaguchi 2017), usual care planning (Mariani 2018; Troquete 2013; Woltmann 2011), or usual pharmacy services (Aljumah 2015). The usual care participants in those studies received no decision-making tool such as a decision aid or electronic decision support system and no decision support by decision coaching. The healthcare providers did not receive any training in SDM.

In Hamann 2011 and Hamann 2017, control participants received cognitive training (Lutz 2005) as a comparison to the intervention group, where participants received an SDM training program.

In Mott 2014, to ensure that participants received equal attention from study staff, control participants attended a 30-minute placebo session.

Conceptual framework of SDM

The authors of Hamann 2006 and Ishii 2017 cited Charles 1997 for their definition of SDM and developed an interprofessional SDM model for inpatients.

Aoki 2019a used the SDM framework developed by Hamann 2006, which included nurse decision coaching before decision-making with a physician, and modified it to be suitable for outpatients.

In Aljumah 2015, the authors used the SDM competency framework, developed by Simmons 2010, which was designed specifically for patients with depression.

Both studies that used an electronic decision support tool - Woltmann 2011 and Yamaguchi 2017 - cited the CommonGround computerised decision support system, which was created in the USA by Patricia Deegan, focusing on facilitating recovery-oriented, shared decision-making (Deegan 2008; Deegan 2010).

The authors of Loh 2007 stated that their approach to training physicians was based on the work of Towle 1999, Elwyn 2000, Elwyn 2001, and Elwyn 2001b.

In Hamann 2011 and Hamann 2017, the content of the training programme for patients was derived from theoretical considerations about patients' contributions to the SDM process (Towle 1999), from an adaptation of related approaches on patient competences in the medical encounter (Cegala 2000; Farin 2014).

The authors of Lovell 2018 cited Coulter 2017 and Montori 2017 for their definition of SDM and created an SDM programme which included a decision aid designed to encourage and directly support the conversations between patients and physicians.

Mariani 2018 cited the SDM principles in dementia and active listening (Gordon 2000), to enhance both verbal and non-verbal communication skills to be used to assess and meet the patients' needs and preferences during the SDM interview.

In Mott 2014, the intervention was based on an existing decision-making model by Elwyn and colleagues (Elwyn 2010; Elwyn 2012),

which identifies SDM components: "choice talk", "option talk", and "decision talk".

Although three of the 15 studies did not refer to any particular concept (LeBlanc 2015; Raue 2019; Troquete 2013), the SDM of Troquete 2013 used a method of periodically monitoring violence risks and treatment needs (Van den Brink 2010).

Excluded studies

After full-text assessment of articles for eligibility, we excluded 174 articles from the original search in January 2020 and 21 articles from the update search in February 2022. The reasons for exclusion were related to the design of the study, the type of participants, and the content of the intervention. Regarding the content of the intervention, the most common reason for exclusion was that the SDM intervention was part of a complex intervention addressing many facets of patient care. In these studies, the effects of SDM intervention could not be isolated. For more details, see Excluded studies.

We also identified 16 ongoing RCTs during the initial search in January 2020 and four ongoing RCTs during the update search in February 2022. Of the 16 ongoing RCTs from the initial search, we identified that one study published and, thus, we moved it to the list of 'studies awaiting classification' in February 2022. Thus, we ultimately identified 19 ongoing studies. For more details, see Ongoing studies.

For studies awaiting classification, initially,we identified five studies (four studies from the update search and one study transferred from the ongoing studies). Ultimately, we identified four studies after removing one duplicate. For more details, see Studies awaiting classification.

Risk of bias in included studies

We report further information on the rating and rationale for risk of bias assessments of the included studies in the risk of bias tables in the Characteristics of included studies, and summarise these in Figure 3 and Figure 4. The risk of bias assessment reported was based on the primary outcomes.

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

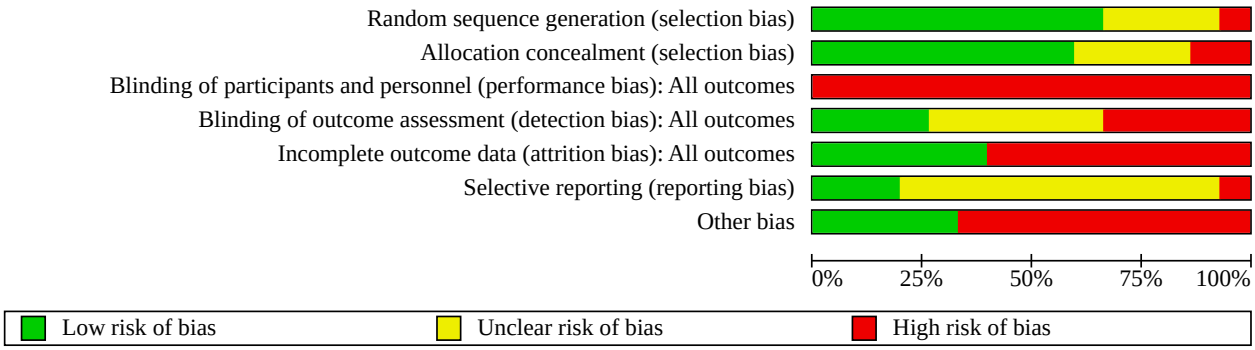
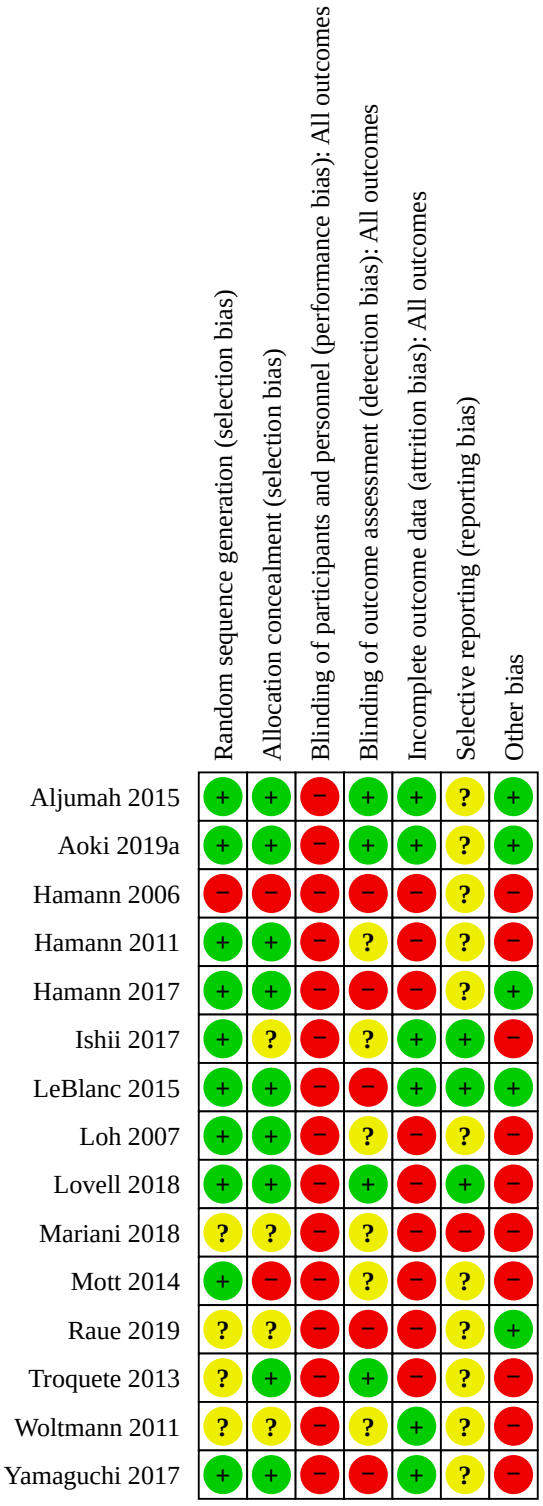


Figure 4. Risk of bias summary: review authors' judgements about each risk of bias item for each included study



Allocation

We considered 10 of 15 studies (67%) to be at low risk of bias for random sequence generation because these trial authors described their randomisation list or computerised randomisation methods (Aljumah 2015; Aoki 2019a; Hamann 2011; Hamann 2017; Ishii 2017; LeBlanc 2015; Loh 2007; Lovell 2018; Mott 2014; Yamaguchi 2017). In one study (7%), sequence generation took place after wards had been paired based on their characteristics (Hamann 2006); we judged this study as having a high risk of bias. We rated four studies (27%) as having an unclear risk of bias because they lacked a specific description of random sequence generation (Mariani 2018; Raue 2019; Troquete 2013; Woltmann 2011).

We rated nine of 15 studies (60%) as being at low risk of bias for allocation concealment: in these, allocation was done by a person with no involvement in the study (Aljumah 2015; Aoki 2019a; LeBlanc 2015; Troquete 2013; Yamaguchi 2017); closed concealment envelopes or drawing blind lots were used (Hamann 2011; Hamann 2017; Loh 2007); or an external telephone randomisation service was used (Lovell 2018). We assessed two studies (13%) as having a high risk of bias for allocation concealment: one study used envelopes (Mott 2014), and one study randomised at the ward level (Hamann 2006). We rated the four remaining studies (27%) as having an unclear risk of bias because they gave no description of allocation concealment (Ishii 2017; Mariani 2018; Raue 2019; Woltmann 2011).

Blinding

Due to the nature of the interventions, blinding of the participants and the personnel delivering the intervention was not possible. Therefore, for the blinding of participants and personnel, we judged all 15 studies to be at high risk of bias in this domain.

For the blinding of outcome assessment, we rated four of 15 studies (27%) as having a low risk of bias (Aljumah 2015; Aoki 2019a; Lovell 2018; Troquete 2013), six (40%) as having an unclear risk of bias (Hamann 2011; Ishii 2017; Loh 2007; Mariani 2018; Mott 2014; Woltmann 2011), and five (33%) as having a high risk of bias (Hamann 2006; Hamann 2017; LeBlanc 2015; Raue 2019; Yamaguchi 2017).

Incomplete outcome data

We considered that six of the 15 studies (40%) were at low risk of attrition bias because a similar and low proportion of participants from either group could not be included in the final analyses (Aljumah 2015; Aoki 2019a; Ishii 2017; LeBlanc 2015; Woltmann 2011; Yamaguchi 2017). We considered nine studies (60%) to be at a high risk of attrition bias because of significant loss to follow-up (Hamann 2006; Hamann 2011; Hamann 2017; Loh 2007; Lovell 2018; Mariani 2018; Mott 2014; Raue 2019; Troquete 2013).

Selective reporting

We rated three studies (20%) as being at a low risk of reporting bias (Ishii 2017; LeBlanc 2015; Lovell 2018); these studies' protocols were registered publicly and outcomes were reported as planned (see: Ishii 2017, secondary reference Ishii 2014; LeBlanc 2015, secondary reference LeBlanc 2013; Lovell 2018, secondary reference Bower 2015). We judged 11 studies (73%) to have an unclear risk of reporting bias because no protocol was publicly available (Aljumah 2015; Aoki 2019a; Hamann 2006; Hamann 2011; Hamann 2017; Loh 2007; Mott 2014; Raue 2019; Troquete 2013; Woltmann 2011; Yamaguchi 2017). We considered Mariani 2018 to be at a high risk of reporting bias because the authors stated in the protocol that the primary outcome was the proportion of dementia residents whose preferences, needs, and related actions were known, satisfied, and documented in their 'life-and-care plan'. However, in the results paper, the primary outcome was the agreement of the residents' 'life-and-care plans' with the five operationalised recommendations.

Other potential sources of bias

Of 15 studies, we rated 10 studies (67%) which discussed other potential sources of bias. We considered the five studies which lacked a sample size calculation and were of a relatively small sample size as being at high risk of bias (Hamann 2011; Mariani 2018; Mott 2014; Woltmann 2011; Yamaguchi 2017). In Ishii 2017 and Troquete 2013, although the sample size calculation was conducted, the participants were fewer than planned, leading to underpowered analyses. In Lovell 2018, missing baseline data for the cohort sample was cluster mean imputed. We considered the three studies in which participants were recruited to the trial after the clusters had been randomised as being at a high risk of bias (Hamann 2006; Loh 2007; Lovell 2018). In addition, three studies did not account for the cluster effect (Hamann 2006; Mariani 2018; Troquete 2013).

Effects of interventions

See: **Summary of findings 1** Shared decision-making interventions compared with usual care for people with mental health conditions

Primary outcomes

Clinical outcomes assessed using measurement tools such as psychiatric scales, depression scales, and anxiety scales

Psychiatric symptoms (for severe mental health conditions)

Two studies reported psychiatric symptom outcomes (Hamann 2006; Yamaguchi 2017; see Table 1). Data from Yamaguchi 2017, using the Brief Psychiatric Rating Scale (BPRS) at six months' follow-up, were available for the analysis. The mean difference (MD) for this study was -1.10 (95% confidence interval (CI) -5.54 to 3.34; 1 study, 53 participants; very low-certainty evidence; Analysis 1.1), indicating little or no difference between groups. One study not included in the analysis reported no statistically significant difference in Positive and Negative Syndrome Scale (PANSS) scores between the intervention and control groups when they were discharged from hospital (Hamann 2006). However, this study did not adequately adjust for clustering and so may have produced overly precise results. Therefore, we are uncertain whether SDM interventions improve psychiatric symptoms compared with control due to very low-certainty evidence.

Depression

Six studies reported depression symptoms (Aljumah 2015; Aoki 2019a; LeBlanc 2015; Loh 2007; Lovell 2018; Raue 2019; see Table 2).

For the outcomes at one to six months' follow-up, data from five studies (using the Montgomery-Åsberg Depression Rating Scale (MADRS), Patient Health Questionnaire-9 (PHQ-9), Quick Inventory of Depressive Symptomatology (QIDS-J), and Hamilton Depression Rating Scale (HDRS)) were available for statistical analysis. The pooled estimate standardised mean difference (SMD) was 0.14 (95% CI -0.19 to 0.47, a small effect; 5 studies, 919 participants;

very low-certainty evidence; Analysis 1.2), indicating little or no difference between groups.

For the sensitivity analysis of the outcomes at one to six months' follow-up, removing the lower-certainty study (Raue 2019), the pooled estimate SMD was -0.03 (95% CI -0.17 to 0.12; a small effect; 4 studies, 717 participants; low-certainty evidence; Analysis 1.3), indicating little or no difference between groups. Sensitivity analysis showed that heterogeneity decreased; however, the overall effect did not change much.

For the outcomes at six months or more, data from five studies (using MADRS, PHQ-9, QIDS-J, and the Hospital Anxiety and Depression Scale - Depression subscale (HADS-D)) were available for statistical analysis. The pooled estimate SMD was 0.21 (95% CI -0.19 to 0.60, a small effect; 5 studies, 1100 participants; very low-certainty evidence; Analysis 1.4), indicating little or no difference between groups.

For the sensitivity analysis of the outcomes at six months or more, removing the lower-certainty study (Raue 2019), the pooled estimate SDM was 0.03 (95% CI -0.10 to 0.17, a small effect; 4 studies, 898 participants; low-certainty evidence; Analysis 1.5), indicating little or no difference between groups. Sensitivity analysis found that heterogeneity decreased; however, the overall effect did not change much.

LeBlanc 2015 reported the remission rate and responsiveness of depression and found little or no difference between the two groups for: remission at three months (risk ratio (RR) 1.06, 95% CI 0.68 to 1.65; 215 participants; low-certainty evidence; Analysis 1.6); remission at six months (RR 1.58, 95% CI 0.97 to 2.55; 210 participants; low-certainty evidence; Analysis 1.7); response at three months (RR 1.09, 95% CI 0.81 to 1.47; 215 participants; low-certainty evidence; Analysis 1.8); or response at six months (RR 1.34, 95% CI 0.98 to 1.83; 210 participants; low-certainty evidence; Analysis 1.9).

Accordingly, we are uncertain if SDM interventions improve depression symptoms compared with control due to low- or very low-certainty evidence.

Anxiety

One study (380 participants) reported on anxiety (Lovell 2018), using the Hospital Anxiety and Depression Scale - Anxiety subscale (HADS-A), at six months' follow-up and found little or no difference between the intervention and control groups (Table 3).

Readmission rates

Three studies conducted in psychiatric wards reported readmission rates between two arms (Hamann 2006; Hamann 2011; Hamann 2017; see Table 4). For the outcomes at one to six months' follow-up, data from two studies were available for the statistical analysis (Hamann 2006; Hamann 2011). The RR was 1.06 (95% CI 0.52 to 2.14; 128 participants; very low-certainty evidence; Analysis 1.10), indicating little or no difference between groups. For six months or more, data from two studies were available for the statistical analysis (Hamann 2006; Hamann 2017). The RR was 1.06 (95% CI 0.77 to 1.46; 249 participants; very low-certainty evidence; Analysis 1.11), indicating little or no difference between groups. In addition, Hamann 2006 did not account for the cluster effect and so may have produced overly precise results. Accordingly, we are uncertain if SDM interventions impact readmission compared with no intervention due to very low-certainty evidence.

Participation (by the person with the mental health condition) or level of involvement in the decision-making process

Six studies reported participation or level of involvement in the decision-making process (Aoki 2019a; Hamann 2006; LeBlanc 2015; Loh 2007; Lovell 2018; Yamaguchi 2017; see Table 5).

Observations on the process of SDM

Two studies assessed participation or level of involvement in the decision-making process by observations on the process of SDM using Observing Patient Involvement in Decision-Making Scale (OPTION) and SDM-18 (LeBlanc 2015; Yamaguchi 2017). The pooled estimate of the SMD was 1.14 (95% CI 0.63 to 1.66, a large effect; 2 studies, 133 participants; very low-certainty evidence; Analysis 1.12), indicating an increase in participation for the group that received the intervention. However, we are uncertain if SDM interventions improve observations on the process of SDM compared with control due to very low-certainty evidence.

Shared decision-making-specific user-reported outcomes from encounters: immediately after encounter

Four studies evaluated patient participation or level of involvement in the decision-making process immediately after decision-making using SDM-specific user-reported outcomes, such as Decision Conflict Scale (DCS), Combined Outcome Measure for Risk Communication and Treatment Decision-Making (COMRADE), and the Man-Song-Hing Scale (Aoki 2019a; Hamann 2006; LeBlanc 2015; Loh 2007). Data from three studies were available for the statistical analysis (Aoki 2019a; LeBlanc 2015; Loh 2007). The pooled estimate of the SMD was 0.63 (95% CI 0.26 to 1.01, a moderate effect; 534 participants; low-certainty evidence; Analysis 1.13), indicating an increase in participation for the group that received the intervention.

In the study not included in the meta-analysis, participants in the intervention group reported significantly greater perceived involvement than those in the control group (Hamann 2006). However, Hamann 2006 failed to adequately adjust for clustering and so may have produced overly precise results.

Shared decision-making-specific user-reported outcomes from encounters: at six months or more

Two studies assessed patient participation or level of involvement in the decision-making process at six months' follow-up, using the Evaluating and Quantifying User and Carer Involvement in Mental Health Care Planning Patient-Reported Outcome Measure (EQUIP ROPM) and the Patient Activation Measure (PAM) (Lovell 2018; Yamaguchi 2017). The pooled estimate of the SMD was 0.13 (95% CI -0.30 to 0.56, a small effect; 398 participants; low-certainty evidence; Analysis 1.14), indicating little or no difference between groups.

Accordingly, SDM interventions may improve SDM-specific user-reported participation outcomes immediately after the encounter compared with control, based on low-certainty evidence. On the other hand, there may be little or no effect of SDM interventions on levels of user-reported involvement compared to control at long-term follow-up, again based on low-certainty evidence.

Secondary outcomes

Recovery

Two studies, Lovell 2018 and Yamaguchi 2017, reported on recovery, using Developing Recovery Enhancing Environments Measure (DREEM) and Self-Identified Stage of Recovery (SISR), respectively (see Table 6). Data from both studies were available for the statistical analysis. The estimate of SMD was 0.10 (95% CI -0.13 to 0.32, a small effect; 313 participants; very low-certainty evidence; Analysis 1.15), indicating little or no difference between the two groups. Thus, we are uncertain whether SDM interventions improve recovery compared with control due to very low-certainty evidence.

Satisfaction

Ten studies reported service users' satisfaction (Aoki 2019a; Hamann 2006; Hamann 2011; Hamann 2017; Ishii 2017; LeBlanc 2015; Loh 2007; Lovell 2018; Woltmann 2011; Yamaguchi 2017; see Table 7).

Overall satisfaction (with care) of person with the mental health condition: immediately after the intervention

Five studies reported on overall satisfaction immediately after the intervention using the Client Satisfaction Questionnaire–8 Japanese version (CSQ-8), German version of the CSQ (ZUF-8), and a 5-point Likert scale (Aoki 2019a; Hamann 2011; Hamann 2017; Loh 2007; Woltmann 2011). Data from four studies were available for the statistical analysis. The pooled estimate of SMD was 0.26 (95% CI -0.29 to 0.80, a small effect; 4 studies, 420 participants; very low-certainty evidence; Analysis 1.16), indicating little or no difference between the two groups. One study not included in the meta-analysis reported no statistically significant difference in ZUF-8 scores between the intervention and control groups (Hamann 2017).

Overall satisfaction at hospital discharge

Two studies conducted in psychiatric wards reported on overall satisfaction at hospital discharge, using CSQ-8 and ZUF-8 (Hamann 2006; Ishii 2017). Ishii 2017 (22 participants) reported on satisfaction at hospital discharge and found little or no difference between the two groups (MD 1.60, 95% CI -1.65 to 4.85; very low-certainty evidence; Analysis 1.17).

Hamann 2006 also reported on satisfaction at discharge and found no statistically significant difference in ZUF-8 scores between the intervention and control groups. However, this study did not adjust for clustering and so may have produced overly precise results.

Overall satisfaction at six months and more

Two studies reported on satisfaction at six months after the intervention using the Verona Service Satisfaction Scale - European Version-54 (VSSS-EU-54) and CSQ-8 (Lovell 2018; Yamaguchi 2017). The pooled estimate of the SMD was 0.09 (95% CI -0.22 to 0.40, a small effect; 2 studies, 400 participants; very low-certainty evidence; Analysis 1.18), indicating little or no difference between the two groups.

Accordingly, we are uncertain if SDM interventions improve the overall satisfaction of people with mental health conditions compared with no intervention due to very low-certainty evidence.

Users' satisfaction concerning decision-making

None of the 15 studies examined the effect of shared decision-making on users' satisfaction concerning decision-making.

Users' satisfaction with received information

LeBlanc 2015 assessed satisfaction with received information immediately after the encounter. The assessment included these elements: right amount of information given; information given was clear; information given was helpful; strong desire to receive information this way for other treatment decisions; and strongly recommend the way information was shared to others, and the results were as follows:

- Right amount of information given: RR 1.00 (95% CI 0.94 to 1.07; 241 participants; low-certainty evidence; Analysis 1.19), indicating little or no difference between groups.
- Information given was clear: RR 1.19 (95% CI 0.98 to 1.44; 241 participants; low-certainty evidence; Analysis 1.20), indicating little or no difference between groups.
- Information given was helpful: RR 1.33 (95% CI 1.08 to 1.65; 241 participants; moderate-certainty evidence; Analysis 1.21), indicating an improvement in the group receiving an SDM intervention compared with control.
- Strong desire to receive information this way for other treatment decisions: RR 1.35 (95% CI 1.08 to 1.68; 241 participants; moderate-certainty evidence; Analysis 1.22), indicating an improvement in the group receiving an SDM intervention compared with control.
- Strongly recommend the way information was shared to others: RR 1.32 (95% CI 1.11 to 1.58; 241 participants; moderate-certainty evidence; Analysis 1.23), indicating an improvement in the group receiving an SDM intervention compared with control.

Therefore, SDM interventions probably improve users' satisfaction with received information (information given was helpful; strongly desire to receive information this way for other treatment decisions; and strongly recommend the way information was shared to others) compared with no intervention, based on moderate-certainty evidence. However, there may be little or no effect on satisfaction with amount and clarity of information, based on low-certainty evidence.

Carer satisfaction

One study (50 participants) reported on carer satisfaction using Carers and Users' Expectations of Services—carer version (CUES-C) and found little or no difference between groups (MD -1.40, 95% CI -6.69 to 3.89; low-certainty evidence; Analysis 1.24) (Lovell 2018, see Table 8). Consequently, SDM interventions may have little or no effect on carer satisfaction compared with no intervention.

Healthcare professional satisfaction

Four studies examined professional satisfaction using a 5-point Likert scale and a professional caregivers' job satisfaction questionnaire (JSQ) (Hamann 2006; LeBlanc 2015; Mariani 2018; Woltmann 2011; see Table 9). Two studies were included in the statistical analysis. On a continuous scale, the MD was 0.70 (95% CI 0.26 to 1.14; 1 study, 20 participants; Analysis 1.25), indicating an increase in professional satisfaction for the group that received SDM compared with control (Woltmann 2011). However, this is based on very low-certainty evidence. On a categorical (original)

scale, the RR was 1.35 (95% CI 1.16 to 1.58; 1 study, 256 participants; moderate-certainty evidence; Analysis 1.26), indicating an increase in professional satisfaction for the group that received SDM compared with control (LeBlanc 2015).

Hamann 2006 used a 5-point Likert scale and reported that psychiatrists in the intervention group were more satisfied with what had been achieved during hospitalisation (SDM mean 3.8/comparison mean 3.5, P = 0.02). However, Hamann 2006 failed to adequately adjust for clustering and so may have produced overly precise results. Mariani 2018 used a professional caregivers' job satisfaction questionnaire and found no difference between the intervention and control groups (34 participants, SDM mean 42.8/comparison mean 43.3, P = 0.58). This study also failed to adequately adjust for clustering and so may have produced overly precise results.

Therefore, regarding healthcare professional satisfaction, the effects were mixed. Consequently, SDM interventions may have little or no effect on healthcare professional satisfaction measured continuously, compared with no intervention, due to low-certainty evidence. On the other hand, SDM interventions probably improve healthcare professionals' satisfaction measured categorically, compared with no intervention, and based on moderate-certainty evidence.

Knowledge

Three studies assessed patient knowledge regarding disease, condition, or treatment options (Hamann 2006; LeBlanc 2015; Woltmann 2011; see Table 10). Data from two studies were available for the statistical analysis (322 participants). The pooled estimate of SMD was 0.41 (95% CI 0.18 to 0.63, a moderate effect; very low-certainty evidence; Analysis 1.27), indicating an improvement in the group receiving an SDM intervention compared with control.

In the study not pooled, the authors measured patient knowledge before discharge using an invalidated questionnaire with 7 multiple-choice questions (Hamann 2006). Patients' knowledge in the intervention group as measured by this scale had improved at discharge (88 participants, SDM mean 15/comparison mean 10.9, P = 0.01) (Hamann 2006). However, Hamann 2006 failed to adequately adjust for clustering and so may have produced overly precise results.

Accordingly, we are uncertain if SDM interventions improve patient knowledge compared with no intervention due to very low-certainty evidence.

Treatment or medication continuation

Clinic visits

Four studies reported on clinic visits using visit rate or visit frequency (Aoki 2019a; Hamann 2011; Ishii 2017; Mott 2014; see Table 11). Data from these four studies were used for the statistical analysis. For one to six months, Mott 2014 reported on psychotherapy visit rate at four months' follow-up and found little or no difference between the groups (RR 0.98, 95% CI 0.37 to 2.59; 20 participants; very low-certainty evidence; Analysis 1.28). For six months or more, three studies reported on clinic visit rate at six months' follow-up (Aoki 2019a; Hamann 2011; Ishii 2017). They found little or no difference between the two groups (RR 1.07, 95% CI 0.93 to 1.23; 171 participants; very low-certainty evidence; Analysis 1.29).

Treatment adherence by service users or healthcare providers

Two studies assessed treatment adherence by service users or healthcare providers (Loh 2007; Hamann 2011). Loh 2007 used two separate treatment adherence outcome measures at six to eight weeks after the intervention: a patient rating and a physician rating. Both were Likert-type scales based on a single question. For the patient rating, there was little or no difference between the two groups (194 participants, SDM mean 4.3/comparison mean 3.9). For the physician rating, there was little or no difference between the two groups (194 participants, SDM mean 4.8/comparison mean 4.3). Hamann 2011 used two separate treatment adherence outcome measures at six months' follow-up: a physician rating of adherence and a patient rating. The physician rating was a five-point Likert scale based on a single question and the patient rating was based on categorical data (Yes/No data). For both patient and physician ratings, little or no differences were found between groups (Hamann 2011).

Accordingly, we are uncertain whether SDM interventions improve treatment continuation compared with no intervention due to very low-certainty evidence.

Medication continuation from one to six months

Four studies examined medication continuation from one to six months (Aljumah 2015; Aoki 2019a; Hamann 2006; Hamann 2017; see Table 12), Two were included in the statistical analysis (Aljumah 2015; Aoki 2019a).

On a continuous scale, two measures were used (the Morisky Medication Adherence Scale (MMAS) and a visual analogue scale (VAS)). The SMD was 0.33 (95% CI 0.10 to 0.57, a small effect; 2 studies, 286 participants; Analysis 1.30), indicating an improvement in medication adherence for the group that received shared decision-making compared with control. However, this is based on low-certainty evidence. In a study not pooled in this meta-analysis, Hamann 2017 (100 participants) reported no statistically significant difference in Medication Adherence Rating Scale (MARS) scores between the groups at six months' follow up (T = 0.36, P = 0.72).

On a categorical scale, one measure of adherence was used (overall adherence determined by patient rating with MARS, physician rating, and plasma level) (Hamann 2006). The RR was 0.74 (95% CI 0.47 to 1.17; one study, 86 participants; very low-certainty evidence; Analysis 1.31), indicating little or no difference in medication continuation between groups.

Medication continuation at six months or more

Seven studies reported on medication continuation at six months or more (Aljumah 2015; Aoki 2019a; Hamann 2006; Hamann 2011; Hamann 2017; LeBlanc 2015; Yamaguchi 2017; see Table 12). Four studies were included in the statistical analysis. On a continuous scale, three measures were used (MMAS, VAS, service user estimated proportion of how much medicine taken). The SMD was 0.27 (95% CI -0.03 to 0.56, a small effect; 4 studies, 394 participants; low-certainty evidence; Analysis 1.32), indicating little or no difference in medication continuation between groups. In a study not pooled in this meta-analysis, Hamann 2017 (85 participants) reported no statistically significant difference in MARS scores between the groups at 12 months' follow-up (T = -0.81, P = 0.42).

On a categorical scale, four measures were used (overall adherence determined by patient rating, physician rating using MARS scale, and plasma level; self-reported if participant were taking medication for psychiatric condition, Yes/No; overall adherence determined by patient rating with Medication Adherence Questionnaire (MAQ), physician rating, and patient clinical visit; proportion of patients who filled their prescription within 30 days). The RR was 1.05 (95% CI 0.94 to 1.17; 4 studies, 577 participants; very low-certainty evidence; Analysis 1.33), indicating little or no difference in medication continuation between groups.

Therefore, we are uncertain whether SDM interventions improve medication continuation compared with no intervention due to very low or low-certainty evidence.

Treatment/medication continuation

Raue 2019 reported the combined proportion of possible antidepressant pills taken, and possible psychotherapy sessions attended over 12 weeks, with no difference reported between the groups (P = 0.154).

Carer participation or level of involvement in SDM process

One study reported on carer participation at six months using a patient-reported outcome measure, PROM-14 (Lovell 2018; see Table 13). The MD for this study was 3.60 (95% CI -0.99 to 8.19; 1 study; 68 participants; low-certainty evidence; Analysis 1.34), indicating little or no difference between groups. Shared decision-making interventions may therefore have little or no effect on carer participation or level of involvement compared with control.

Relationship or interaction between service users and healthcare professionals

Relationship between service users and healthcare professionals, assessed by users

Four studies reported on the relationship between service users and healthcare professionals, as assessed by users, using the Trust in Physician Scale, California Psychotherapy Alliance Scale (CALPAS), and Scale to Assess Therapeutic Relationship (STAR) (Hamann 2011; Hamann 2017; Lovell 2018; Yamaguchi 2017; see Table 14). Data from three studies (457 participants) were available for the statistical analysis (Hamann 2011; Lovell 2018; Yamaguchi 2017).The pooled estimate of SMD was -0.13 (95% CI -0.54 to 0.28, a small effect; very low-certainty evidence; Analysis 1.35), indicating little or no difference between two groups. One study reported on service user-professional relationship assessed by users using the Trust in Physician Scale but no data were available to compute a standardised mean difference (Hamann 2017). This study reported that participants in the intervention group showed no decline in trust in their physicians compared with the control group (T = -1.15, P = 0.25) (Hamann 2017).

Relationship between service users and healthcare professionals, assessed by professionals

Four studies reported on the relationship between service users and healthcare professionals, as assessed by professionals, using the Working Alliance Inventory (WAI), Difficult Doctor-Patient Relationship Questionnaire (DDPRQ), Therapeutic Alliance scale, and Scale to Assess Therapeutic Relationship (STAR) (Hamann 2006; Hamann 2011; Hamann 2017; Yamaguchi 2017; Table 14). Data from two studies (114 participants) were available for statistical analysis (Hamann 2011; Yamaguchi 2017). The pooled estimate of SMD was 0.17 (95% CI -0.31 to 0.65, a small effect; very low-certainty evidence; Analysis 1.36), indicating little or no difference between two groups. Of the two studies not used for the statistical analysis, Hamann 2006 reported that participants in the intervention group did not differ from those in the control group in cooperation, as reflected in the WAI (therapist version) (mean 60.6/60.9, P > 0.05). This study did not adjust for clustering and so may have produced overly precise results. Hamann 2017 reported on therapeutic alliance and found no difference in DDPRQ scores between the intervention and control groups (T = -0.90, P = 0.37)

Accordingly, we are uncertain whether SDM interventions improve relationships or interactions between service users and healthcare professionals compared with control as results are based on very low-certainty evidence.

Health service use outcomes

Length of consultation

Three studies reported on consultation duration or time spent in individual contacts between psychiatrist and patient (Aoki 2019a; Hamann 2006; Loh 2007; see Table 15). Data from two studies (282 participants) assessing consultation duration (minutes) were available for the statistical analysis (Aoki 2019a; Loh 2007). The pooled estimate of SMD was 0.09 (95% CI -0.24 to 0.41, a small effect; moderate-certainty evidence; Analysis 1.37), indicating little or no difference between the two groups. Although the authors of the Aoki 2019a trial reported that the median duration of the SDM intervention was 26 minutes and 24 minutes for control, we used mean duration, which the authors provided us, for the statistical analysis in this review. In the study not pooled in the meta-analysis, Hamann 2006 reported that the participants of the intervention group did not differ from those in the control group in the time spent in individual contact with psychiatrists, as reported by the participant (SDM mean 64 minutes/control mean 60 minutes, P > 0.05). However, Hamann 2006 failed to adequately adjust for clustering and so may have produced overly precise results.

Therefore, SDM interventions probably have little or no effect on length of consultation compared with no intervention, based on moderate-certainty evidence.

Length of hospital stay

One study conducted in a psychiatric ward reported on length of hospital stay (days) (Ishii 2017; see Table 15). The MD for this study was 0.20 (95% CI -27.84 to 28.24; 22 participants; very low-certainty evidence; Analysis 1.38), indicating little or no difference between groups. Accordingly, we are uncertain whether SDM interventions improve length of hospital stay compared with no intervention due to very low-certainty evidence.

Adverse outcomes

There were no adverse effects on health outcomes and no other adverse events reported.

Subgroup analysis and investigation of heterogeneity

Insufficient studies prevented the planned subgroup analyses of care setting, types of intervention target population, mental illness severity of people with mental health conditions, and intervention types. However, two studies used cognitive training in the control group (Hamann 2011; Hamann 2017). The other 13 studies had usual care as the control group. Therefore, we conducted subgroup

analysis according to control group (SDM versus usual care and SDM versus cognitive training) for the primary outcomes as follows.

Clinical outcomes: readmission (one to six months)

When considered separately by subgroups for SDM versus usual care and SDM versus cognitive training, readmission (one to six months) showed no difference between studies that used usual care versus those that used cognitive training as the control group (RR 1.03 versus RR 1.12; test for subgroup difference P = 0.91, I^2 = 0%; Analysis 1.10).

Clinical outcomes: readmission (six months or more)

When analysing SDM versus usual care and SDM versus cognitive training, readmission (six months or more) showed no difference between studies that used usual care versus those that used cognitive training as the control group (RR 1.14 versus RR 1.00; test for subgroup difference P = 0.69, I^2 = 0%; Analysis 1.11).

For other outcomes, we could not conduct formal subgroup analyses because there were too few studies in each subgroup.

Sensitivity analysis

As previously described, we conducted sensitivity analyses for depression symptoms, removing lower-certainty studies (high overall risk of bias) for the analyses.

DISCUSSION

Summary of main results

In this update review, we added 13 new studies to the two studies from the original Cochrane Review for a total of 15 studies comparing SDM for mental health conditions to usual care (12 studies), cognitive training (two studies), or 30-minute placebo session (one study).

The 15 studies recruited a total of 3141 people with mental health conditions. The number of included studies has increased considerably in ten years (i.e. the time elapsed between the previous and present versions of this review). This suggests that this field has been garnering attention and rapidly expanding. Although the majority of the countries included were in Europe or the USA, three studies were in Japan. This shows that SDM in psychiatry has been attracting a lot of attention in middle- and upper-income countries. We also observed one study by international collaborators. Regarding the setting, various fields – including primary care, outpatient services, community care, or psychiatric wards – were represented. The clinical conditions also covered many kinds of mental health conditions, such as schizophrenia, depression, bipolar disorder, dementia, and post-traumatic stress disorder (PTSD). Although SDM is a common key concept for all included studies, the content of interventions, such as the duration and healthcare providers, varied.

Primary Outcomes

There were little or no differences in effects between groups receiving the intervention or control for clinical outcomes, such as psychiatric symptoms, depression, anxiety, and readmission.

We are uncertain if SDM interventions for people with mental health conditions improve observed level of participation in the SDM process, but this approach may increase the service users' self-reported participation or level of involvement in the decision-making process compared with usual care in the short term. There was insufficient evidence for sustained participation in the decision-making process over the longer term.

Moreover, we graded the certainty of the evidence for most of the primary outcomes described above as low or very low, which means that results are likely to change with more research.

Secondary outcomes

We are uncertain about the effects of SDM interventions on recovery.

For service users' satisfaction, while one study which assessed some aspects of users' satisfaction with received information immediately after the encounter using categorical measurements found that those receiving the SDM intervention are probably more satisfied, we are uncertain about effects on overall satisfaction levels. No included studies reported users' satisfaction with decision-making.

Regarding carer satisfaction, one study reported there may be little or no difference between two groups.

Several studies assessed healthcare professionals' satisfaction and the results were mixed: some suggested there may be little or no effect on satisfaction levels, while one study using another measure found that SDM interventions probably improve healthcare professionals' satisfaction compared with no intervention.

Regarding patient knowledge, although three studies showed that participants' knowledge in SDM groups had improved compared with control, this is a small effect and very low-certainty evidence. Therefore, we are uncertain about effects.

The results were mixed for treatment or medication adherence in the short term, and findings were based on low- or very low-certainty evidence. Accordingly, we are uncertain about the effects. We are also uncertain about both treatment and medication adherence over the longer term.

There may be little or no difference in carer participation, and we are uncertain about the effects on the relationship between service users and healthcare professionals, and health service use outcomes, such as length of hospital stay. Shared decision-making interventions probably have little or no effect on consultation length.

No adverse events were reported.

Overall completeness and applicability of evidence

This review appears to highlight two benefits for clinical settings. First, people with mental health conditions receiving the SDM intervention may be more involved in the decision-making process, compared with usual care. Second, there was probably no difference between intervention and control groups with regard to the consultation duration. Shared decision-making emphasises the process of conversation between the service user and healthcare provider. Concerns are then sometimes raised that SDM interventions may prolong the consultation duration. Accordingly, our results may help to address these concerns.

However, overall, for most outcomes of interest in this review, the effects were of small or negligible size, and the evidence was of low or very low certainty. Thus, there is a low level of certainty about the findings based on the studies assembled thus far. On the other hand, the benefits described above could be nonetheless clinically important. This is because greater levels of involvement in the decision-making process appeared to be consistent with the concept of personal recovery in the mental health field, which consists of elements such as re-establishment of identity, finding meaning in life, empowerment, and sense of responsibility (Van Eck 2018). The recovery process places control in the hands of the individual and not the professional (Jacobson 2001). Accordingly, it is worth mentioning that SDM interventions for people with mental health conditions are increasing, and greater emphasis is being placed on the collaborative nature of interactions among healthcare providers, people with mental health conditions, and their families. In addition, the findings of this update review also suggest that people receiving usual care may not be as involved in the decision-making processes as they wish. This means that there is a need to continue exploring further interventions to promote service users' involvement and autonomy in this field.

We found that a variety of scales was used to measure service users' involvement in decision-making processes. This indicates that there is not yet consensus on a standardised scale to measure the level of service user involvement in SDM interventions for people with mental illness, which may contribute to the variability in effects across studies.

The meta-analyses showed considerable heterogeneity for almost all outcomes. The heterogeneity of reporting possibly may be due to the fact that SDM interventions are complex and that complexity is reflected in the range of scales and approaches to measurement in use. It is notable that there was also considerable diversity in the components of the SDM interventions adopted by the included studies. These variations included issues of timing (such as those that were implemented during consultation versus those that required the service user to prepare before consultation), use of tools (such as those that used decision support tools versus those that did not), and variability in whom the intended target of the SDM intervention was (those that involved only the physician versus those involved an interprofessional team). Considerable diversity was also found in follow-up periods for outcome assessment. Many studies were also underpowered to detect important differences in outcomes. Heterogeneity in the various outcomes may also reflect the inclusion of clinically diverse studies in this review update. Therefore, it should be remembered that the pooled effect estimates may not be applicable across the board (e.g. to different persons, mental health conditions, or situations).

While there was diversity in the SDM interventions studied, most participants included were adults with severe mental illnesses, such as schizophrenia, depression, and bipolar disorder, in higher-income countries (Europe, the USA, and Japan). We did not find any studies which included children or those in low- and middle-income countries. People with dementia were included in only one trial (Mariani 2018), although the older population is increasing globally. Shared decision-making interventions targeting children with mental health conditions have been reported (Brinkman 2011; Abrines-Jaume 2016; Levy 2016; Liverpool 2021b), but there are as yet no available RCTs through which effects of these interventions in children might be determined. Autonomy and self-determination of these vulnerable populations should be advocated from the standpoint of recovery. Thus, further research for these under-researched populations, including children and people in low- and middle-income countries, is also needed.

Implementation of SDM interventions in the clinical environment requires consideration in terms of healthcare costs, although there were no studies which evaluated cost-effectiveness of the interventions in this update review. Cost-effectiveness should be assessed and examined in future trials.

Whether the intervention was implemented with fidelity is an important consideration when assessing the outcomes of SDM interventions. However, this aspect of implementation was not clearly reported, except by one study (Yamaguchi 2017).

Furthermore, the number of identified studies was relatively small overall. This limited our ability to conduct further analyses, such as subgroup analyses, to further investigate potential modifiers of the effects of SDM interventions.

Certainty of the evidence

We assessed the methodological risk of bias of included studies in this update review in accordance with the *Cochrane Handbook* (Higgins 2011), and used the GRADE criteria to rank the certainty of the evidence (Schünemann 2011).

GRADE appraisal of the certainty of the evidence indicated low- or very low-certainty evidence for almost all outcomes in this updated review. We provide a summary of the reasons for downgrading below.

We assessed the methodological limitations of included studies and rated several studies as having a high risk of bias. It should also be noted that we rated many of the studies as 'unclear risk' for several items as we did not have enough information to assess the risk of bias based on the information available to us. We rated five or more studies as at unclear or high risk of bias for the key items of sequence generation and allocation concealment. Regarding blinding of participants, none of the studies could be rated as 'low risk' of bias due to the nature of the intervention; we rated all as 'high risk'. For blinding of outcome assessors, we rated only four studies as having a low risk of bias, and the remainder as having a high or unclear risk of bias. In 12 of the 15 studies, the risk of selective outcome reporting was high or unclear (the majority of studies had no published protocol), indicating that bias may be present due to not reporting all findings. Because of the small number of studies that assessed common outcomes, it was not possible to analyse publication bias due to failure to publish negative studies.

For imprecision, several (six of 15 studies) lacked statistical power because of the small sample sizes studied. We also found statistically significant levels of heterogeneity in several outcomes and this was a common reason for downgrading the certainty of the evidence. For example, there was high heterogeneity in depressive symptoms and service user involvement, which were measured with different scales. Several knowledge scales that were not standardised were used. Moreover, only five of the 15 included studies assessed the primary outcome; namely, the extent to which interventions can engage service users in the decision-making process. Furthermore, we found that these five studies did not use a common scale, but rather various kinds of scales.

Outcomes measured in very different ways was a common reason for downgrading the evidence due to indirectness. Thus, we expect that the certainty of the evidence in this area will improve if researchers develop or recognise (or both), and use, validated common measurements to assess the impact of interventions.

Moreover, the 15 studies varied in the setting, the diseases targeted, the nature of the decision-making about what to choose, the elements of decision support provided to service users including decision support tools, the type of comparison provided (the content of the intervention compared with usual care), and the targeted outcome measures. This too contributed to inconsistency across studies.

For the reasons described above, the overall evidence certainty of the results of this update review is low or very low, which limits our confidence in the results. In conclusion, more and better studies are needed to increase the certainty of the evidence in this field and to inform decisions about implementation of SDM interventions in mental health services.

Potential biases in the review process

Although we took every effort to minimise the potential for biases in the review process, three sources of potential bias may exist.

First, while our searches were comprehensive, there is a possibility that some relevant studies were missed for assessment by the review.

Second, a potential bias in reviews in this area is the adoption of clear criteria for what constitutes an SDM intervention for people with mental health conditions. We inherited the original review and clearly defined SDM based on Charles and colleagues' criteria (Charles 1997). This allowed us to establish a standard procedure for conducting this update review. Although SDM research has received a lot of attention, not only in this area, and the overall number of related publications has been increasing over the years, different researchers often use various definitions of SDM (Makoul 2006). For example, even when authors define SDM, there may be no choice or decision-making involved, only the facilitation of communication to encourage service users to speak up in the consultation (Moncrieff 2016), or motivational interviewing, which aims to increase motivation for a particular treatment (Ludman 2002). Shared decision making requires equipoise in decision-making (Elwyn 2006). That is, there is a range of possible and appropriate treatment options. In the process of choosing one of the options (including choosing none), the preferences and values of the service user and the health care provider regarding the options are clarified, and it is essential to make decisions based on those preferences and values. What SDM 'looks like' in mental health decision-making may nonetheless be potentially somewhat different from how it is encountered in other healthcare areas (Zisman-Ilani 2017). This may make selecting the studies for this review open to bias.

Third, the review included studies undertaken by some review authors. Assessment for inclusion, data extraction, and certainty assessment of these studies was undertaken by review authors not involved in the primary studies, in order to minimise any potential bias. On the other hand, this is also a strength of this update because the review team is composed of individuals with experience in SDM for those with mental health conditions.

Agreements and disagreements with other studies or reviews

There are some systematic and narrative reviews related to this topic. A review by James and Quirk identified a 'rationale for SDM' as any argument or reason for SDM in mental health care outlined by authors in a journal paper and which described the rationales (James 2017). Their review excluded raw data or outcome findings of experimental trials. A review by Zisman-Ilani and colleagues indicated unique elements of SDM in mental health, such as facilitating patient motivation and providing patient communication skills training, which were rarely seen in other medical fields (Zisman-Ilani 2017). However, this review was also descriptive and did not attempt statistical synthesis of the outcomes. Stovell and colleagues conducted a systematic review of shared treatment decision-making for psychosis, which identified 11 RCTs and showed small beneficial effects on indices of treatment-related empowerment (Stovell 2016). However, given its focus on treatment decisions concerning psychosis, this review did not consider other mental health conditions and rehabilitation or care plan decisions beyond medical treatments.

A Cochrane Review regarding interventions for increasing the use of SDM by healthcare professionals has been completed (Légaré 2018). The review suggests that interventions by health care providers to promote the use of SDM may slightly improve participants' mental health-related quality of life compared with usual care, with little or no difference in physical health-related quality of life (Légaré 2018). A Cochrane Review focusing on the effects of decision aids, a tool which may promote SDM, has also been conducted and updated periodically to reflect recent evidence (Stacey 2017). This review found that in a variety of decision-making situations, people who received the decision support tool intervention gained more knowledge and were better able to clarify their values compared with those receiving usual care. Those who used the tools also took a more active role in decision-making, a finding aligned with our results in this update review indicating that participants may perceive greater levels of involvement.

A Cochrane Review that aimed to determine the effects of decision coaching was published in 2021 (Jull 2021). This was the first version of the review and included 28 studies, which suggests that decision support interventions are recently gathering much attention. The review found that decision coaching did not indicate any adverse effects and may improve participants' knowledge.

In addition, SDM interventions have attracted attention in various areas dealing with physical diseases. A Cochrane Review exploring whether SDM interventions reduce the use of antibiotics for acute respiratory infections in primary care has been published (Coxeter 2015). The review found that SDM interventions significantly reduced antibiotic prescriptions for acute respiratory infections, compared with usual care (Coxeter 2015). Another Cochrane Review evaluated the effects and harms of SDM interventions in asthma treatment. The number of studies included in the review was relatively small, and each study was different, so meta-analysis was not possible (Kew 2017). However, evidence from individual studies indicated that SDM may improve quality of life and asthma control, and may reduce medical visits for asthma (Kew 2017).

Although this update review did not find the effects regarding improvement of clinical symptoms due to low- or very low-

certainty evidence, evaluations of these SDM interventions in the other somatic areas suggest that SDM interventions may potentially improve clinical outcomes. Efforts to promote consumer involvement in health and decision-making and to enable the delivery of more person-centred care should continue, and focusing on SDM interventions and their use in practice may be one means of promoting care that aligns with these principles.

There is a growing number of SDM interventions in various areas and reviews are being conducted. Overall, however, the certainty of the evidence seems to be moderate, low, or very low, and we are not yet convinced of the effectiveness of SDM interventions in any area for improving health outcomes. More and better studies, including agreed components of SDM and core outcomes and measures, are needed to increase the certainty of the evidence in this field. Shared decision-making continues to be supported from values-based healthcare and ethical perspectives, has gained policy prominence, and major guidelines have been published to promote its more routine use in clinical practice (NICE 2009; NICE 2015). We need to continue making efforts to implement the recommendations of these guidelines into clinical practice.

AUTHORS' CONCLUSIONS

Implications for practice

This updated review included 13 new studies published since 2010, for a total of 15 randomised and cluster-randomised controlled trials. We found that shared decision-making (SDM) interventions for those with mental health conditions may improve user-reported involvement in the decision-making process compared with usual care, probably without extending consultation duration.

The settings of implementation, target diseases, and components of the intervention were diverse, and the follow-up periods were also heterogeneous. This has important implications for how interventions need to be adapted to treatment content and environmental characteristics.

Overall, the certainty of evidence for the most results was shown to be low or very low. There were no adverse events reported.

Implications for research

Although this updated review includes an additional three studies conducted in Japan, most of the studies were conducted in North America, the United Kingdom, and Europe. This updated review included variations in the settings, the components of SDM interventions, and the components of intervention methods used for comparison and control. Many studies included decision aids and decision coaching as the components of SDM interventions. For comparisons, most studies had usual care but two studies provided cognitive training.

Future trials need to be added to this systematic review in order to more accurately capture the effects of SDM interventions in people with mental health conditions. Various populations such as children, older persons with cognitive impairment, or those in lower-income countries should be also included in future studies.

Some studies are known to be awaiting assessment or in progress and the availability of more studies may provide an opportunity to explore reasons for the heterogeneity of results.

In future, the fidelity of SDM interventions also needs to be assessed, to ensure that they were appropriately implemented as intended. Regarding the risk of bias, future studies should require researchers to more fully disclose their methods, publish their protocols, and report results in detail. Researchers in this field also need to recognise and use a common observer-based measurement which assesses the degree of service-user involvement in the decision-making process. This can be addressed through a formal Core Outcome Set development process (COMET 2021). Finally, future research should seek to address the adverse effects of SDM approaches and the cost-effectiveness of interventions.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Aljumah 2015

Study characteristics	
Methods	Randomised controlled trial
Participants	Outpatients of psychiatric hospital newly diagnosed with a major depressive disorder (DSM-IV) (n = 239) Comparator: usual pharmacy services Mean age not given. Intervention group 51% female, control group 49% female
Interventions	Before the SDM session started, the research team distributed a decision aid to participants. This was developed and validated by Aljumah and colleagues and is specifically designed for Arabic-speaking people. The SDM session delivered by pharmacists focused on enhancing participants' involvement in decision-making by assessing their beliefs and knowledge about antidepressants.
Outcomes	• Medication adherence: the Morisky Medication Adherence Scale (MMAS, validated; Morisky 2008) (Baseline, 3 months, and 6 months) • Specific necessity: Patients' Beliefs about Medicine Questionnaire Specific version (BMQ-Specific, validated; Horne 1999) (Baseline, 3 months, and 6 months) • Specific concerns: Patients' Beliefs about Medicine Questionnaire Specific version (BMQ-Specific, validated; Horne 1999) (Baseline, 3 months, and 6 months) • General harm: Patients' Beliefs about Medicine Questionnaire General version (BMQ-General, validated; Horne 1999) (Baseline, 3 months, and 6 months) • General overuse: Patients' Beliefs about Medicine Questionnaire General version (BMQ-General, validated; Horne 1999) (Baseline, 3 months, and 6 months)

Aljumah 2015 *(Continued)*

- Severity of depression: Montgomery–Åsberg Depression Rating Scale (MADRS, validated; Montgomery 1979) (Baseline, 3 months, and 6 months)
- Health-related quality of life: (EQ-5D, validated; EuroQol Group 1990) (Baseline, 3 months, and 6 months)
- Health-related quality of life: visual analogue scale (VAS) (Baseline, 3 months, and 6 months)
- Patient satisfaction with treatment: Treatment Satisfaction Questionnaire for Medication (TSQM, validated; Atkinson 2004) (Baseline, 3 months, and 6 months)
- Beneficial effect of pharmaceuticals: (do not state validity) (Baseline, 3 months, and 6 months)
- Beliefs about medicines: (do not state validity) (Baseline, 3 months, and 6 months)
- Sensitive: (do not state validity) (Baseline, 3 months, and 6 months)

Notes	The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using a computer-generated list
Allocation concealment (selection bias)	Low risk	The computer-generated allocation was done by a research assistant with no clinical involvement in the trial.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Pharmacists and psychiatrists were not blinded to the participants' group allocation. Participants knew to which group they belonged because of characteristics of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The assistant who collected data was blind to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal loss to follow-up in both intervention and control group: (8%) for both and equal across groups
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	No evidence of other risks of bias

Aoki 2019a

Study characteristics

Methods	Randomised controlled trial
Participants	University student outpatients with a first-time diagnosis of DSM-IV major depressive episode (major depressive disorder or depressive phase of bipolar disorder) (n = 88) Comparator: usual care Mean age intervention group: 21.8 years (SD 1.9); mean age control group 22.1 years (SD 2.0) Intervention group 43% female, control group 47% female

Aoki 2019a *(Continued)*

Interventions	Step 1. Initial option presentation consultation. The clinician informed the participant of the diagnosis and wrote treatment options on scratch paper for the participant to review at home. The clinician also provided the participant with the decision aid booklet, comprising general information about mood disorders and treatment options. Step 2. External deliberation and decision coaching with a nurse. At home, the participant reviewed the list of treatment options with the decision aid to facilitate the deliberation of treatment options by reviewing the information on the options, including pros and cons, and considering which features of options matter most. A couple of days after the initial consultation, the participant and a public health nurse discussed the treatment options at the service or on the phone. Step 3. Decision-making consultation. One week after the initial consultations, the participant visited the clinician for a decision-making consultation. The clinician clarified the participant's understanding and started discussions on topics that depended on the participant's understanding. They discussed treatment options and decided on the treatment.
Outcomes	• Satisfaction with communication: Combined Outcome Measure for Risk Communication and Treatment Decision-making Effectiveness (COMRADE, validated; Edwards 2003) (after decision-making consultation in intervention group and after initial consultation in control group) • Confidence in decision: Combined Outcome Measure for Risk Communication and Treatment Decision-making Effectiveness (COMRADE, validated; Edwards 2003) (after decision-making consultation in intervention group and after initial consultation in control group) • Patient satisfaction: Questionnaire - Client Satisfaction Questionnaire (CSQ-8, validated; Attkisson 1982) (after decision-making consultation in intervention group and after initial consultation in control group) • Consultation duration: minutes (during initial consultation) • Whether to look up treatment options/treatment received (between initial and decision-making consultation in intervention arm and after initial consultation in control arm) • Whether to share information with others (between initial and decision-making consultation in intervention arm and after initial consultation in control arm) • Adherence with outpatient visits (each clinic visit or did not attend for 6 months' follow-up) • Severity of depression: 16-item (QIDS-SR, validated; Rush 2003) (completed at each clinic visit for 6 months' follow-up) • Medication adherence: visual analogue scale (VAS) (completed at each clinic visit for 6 months' follow-up)
Notes	The authors declared that this study did not receive any specific grant from funding agencies. We asked the authors for means and SDs for COMRADE and consultation duration, and used them in this review. They also provided us with numbers of those who continued to visit the service after 6 months.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned to one of two arms, following the restricted randomisation and minimisation method of item 8 in CONSORT 2010 (Moher 2012).
Allocation concealment (selection bias)	Low risk	The randomisation was conducted by a research assistant not directly involved in the study.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Clinicians and nurses were not blinded because of the design of the study.

Aoki 2019a *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	A research assistant blinded to group allocation collected data.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Three month surveys > 40% of participants withdrew/excluded in both groups. Six month surveys - more participants were excluded in the control group compared with intervention group. However, ITT analysis was performed. There was also little difference in reasons for withdrawals between groups. Moreover, regarding the initial surveys, there were only 3 withdrawals in the intervention group. The main outcome was COMRADE immediately after the intervention. The sample size was calculated based on the main outcome.
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	No evidence of other risks of bias

Hamann 2006

Study characteristics	
Methods	Cluster-randomised controlled trial (unit of randomisation = ward)
Participants	Inpatients with ICD-10 diagnosis of schizophrenia or schizophreniform disorder (F20/F23) (n = 107) Comparator: usual care Mean age intervention group: 35.5 years (SD 11.9); mean age control 39.6 years (SD 10.8) Intervention group 41% female, control group 53% female
Interventions	Participants: decision aid - 16-page booklet. Participants were assisted in working through this by nurses. Duration 30 to 60 minutes. Participants met with their physicians within 24 hours afterwards for a planning talk. Nurses: instructed on use of decision aids. Physicians: two information sessions on SDM and the required communication skills.
Outcomes	Physician-rated: • Psychopathology: Positive and Negative Syndrome Scale for Schizophrenia (PANSS, validated; Kay 1987) (Baseline and at discharge) • Global Assessment of Functioning (GAF, validated; APA 2000) (6 and 18 months after discharge) • Severity of illness: Clinical Global Impressions Scale (CGI, validated; Guy 1976) (6 and 18 months after discharge) • Rating of time spent per week with participant (at discharge) • Rehospitalisation (6 and 18 months after discharge - dichotomous outcome) • Provider satisfaction (invalidated; 5-point Likert scale at point of discharge) Patient-rated: • Patient satisfaction (ZUF-8, German version of the CSQ - validated; Schmidt 1989) (at discharge) • Risk communication and confidence in decision (COMRADE - validated; Edwards 1999) (immediately after the intervention and at discharge) • Patient knowledge (invalidated questionnaire, at discharge) • Attitude towards treatment: the Drug Attitude Inventory (DAI, validated; Hogan 1983) (at discharge)

Hamann 2006 *(Continued)*

- Doctor-patient relationship: Working Alliance Inventory (WAI, validated; Horvath 1989) (at discharge)
- Estimated compliance from physician's point of view (at discharge)
- Number of drug switches (at discharge)
- Prescribed antipsychotic class (1st or 2nd generation antipsychotic class) (at discharge)
- Psychoeducation uptake (at discharge)
- Socio-therapeutic intervention uptake (at discharge)
- How often main antipsychotic was switched (within 6 months after discharge)

Composite measure:

- Participant concordance with treatment plan - dichotomous outcome (based on participant completion of Medication Adherence Rating Scale (MARS) questionnaire, patient compliance as rated by the physician on a 4-point scale, and plasma levels of antipsychotics) rated at 6 and 18 months' after discharge

Notes	This trial was funded by the German Ministry of Health and Social Security (217-43794-5/9) within the funding project Der Patient als Partner im medizinischen Entscheidungsprozess.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Sequence generation took place after wards had been paired based on their characteristics, so this is not truly random.
Allocation concealment (selection bias)	High risk	Randomisation was at the ward level. Adequate allocation concealment at the level of the participant would not be possible.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which arm they belonged because of characteristics of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Psychiatrists and nurses as assessors were not blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant loss to follow-up. For some outcomes, it was not clear how many participants were lost from each group, and what the reasons for missing data were. The participant flow chart gives the number of participants who withdrew consent after joining the study (five (9%) in the intervention group and one (2%) in the control group). However, the Hamann 2006 results table (Table 1) indicates the total numbers lost to follow-up (not just withdrawals). The number of respondents for control and intervention groups combined is: for Combined Outcome Measure for Risk Communication and Treatment Decision Effectiveness (COMRADE) after intervention n = 75 (66%), COMRADE before discharge n = 82 (73%), knowledge before discharge n = 88 (78%), and patient global satisfaction ZUF-8 n = 83 (73%). In the longer-term follow-up (2007 data, see Hamann 2006) data were unavailable for 71 participants (66%).
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	High risk	Participants were recruited to the trial after the clusters had been randomised. Primary (/secondary) outcomes were not prespecified. Clustering was not accounted for in the analysis.

Hamann 2011

Study characteristics	
Methods	Randomised controlled trial
Participants	Inpatients of University Psychiatric Hospital with schizophrenia or schizoaffective disorder according to the ICD-10 (n = 61) Comparator: cognitive training Overall mean age 40.7 (SD 11.7). (No mean age given for each group) Overall, 62% were female (the number of female participants per group not stated).
Interventions	Training consisted of five one-hour sessions for a group of five to eight participants. The content of the training was derived from theoretical considerations about participants' contributions to the shared decision-making process, from an adaptation of related approaches from somatic medicine, and from pilot testing the training. The training sessions included motivational aspects, such as prospects of participation, and behavioural aspects, including role-play exercises.
Outcomes	Participants: • Autonomy: Autonomy Preference Index, API (validated; Ende 1989) (post intervention and then 6 months post hospital discharge). • Responsibility for decision-making: possible scores range from 14 to 70 (do not state validity) (post intervention and then 6 months post hospital discharge) • Decision self-efficacy: the Decision Self-Efficacy Scale (validated; O'Connor 1995b) (post intervention) • Specific necessity: Patients' Beliefs about Medicine Questionnaire Specific version, BMQ-Specific (validated; Horne 1999) (post intervention) • Specific concerns: Patients' Beliefs about Medicine Questionnaire Specific version, BMQ-Specific (validated; Horne 1999) (post intervention) • General harm: Patients' Beliefs about Medicine Questionnaire General version, BMQ-General (validated; Horne 1999) (post intervention) • General overuse: Patients' Beliefs about Medicine Questionnaire General version, BMQ-General (validated; Horne 1999) (post intervention) • Patient satisfaction: satisfaction with treatment scale of the ZUF-8 (validated; Schmidt 1989) (post intervention) • Trust in physician: Trust in Physician Scale (validated; Anderson 1990) (post intervention) • Self-responsibility: Multidimensional Health Locus of Control Scale (validated; Wallston 1978) (post intervention) • Self-blame: Multidimensional Health Locus of Control Scale (validated; Wallston 1978) (post intervention) • Powerful others: Multidimensional Health Locus of Control Scale (validated; Wallston 1978) (post intervention) • Chance: Multidimensional Health Locus of Control Scale (validated; Wallston 1978) (post intervention) • "Who makes important decisions about your medical treatment?" (post intervention and then 6 months post hospital discharge) • "Are you still in psychiatric treatment?" (6 months post hospital discharge) • "Are you still taking medication for your psychiatric condition?" (6 months post hospital discharge) Physicians: • Difficult doctor-patient relationship: Difficult Doctor-Patient Relationship Questionnaire, DDPRQ (validated; Hahn 1994) (post intervention) • Decisional capacity: possible scores range from 16 to 90 (do not state validity) (post intervention) • Therapeutic alliance: possible scores range from 6 to 36 (do not state validity) (post intervention)

Hamann 2011 *(Continued)*

- "Has this patient shown up at your practice since being discharged from the hospital?" (6 months post hospital discharge)
- "Has this patient been hospitalised in the preceding 6 months?" (6 months post hospital discharge)
- "How do you estimate your patient's compliance?" (6 months post hospital discharge)
- "How much does this patient engage in planning or his or her therapy?" (6 months post hospital discharge)

Notes	This work was supported by research project grant 2168-1746.1/2007 from the German-Israeli Foundation for Scientific Research and Development and a Young Minds in Psychiatry Award from the American Psychiatric Association. The authors report no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used a randomisation list
Allocation concealment (selection bias)	Low risk	Closed allocation concealment envelopes were prepared.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which arm they belonged because of the characteristics of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No specific information
Incomplete outcome data (attrition bias) All outcomes	High risk	This study assessed outcomes 6 months after hospital discharge. However, there was no mention of loss to follow-up or no loss to follow-up. Missing data were not presented.
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	High risk	Small sample size. No sample size calculation

Hamann 2017

Study characteristics

Methods	Randomised controlled trial
Participants	Inpatients in acute words of psychiatric hospital with a diagnosis of schizophrenia or schizophreniform disorder (n = 264) Comparator: cognitive training Mean age intervention group: 36.4 years (SD 12.6); mean age control 38.2 years (SD 12.2) Intervention group 41% female, control group 53% female
Interventions	A five-session SDM-training for inpatients with schizophrenia. The SDM-training sessions included motivational (e.g. prospects of participation, patient rights, communication skills, and preparing for ward

Hamann 2017 *(Continued)*

	rounds and consultations) and behavioural aspects (e.g. role plays) and addressed important aspects of the patient–doctor interaction, such as question asking or giving feedback.
Outcomes	Patient-rated: • Medication adherence: Medication Adherence Questionnaire, MAQ (validated; Morisky 1986) (12 months after hospital discharge) • Medication adherence: Medication Adherence Rating Scale, MARS (validated; Thompson 2000) (6 months and 12 months after hospital discharge) • Adherence with outpatient visits: patient reported yes or no (12 months after hospital discharge) • Autonomy: Autonomy Preference Index, API (validated; Ende 1989) (post intervention, 6 months and 12 months after discharge) • Specific necessity: Patients' Beliefs about Medicine Questionnaire Specific version, BMQ-Specific (validated; Horne 1999) (post intervention) • Specific concerns: Patients' Beliefs about Medicine Questionnaire Specific version, BMQ-Specific (validated; Horne 1999) (post intervention) • General harm: Patients' Beliefs about Medicine Questionnaire General version, BMQ-General (validated; Horne 1999) (post intervention) • General overuse: Patients' Beliefs about Medicine Questionnaire General version, BMQ-General (validated; Horne 1999) (post intervention) • Patient satisfaction: satisfaction with treatment scale of the ZUF-8 (validated; Schmidt 1989) (post intervention) • Responsibility for decision-making: 15 questions on different aspects of the treatment process (post intervention, 6 months and 12 months after discharge) • Trust in physician: Trust in Physician Scale (validated; Glattacker 2007) (post intervention) • Rating of perceived profit from visiting intervention group session: "Who makes important decisions about your medical treatment?'' (post intervention) Doctor-rated: • Clinical global impression: Clinical Global Impression, CGI (validated; Guy 1976) (post intervention) • "Who makes important decisions about the patient's medical treatment?'' (post intervention, 6 months and 12 months after discharge) • Difficult doctor-patient relationship: Difficult Doctor-Patient Relationship Questionnaire, DDPRQ (validated; Hahn 1994) (post intervention) • Doctors' rating of patient behaviour in the consultation ''Patient explicitly requested a talk with the doctor'' (post intervention) • Doctors' rating of patient behaviour in the consultation ''Patient asked questions'' (post intervention) • Doctors' rating of patient behaviour in the consultation ''Patient expressed an opinion" (post intervention) • Doctors' rating of patient behaviour in the consultation ''Patient prepared for the consultation (e.g. using a leaflet)'' (post intervention) • Doctors' rating of patient behaviour in the consultation ''Patient brought a relative to the consultation'' (post intervention) • Doctors' rating of patient behaviour in the consultation "Patient made treatment proposal'' (post intervention) • Doctors' rating of patient behaviour in the consultation "Patient asked for treatment alternatives'' (post intervention) • Doctors' rating of patient behaviour in the consultation ''Patient objected to the doctor's recommendations'' (post intervention) • Doctors' rating of patient behaviour in the consultation: sum score (post intervention) • Hospitalised within 12 months (12 months after discharge)
Notes	The study was funded by the German Ministry for Research and Education. JH and WK received lecture honoraria from JnJ, Lilly and Otsuka and research grants from JnJ and Lilly.

Hamann 2017 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Separate randomisation lists for every study centre (block size = 4) were used.
Allocation concealment (selection bias)	Low risk	Numbered, closed, allocation concealment envelopes were generated prior to the study by statistical department
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Psychiatrists who did doctor-reported outcomes were not blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	> 30% loss to follow-up for both groups for the primary outcome. The reasons were not detailed and therefore it is unclear if reasons differ between the groups.
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	No evidence of other risks of bias

Ishii 2017

Study characteristics	
Methods	Randomised controlled trial
Participants	Inpatients in acute ward of psychiatric hospital with a diagnosis of schizophrenia spectrum disorder, including schizophrenia, schizotypal, and delusional disorders, defined according to the diagnosis codes F20–F29 in the ICD-10 (n = 24). Comparator: usual care Mean age intervention group: 41.6 years (SD 13.6); mean age control 37.4 years (SD 9.8) Intervention group 27% female, control group 31% female
Interventions	The programme was a 15- to 20-minute weekly intervention lasting the duration of the participants' acute psychiatric ward stay, with a maximum of 90 days. Sessions were held on a certain day and time every week during the hospitalisation. They involved three sequential elements: (1) the participant answered the questionnaire regarding their perception of ongoing treatment; (2) the participant and staff held a session in which they shared information and their preferences (a 15- to 20-minute meeting), and (3) the participant and staff created a weekly care plan sheet.
Outcomes	• Patient satisfaction: Questionnaire - Client Satisfaction Questionnaire, CSQ-8 (validated; Attkisson 1982) (at hospital discharge) • Functioning: Global Assessment of Functioning, GAF (validated; Jones 1995) (at hospital discharge) • Average length of stay (at hospital discharge)

Ishii 2017 *(Continued)*

- Attitude towards medication: Japanese version of the Drug Attitude Inventory-10, DAI-10 (validated; Hogan 1983) (at hospital discharge)
- Adherence with outpatient visits: whether a participant received outpatient psychiatric treatment within 30 days prior to follow-up time on medical records (6 months after discharge)

Notes	This study was supported by Health and Labor Sciences Research Grant for Comprehensive Research on Disability Health and Welfare from the Japanese Ministry of Health, Labour and Welfare (H23-Seishin-Ippan-008). The authors declared that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used a computer-generated random number sequence
Allocation concealment (selection bias)	Unclear risk	No specific information
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which arm they belonged because of the characteristics of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No specific information
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low loss to follow-up rate (< 20%)
Selective reporting (reporting bias)	Low risk	The protocol is available and expected outcomes were reported as planned by the study.
Other bias	High risk	Small sample size. The protocol stated: "We estimate that a sample size of 26 patients per arm is required, and 58 patients will be included", but 24 patients participated in this study.

LeBlanc 2015

Study characteristics

Methods	Cluster-randomised controlled trial
Participants	Primary care patients with moderate to severe depression, a Patient Health Questionnaire (PHQ-9) score of 10 or higher (n = 301) Comparator: usual care Mean age intervention group: 43.2 years (SD 15.6); mean age control 43.9 years (SD 15.1) Intervention group 72% female, control group 62% female
Interventions	The decision aid, laminated 10.16 cm × 25.40 cm cards, presents general considerations about antidepressant efficacy and then adverse effects in terms that matter to patients: weight change, sleep, libido, discontinuation, and cost. The decision aid was briefly (< 10 minutes) demonstrated to clini-

LeBlanc 2015 *(Continued)*

	cians (i.e. how to use the decision aid) prior to enrolment of their first participant. A video clip and story board demonstrating the basic use of the decision aid remained available, as well as a leaflet for participants to take home. Clinicians in the intervention group were to use the decision aid during the consultation with their patients. The authors developed the decision aid in close collaboration with stakeholders, including patients. The authors also engaged stakeholders throughout the set-up and conduct of the trial, seeking insights primarily on eligibility criteria, choice of outcomes, and recruitment strategies.
Outcomes	Participants: • Decisional conflict: Decisional Conflict Scale, DCS (validated; O'Connor 1995a) (immediately after the clinical encounter) • Knowledge: tailored to information in the DA (validated; O'Conner 2000) (immediately after the clinical encounter) • Knowledge: depression in general (validated; O'Conner 2000) (immediately after the clinical encounter) • Knowledge: overall both tailored and generic (validated; O'Conner 2000) (immediately after the clinical encounter) • Satisfaction: right amount of information given (immediately after the clinical encounter) • Satisfaction: information given was extremely clear (immediately after the clinical encounter) • Satisfaction: information given was extremely helpful (immediately after the clinical encounter) • Satisfaction: strongly desire to receive information this way for other treatment decisions (immediately after the clinical encounter) • Satisfaction: strongly recommend the way information was shared to others (immediately after the clinical encounter) • Severity of depression: Patient Health Questionnaire-PHQ9 score (validated; Kroenke 2001) (3 and 6 months) • Remission: Patient Health Questionnaire-PHQ score < 5 (validated; Kroenke 2001) (3 and 6 months) • Responsiveness: Patient Health Questionnaire-PHQ score < 5 (validated; Kroenke 2001) (3 and 6 months) • Medication adherence: participant reported medication usage (at time of encounter) • Medication adherence: participant reported medication usage (after the encounter) • Medication adherence: pharmacy records and medical records (for the trial period) • Medication adherence: primary adherence as proportion of participants who filled their prescription within 30 days (at time and after encounter, not more specific about timing) • Medication adherence: secondary adherence as the proportion of participants with a percentage of days covered greater than 80% (after encounter, not more specific about timing) Clinicians: • Decisional conflict: Decisional Conflict Scale, DCS (validated; O'Connor 1995a) (immediately after the clinical encounter) • Involvement of patients in the decision-making process: Observing PatienT Involvement in shared decisiON making, OPTION scale (validated; Elwyn 2005) (assessed from video recording on the encounter) • Satisfaction: acceptability of information sharing, one-item, 5-point Likert scale (immediately after the clinical counter)
Notes	This study was funded by the Agency for Healthcare and Quality Research under the American Recovery and Reinvestment Act of 2009 (iADAPT-1 grant R18 HS019214). Conflict of interest disclosures: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement

LeBlanc 2015 *(Continued)*

Random sequence generation (selection bias)	Low risk	A statistician performed the randomisation. The authors paired practices by size and by whether they had implemented the DIAMOND (Depression Improvement Across Minnesota, Offering a New Direction) program, a practice redesign initiative to improve depression care through the use of care coordinators.
Allocation concealment (selection bias)	Low risk	A statistician performed the randomisation centrally.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and clinicians were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Study team members were aware of the assigned arms.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Large number of people participated in post encounter survey (allocation: intervention 159, control 142) (post encounter: intervention 140, control 118), although dropouts at 3 and 6 months were very large. Main outcome was decisional conflict post encounter.
Selective reporting (reporting bias)	Low risk	All outcomes planned in the protocol were undertaken in the study.
Other bias	Low risk	No evidence of other risks of bias

Loh 2007

Study characteristics	
Methods	Cluster-randomised controlled trial (unit of randomisation = physician)
Participants	Primary care patients newly diagnosed with depression (Patient Health Questionnaire (PHQ)) (n = 405) Comparator: usual care Around two-thirds of the participants were female. The average age of the control group was around 41 years (SD 13) and the average age of the intervention group was around 49 years (SD 17).
Interventions	Participants: a decision board for use during consultation was handed out to participants to take away. Printed patient information combining evidence-based knowledge about depression care with specific encouragement for patients to be active in the decision-making process. Physicians: modules on guideline-concordant depression care. Enhancing skills for involving patients in the decision-making process. Facilitation practice, role-playing and video examples of high-quality decision-making. Standardised case vignettes. 5 scheduled training events over a 6-month period.
Outcomes	Patient participation doctor facilitation (PICS-DF, validated Lerman 1990) Patient participation information seeking (PICS-IS, validated Lerman 1990) Patient participation Man-Song-Hing Scale (Man-Song-Hing 1999) Consultation time

Loh 2007 *(Continued)*

	Levels of depression (measured by Patient Health Questionnaire-9 (PHQ 9) Spitzer 1999) Patient satisfaction (ZUF-8 German version of the CSQ - validated; Schmidt 1989) Patient assessment of treatment adherence (1 question on a 5-point Likert scale) Physician assessment of treatment adherence (1 question on a 5-point Likert scale)
Notes	The study was funded by the German Ministry of Health (BMGS Grant 217-43794-5/6). Celia E. Wills is a past recipient of a US National Institute of Mental Health Mentored Clinical Scientist Career Development (K08) Award (MH01721; 2000-2005) on depression treatment decision-making of primary care patients.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Two-thirds of the general practitioners were randomly assigned to the intervention group by drawing blinded lots under supervision of the principal investigator and two researchers.
Allocation concealment (selection bias)	Low risk	Drawing blinded lots
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which arm they belonged because of characteristics of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No specific description
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant loss to follow-up
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	High risk	Participants were recruited to the trial after the clusters had been randomised.

Lovell 2018

Study characteristics

Methods	Cluster-randomised controlled trial
Participants	All teams within the participating National Health Service (NHS) Trusts, patients aged 18+ with a severe and enduring mental illness (including psychosis, bipolar disorder, schizophrenia, personality disorder) (n = 604) Comparator: usual care Age intervention group: 18 to 24 years, 21 people (6.33%); 25 to 44 years, 114 people (34.34%); 45 to 64 years, 177 people (53.31%); 65+ years, 11 people (3.31%). Age control group: 18 to 24 years, 17 people (6.25%); 25 to 44 years, 99 people (36.40%); 45 to 64 years, 134 people (49.26%); 65+ years: 16 people (5.88%). (Mean age not reported)

Lovell 2018 *(Continued)*

	Intervention group 60% female, control group 58% female
Interventions	Training included a range of formats: face-to-face, self-directed learning, and follow-up supervision. The consensus exercise indicated a minimum of 15 hours and maximum of 30. 2 days (12 hours) plus 6 hours of follow-up supervision and 8 hours of self-directed learning (optional). Hence, each health professional received 18 hours of facilitated training and an additional optional 8 hours of self-directed learning.
Outcomes	• Perceived Autonomy Support: the Health Care Climate Questionnaire, HCCQ-10 (validated; Ludman 2002) (6 months after intervention) • User involvement in care planning (service users): Equip patient-reported outcome measure, EQUIP PROM (validated; Bee 2016) (6 months after intervention) • User involvement in care planning (carers): Equip patient-reported outcome measure, EQUIP PROM-14 (validated; Bee 2016) (6 months after intervention) • Satisfaction (service users): Verona Service Satisfaction Scale, VSSS-EU-54 (validated; Ruggeri 1993; Ruggeri 2000) (6 months after intervention) • Satisfaction (carers): Carers and Users' Expectations of Services - carer version, CUES-C (validated; Lelliott 2003) (6 months after intervention) • Medication side effects: the Glasgow Antipsychotic Side-effect Scale, GASS (validated; Waddell 2008) (6 months after intervention) • Well-being: the Warwick-Edinburgh Mental Well-being Scale (validated; Tennant 2007) (6 months after intervention) • Recovery and hope: Developing Recovery Enhancing Environments Measure (validated; Ridgway 2004) (6 months after intervention) • Anxiety Symptoms: Hospital Anxiety and Depression Scale, HADS-A (validated; Zigmond 1983) (6 months after intervention) • Depression Symptoms: Hospital Anxiety and Depression Scale, HADS-D (validated; Zigmond 1983) (6 months after intervention) • Alliance/engagement: California Psychotherapy Alliance Scale, CALPAS (validated; Gaston 1991) (6 months after intervention) • Quality of life: World Health Organisation Quality of Life, WHOQOLBREF (validated; Skevington 2004) (6 months after intervention) • Economic outcome, Health Status: the EQ-5D-5L to assess health status and to estimate Quality-Adjusted Life Years, QALYs (validated; Janssen 2013) (6 months after intervention) • Economic outcome: service use questionnaire to identify the range of services used by each trial participant and how much they used each service (6 months after intervention)
Notes	This study was funded by the National Institute for Health Research's Programme Grants for Applied Research (RP-PG1210-12007). The Author declared that there was no conflict of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocated randomly
Allocation concealment (selection bias)	Low risk	Allocation was determined through an external telephone randomisation service.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which arm they belonged because of the characteristics of the intervention.

Lovell 2018 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers blind to allocation assisted participants in completing measures at baseline and 6 months.
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant loss to follow-up. Allocated (397 intervention; 319 control). Analysed (271 intervention; 226 control)
Selective reporting (reporting bias)	Low risk	All outcomes described in the protocol were reported.
Other bias	High risk	Participants were recruited to the trial after the clusters had been randomised. Missing baseline data for the cohort sample were cluster mean imputed.

Mariani 2018

Study characteristics	
Methods	Cluster-randomised controlled trial
Participants	Individuals having a diagnosis of dementia based on DSM-IV (APA 2000) (n = 49) Comparator: usual care planning Mean age intervention group: 84.0 years (SD 7.3) in Italy; 78.8 years (SD 14.5) in the Netherlands. Mean age control group: 88.5 years (SD 6.2) in Italy; 87.1 years (SD 5.8) in the Netherlands Intervention group: 85% female in Italy; 78% female in the Netherlands. Control group 71% female in Italy; 77% female in the Netherlands
Interventions	**Training for professionals** Professionals attended training sessions of 12 hours that focused on the principles of SDM and active listening in the dementia context and on their application to the care planning process. The training programme consisted of 3 meetings of 4 hours each, involved role-play, and both theoretical and practical lessons. **SDM interview** After the training, professionals had SDM interviews with the residents and their family caregivers to stimulate and facilitate the residents' expression of their preferences and wishes and to translate them into care objectives. After the interview, professionals updated the residents' 'life-and-care plans' by reporting the outcomes of the conversation. The residents and relatives then read it, and signed for agreement the developed care plans.
Outcomes	• Whether the items in Recommendation 1 (i.e. "The facility must develop a comprehensive care plan addressing the resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment. Nursing documentation should be person-centered and give emphasis to psychosocial aspects") were present or not in the care plan; a case report form was examined (6 months after the SDM interviews) • Whether the items in Recommendation 2 (i.e. "The care plan should include a well-defined problem-statement and should outline SMART (Specific, Measurable, Achievable, Realistic, Timely) goals of care") were present or not in the care plan; a case report form was examined (6 months after the SDM interviews) • Whether the items in Recommendation 3 (i.e. "The care plan must provide specific interventions to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident") were present or not in the care plan; a case report form was examined (6 months after the SDM interviews)

Mariani 2018 *(Continued)*

- Whether the items in Recommendation 4 (i.e. "The care plan should specify the measurements or a timetable for objectives implementation and identify when care objectives are met") were present or not in the care plan; a case report form was examined (6 months after the SDM interviews)
- Whether the items in Recommendation 5 (i.e. "The nursing team facilitates patients and/or family representative participation in the development and implementation of the resident's care plan, respects patients' beliefs and values the relationship with him/her") were present or not in the care plan; a case report form was examined (6 months after the SDM interviews)
- Dementia patients' quality of life: Dementia quality of life Instrument, DQoL (validated; Brod 1999) (6 months after the SDM interviews)
- Family caregivers' quality of life: the EuroQoL (validated; EuroQol Group 1990) (6 months after the SDM interviews)
- Sense of competence of the family caregivers of dementia residents: Short Sense of Competence Questionnaire, SSCQ (validated; Vernooij-Dassen 1999) (6 months after the SDM interviews)
- Professional caregivers' Job Satisfaction Questionnaire: JSQ (validated; Orrung Wallin 2013) (6 months after the SDM interviews)

Notes	Supported by the European Union's Seventh Framework Program FP7/2007-2013 under grant agreement n°258883. The authors declared that there was no conflict of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	One ward randomly assigned to the intervention group and the other to the control group, but no specific description
Allocation concealment (selection bias)	Unclear risk	No specific information
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which arm they belonged because of the characteristics of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Whether outcome assessors were blinded or not was unclear.
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant loss to follow-up. Allocated: 17 intervention; 15 control. Analysed: 9 intervention; 13 control
Selective reporting (reporting bias)	High risk	Protocol: the primary outcome measure was the proportion of dementia residents whose preferences, needs, and related actions were known, satisfied, and documented in their 'life-and-care plan' (Detering 2010; see secondary reference Mariani 2016). Results paper: the primary outcome was the agreement of the residents' 'life-and-care plans' with the five operationalised recommendations.
Other bias	High risk	Small sample size. No sample size calculation. Clustering was not accounted for in the analysis.

Mott 2014

Study characteristics

Mott 2014 *(Continued)*

Methods	Randomised controlled trial
Participants	People diagnosed with PTSD and had served at least one tour in Iraq or Afghanistan. (PTSD diagnosis was confirmed with the PTSD Symptom Checklist at baseline) (n = 27). Comparator: a 30-minute placebo session Mean age: 29.3 years (SD 5.5) (no information about each group) Overall, 15% female (the number of female participants per group not stated)
Interventions	**SDM intervention and a decision aid:** The SDM intervention manual guides clinicians through a 30-minute decision-making session based on a decision-making model by Elwyn and colleagues (Elwyn 2010; Elwyn 2012), which identifies SDM components, including "choice talk," a planning step in which the provider indicates that a choice exists and that the participant can have a role in treatment decisions; "option talk," during which the provider gives detailed information about benefits/risks, mechanisms, and effectiveness of treatments using a decision aid; and "decision talk," during which the participant and provider dialogue about preferences, eventually eliciting a decision. The intervention manual also included example scripts and prompts for describing and discussing treatment options. The decision aid included a comparison chart that summarised the central aspects of each featured treatment and briefly described alternative PTSD treatments, inviting participants to request further details about these options. SDM sessions were completed in person or via phone.
Outcomes	• Treatment preferences: participants selected more than one treatment option (during intervention) • Treatment engagement: study staff reviewed participants' medical records (at 4 months' follow-up)
Notes	This research was supported by the Office of Academic Affiliations VA Advanced Fellowship Program in Mental Illness Research and Treatment, the Department of Veterans Affairs South Central Mental Illness Research Education and Clinical Center (MIRECC), and the VA HSR&D Houston Center of Excellence (HFP90-020).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used a computer-generated randomisation sequence
Allocation concealment (selection bias)	High risk	Used envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which arm they belonged because of the characteristics of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Clinical providers were not blinded, but study staff were not sure if they were blinded or not.
Incomplete outcome data (attrition bias)	High risk	Significant loss to follow-up. Allocated: 13 SDM; 14 control. Analysed: 9 SDM; 11 control.

Mott 2014 *(Continued)*

All outcomes

Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	High risk	Small sample size. No sample size calculation

Raue 2019

Study characteristics	
Methods	Randomised controlled trial
Participants	Outpatients of age 65 years and older, screen positive (Patient Health Questionnaire-9 (PHQ-9) score > 9) for depression, in addition to primary care physician recommendation for depression treatment (n = 202) Comparator: usual care Mean age intervention group: 72.2 years (SD 5.4); control group: 71.9 years (SD 5.6) Intervention group 81% female, control group 82% female
Interventions	SDM intervention consisted of a 30-minute in-person meeting followed by 2 weekly 10- to 15-minute telephone calls by nurses. Nurses discussed the participant's depressive symptoms and provided psychoeducation using decision-aid material to further clarify participants' values. During follow-up calls, if participants encountered difficulty because of poor motivation, stigma, poor access, high cost, or lack of service availability, nurses attempted to address unresolved treatment barriers and re-engaged participants in SDM processes.
Outcomes	12-week adherence, number of participants who adhered to physician-recommended treatment (12 weeks after intervention) • initiation of any mental health care, including mental health evaluation, psychotherapy or antidepressant medication (any versus none) • initiation of psychotherapy (any versus none) • frequency of psychotherapy visits • initiation of antidepressant medication (any versus none) • total number of pills taken; self-reported amount Depression symptoms: Hamilton Depression Rating Scale (HDRS) change score from baseline (validated; Hamilton 1960) (4-, 8-, and 12-week follow-up points)
Notes	Grant support was provided by the National Institute of Mental Health R01 MH084872.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No specific information
Allocation concealment (selection bias)	Unclear risk	No specific information

Raue 2019 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which group they belonged.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Research assistants as assessors were aware of randomisation status.
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant loss to follow-up
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	No evidence of other risks of bias

Troquete 2013

Study characteristics	
Methods	Cluster-randomised controlled trial
Participants	Case managers (n = 58) and clients of outpatient forensic psychiatric services (n = 632) Comparator: usual care planning Mean age case managers: 41.7 years (SD 10.4, range 22 to 59). Mean age clients intervention group: 40.0 years (SD 11.2); control group: 39.1 years (SD 12.4) Case manager 59% female. Clients intervention group 6% female; clients control group 13% female.
Interventions	The intervention consisted of two parts: a structured approach to risk assessment, and a care plan evaluation utilising the key strengths and vulnerabilities identified during the first part of the intervention. Case managers first assessed the client's risk and protective factors with the START (Short Term Assessment of Risk and Treatability). Clients did the same, using a specially-developed client version of the START. Both case manager and client identified the client's key strengths and critical vulnerabilities and then discussed them, with the aim of agreeing on the types of care to be included in the new treatment plan. Case managers were trained, and clients received no training, but case managers answered their questions if necessary.
Outcomes	The proportion of clients with one or more violent or criminal incidents (in the 6 months before the end of follow-up)
Notes	The study was funded by a grant from ZonMw, the Netherlands Organisation for Health Research and Development (grant 100 003 023). The authors declared that there were no conflicts of interest.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No specific description

Troquete 2013 *(Continued)*

Allocation concealment (selection bias)	Low risk	The second author, who was masked to the case managers' identities, executed the randomisation procedure.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Masking of clients or case managers was not an option.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers were masked to client randomisation status.
Incomplete outcome data (attrition bias) All outcomes	High risk	Significant loss to follow-up. Allocated: 558 intervention; 569 control. Analysed: 310 intervention; 324 control.
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	High risk	Based on a pilot study, a power analysis indicated that 340 participants should be included in each study group. Analysed: 310 intervention; 324 control. Clustering was not accounted for in the analysis.

Woltmann 2011

Study characteristics	
Methods	Cluster-randomised controlled trial
Participants	Case managers (n = 20) and clients who received case management from the case manager (n = 80). Clients could participate only if they were scheduled for a regularly-occurring six-month care plan. Comparator: usual care planning Mean age case managers intervention group: 47 years (SD 12); control group: 31 years (SD 7). Mean age clients intervention group: 47 years (SD 7); control group: 46 years (SD 11). Case managers: intervention group 80% female; control group 60% Clients: intervention group 37.5%; control group 30%
Interventions	A three-step EDSS (electronic decision support system) process. First, clients indicated their top priorities and ideas for services at a touch-screen-enabled computer kiosk. Second, the information was electronically sent to the clients' case managers, who then completed a similar process. Finally, the two perspectives were merged electronically and presented graphically in a shared decision-making session with the dyad. Case managers were given a brief manual and a one-hour didactic and practice session, in which they were able to try out the technology and ask questions.
Outcomes	• Case manager satisfaction: 6 statements related to satisfaction, a 5-point Likert scale (after participation) • Client satisfaction: 7 statements related to satisfaction, a 5-point Likert scale (after participation) • Client knowledge: knowledge of the care plan (two to four days after the care planning session)

Woltmann 2011 *(Continued)*

Notes	This study was funded by the West Family Foundation and the Segal Family Foundation. The authors reported no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No specific description
Allocation concealment (selection bias)	Unclear risk	No specific description
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which group they belonged.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Participants, providers, and outcome assessors were not blinded; unclear whether data analysts were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Satisfaction (case managers, clients) did not have missing data. Knowledge had missing data, but not significant number (intervention: 90% provided data; control: 83% provided data).
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	High risk	Primary (/secondary) outcomes were not prespecified. No sample size calculation

Yamaguchi 2017

Study characteristics

Methods	Randomised controlled trial
Participants	Outpatients who used psychiatric day care or home-visit nursing (outreach services) (n = 56) Comparator: usual care Mean age intervention group: 39.4 years (SD 11.6); mean age control group 38.2 years (SD 9.5) Intervention group 38% female, control group 44% female
Interventions	Outpatients visited decision support centres, and they first met with peer support specialists, who helped them use the decision support tool, Support for Hope And Recovery (SHARE), by sharing their recovery experiences. SHARE guided participants in identifying personal values and treatment preferences. Before consultations, participants used SHARE to rate their condition and concerns. During consultations, doctors were encouraged to confirm the participant's personal recovery goals. Doctors then proceeded with consultation on the basis of the participant's condition and concerns as entered in SHARE. In addition, as part of shared decision-making, doctors were expected to discuss treatment or self-management behaviours based on the participant's personal recovery goals. At the end of the consultation, the participant and the doctor determined the treatment or self-management

Yamaguchi 2017 *(Continued)*

	behavior for follow-up at the next consultation, after which the doctor confirmed shared decision-making content with the participant and entered it into SHARE.
Outcomes	• Core components of SDM: scoring the transcripts of conversations between participants and doctors during consultation, SDM-18 (validated; Salyers 2012) (during consultation) • Therapeutic relationship: Scale to Assess Therapeutic Relationship (STAR)-Clinician, doctor-rated (validated; McGuire-Snieckus 2007) (after 6 months' follow-up) • Therapeutic relationship: STAR-Patient, patient-rated (validated; McGuire-Snieckus 2007) (after 6 months' follow-up) • Interpersonal process: the Interpersonal Processes of Care Survey Short (validated; Stewart 2007) (after 6 months' follow-up) • Patient activation: Patient activation measure, PAM (validated; Fujita 2010) (after 6 months' follow-up) • Satisfaction: Client Satisfaction Questionnaire–8, CSQ-8 (validated; Attkisson 1982) (after 6 months' follow-up) • Weight (after 6 months' follow-up) • Psychiatric symptoms: Brief Psychiatric Rating Scale, BPRS (validated; Overall 1988) (after 6 months' follow-up) • Functioning: Global Assessment of Functioning, GAF (validated; Jones 1995) (after 6 months' follow-up) • Severity of side effects: the Drug-Induced Extrapyramidal Symptom Scale, DIEPSS (Inada 1995) (after 6 months' follow-up) • Medication adherence: Morisky Medication Adherence Scale, MMAS (validated; Morisky 2008) (after 6 months' follow-up) • QOL: World Health Organization Quality of Life 26, WHO-QOL26 (validated; Tasaki 2007) (after 6 months' follow-up) • Recovery: Self-Identified Stage of Recovery, SISR (validated; Chiba 2010) (after 6 months' follow-up)
Notes	This work was supported by JSPS KAKENHI (grant-in-aid for scientific research [B] 25293123) from the Ministry of Education, Culture, Sports, Science and Technology, Japan. The authors reported no financial relationships with commercial interests. The authors kindly provided sum scores of Self-Identified Stage of Recovery Part-A, Part-B, STAR-Clinician, and STAR-Patient when requested although they reported only scores of sub-items in the trial report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly allocated to either the shared decision-making system group or a treatment-as-usual group.
Allocation concealment (selection bias)	Low risk	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. This researcher created the allocation sequence and prepared all the envelopes with allocation results for the participants.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding service providers and participants to the group allocation was not possible given the nature of the study.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessed by doctors who were not blind to participants' study groups
Incomplete outcome data (attrition bias)	Low risk	Dropouts were not significant. Allocated: 28 SDM; 28 control. Analysed: 26 SDM; 27 control.

Yamaguchi 2017 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	High risk	Lacked statistical power because of the relatively small sample size

DA: decision aid; **DSM-IV:** Diagnostic and Statistical Manual of Mental Disorders, 4th Edition; **ICD-10:** International Classification of Diseases, 10th Revision; **ITT:** intention to treat (analysis); **PTSD:** post-traumatic stress disorder; **SD(s):** standard deviation(s); **SDM:** shared decision-making

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
ACTRN12617000840381	Ineligible population
ACTRN12618000229279	Ineligible population
ACTRN12618000539235	Ineligible population
Alegria 2018	Ineligible population
Alexopoulos 2016	Ineligible intervention and population
Ali 2015	Ineligible study design
Allaire 2012	Ineligible population
Alphs 2014	Ineligible study design
An 2017	Not a randomised controlled trial
Andersson 2011	Ineligible study design
Arvidsson 2014	Ineligible intervention (a communication checklist tool intervention)
Aschbrenner 2014	Ineligible study design
Avey 2018	Ineligible study design
Baker-Ericzen 2015	Ineligible study design
Balestrieri 2020	Ineligible intervention; support for GP's clinical decision
Barrett 2013	Ineligible population
Bartels 2013	Ineligible study design
Bauer 2014	Ineligible population
Bauer 2016	Ineligible study design
Becker 2016	Ineligible study design

Study	Reason for exclusion
Bieber 2017	Ineligible intervention
Boehmer 2014	Ineligible study design
Bonin 2020	Ineligible intervention
Brenes 2018	Ineligible population
Brinkman 2013	Not a randomised controlled trial
Brodney 2021	Ineligible intervention; only decision aid
Brogan 2010	Ineligible intervention
Bruner 2011	Not a randomised controlled trial
Büchi 2010	Not a randomised controlled trial
Burn 2019	Not a randomised controlled trial
Butler 2015	Ineligible population
Campbell 2014	Not a randomised controlled trial
Carey 2020	Ineligible intervention; not SDM
Carlini 2017	Ineligible study design
Chakraborty 2009	Ineligible study design
Chakraborty 2016	Ineligible study design
Cheng 2021	Ineligible intervention; not SDM
Choi 2017	Ineligible study design
Christopher 2012	Ineligible study design
Clark 2011	Ineligible intervention
Cooper 2013	Ineligible intervention
Cooper 2014	Ineligible population
Cooper 2015	Not a randomised controlled trial
Coventry 2015	Ineligible population
Curtis 2018	Ineligible population
Davis 2011	Ineligible study design
Deegan 2010	Ineligible study design (review)
Deen 2012	Ineligible population

Study	Reason for exclusion
De Haan 2011	Ineligible population
De Jong 2019	Ineligible intervention
Delman 2015	Ineligible study design
Dillon 2017	Ineligible population
Dixon 2012	Study protocol; no data available
Donker 2009	Ineligible intervention
Dopheide 2020	Ineligible study design (discussion paper)
Drake 2015	Ineligible study design (review)
DRKS00007956	Ineligible intervention
DRKS00017653	Ineligible intervention
Druss 2010	Ineligible population
Dwight-Johnson 2010	Ineligible population
Easter 2017	Ineligible population
Edbrooke-Childs 2016	Ineligible intervention (SDM not mentioned; a support tool only)
Edbrooke-Childs 2019	Ineligible study design (observational study)
Family Medicine Forum Research Proceedings 2014	Ineligible study design
Farrelly 2011	Ineligible intervention (joint crisis planning)
Fiks 2011	Not a randomised controlled trial
Finnerty 2018	Not a randomised controlled trial
Finnerty 2019	Not a randomised controlled trial
Fisher 2018	Ineligible study design
Fisher 2020	Ineligible intervention, only decision aid
Flückiger 2012	Not a randomised controlled trial
Fortney 2010	Ineligible study design (review)
Furukawa 2018	Ineligible study design (systematic review)
Gandi 2010	Ineligible study design
Gioia 2014	Ineligible study design

Study	Reason for exclusion
Glick 2011	Ineligible study design (systematic review)
Goff 2010	Ineligible study design (review)
Goulding 2018	Ineligible study design
Gray 2010	Ineligible study design (review)
Grootens 2019	Ineligible study design (review)
Grote 2015	Ineligible population
Gunlicks-Stoessel 2016	Ineligible intervention
Gvirts 2018	Ineligible intervention
Hahn 2009	Ineligible study design (review)
Hamann 2014	Ineligible intervention (decision aid intervention only)
Handelzalts 2010	Ineligible population
Hayes 2019	Not a randomised controlled trial
He 2016	Ineligible intervention
Hell 2021	Ineligible intervention; informed decision
Henderson 2013	Ineligible population
Henderson 2018	Ineligible intervention (joint crisis plan)
Heres 2012	Ineligible study design (review)
Hessinger 2018	Not a randomised controlled trial
Hoffman 2014	Ineligible study design (editorial)
Hohl-Radke 2018	Ineligible intervention
Holzhüter 2020	Ineligible intervention; informed choice
Hopp 2011	Ineligible study design (editorial)
Howard 2009	Ineligible intervention
Hsu 2013	Ineligible study design
Huijbregts 2013	Ineligible intervention
Hunkeler 2012	Ineligible intervention
ISRCTN11230559	Ineligible intervention

Study	Reason for exclusion
ISRCTN14184328	Ineligible intervention (communication training to increase the frequency of patient-led informed choices)
ISRCTN16140131	Not a randomised controlled trial
ISRCTN38536761	Ineligible intervention
ISRCTN51103766	Ineligible intervention (routine outcome monitoring)
Johnson 2012	Ineligible population
Joosten 2009	Ineligible intervention (motivational interview)
Joosten 2011a	Ineligible population
Joosten 2011b	Ineligible population
Jørgensen 2014	Ineligible study design (a paper about recruitment to RCT)
Kageyama 2014	Not a randomised controlled trial
Kaminskiy 2019	Not a randomised controlled trial
Katz 2016	Ineligible intervention
Khalifeh 2019	Ineligible intervention (decision aid intervention only)
Kroenke 2015	Ineligible study design (review, commentary)
Kwong 2013	Ineligible intervention
Lagomasino 2017	Ineligible intervention (collaborative care)
Lara-Cabrera 2016	Ineligible intervention (educational intervention; information about options; encouraging participation; care plans). No treatment choice
Le 2014	Ineligible intervention
Lee 2015	Not a randomised controlled trial
Liverpool 2021a	Ineligible population
Lokman 2017	Ineligible intervention (intervention was only for physicians' decision-making)
Lord 2017	Ineligible intervention (decision aid intervention supporting only carers' decision-making)
Lutz 2022	Ineligible intervention (support for clinician decision)
MacInnes 2013	Ineligible intervention (a structured communication approach)
Mackay 2011	Not a randomised controlled trial (editorial)
Maj 2021	Ineligible study design (discussion paper)
Malloy-Weir 2017	Not a randomised controlled trial

Study	Reason for exclusion
Marshall 2013	Not a randomised controlled trial
Metz 2018	Ineligible intervention (several elements, including routine outcome monitoring and SDM)
Moncrieff 2016	Ineligible intervention (a medication review tool intervention which motivated participants to encourage communication with doctors). SDM intervention was not mentioned
Mooney 2020	Ineligible study design; ineligible intervention
Mort 2013	Not a randomised controlled trial
Muehlschlegel 2021	Ineligible population; ineligible intervention
NCT01253993	Ineligible study design (case control study)
NCT02364544	Not a randomised controlled trial
NCT02507349	Ineligible intervention (person-centred care)
NCT02989805	Ineligible intervention (care manager intervention versus peer intervention)
NCT03070977	Ineligible intervention (interprofessional training)
NCT03258632	Ineligible intervention (tool intervention only)
NCT03539068	Ineligible population
NCT03869177	Ineligible intervention (family involvement and support, family psychoeducation in single-family groups)
NCT04562038	Ineligible population
NCT04593472	Ineligible intervention (advance care planning)
NCT04601194	Ineligible study design
NCT05156073	Ineligible study design
Nieboer 2011	Ineligible intervention (tool intervention and counselling)
NL7775	Ineligible intervention (routine outcome monitoring)
NTR4531	Ineligible intervention (own choice)
NTR5773	Ineligible intervention (advanced care planning)
NTR6352	Ineligible intervention (psychoeducation intervention)
Nuss 2018	Ineligible study design
Pachoud 2015	Not a randomised controlled study
Park 2020	Ineligible study design
Perestelo-Perez 2017a	Ineligible intervention (decision aid intervention only)

Study	Reason for exclusion
Perestelo-Perez 2020	Ineligible intervention (decision aid intervention only)
Priebe 2013	Not a randomised controlled trial
Puri 2014	Ineligible study design (opinion)
Raffi 2018	Ineligible study design (case study)
Rapoport 2018	Ineligible intervention (decision support tool for physicians only)
Rickles 2017	Not a randomised controlled trial (review)
Robinson 2018	Ineligible intervention (a medication review tool intervention which motivated participants to encourage communication with doctors); SDM intervention was not mentioned
Roe 2015	Not a randomised controlled trial (editorial)
Rossom 2018	Ineligible intervention (tool intervention for psychiatrists only)
Schenker 2009	Not a randomised controlled trial (commentaries)
Schwarz 2012	Ineligible participants
Simon 2012	Ineligible intervention (tool intervention only)
Snynder 2013	Ineligible intervention (decision aid intervention for surrogate decision-makers)
Steinwachs 2011	Ineligible intervention (tool intervention only for patients who will consult a doctor)
Stirling 2012	Ineligible intervention (decision aid intervention only)
Stratton 2019	Ineligible intervention (decision aid intervention only)
Strauss 2015	Not a randomised controlled trial (a quasi-experimental group comparison design)
Stutz 2012	No full text available
Taylor 2012	Ineligible study design
Thomas 2019	Not a randomised controlled trial (cross-sectional study)
Trabut 2015	Ineligible study design
Treichler 2020	Ineligible study design
Treichler 2021	Ineligible study design
Tseng 2010	Ineligible population (diabetes); ineligible study design (cross-sectional study)
Van der Krieke 2013	Ineligible comparison: both intervention and comparison group received routine outcome monitoring and SDM
Van der Voort 2015	Ineligible intervention; has several elements other than SDM
Van Duin 2021	Ineligible intervention: SDM plus individual placement and support (IPS) and cognitive training

Study	Reason for exclusion
Velligan 2017	Ineligible intervention (decision coaching intervention only)
Vigod 2019	Ineligible intervention (decision aid intervention only)
Villar 2013	Ineligible study design (a quasi-experimental design)
Volker 2015	Ineligible intervention (decision aid intervention only)
Weiss 2010	Ineligible intervention (tool intervention only)
Westermann 2013	Ineligible intervention (several elements, including counselling in dialogue and SDM)

SDM: shared decision-making

Characteristics of studies awaiting classification *[ordered by study ID]*

Fung 2021

Methods	Randomised controlled trial
Participants	People newly diagnosed with obstructive sleep apnoea (OSA)
Interventions	Experimental: web-based patient decision aid plus a paper workbook Comparator: general sleep education
Outcomes	• Decisional Conflict Scale • Preparation for Decision-Making scale • OSA knowledge
Notes	ClinicalTrials.gov Identifier: NCT03138993

Hamann 2020

Methods	A cluster-randomised trial
Participants	Inclusion criteria • Age 18 to 65 years • Male and female participants • Inpatients of participating hospitals • Diagnosis of schizophrenia or schizoaffective disease (ICD-10: F20/F25) • Capable of participating in 60-minute group intervention • Being able to provide written informed consent Exclusion criteria • Mental retardation • Insufficient proficiency in German language to discuss treatment decisions
Interventions	On wards allocated to the intervention group, personnel will receive communication training (addressing how to implement SDM for various scenarios) and participants will receive a group intervention addressing participant skills for SDM.

Hamann 2020 *(Continued)*

Outcomes	The main outcome parameter will be participants' perceived involvement in decision-making during the inpatient stay, measured with the SDM-Q-9 questionnaire. Secondary objectives include the therapeutic relationship and long-term outcomes, such as medication adherence and rehospitalisation rates.
Notes	

Langer 2022

Methods	Randomised controlled trial
Participants	Youth and their caregivers who sought treatment for anxiety or depression
Interventions	Experimental: clinicians guided youth and caregivers through a collaborative treatment planning process that relies on research findings to inform three primary decisions: (a) treatment target problem(s), (b) treatment participants, and (c) treatment techniques. Comparator: clinician guided condition
Outcomes	• Involvement in the treatment planning process • Caregivers' decisional conflict and regret • Treatment length • Satisfaction with decisions • Engagement
Notes	

MacDonald-Wilson 2021

Methods	A cluster-randomised design with a mixed-methods approach
Participants	Medicaid-enrolled adults receiving psychiatric care in participating community mental health centres
Interventions	Experimental: person-centred care supported participants in completing computerised health reports and preparing to work with providers on collaborative decision-making about psychiatric care. Comparator: measurement-based care used computerised, systematic symptom and medication screenings to inform provider decision-making.
Outcomes	Patient experience of medication management and shared decision-making during psychiatric care
Notes	

ICD-10: International Classification of Diseases, 10th Revision; **SDM:** shared decision-making; **SDM-Q-9:** Shared Decision-Making Questionnaire-9

Characteristics of ongoing studies *[ordered by study ID]*

Battersby 2018

Study name	Improving cardiovascular health and quality of life in people with severe mental illness: a randomised trial of a 'partners in health' intervention
Methods	Randomised controlled trial
Participants	People with severe mental illness
Interventions	A framework and tools to engage the participant in a collaborative, structured, self-management assessment. Tailored planning, motivational enhancement, disease management, prevention, coordination and outcome measurement will be provided by mental health nurses.
Outcomes	Primary outcomes: absolute cardiovascular disease risk and health-related quality of life in 12 months. Secondary outcomes: 7-day point prevalence smoking abstinence; self-management capacity; patient engagement; patient receipt of care consistent with chronic care management (CCM); mental health measures extracted from clinical data; waist/height ratio; cardiovascular disease (CVD) incidence; the HoNOS measure of health and social functioning; proportion of participants reporting 50% or more reduction in smoking relative to baseline.
Starting date	May 2017
Contact information	Malcolm Battersby, malcolm.battersby@flinders.edu.au
Notes	

ISRCTN36203678

Study name	DECIDE Study: Shared decision making for treatment at discharge with schizophrenic inpatients
Methods	Prospective single-centre randomised controlled trial
Participants	People with schizophrenia and schizoaffective disorders.
Interventions	Shared decision-making (SDM) group: participants receive the SDM programme which is delivered by trained psychiatrists and nurses and consists of two stages, informative and deliberative. Treatment as usual (TAU) group: participants receive treatment as usual for the duration of the intervention.
Outcomes	Primary outcome: antipsychotic treatment adherence and the Drug Attitude Inventory at baseline, 3, 6 and 12 months. Secondary outcomes: readmission rate, quality of doctor-patient relationship, patient satisfaction with intervention and confidence on decision taken, and patient perception of hospitalisation at discharge.
Starting date	January 2014
Contact information	José Ildefonso Pérez-Revuelta, Unidad de Hospitalización de Salud Mental Hospital Jerez de la Frontera Carretera de Circunvalación s/n Jerez de la Frontera Cádiz

ISRCTN36203678 *(Continued)*

	11407 Spain
Notes	

Merle 2021

Study name	Trained Patient Involvement to Promote the Resumption of CPAP in Patients Who Have Discontinued Its Use
Methods	A prospective, multicentre, randomised controlled trial
Participants	Adults with an established diagnosis of severe obstructive sleep apnoea (OSAS) (Apnea-Hypopnea Index (AHI) > 30 events/hour) who have discontinued continuous positive airway pressure (CPAP) by returning their device to the home care provider within 4 to 12 months after CPAP initiation will be recruited according to a study flow chart
Interventions	Trained peers will meet participants by video conference. The 1st session is to identify and understand the underlying reasons for stopping CPAP treatment and to identify difficulties encountered by the participant (advantages and disadvantages of CPAP treatment). The 2nd session is to define his/her objectives and priorities. During the last session, participants and trained peers will discuss how to strengthen the participant's motivation to change and how to plan for this. Control group: care as usual
Outcomes	Primary outcome: the resumption of CPAP after discontinuation at 6 months. Secondary outcomes: adherence to CPAP, factors associated with resumption of CPAP, patient satisfaction at 6 months, the feasibility and the execution of the intervention and peer satisfaction.
Starting date	September 2021
Contact information	Christophe Pison; CPison@chu-grenoble.fr
Notes	NCT04538274

NCT01420575

Study name	Decision Aid to Facilitate Shared Decision Making During Treatment in Schizophrenia
Methods	Randomised controlled trial
Participants	People with schizophrenia/schizoaffective disorder
Interventions	Experimental arm: visual decision aid and shared decision-making Active comparator arm: usual care
Outcomes	Primary outcome: differences in decisional conflict scores between the two groups in 12 weeks
Starting date	August 2011
Contact information	Sriram Ramaswamy, Omaha Veterans Affairs Medical Center

NCT01420575 *(Continued)*

	Omaha, Nebraska, United States, 68105
Notes	

NCT01657708

Study name	Implementation of Shared Decision Making Model in Psychiatric Rehabilitation Setting
Methods	Randomised controlled trial
Participants	Adults (over age 18), with severe mental illness
Interventions	A shared decision-making intervention during the referral process to psychiatric rehabilitation services
Outcomes	Primary outcome: adherence to psychiatric rehabilitation services in 2 years
Starting date	August 2012
Contact information	Noa Patya, noapa@clalit.org.il
Notes	

NCT01710306

Study name	Web and Shared Decision Making for Reserve/National Guard Women's PTSD Care
Methods	Randomised controlled trial
Participants	Women who screen positive for PTSD
Interventions	1) A concierge nurse case manager who uses shared decision-making to engage veterans in evidence-based psychotherapy (EBP); or 2) usual outreach to determine what engagement approach women prefer.
Outcomes	Primary outcome: number of participants with Veterans' Affairs mental health care engagement at baseline and within 6 and 12 months. Secondary outcome: patient activation
Starting date	October 2012
Contact information	Anne G. Sadler, Iowa City VA Health Care System, Iowa City, IA
Notes	

NCT02716324

Study name	Communication to Improve Shared Decision-Making in ADHD

NCT02716324 *(Continued)*

Methods	Randomised controlled trial
Participants	Children (5 to 12 years) with ADHD
Interventions	Active comparator arm: ADHD Portal, an electronic communication tool for communicating information between clinicians, teachers, and parents. Experimental arm: ADHD Portal plus care manager
Outcomes	Primary outcome: change in Vanderbilt Parent Rating Scales at baseline (Visit 1), 3 months (Visit 2), 6 months (Visit 3), and 9 to 12 months (Visit 4). Secondary outcomes: goal attainment, treatment initiation and use of services, treatment adherence and use of services, school performance, student engagement, teacher connectedness, peer relationships, family relationships, and engagement
Starting date	March 2016
Contact information	James Guevara The Children's Hospital of Philadelphia Philadelphia, Pennsylvania, United States, 19104
Notes	

NCT03624829

Study name	Shared Care and Usual Health Care for Mental and Comorbid Health Problems
Methods	Cluster-randomised trial
Participants	GP patients with mental disorders
Interventions	The intervention is an adapted version of shared care with close collaboration by services and professional groups, mainly localised in three GP centres.
Outcomes	Primary outcome: referrals from GPs to mental health outpatient clinics in 12 months. Secondary outcomes: referrals from GPs to mental health inpatient wards; waiting time from the referral to the first consultation; number of GP consultations; number of outpatient consultations; number of inpatient days; length of an outpatient treatment episode; length of an inpatient stay; days from the inpatient admission to discharge after a referral to the inpatient ward; length of sick leave; type of health problem; the severity of psychiatric symptoms; the severity of impairment in functioning; self-reported mental health problems; self-reported impairment in functioning due to health problems; and patient satisfaction with health services and overall quality of life.
Starting date	August 2018
Contact information	Tormod Fladby University Hospital, Akershus
Notes	

NCT03887390

Study name	Depression Medication Choice Decision Aid

NCT03887390 *(Continued)*

Methods	Randomised controlled trial
Participants	People with depression
Interventions	Participants in depression medication choice arm will have the Depression Medication Choice decision aid be made available to their clinician to be used during their clinical encounter. Participants in usual care arm will receive care as usual.
Outcomes	Primary outcome: changes in decisional conflict Secondary outcomes: participant engagement; changes in severity of symptoms; decision-making preference; global quality of life; changes in medication adherence; fidelity to the intervention delivery; changes in knowledge; changes in satisfaction and acceptability.
Starting date	March 2019
Contact information	Annie LeBlanc Laval University Réseau-1 Québec CERSSPL
Notes	

NCT04175366

Study name	Shared Decision Making in Psychiatric Inpatient Care (DEAL)
Methods	Randomised controlled trial
Participants	Psychiatric inpatients with psychosis
Interventions	Intervention with SDM procedure regarding decision on planning of care and treatment before discharge. The control arm will receive discharge planning as usual.
Outcomes	Primary outcome: level of patient-perceived participation Secondary outcomes: percentage of carried out planned outpatient visits; number of rehospitalisations; days of compulsory care; number of episodes of compulsory care; number of inpatient days; number of emergency visits; days until rehospitalisation; percentage of decisions on social support carried out; and level of quality of Life.
Starting date	November 2019
Contact information	Mikael Sandlund mikael.sandlund@umu.se
Notes	

NCT04504149

Study name	Shared Decision Making for PTSD in Primary Care (PRIMED-PTSD)
Methods	Randomised controlled trial
Participants	Veterans with post-traumatic stress disorder (PTSD)

NCT04504149 *(Continued)*

Interventions	Experimental: a primary care-based shared decision-making intervention Control: usual care
Outcomes	Primary outcomes: a 3-item patient-reported measure of shared decision-making (CollaboRATE) in 2 weeks and utilisation of evidence-based psychotherapies for PTSD in 6 months Secondary outcomes: knowledge, decisional conflict, perceived stigma and barriers, self-efficacy, physician trust.
Starting date	October 2022
Contact information	Jessica A Chen Jessica.Chen663@va.gov
Notes	

NCT04902391

Study name	A Patient-Partnered, Pan-Canadian, Comparative Effectiveness Evaluation of an Acute Pediatric Mental Health and Addiction Care Bundle
Methods	Randomised controlled trial
Participants	Those with mental disorders age 8 to 17.99 years
Interventions	Intervention group: an evidence-based bundle of care with SDM framework (Choice and Partnership) Control group: usual care
Outcomes	Primary outcomes: well-being Secondary outcomes: satisfaction, quality of life, long-term well-being, median duration of the index evidenced-based bundle of care, proportion of emergency department visits, and emergency department visits that concluded in hospital admission
Starting date	November 2021
Contact information	
Notes	

NTR1822

Study name	Shared decision making: the effects of a decision aid for Turkish and Moroccan mental health care clients with depression on the client caregiver relationship
Methods	Unclear
Participants	People with depression

NTR1822 *(Continued)*

Interventions	Use of web-based Decision Aid Depression (kiesBeter.nl) for Turkish and Moroccan clients in a healthcare setting
Outcomes	Primary outcome: therapeutic relationship in community mental health care
Starting date	2009
Contact information	
Notes	

NTR6737

Study name	Resourcegroups: effectiveness, costs and meaning/ The resource group method in severe mental illness: study protocol for a randomised controlled trial and a qualitative multiple case study
Methods	Randomised controlled trial
Participants	Community-based outpatient psychiatric care for people with severe mental illness
Interventions	Intervention arm: the resource group (RG) method integrated in Flexible Assertive Community Treatment (FACT; 90 patients). RG will work together on fulfilling patients' recovery plan. By adopting shared decision-making processes and stimulating collaboration of different support systems, a broad and continuous support of patients' chosen goals and wishes will be preserved and problem solving and communication skills of the RG members will be addressed. Control arm: standard FACT (90 patients)
Outcomes	Primary outcome: empowerment Secondary outcomes: quality of life; personal, community and clinical recovery; general, social and community functioning; general psychopathological signs and symptoms; and societal costs
Starting date	2017
Contact information	Cathelijn D. Tjaden Department of Reintegration and Community Care, Trimbos Institute Utrecht, The Netherlands ctjaden@trimbos.nl
Notes	

Samalin 2018

Study name	Shared Medical Decision Making in the Prophylactic Treatment of Bipolar Disorder
Methods	Cluster-randomised trial
Participants	Adults with bipolar disorder
Interventions	The intervention will consist of applying the standardised SDM process as developed by the Ottawa Hospital Research Institute in order to choose the maintenance treatment of bipolar disorder. A multidisciplinary team developed a decision aid "choose my long-term treatment with my doctor" for bipolar disorder patients to clarify possible therapeutic options.

Samalin 2018 *(Continued)*

Outcomes	Primary outcome: patient's level of adherence of ongoing treatment at 12 months Secondary outcomes: difference between the 2 groups of patients in terms of adherence to maintenance drug therapy based on other measures (self-assessment scale and plasma levels of mood stabilisers). Decisional conflict, satisfaction with care and involvement in decision-making, beliefs about treatment, therapeutic relationship, knowledge about information for medical decision and clinical outcomes (depression, mania, functioning and quality of life)
Starting date	August 2017
Contact information	Ludovic Samalin lsamalin@chu-clermontferrand.fr
Notes	

UMIN000020498

Study name	Utility of Keio Shared Decision Making (K-SDM) program for depression: an interventional study
Methods	Cluster-randomised trial
Participants	People with major depressive disorder
Interventions	Intervention: participants will receive the K-SDM program for adherence. Control: participants will receive the usual medication counselling.
Outcomes	1) Medication Possession Ratio (MPR) at 6 months after discharge 2) Remission rate (i.e. a score of < 5 in Quick Inventory of Depressive Symptomatology-Self Report (QIDS-SR)) at 6 months after discharge
Starting date	January 2016
Contact information	Hiroyuki Uchida Department of Neuropsychiatry Keio University School of Medicine 35 Shinanomachi, Shinjuku-ku, Tokyo 160-8582, Japan hiroyuki.uchida.hu@gmail.com
Notes	

UMIN000034397

Study name	A multicenter, cluster-randomised controlled trial to investigate the effectiveness of the treatment guideline for major depressive disorder in Japan
Methods	Cluster-randomised trial
Participants	People with major depressive disorder
Interventions	The intervention will be carried out in a one-day workshop. The training programme consists of lectures (treatment guideline for major depressive disorder) and group education (social function, quality of life (QOL), and shared decision-making). The control group will be under the "treatment as usual" condition without the intervention.

UMIN000034397 *(Continued)*

Outcomes	Primary outcome: shared decision-making scores at baseline, 4 weeks, and 12 weeks after enrolment in the study. Secondary outcomes: 1) Client Satisfaction Questionnaire (CSQ-8-J) scores at baseline, 4 weeks, and 12 weeks 2) EuroQol 5 Dimension (EQ-5D) scores at baseline, 4 weeks, and 12 weeks 3) Trust in Physician Scale (TPS) scores at baseline, 4 weeks, and 12 weeks 4) Quick Inventory of Depressive Symptomatology (QIDS-J) scores at baseline, 4 weeks, and 12 weeks
Starting date	September 2018
Contact information	Koichiro Watanabe Department of Neuropsychiatry, School of Medicine, Kyorin University 6-20-2 Shinkawa, Mitaka, Tokyo 181-8611, Japan koichiro@tke.att.ne.jp
Notes	

Vitger 2019

Study name	The Efficacy of Using a Smartphone App to Support Shared Decision Making in People With a Diagnosis of Schizophrenia
Methods	Randomised controlled trial
Participants	People with schizophrenia-spectrum disorders in an outpatient treatment setting
Interventions	Intervention group will receive treatment as usual together with the Momentum app to support shared decision-making. Control group will receive treatment as usual without the Momentum app.
Outcomes	Primary outcome: change in patient activation at baseline, 3 months and end of intervention (6 months). Secondary outcomes: changes in self-efficacy, preparedness for decision-making, hope, the efficacy of interactions, treatment satisfaction, usage of the Momentum app, treatment alliance, clinical decision-making style, service engagement, positive symptoms, negative symptoms, and level of functioning
Starting date	June 2018
Contact information	Tobias Vitger tobias.vitger@regionh.dk
Notes	

Zisman-Ilani 2021

Study name	Decision-making and Decision Support Among Emerging Adults With First Episode Psychosis
Methods	Randomised controlled trial
Participants	Those experiencing early psychosis aged 18 to 25 years

Zisman-Ilani 2021 *(Continued)*

Interventions	Experimental: one-page decision aid for use during the psychiatric consultation to help participants and clinicians discuss relevant treatment options pertaining to antipsychotics No intervention: treatment as usual (TAU)
Outcomes	Primary outcomes: knowledge, self-efficacy, attitudes, decisional conflict, a 3-item patient-reported measure of shared decision-making (CollaboRATE), change in medication adherence, change in service use, and service engagement Secondary outcomes: apathy, attachment style, working alliance, trust, cognitive function, insight, and self-stigma
Starting date	February 2019
Contact information	
Notes	NCT04373590

ADHD: attention-deficit/hyperactivity disorder; **PTSD:** post-traumatic stress disorder; **SDM:** shared decision-making

DATA AND ANALYSES

Comparison 1. Shared decision-making versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Clinical outcomes - psychiatric symptoms	1	53	Mean Difference (IV, Random, 95% CI)	-1.10 [-5.54, 3.34]
1.2 Clinical outcomes - depression (1 to 6 months)	5	919	Std. Mean Difference (IV, Random, 95% CI)	0.14 [-0.19, 0.47]
1.3 Clinical outcomes - depression (1 to 6 months) - sensitivity analysis removing low-quality studies	4	717	Std. Mean Difference (IV, Random, 95% CI)	-0.03 [-0.17, 0.12]
1.4 Clinical outcomes - depression (6 months or more)	5	1100	Std. Mean Difference (IV, Random, 95% CI)	0.21 [-0.19, 0.60]
1.5 Clinical outcomes - depression (6 months or more) - sensitivity analysis removing low-quality studies	4	898	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.10, 0.17]
1.6 Clinical outcomes - depression remission (1 to 6 months)	1	215	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.68, 1.65]
1.7 Clinical outcomes - depression remission (6 months or more)	1	210	Risk Ratio (M-H, Random, 95% CI)	1.58 [0.97, 2.55]
1.8 Clinical outcomes - depression response (1 to 6 months)	1	215	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.81, 1.47]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.9 Clinical outcomes - depression response (6 months or more)	1	210	Risk Ratio (M-H, Random, 95% CI)	1.34 [0.98, 1.83]
1.10 Clinical outcomes - readmission rates (1 to 6 months)	2	128	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.52, 2.14]
1.10.1 SDM versus usual care	1	73	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.43, 2.44]
1.10.2 SDM versus cognitive training	1	55	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.34, 3.73]
1.11 Clinical outcomes - readmission rates (6 months or more)	2	249	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.77, 1.46]
1.11.1 SDM versus usual care	1	79	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.73, 1.78]
1.11.2 SDM versus cognitive training	1	170	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.63, 1.57]
1.12 Participation - observations on the process of SDM	2	133	Std. Mean Difference (IV, Random, 95% CI)	1.14 [0.63, 1.66]
1.13 Participation - SDM-specific user-reported outcomes from encounters (immediately after intervention)	3	534	Std. Mean Difference (IV, Random, 95% CI)	0.63 [0.26, 1.01]
1.14 Participation - SDM-specific user-reported outcomes from encounters (6 months or more)	2	398	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.30, 0.56]
1.15 Recovery	2	313	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.13, 0.32]
1.16 Satisfaction - overall users' satisfaction immediately after intervention	4	420	Std. Mean Difference (IV, Random, 95% CI)	0.26 [-0.29, 0.80]
1.17 Satisfaction - overall users' satisfaction at hospital discharge	1	22	Mean Difference (IV, Random, 95% CI)	1.60 [-1.65, 4.85]
1.18 Satisfaction - overall users' satisfaction in 6 months or more	2	400	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.22, 0.40]
1.19 Satisfaction - users' satisfaction with received information: right amount of information (categorical)	1	241	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.94, 1.07]
1.20 Satisfaction - users' satisfaction with received information: information given was clear (categorical)	1	241	Risk Ratio (M-H, Random, 95% CI)	1.19 [0.98, 1.44]
1.21 Satisfaction - users' satisfaction with received information: information given was helpful (categorical)	1	241	Risk Ratio (M-H, Random, 95% CI)	1.33 [1.08, 1.65]

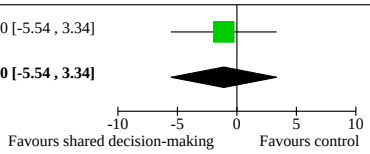
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.22 Satisfaction - users' satisfaction with received information: strongly desire to receive information this way for other treatment decisions (categorical)	1	241	Risk Ratio (M-H, Random, 95% CI)	1.35 [1.08, 1.68]
1.23 Satisfaction - users' satisfaction with received information: strongly recommend the way information was shared to others (categorical)	1	241	Risk Ratio (M-H, Random, 95% CI)	1.32 [1.11, 1.58]
1.24 Satisfaction - carer satisfaction	1	50	Mean Difference (IV, Random, 95% CI)	-1.40 [-6.69, 3.89]
1.25 Satisfaction - healthcare professional satisfaction	1	20	Mean Difference (IV, Random, 95% CI)	0.70 [0.26, 1.14]
1.26 Satisfaction - healthcare professional satisfaction (categorical)	1	256	Risk Ratio (M-H, Random, 95% CI)	1.35 [1.16, 1.58]
1.27 Knowledge	2	322	Std. Mean Difference (IV, Random, 95% CI)	0.41 [0.18, 0.63]
1.28 Treatment continuation - clinic visits (1 to 6 months)	1	20	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.37, 2.59]
1.29 Treatment continuation - clinic visits (6 months or more)	3	171	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.93, 1.23]
1.30 Medication continuation (1 to 6 months)	2	286	Std. Mean Difference (IV, Random, 95% CI)	0.33 [0.10, 0.57]
1.31 Medication continuation (1 to 6 months) (categorical)	1	86	Risk Ratio (M-H, Random, 95% CI)	0.74 [0.47, 1.17]
1.32 Medication continuation (6 months or more)	4	394	Std. Mean Difference (IV, Random, 95% CI)	0.27 [-0.03, 0.56]
1.33 Medication continuation (6 months or more) (categorical)	4	577	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.94, 1.17]
1.34 Carer participation	1	68	Mean Difference (IV, Random, 95% CI)	3.60 [-0.99, 8.19]
1.35 Relationship between service users and healthcare professionals, assessed by users	3	457	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.54, 0.28]
1.36 Relationship between service users and healthcare professionals, assessed by healthcare professionals	2	114	Std. Mean Difference (IV, Random, 95% CI)	0.17 [-0.31, 0.65]
1.37 Health service use outcomes - length of consultation	2	282	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.24, 0.41]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.38 Health service use outcomes - length of hospital stay	1	22	Mean Difference (IV, Random, 95% CI)	0.20 [-27.84, 28.24]

Analysis 1.1. Comparison 1: Shared decision-making versus control, Outcome 1: Clinical outcomes - psychiatric symptoms

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Yamaguchi 2017	34	7.9	26	35.1	8.6	27	100.0%	-1.10 [-5.54 , 3.34]		+ + − − + ? −
Total (95% CI)			**26**			**27**	**100.0%**	**-1.10 [-5.54 , 3.34]**		

Heterogeneity: Not applicable
Test for overall effect: Z = 0.49 (P = 0.63)
Test for subgroup differences: Not applicable

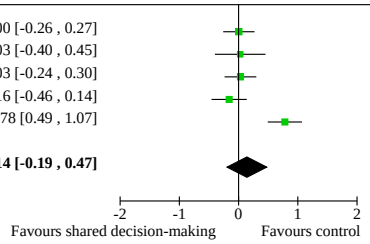


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.2. Comparison 1: Shared decision-making versus control, Outcome 2: Clinical outcomes - depression (1 to 6 months)

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Aljumah 2015	21.07	12.21	110	21.01	12.63	110	21.0%	0.00 [-0.26 , 0.27]		+ + − + + ? +
Aoki 2019a	10.49	5.12	35	10.34	5.68	53	17.3%	0.03 [-0.40 , 0.45]		+ + − + + ? +
LeBlanc 2015	9.2	6.3	114	9	6.4	101	20.9%	0.03 [-0.24 , 0.30]		+ + − − + + +
Loh 2007	13.7	5.8	128	14.6	5.3	66	20.3%	-0.16 [-0.46 , 0.14]		+ + − ? − ? −
Raue 2019	12.4	0.8	114	11.7	1	88	20.5%	0.78 [0.49 , 1.07]		? ? − − − ? +
Total (95% CI)			**501**			**418**	**100.0%**	**0.14 [-0.19 , 0.47]**		

Heterogeneity: Tau² = 0.12; Chi² = 24.76, df = 4 (P < 0.0001); I² = 84%
Test for overall effect: Z = 0.82 (P = 0.41)
Test for subgroup differences: Not applicable

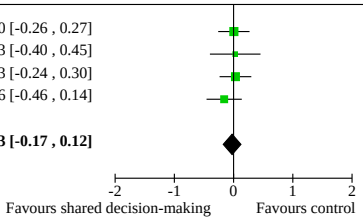


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.3. Comparison 1: Shared decision-making versus control, Outcome 3: Clinical outcomes - depression (1 to 6 months) - sensitivity analysis removing low-quality studies

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Aljumah 2015	21.07	12.21	110	21.01	12.63	110	31.8%	0.00 [-0.26 , 0.27]	+ + − + + ? +
Aoki 2019a	10.49	5.12	35	10.34	5.68	53	12.2%	0.03 [-0.40 , 0.45]	+ + − + + ? +
LeBlanc 2015	9.2	6.3	114	9	6.4	101	30.9%	0.03 [-0.24 , 0.30]	+ + − − + + +
Loh 2007	13.7	5.8	128	14.6	5.3	66	25.1%	-0.16 [-0.46 , 0.14]	+ + − ? − ? −
Total (95% CI)			**387**			**330**	**100.0%**	**-0.03 [-0.17 , 0.12]**	

Heterogeneity: Tau² = 0.00; Chi² = 1.06, df = 3 (P = 0.79); I² = 0%
Test for overall effect: Z = 0.33 (P = 0.74)
Test for subgroup differences: Not applicable

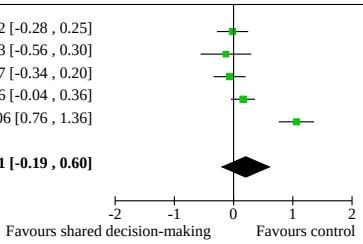


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.4. Comparison 1: Shared decision-making versus control, Outcome 4: Clinical outcomes - depression (6 months or more)

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Aljumah 2015	20.65	11.97	110	20.86	12.54	110	20.5%	-0.02 [-0.28 , 0.25]	+ + − + + ? +
Aoki 2019a	9.57	5.8	35	10.36	6.17	53	17.9%	-0.13 [-0.56 , 0.30]	+ + − + + ? +
LeBlanc 2015	8.9	5.9	109	9.3	5.9	101	20.4%	-0.07 [-0.34 , 0.20]	+ + − − + + +
Lovell 2018	9.8	5.5	208	8.9	5.8	172	21.3%	0.16 [-0.04 , 0.36]	+ + − + − + −
Raue 2019	12.9	0.8	114	12	0.9	88	20.0%	1.06 [0.76 , 1.36]	? ? − − − ? +
Total (95% CI)			**576**			**524**	**100.0%**	**0.21 [-0.19 , 0.60]**	

Heterogeneity: Tau² = 0.18; Chi² = 41.06, df = 4 (P < 0.00001); I² = 90%
Test for overall effect: Z = 1.01 (P = 0.31)
Test for subgroup differences: Not applicable

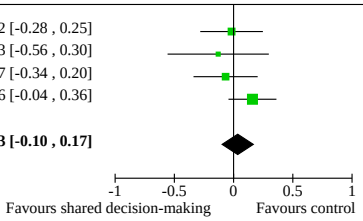


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.5. Comparison 1: Shared decision-making versus control, Outcome 5: Clinical outcomes - depression (6 months or more) - sensitivity analysis removing low-quality studies

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Aljumah 2015	20.65	11.97	110	20.86	12.54	110	24.7%	-0.02 [-0.28 , 0.25]	+ + − + + ? +
Aoki 2019a	9.57	5.8	35	10.36	6.17	53	9.5%	-0.13 [-0.56 , 0.30]	+ + − + + ? +
LeBlanc 2015	8.9	5.9	109	9.3	5.9	101	23.6%	-0.07 [-0.34 , 0.20]	+ + − − + + +
Lovell 2018	9.8	5.5	208	8.9	5.8	172	42.2%	0.16 [-0.04 , 0.36]	+ + − + − + −
Total (95% CI)			**462**			**436**	**100.0%**	**0.03 [-0.10 , 0.17]**	

Heterogeneity: Tau² = 0.00; Chi² = 2.72, df = 3 (P = 0.44); I² = 0%
Test for overall effect: Z = 0.52 (P = 0.60)
Test for subgroup differences: Not applicable

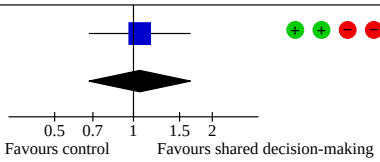


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.6. Comparison 1: Shared decision-making versus control, Outcome 6: Clinical outcomes - depression remission (1 to 6 months)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
LeBlanc 2015	31	114	26	101	100.0%	1.06 [0.68 , 1.65]	+ + − − + + +
Total (95% CI)		**114**		**101**	**100.0%**	**1.06 [0.68 , 1.65]**	
Total events:	31		26				

Heterogeneity: Not applicable
Test for overall effect: Z = 0.24 (P = 0.81)
Test for subgroup differences: Not applicable

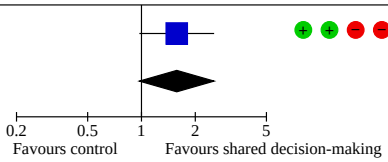


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.7. Comparison 1: Shared decision-making versus control, Outcome 7: Clinical outcomes - depression remission (6 months or more)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
LeBlanc 2015	34	109	20	101	100.0%	1.58 [0.97 , 2.55]	+ + − − + + +
Total (95% CI)		**109**		**101**	**100.0%**	**1.58 [0.97 , 2.55]**	
Total events:	34		20				

Heterogeneity: Not applicable
Test for overall effect: Z = 1.85 (P = 0.06)
Test for subgroup differences: Not applicable

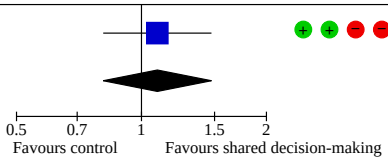


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.8. Comparison 1: Shared decision-making versus control, Outcome 8: Clinical outcomes - depression response (1 to 6 months)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
LeBlanc 2015	53	114	43	101	100.0%	1.09 [0.81 , 1.47]	+ + − − + + +
Total (95% CI)		**114**		**101**	**100.0%**	**1.09 [0.81 , 1.47]**	
Total events:	53		43				

Heterogeneity: Not applicable
Test for overall effect: Z = 0.57 (P = 0.57)
Test for subgroup differences: Not applicable

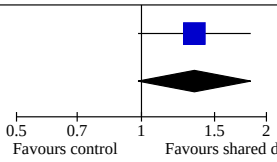


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.9. Comparison 1: Shared decision-making versus control, Outcome 9: Clinical outcomes - depression response (6 months or more)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
LeBlanc 2015	55	109	38	101	100.0%	1.34 [0.98 , 1.83]
Total (95% CI)		**109**		**101**	**100.0%**	**1.34 [0.98 , 1.83]**
Total events:	55		38			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.84 (P = 0.07)
Test for subgroup differences: Not applicable

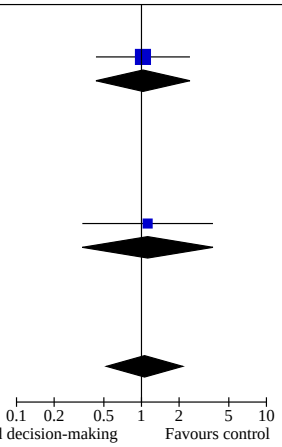


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.10. Comparison 1: Shared decision-making versus control, Outcome 10: Clinical outcomes - readmission rates (1 to 6 months)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.10.1 SDM versus usual care						
Hamann 2006	8	36	8	37	65.9%	1.03 [0.43 , 2.44]
Subtotal (95% CI)		**36**		**37**	**65.9%**	**1.03 [0.43 , 2.44]**
Total events:	8		8			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.06 (P = 0.95)						
1.10.2 SDM versus cognitive training						
Hamann 2011	5	29	4	26	34.1%	1.12 [0.34 , 3.73]
Subtotal (95% CI)		**29**		**26**	**34.1%**	**1.12 [0.34 , 3.73]**
Total events:	5		4			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.19 (P = 0.85)						
Total (95% CI)		**65**		**63**	**100.0%**	**1.06 [0.52 , 2.14]**
Total events:	13		12			

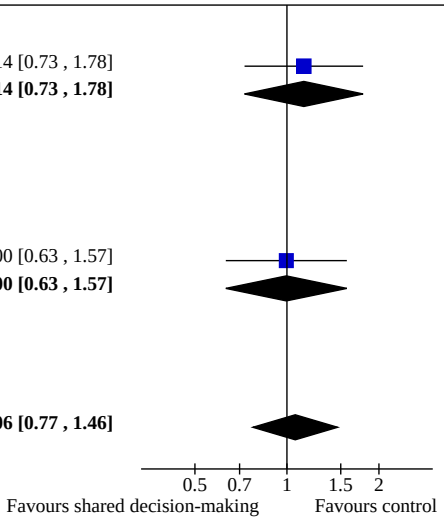
Heterogeneity: Tau² = 0.00; Chi² = 0.01, df = 1 (P = 0.91); I² = 0%
Test for overall effect: Z = 0.16 (P = 0.87)
Test for subgroup differences: Chi² = 0.01, df = 1 (P = 0.91), I² = 0%



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

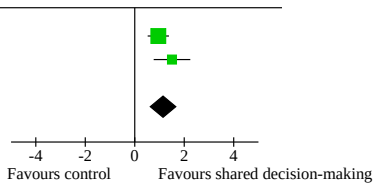
Analysis 1.11. Comparison 1: Shared decision-making versus control, Outcome 11: Clinical outcomes - readmission rates (6 months or more)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.11.1 SDM versus usual care						
Hamann 2006	20	38	19	41	51.0%	1.14 [0.73 , 1.78]
Subtotal (95% CI)		**38**		**41**	**51.0%**	**1.14 [0.73 , 1.78]**
Total events:	20		19			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.56 (P = 0.58)						
1.11.2 SDM versus cognitive training						
Hamann 2017	29	95	23	75	49.0%	1.00 [0.63 , 1.57]
Subtotal (95% CI)		**95**		**75**	**49.0%**	**1.00 [0.63 , 1.57]**
Total events:	29		23			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.02 (P = 0.98)						
Total (95% CI)		**133**		**116**	**100.0%**	**1.06 [0.77 , 1.46]**
Total events:	49		42			
Heterogeneity: Tau² = 0.00; Chi² = 0.17, df = 1 (P = 0.68); I² = 0%						
Test for overall effect: Z = 0.39 (P = 0.70)						
Test for subgroup differences: Chi² = 0.16, df = 1 (P = 0.69), I² = 0%						



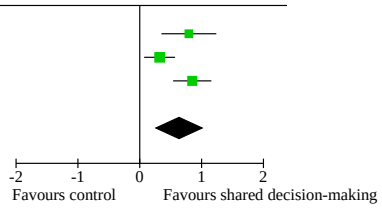
Analysis 1.12. Comparison 1: Shared decision-making versus control, Outcome 12: Participation - observations on the process of SDM

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
LeBlanc 2015	46.6	16	57	32.5	12.5	39	65.4%	0.95 [0.52 , 1.38]
Yamaguchi 2017	6.3	1.3	18	4.3	1.3	19	34.6%	1.51 [0.77 , 2.25]
Total (95% CI)			**75**			**58**	**100.0%**	**1.14 [0.63 , 1.66]**
Heterogeneity: Tau² = 0.06; Chi² = 1.60, df = 1 (P = 0.21); I² = 38%								
Test for overall effect: Z = 4.35 (P < 0.0001)								
Test for subgroup differences: Not applicable								



Analysis 1.13. Comparison 1: Shared decision-making versus control, Outcome 13: Participation - SDM-specific user-reported outcomes from encounters (immediately after intervention)

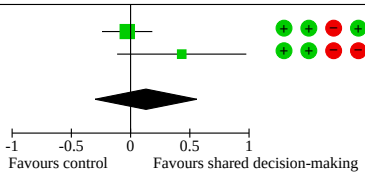
Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Aoki 2019a	83.28	10.86	35	73.28	13.43	53	27.7%	0.79 [0.35 , 1.24]
LeBlanc 2015	79.7	16.13	138	74.5	16.13	114	37.7%	0.32 [0.07 , 0.57]
Loh 2007	28	2.9	128	25.5	3	66	34.6%	0.85 [0.54 , 1.16]
Total (95% CI)			**301**			**233**	**100.0%**	**0.63 [0.26 , 1.01]**
Heterogeneity: Tau² = 0.08; Chi² = 7.92, df = 2 (P = 0.02); I² = 75%								
Test for overall effect: Z = 3.33 (P = 0.0009)								
Test for subgroup differences: Not applicable								



Analysis 1.14. Comparison 1: Shared decision-making versus control, Outcome 14: Participation - SDM-specific user-reported outcomes from encounters (6 months or more)

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Lovell 2018	21.3	9.6	192	21.6	11.2	153	65.5%	-0.03 [-0.24 , 0.18]	+ + − + − + −
Yamaguchi 2017	52.3	18.1	26	45.8	10.8	27	34.5%	0.43 [-0.11 , 0.98]	+ + − − + ? −
Total (95% CI)			**218**			**180**	**100.0%**	**0.13 [-0.30 , 0.56]**	

Heterogeneity: Tau² = 0.06; Chi² = 2.38, df = 1 (P = 0.12); I² = 58%
Test for overall effect: Z = 0.59 (P = 0.55)
Test for subgroup differences: Not applicable

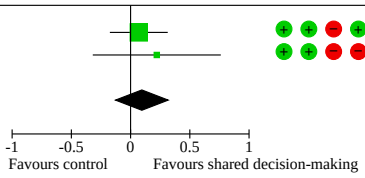


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.15. Comparison 1: Shared decision-making versus control, Outcome 15: Recovery

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Lovell 2018	43.5	13.3	142	42.6	12.5	118	83.0%	0.07 [-0.17 , 0.31]	+ + − + − + −
Yamaguchi 2017	18.23	6.06	26	16.96	5.24	27	17.0%	0.22 [-0.32 , 0.76]	+ + − − + ? −
Total (95% CI)			**168**			**145**	**100.0%**	**0.10 [-0.13 , 0.32]**	

Heterogeneity: Tau² = 0.00; Chi² = 0.25, df = 1 (P = 0.62); I² = 0%
Test for overall effect: Z = 0.84 (P = 0.40)
Test for subgroup differences: Not applicable

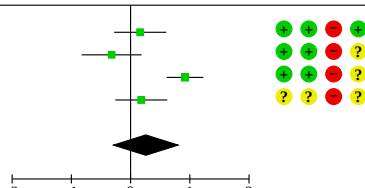


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.16. Comparison 1: Shared decision-making versus control, Outcome 16: Satisfaction - overall users' satisfaction immediately after intervention

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Aoki 2019a	24.31	2.9	32	23.75	3.71	53	24.8%	0.16 [-0.28 , 0.60]	+ + − + + ? +
Hamann 2011	25.5	4.1	32	26.7	3.2	29	23.5%	-0.32 [-0.83 , 0.19]	+ + − ? − ? −
Loh 2007	29.8	2.7	128	27	3.6	66	26.9%	0.92 [0.61 , 1.23]	+ + − ? − ? −
Woltmann 2011	3.88	0.54	40	3.78	0.56	40	24.8%	0.18 [-0.26 , 0.62]	? ? − ? + ? −
Total (95% CI)			**232**			**188**	**100.0%**	**0.26 [-0.29 , 0.80]**	

Heterogeneity: Tau² = 0.26; Chi² = 20.57, df = 3 (P = 0.0001); I² = 85%
Test for overall effect: Z = 0.92 (P = 0.36)
Test for subgroup differences: Not applicable

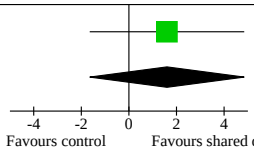


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.17. Comparison 1: Shared decision-making versus control, Outcome 17: Satisfaction - overall users' satisfaction at hospital discharge

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Ishii 2017	23.7	3.9	9	22.1	3.7	13	100.0%	1.60 [-1.65 , 4.85]
Total (95% CI)			**9**			**13**	**100.0%**	**1.60 [-1.65 , 4.85]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.97 (P = 0.33)
Test for subgroup differences: Not applicable

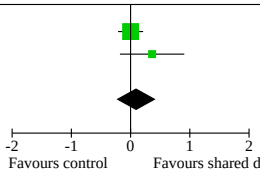


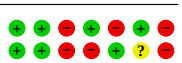
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.18. Comparison 1: Shared decision-making versus control, Outcome 18: Satisfaction - overall users' satisfaction in 6 months or more

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Lovell 2018	3.5	0.7	191	3.5	0.8	156	74.7%	0.00 [-0.21 , 0.21]
Yamaguchi 2017	26	4.4	26	24.3	4.8	27	25.3%	0.36 [-0.18 , 0.91]
Total (95% CI)			**217**			**183**	**100.0%**	**0.09 [-0.22 , 0.40]**

Heterogeneity: Tau² = 0.02; Chi² = 1.49, df = 1 (P = 0.22); I² = 33%
Test for overall effect: Z = 0.58 (P = 0.56)
Test for subgroup differences: Not applicable



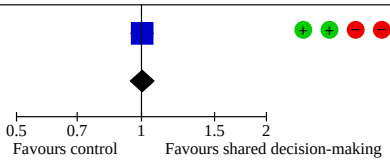


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.19. Comparison 1: Shared decision-making versus control, Outcome 19: Satisfaction - users' satisfaction with received information: right amount of information (categorical)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
LeBlanc 2015	124	132	102	109	100.0%	1.00 [0.94 , 1.07]
Total (95% CI)		**132**		**109**	**100.0%**	**1.00 [0.94 , 1.07]**
Total events:	124		102			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.12 (P = 0.91)
Test for subgroup differences: Not applicable

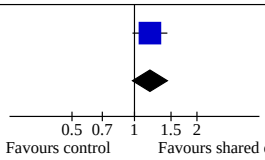


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.20. Comparison 1: Shared decision-making versus control, Outcome 20: Satisfaction - users' satisfaction with received information: information given was clear (categorical)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
LeBlanc 2015	92	132	64	109	100.0%	1.19 [0.98 , 1.44]
Total (95% CI)		**132**		**109**	**100.0%**	**1.19 [0.98 , 1.44]**
Total events:	92		64			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.74 (P = 0.08)
Test for subgroup differences: Not applicable

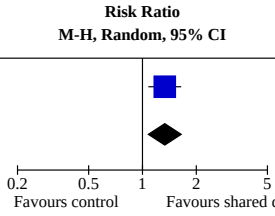


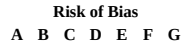
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.21. Comparison 1: Shared decision-making versus control, Outcome 21: Satisfaction - users' satisfaction with received information: information given was helpful (categorical)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
LeBlanc 2015	92	132	57	109	100.0%	1.33 [1.08 , 1.65]
Total (95% CI)		**132**		**109**	**100.0%**	**1.33 [1.08 , 1.65]**
Total events:	92		57			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.66 (P = 0.008)
Test for subgroup differences: Not applicable



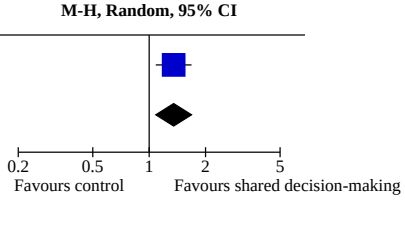


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.22. Comparison 1: Shared decision-making versus control, Outcome 22: Satisfaction - users' satisfaction with received information: strongly desire to receive information this way for other treatment decisions (categorical)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
LeBlanc 2015	90	132	55	109	100.0%	1.35 [1.08 , 1.68]
Total (95% CI)		**132**		**109**	**100.0%**	**1.35 [1.08 , 1.68]**
Total events:	90		55			

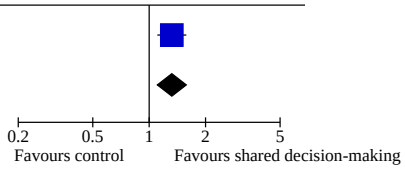
Heterogeneity: Not applicable
Test for overall effect: Z = 2.69 (P = 0.007)
Test for subgroup differences: Not applicable



Analysis 1.23. Comparison 1: Shared decision-making versus control, Outcome 23: Satisfaction - users' satisfaction with received information: strongly recommend the way information was shared to others (categorical)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
LeBlanc 2015	104	132	65	109	100.0%	1.32 [1.11 , 1.58]
Total (95% CI)		**132**		**109**	**100.0%**	**1.32 [1.11 , 1.58]**
Total events:	104		65			

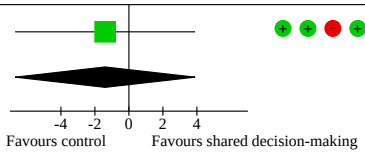
Heterogeneity: Not applicable
Test for overall effect: Z = 3.07 (P = 0.002)
Test for subgroup differences: Not applicable



Analysis 1.24. Comparison 1: Shared decision-making versus control, Outcome 24: Satisfaction - carer satisfaction

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Lovell 2018	22.7	9.1	24	24.1	10	26	100.0%	-1.40 [-6.69 , 3.89]	+ + − + − + −
Total (95% CI)			**24**			**26**	**100.0%**	**-1.40 [-6.69 , 3.89]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 0.52 (P = 0.60)
Test for subgroup differences: Not applicable

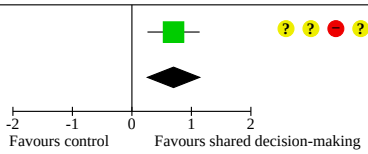


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.25. Comparison 1: Shared decision-making versus control, Outcome 25: Satisfaction - healthcare professional satisfaction

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Woltmann 2011	4	0.5	10	3.3	0.5	10	100.0%	0.70 [0.26 , 1.14]	? ? − ? + ? −
Total (95% CI)			**10**			**10**	**100.0%**	**0.70 [0.26 , 1.14]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 3.13 (P = 0.002)
Test for subgroup differences: Not applicable

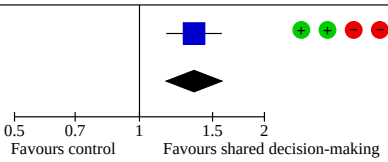


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.26. Comparison 1: Shared decision-making versus control, Outcome 26: Satisfaction - healthcare professional satisfaction (categorical)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
LeBlanc 2015	119	139	74	117	100.0%	1.35 [1.16 , 1.58]	+ + − − + + +
Total (95% CI)		**139**		**117**	**100.0%**	**1.35 [1.16 , 1.58]**	
Total events:	119		74				

Heterogeneity: Not applicable
Test for overall effect: Z = 3.85 (P = 0.0001)
Test for subgroup differences: Not applicable

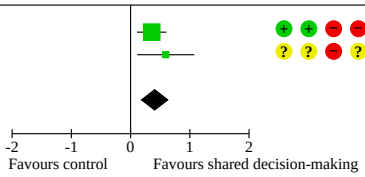


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.27. Comparison 1: Shared decision-making versus control, Outcome 27: Knowledge

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
LeBlanc 2015	63.5	21.5	137	56.3	18.4	116	79.0%	0.36 [0.11 , 0.61]	+ + − − + + +
Woltmann 2011	75	28	36	57	32	33	21.0%	0.59 [0.11 , 1.08]	? ? − ? + ? −
Total (95% CI)			**173**			**149**	**100.0%**	**0.41 [0.18 , 0.63]**	

Heterogeneity: Tau² = 0.00; Chi² = 0.73, df = 1 (P = 0.39); I² = 0%
Test for overall effect: Z = 3.59 (P = 0.0003)
Test for subgroup differences: Not applicable

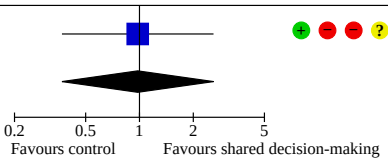


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.28. Comparison 1: Shared decision-making versus control, Outcome 28: Treatment continuation - clinic visits (1 to 6 months)

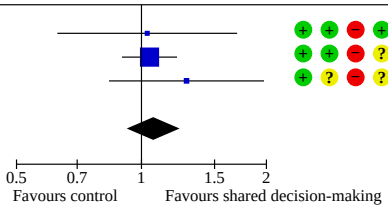
Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
Mott 2014	4	9	5	11	100.0%	0.98 [0.37 , 2.59]	+ − − ? − ? −
Total (95% CI)		**9**		**11**	**100.0%**	**0.98 [0.37 , 2.59]**	
Total events:	4		5				

Heterogeneity: Not applicable
Test for overall effect: Z = 0.05 (P = 0.96)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.29. Comparison 1: Shared decision-making versus control, Outcome 29: Treatment continuation - clinic visits (6 months or more)

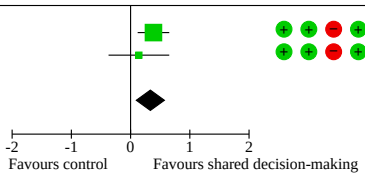


Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Aoki 2019a	15	35	22	53	7.7%	1.03 [0.63 , 1.70]
Hamann 2011	30	32	26	29	82.0%	1.05 [0.90 , 1.22]
Ishii 2017	8	9	9	13	10.3%	1.28 [0.84 , 1.97]
Total (95% CI)		**76**		**95**	**100.0%**	**1.07 [0.93 , 1.23]**
Total events:	53		57			

Heterogeneity: Tau² = 0.00; Chi² = 0.81, df = 2 (P = 0.67); I² = 0%
Test for overall effect: Z = 0.92 (P = 0.36)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.30. Comparison 1: Shared decision-making versus control, Outcome 30: Medication continuation (1 to 6 months)



Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Aljumah 2015	5.79	1.89	110	5.04	1.98	110	78.7%	0.39 [0.12 , 0.65]
Aoki 2019a	8.79	1.44	22	8.57	1.6	44	21.3%	0.14 [-0.37 , 0.65]
Total (95% CI)			**132**			**154**	**100.0%**	**0.33 [0.10 , 0.57]**

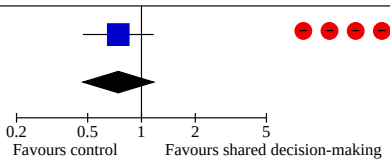
Heterogeneity: Tau² = 0.00; Chi² = 0.70, df = 1 (P = 0.40); I² = 0%
Test for overall effect: Z = 2.76 (P = 0.006)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.31. Comparison 1: Shared decision-making versus control, Outcome 31: Medication continuation (1 to 6 months) (categorical)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Hamann 2006	16	39	26	47	100.0%	0.74 [0.47 , 1.17]
Total (95% CI)		**39**		**47**	**100.0%**	**0.74 [0.47 , 1.17]**
Total events:	16		26			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.29 (P = 0.20)
Test for subgroup differences: Not applicable

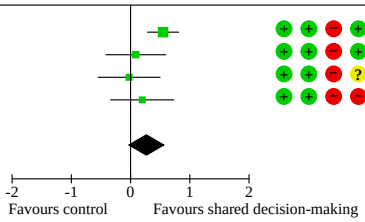


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.32. Comparison 1: Shared decision-making versus control, Outcome 32: Medication continuation (6 months or more)

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Aljumah 2015	5.99	1.88	110	4.94	1.94	110	39.0%	0.55 [0.28 , 0.82]
Aoki 2019a	8.58	1.44	22	8.44	1.62	44	21.1%	0.09 [-0.42 , 0.60]
Hamann 2011	4	11	29	4.2	0.9	26	20.2%	-0.02 [-0.55 , 0.50]
Yamaguchi 2017	5.7	1.5	26	5.4	1.5	27	19.7%	0.20 [-0.34 , 0.74]
Total (95% CI)			**187**			**207**	**100.0%**	**0.27 [-0.03 , 0.56]**

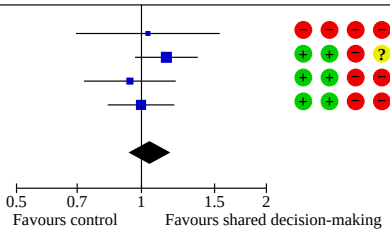
Heterogeneity: Tau² = 0.04; Chi² = 5.30, df = 3 (P = 0.15); I² = 43%
Test for overall effect: Z = 1.77 (P = 0.08)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.33. Comparison 1: Shared decision-making versus control, Outcome 33: Medication continuation (6 months or more) (categorical)

Study or Subgroup	Shared decision-making Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
Hamann 2006	18	30	22	38	7.5%	1.04 [0.70 , 1.54]		
Hamann 2011	25	25	20	23	39.3%	1.15 [0.96 , 1.37]		
Hamann 2017	51	91	49	82	18.4%	0.94 [0.73 , 1.21]		
LeBlanc 2015	94	154	82	134	34.8%	1.00 [0.83 , 1.20]		
Total (95% CI)		**300**		**277**	**100.0%**	**1.05 [0.94 , 1.17]**		
Total events:	188		173					

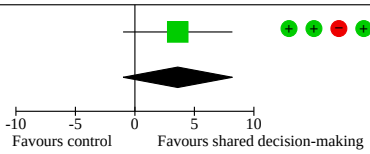


Heterogeneity: Tau² = 0.00; Chi² = 2.64, df = 3 (P = 0.45); I² = 0%
Test for overall effect: Z = 0.80 (P = 0.43)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.34. Comparison 1: Shared decision-making versus control, Outcome 34: Carer participation

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Lovell 2018	20.1	8	22	16.5	10.9	46	100.0%	3.60 [-0.99 , 8.19]		
Total (95% CI)			**22**			**46**	**100.0%**	**3.60 [-0.99 , 8.19]**		



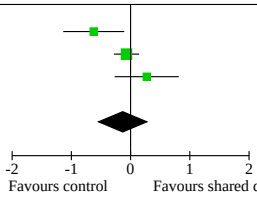
Heterogeneity: Not applicable
Test for overall effect: Z = 1.54 (P = 0.12)
Test for subgroup differences: Not applicable

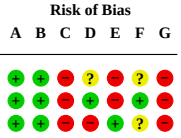
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.35. Comparison 1: Shared decision-making versus control, Outcome 35: Relationship between service users and healthcare professionals, assessed by users

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Hamann 2011	41.8	7.4	32	46.4	7.2	29	28.2%	-0.62 [-1.14 , -0.11]
Lovell 2018	4.8	1.4	191	4.9	1.5	152	44.8%	-0.07 [-0.28 , 0.14]
Yamaguchi 2017	39.38	5.58	26	37.81	5.78	27	27.0%	0.27 [-0.27 , 0.81]
Total (95% CI)			**249**			**208**	**100.0%**	**-0.13 [-0.54 , 0.28]**

Heterogeneity: Tau² = 0.09; Chi² = 5.83, df = 2 (P = 0.05); I² = 66%
Test for overall effect: Z = 0.64 (P = 0.52)
Test for subgroup differences: Not applicable



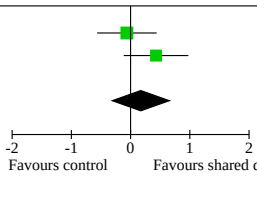


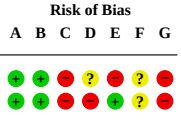
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.36. Comparison 1: Shared decision-making versus control, Outcome 36: Relationship between service users and healthcare professionals, assessed by healthcare professionals

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Hamann 2011	23.8	4.7	32	24.1	4.8	29	52.4%	-0.06 [-0.57 , 0.44]
Yamaguchi 2017	38.73	7.82	26	34.96	9.35	27	47.6%	0.43 [-0.12 , 0.98]
Total (95% CI)			**58**			**56**	**100.0%**	**0.17 [-0.31 , 0.65]**

Heterogeneity: Tau² = 0.05; Chi² = 1.69, df = 1 (P = 0.19); I² = 41%
Test for overall effect: Z = 0.70 (P = 0.48)
Test for subgroup differences: Not applicable



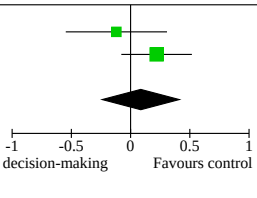


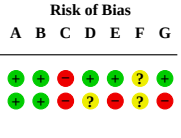
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.37. Comparison 1: Shared decision-making versus control, Outcome 37: Health service use outcomes - length of consultation

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Aoki 2019a	28.71	12.66	35	30.49	15.91	53	39.4%	-0.12 [-0.55 , 0.31]
Loh 2007	29.2	10.7	128	26.7	12.5	66	60.6%	0.22 [-0.08 , 0.52]
Total (95% CI)			**163**			**119**	**100.0%**	**0.09 [-0.24 , 0.41]**

Heterogeneity: Tau² = 0.02; Chi² = 1.63, df = 1 (P = 0.20); I² = 39%
Test for overall effect: Z = 0.52 (P = 0.61)
Test for subgroup differences: Not applicable



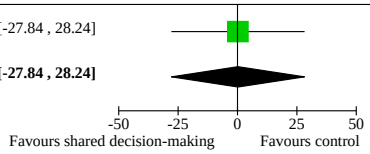


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.38. Comparison 1: Shared decision-making versus control, Outcome 38: Health service use outcomes - length of hospital stay

Study or Subgroup	Shared decision-making Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Ishii 2017	66.7	40.4	9	66.5	17.4	13	100.0%	0.20 [-27.84 , 28.24]	+ ? − ? + + −
Total (95% CI)			**9**			**13**	**100.0%**	**0.20 [-27.84 , 28.24]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 0.01 (P = 0.99)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

ADDITIONAL TABLES

Table 1. Psychiatric symptoms

Study	Scale used	Timing	N SDM	SDM mean	N comparison	Comparison mean	Note
Hamann 2006	Positive and Negative Syndrome Scale, PANSS	At discharge	-	58	-	59.3	P > 0.05
Yamaguchi 2017	Brief Psychiatric Rating Scale, BPRS	After 6 months' follow-up	26	34.0 (SD 7.9)	27	35.1 (SD 8.6)	P = 0.31

SDM: shared decision-making

Table 2. Depression

Study	Scale used	Timing	N SDM	SDM mean	N comparison	Comparison mean	Notes
Aljumah 2015	Montgomery-Åsberg Depression Rating Scale, MADRS	3 months	110	21.07 (SD 12.21)	110	21.01 (SD 12.63)	P = 0.971
Aljumah 2015	Montgomery-Åsberg Depression Rating Scale, MADRS	6 months	110	20.65 (SD 11.97)	110	20.86 (SD 12.54)	P = 0.897
Aoki 2019a	Quick Inventory of Depressive Symptomatology, QIDS-J	3 months	35	10.49 (SD 5.12)	53	9.57 (SD 5.80)	No difference
Aoki 2019a	Quick Inventory of Depressive Symptomatology, QIDS-J	6 months	35	10.34 (SD 5.68)	53	10.36 (SD 6.17)	No difference
LeBlanc 2015	Patient Health Questionnaire-9, PHQ-9	3 months	114	9.0	101	9.2	P = 0.78
LeBlanc 2015	Patient Health Questionnaire-9, PHQ-9	6 months	109	8.9	101	9.3	P = 0.91
LeBlanc 2015	Remission rate, PHQ score < 5	3 months	114	19.6%	101	18.7%	P = 0.85
LeBlanc 2015	Remission rate, PHQ score < 5	6 months	109	21.5%	101	14.4%	P = 0.18
LeBlanc 2015	Responsiveness, > 50% PHQ-9 improvement	3 months	114	33.5%	101	30.9%	P = 0.77
LeBlanc 2015	Responsiveness, > 50% PHQ-9 improvement	6 months	109	34.8%	101	27.3%	P = 0.15

Table 2. Depression *(Continued)*

Loh 2007	Patient Health Questionnaire-9, PHQ-9	6-8 weeks	128	13.7 (SD 5.8)	66	14.6 (SD 5.3)	P = 0.610
Lovell 2018	The Depression subscale of the Hospital Anxiety and Depression Scale, HADS-D	6 months	208	9.8 (SD 5.5)	172	8.9 (SD 5.8)	P = 0.963
Raue 2019	Hamilton Depression Rating Scale, HDRS	8 weeks	114	12.4 (0.8)	88	11.7 (1.0)	No difference
Raue 2019	Hamilton Depression Rating Scale, HDRS	12 weeks	114	12.9 (0.8)	88	12.0 (0.9)	No difference

SDM: shared decision-making

Table 3. Anxiety

Study	Scale used	Timing	N SDM	SDM mean	N comparison	Comparison mean	Notes
Lovell 2018	The Anxiety subscale of the Hospital Anxiety and Depression Scale, HADS-A	6 months	208	12.1 (SD 5.4)	172	10.9 (SD 5.9)	P = 0.339

SDM: shared decision-making

Table 4. Readmission rate

Study	Scale used	Timing	N SDM	SDM mean	N comparison	Comparison mean	Notes
Hamann 2006	Rehospitalisation rate	6 months	36	22%	37	22%	P > 0.05
Hamann 2006	Rehospitalisation rate	18 months	38	53%	41	46%	P > 0.05
Hamann 2011	Rehospitalisation rate	6 months	29	17%	26	15%	P = 0.57
Hamann 2017	Rehospitalisation rate	12 months	95	31%	75	31%	P = 0.98

SDM: shared decision-making

Table 5. Participation (by the person with mental health condition) or level of involvement in the decision-making process

Study	Scale used	Timing	N SDM	SDM mean	N comparison	Comparison mean	Notes
Aoki 2019a	Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness, COMRADE communication	After decision-making	32	median 44	53	median 38	P < 0.001
Aoki 2019a	Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness, COMRADE confidence	After decision-making	32	median 41	53	median 37	P = 0.005
Hamann 2006	Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness, COMRADE total	After the intervention		79.5		69.7	P = 0.03 n = 75 (Total number of participants)
LeBlanc 2015	Decisional Conflict Scale, DCS (0 = conflict, 100 = comfort)	After encounter	138	79.7	114	74.5	P = 0.01
LeBlanc 2015	Participation-Involvement patient, OPTION (observation)	Assessed from video recording on the encounter	57	46.6	39	32.5	P = 0.01
Loh 2007	Man-Song-Hing Scale	After intervention	128	28.0 (SD 2.9)	66	25.5 (SD 3.0)	P = 0.003
Lovell 2018	Equip patient reported outcome measure, EQUIP PROM-14	6 months	192	21.3 (SD 9.6)	153	21.6 (SD 11.2)	P = 0.715
Yamaguchi 2017	Core components of SDM, SDM-18	During consultation	18	6.3 (SD 1.3)	19	4.1 (SD 1.3)	P < 0.001
Yamaguchi 2017	Patient activation measure, PAM	6 months	26	52.3 (SD 18.1)	27	45.8 (SD 10.8)	

SDM: shared decision-making

Table 6. Recovery

Study	Scale used	Timing	N SDM	SDM mean	N control	Control mean	Notes

Table 6. Recovery *(Continued)*

Lovell 2018	Developing Recovery Enhancing Environments Measure, DREEM	6 months	142	43.5 (SD 13.3)	118	42.6 (SD 12.5)	P = 0.990
Yamaguchi 2017	Self-Identified Stage of Recovery, SISR Part A	6 months	26	3.19 (SD 1.2)	27	2.93 (SD 1.36)	P = 0.99
Yamaguchi 2017	Self-Identified Stage of Recovery, SISR Part B	6 months	26	15.04 (SD 5.38)	27	14.04 (SD 4.15)	P = 0.40

SDM: shared decision-making

Table 7. Service user satisfaction

Study	Scale used	Timing	N SDM	SDM mean	N control	Control mean	Notes
Aoki 2019a	Client Satisfaction Questionnaire–8 Japanese version, CSQ-8	After decision making	32	24.31 (SD 2.90)	53	23.75 (SD 3.71)	No difference
Hamann 2006	Overall satisfaction, German version of the Client Satisfaction Questionnaire, ZUF-8	At hospital discharge	-	16.3 (SD 3.7)	-	16.4 (SD 3.2)	P = 0.42
Hamann 2011	Overall satisfaction, German version of the Client Satisfaction Questionnaire, ZUF-8	Post intervention	32	25.5 (SD 4.1)	29	26.7 (SD 3.2)	P = 0.23
Hamann 2017	Overall satisfaction, German version of the Client Satisfaction Questionnaire, ZUF-8	Post intervention	-	25.7 (SD 4.2)	-	25.8 (SD 5.2)	P = 0.88
Ishii 2017	Overall satisfaction, Client Satisfaction Questionnaire–8 Japanese version, CSQ-8	At hospital discharge	9	23.7 (SD 3.9)	13	22.1 (SD 3.7)	No difference
LeBlanc 2015	User satisfaction - right amount of information	Immediately after encounter	132	92.5%	109	91.9%	P = 0.81
LeBlanc 2015	User satisfaction - information given was clear	Immediately after encounter	132	68.7%	109	58.7%	P = 0.09
LeBlanc 2015	User satisfaction - information given was helpful	Immediately after encounter	132	69.2%	109	52.8%	P = 0.01

Table 7. Service user satisfaction *(Continued)*

LeBlanc 2015	User satisfaction - strongly desire to receive information this way for other treatment decisions	Immediately after encounter	132	68.2%	109	50.5%	P = 0.005
Lovell 2018	User satisfaction - strongly recommend the way information was shared to others	Immediately after encounter	132	77.6%	109	59.1%	P = 0.002
Loh 2007	Overall satisfaction, German version of the Client Satisfaction Questionnaire, ZUF-8	Post intervention	128	29.8 (SD 2.7)	66	27.0 (SD 3.6)	P = 0.014
Lovell 2018	Overall satisfaction, Verona Service Satisfaction Scale - European Version-54, VSSS-EU-54	6 months	191	3.5 (SD 0.7)	156	3.5 (SD 0.8)	P = 0.045
Woltmann 2011	Overall satisfaction, Seven statements related to satisfaction, a 5-point Likert scale	Post participation	40	3.88 (SD 0.54)	40	3.78 (SD 0.56)	No difference
Yamaguchi 2017	Overall satisfaction, Client Satisfaction Questionnaire–8 Japanese version, CSQ-8	6 months	26	26.0 (4.4)	27	24.3 (4.8)	P = 0.21

SDM: shared decision-making

Table 8. Carer satisfaction

Study	Scale used	Timing	N SDM	SDM mean	N comparison	Comparison mean	Notes
Lovell 2018	Carers and Users' Expectations of Services - carer version, CUES-C	6 months	24	22.71	26	24.12	No difference

Table 9. Healthcare provider satisfaction

Study	Scale used	Timing	N SDM	SDM mean	N comparison	Comparison mean	Notes
Hamann 2006	5-point Likert scale: overall satisfaction with what had been achieved during hospitalisation	At discharge	-	3.8	-	3.5	P = 0.02

Table 9. Healthcare provider satisfaction *(Continued)*

LeBlanc 2015	Satisfied/extremely satisfied 1-item, 5-point Likert scale	Immediately after the clinical encounter	139	54%	117	76.3%	P = 0.02
Mariani 2018	Professional caregivers' job satisfaction questionnaire, JSQ	6 months	16	42.84 (SD 14.33)	18	43.33 (SD 10.97)	P = 0.576
Woltmann 2011	Case manager satisfaction, 6 statements related to satisfaction, a 5-point Likert scale	After participation	10	4 (SD 0.5)	10	3.3 (SD 0.5)	P = 0.002

Table 10. Knowledge

Study	Scale used	Timing	N SDM	SDM mean	N control	Control mean	Notes
Hamann 2006	Patient knowledge about their disease, original items with 7 multiple-choice questions	At discharge	-	15.0 (SD 4.4)	-	10.9 (SD 5.4)	P = 0.01 n = 88 (total number of participants)
LeBlanc 2015	Overall knowledge including both tailored to information in the decision aid and generic information about depression	Immediately after the clinical encounter	138	63.5	116	56.3	P = 0.03
Woltmann 2011	Client knowledge of the care plan (plan goals recalled)	2 to 4 days after the care planning session	36	75%	33	57%	P = 0.02

SDM: shared decision-making

Table 11. Treatment continuation

Study	Scale used	Timing	N SDM	SDM mean	N control	Control mean	Notes
Aoki 2019a	Adherence with outpatient visits	6 months	35	56%	53	51%	P = 0.656
Hamann 2011	"Has this patient shown up at your practice since being discharged from the hospital?" (Physicians answered yes/no)	6 months	32	94%	29	90%	P = 0.45

Table 11. Treatment continuation *(Continued)*

Hamann 2011	"Are you still in psychiatric treatment?" (Participants answered yes/no)	6 months	25	100%	23	91%	P = 0.22
Hamann 2011	"How much does this patient engage in planning for his or her therapy?" (Physicians answered)	6 months	25	3.5 (SD 0.9)	23	3.2 (SD 0.9)	P = 0.19
Ishii 2017	Whether a patient received outpatient psychiatric treatment within 30 days prior to follow-up time on medical records	6 months	9	88.9%	13	69.2%	No difference
Loh 2007	Participant assessment of treatment adherence	6-8 weeks	128	4.3 (SD 0.9)	66	3.9 (SD 1.0)	No difference
Loh 2007	Physician assessment of treatment adherence	6-8 weeks	128	4.8 (SD 0.6)	66	4.3 (SD 1.1)	No difference
Mott 2014	Initiated psychotherapy visits 1 to 9	4 months	9	44%	11	45%	No difference

Table 12. Medication continuation

Study	Scale used	Timing	N SDM	SDM mean	N control	Control mean	Notes
Aljumah 2015	Morisky Medication Adherence Scale, MMAS	3 months	110	5.79 (SD 1.89)	110	5.04 (SD 1.98)	P = 0.004
Aljumah 2015	Morisky Medication Adherence Scale, MMAS	6 months	110	5.99 (SD1.88)	110	4.94 (SD 1.94)	P < 0.0001
Aoki 2019a	Visual analogue scale, VAS	3 months	22	8.79 (SD 1.44)	44	8.57 (SD 1.60)	P = 0.910
Aoki 2019a	Visual analogue scale, VAS	6 months	22	8.58 (SD 1.44))	44	8.44 (SD 1.62	P = 0.872
Hamann 2006	Estimated compliance from physician's point of view	At discharge	-	1.7	-	2.0	P > 0.05
Hamann 2006	Overall compliance determined by participant rated, physician rated, and plasma level	6 months after discharge	39	41%	47	55%	P > 0.05

Table 12. Medication continuation *(Continued)*

Hamann 2006	Overall compliance determined by participant rated, physician rated, and plasma level	18 months after discharge	30	60%	38	58%	P > 0.05
Hamann 2011	"Are you still taking medication for your psychiatric condition?" (Participants answered yes/no)	6 months post hospital discharge	25	100%	23	87%	P = 0.10
Hamann 2011	"How do you estimate your patient's compliance?" (Physician assessed)	6 months post hospital discharge	29	4.0 (SD 1.1)	26	4.2 (SD 0.9)	P = 0.78
Hamann 2017	Medication Adherence Rating Scale, MARS	6 months post hospital discharge	-	2.6 (2.1)	-	2.5 (2.2)	P = 0.72 n = 100 (total number of participants)
Hamann 2017	Medication Adherence Rating Scale, MARS	12 months post hospital discharge	-	2.4 (2.1)	-	2.8 (2.3)	P = 0.42 n = 85 (total number of participants)
LeBlanc 2015	Participants reported medication usage	After encounter	154	89.9%	134	79.1%	P = 0.15
LeBlanc 2015	Filled prescription within 30 days	For trial period	154	86.2%	134	93.2%	P = 0.19
LeBlanc 2015	% proportion of days covered (PDC) > 80% (of filled prescription)	For trial period	113	94.7%	93	97.8%	P = 0.67
Raue 2019	Initiation of antidepressant medication in the Cornel Service Index	12 weeks after intervention	103	23.3%	78	15.4%	P = 0.154
Yamaguchi 2017	Morisky Medication Adherence Scale, MMAS	6 months	26	5.7 (SD 1.5)	27	5.4 (SD 1.5)	P = 0.74

SDM: shared decision-making

Table 13. Carer participation in decision-making

Study	Scale used	Timing	N SDM	SDM mean	N control	Control mean	Notes

Table 13. Carer participation in decision-making *(Continued)*

Lovell 2018	User involvement in care planning (carers): Equip patient-reported outcome measure, PROM-14	6 months	22	20.1 (SD 8.0)	46	16.5 (SD 10.9)	P = 0.899

SDM: shared decision making

Table 14. Relationship between service users and healthcare providers

Study	Scale used	Timing	N SDM	SDM mean	N control	Control mean	Notes
Hamann 2006	Working Alliance Inventry, WAI (by physicians)	At discharge	-	60.6	-	69.0	P > 0.05
Hamann 2011	Difficult Doctor-Patient Relationship Questionnaire, DDPRQ (by physician)	At discharge	32	40.4 (SD 7.6)	29	44.6 (SD 8.4)	P = 0.05
Hamann 2011	Trust in physician (by participant)	At discharge	32	41.8 (SD 7.4)	29	46.4 (SD 7.2)	P = 0.02
Hamann 2011	Therapeutic alliance (by physician)	Post intervention	32	23.8 (SD 4.7)	29	24.1 (SD 4.8)	P = 0.83
Hamann 2017	Difficult Doctor-Patient Relationship Questionnaire, DDPRQ (by physician)	At discharge	-	43.0 (SD 8.1)	-	44 (SD 7.4)	P = 0.37
Hamann 2017	Trust in physician (by participant)	At discharge	-	40.3 (SD 7.5)	-	41.1 (SD 6.8)	P = 0.25
Lovell 2018	California Psychotherapy Alliance Scale, CALPAS	6 months	191	4.8 (SD 1.4)	152	4.9 (SD 1.5)	P = 0.949
Yamaguchi 2017	Relationship-Scale to Assess Therapeutic Relationship, STAR. Positive collaboration (by clinician)	6 months	26	18.7 (SD 3.2)	27	17.7 (SD 3.9)	P = 0.07
Yamaguchi 2017	Relationship-STAR, emotional difficulties (by clinician)	6 months	26	10.8 (SD 1.3)	27	10.5 (SD 1.2)	P = 0.59
Yamaguchi 2017	Relationship-STAR, positive clinician input (by clinician)	6 months	26	9.9 (SD 1.7)	27	9.6 (SD 1.4)	P = 0.17
Yamaguchi 2017	Relationship-STAR, positive collaboration (by participant)	6 months	26	19.4 (SD 5.6)	27	17.2 (SD 5.5)	P = 0.05

Table 14. Relationship between service users and healthcare providers *(Continued)*

Yamaguchi 2017	Relationship-STAR, positive clinician input (by participant)	6 months	26	9.0 (SD 2.2)	27	7.7 (SD 2.9)	P = 0.03
Yamaguchi 2017	Relationship-STAR, non-supportive clinician input (by participant)	6 months	26	10.4 (SD 2.4)	27	10 (SD 2.6)	P = 0.69

Table 15. Health service use outcomes

Study	Scale used	Timing	N SDM	SDM mean	N control	Control mean	Notes
Aoki 2019a	Consultation duration (minutes)	During initial consultation	35	28.71 (SD 12.66)	53	30.49 (SD 15.91)	P = 0.983
Hamann 2006	Rating of time spent per week with participant (minutes)	At discharge	-	64.0	-	60.0	P > 0.05
Ishii 2017	Length of stay (days)	At hospital discharge	9	66.7 (SD 40.4)	13	66.5 (SD 17.4)	No difference
Loh 2007	Consultation duration (minutes)	During consultation	128	29.2 (SD 10.7)	66	26.7 (SD 12.5)	No difference

SDM: shared decision-making

APPENDICES

Appendix 1. Cochrane Library on Wiley search strategy

14 January 2020

#1 MeSH descriptor: [Mental Health] this term only 1376

#2 MeSH descriptor: [Mental Health Services] explode all trees 6462

#3 MeSH descriptor: [Psychotherapy] explode all trees 22610

#4 MeSH descriptor: [Psychiatry] explode all trees 475

#5 MeSH descriptor: [Community Mental Health Centers] this term only 111

#6 MeSH descriptor: [Hospitals, Psychiatric] this term only 240

#7 MeSH descriptor: [Psychiatric Nursing] this term only 183

#8 MeSH descriptor: [Substance Abuse Treatment Centers] this term only 350

#9 MeSH descriptor: [Mental Disorders] explode all trees 67051

#10 MeSH descriptor: [Behavioral Symptoms] explode all trees 19648

#11 MeSH descriptor: [Mentally Ill Persons] this term only 47

#12 (((mental* or psychiatric or emotion*) NEAR (ill* or disorder* or health*))):ti,ab,kw (Word variations have been searched) 36558

#13 (((chronic* or severe*) NEAR mental*)):ti,ab,kw (Word variations have been searched) 2432

#14 ((schizo* or psychos#s or psychotic* or neuros#s or neurotic* or depressive or depression or anxiety disorder*)):ti,ab,kw (Word variations have been searched) 104625

#15 MeSH descriptor: [Psychology] this term only 270

#16 {OR #1-#15} 170596

#17 (((shar* or join*) NEAR5 decision making)):ti,ab,kw (Word variations have been searched) 15834

#18 (((involv* or include* or inclusive* or inclusion or participat* or collaborat* or share? or sharing or join*) NEAR (decision* or decid*))):ti,ab,kw (Word variations have been searched) 3965

#19 (patient cent?red communication):ti,ab,kw (Word variations have been searched) 2791

#20 {OR #17-#19} 19666

#21 MeSH descriptor: [Decision Making] explode all trees 4023

#22 ((decision* NEAR analys*)):ti,ab,kw (Word variations have been searched) 2102

#23 (((making or make or made or arriv*) NEAR5 decision*)):ti,ab,kw (Word variations have been searched) 29200

#24 (decid*):ti,ab,kw (Word variations have been searched) 7824

#25 ((negotiat* or agreement or consensus or concordance or (shar* NEAR information) or (risk* NEAR communicat*))):ti,ab,kw (Word variations have been searched) 27286

#26 (((understand* or understood) NEAR (check* or clarif* or ascertain*))):ti,ab,kw (Word variations have been searched) 121

#27 ((problem* N2 defin*)):ti,ab,kw (Word variations have been searched) 7

#28 MeSH descriptor: [Problem Solving] this term only 1503

#29 ((decision aid* or decision support or checklist*)):ti,ab,kw (Word variations have been searched) 15383

#30 MeSH descriptor: [Decision Support Techniques] this term only 779

#31 MeSH descriptor: [Decision Theory] explode all trees 165

#32 ((treatment NEAR (option* or choice* or choos* or prefer*))):ti,ab,kw (Word variations have been searched) 24857

#33 (((patient or user or consumer or carer or caregiver or care giver) NEAR (preference* or choice* or expectation* or understanding or involvement or participation))):ti,ab,kw (Word variations have been searched) 70356

#34 {OR #21-#33} 151029

#35 MeSH descriptor: [Professional-Patient Relations] this term only 758

#36 MeSH descriptor: [Physician-Patient Relations] this term only 1364

#37 MeSH descriptor: [Professional-Family Relations] this term only 206

#38 MeSH descriptor: [Conflict (Psychology)] this term only 320

#39 ((family NEAR (cent?red or focus?ed))):ti,ab,kw (Word variations have been searched) 1900

#40 MeSH descriptor: [Community Participation] explode all trees 1548

#41 MeSH descriptor: [Patient Acceptance of Health Care] this term only 2834

#42 MeSH descriptor: [Consumer Behavior] explode all trees 792

#43 MeSH descriptor: [Cooperative Behavior] this term only 963

#44 {OR #35-#43} 9985

#45 #34 AND #44 3747

#46 #20 OR #45 22299

#47 #46 AND #16 4278

Appendix 2. EMBASE search strategy

14 January 2020

1. exp mental health/

2. exp mental health care/

3. exp psychiatry/

4. exp psychiatric treatment/

5. exp drug dependence treatment/

6. exp mental disease/

7. mental patient/

8. ((mental* or psychiatric or emotion*) adj (ill* or disorder* or health*)).tw.

9. ((chronic* or severe*) adj mental*).tw.

10. (schizo* or psychos#s or psychotic* or neuros#s or neurotic* or depressive or depression or anxiety disorder*).tw.

11. "ethnic difference"/

12. or/1-11

13. ((shar* or join* or concordan*) adj5 decision making).tw.

14. ((involv* or include* or inclusive* or inclusion or participat* or collaborat* or share? or sharing or join* or concordan* or partner*) adj7 (decision* or decid*)).tw.

15. patient cent?red communication.tw.

16. partnership model*.tw.

17. or/13-16

18. decision making.mp.

19. consensus/

20. (decision* adj analys*).tw.

21. ((making or make or made or arriv* or disclos*) adj5 decision*).tw.

22. decid*.tw.

23. (negotiat* or agreement or consensus or concordan* or partnership or (shar* adj information) or (risk* adj communicat*)).tw.

24. ((understand* or understood) adj5 (check* or clarif* or ascertain*)).tw.

25. (problem* adj2 defin*).tw.

26. problem solving/

27. problem identification/

28. (decision aid* or decision support or checklist*).tw.

29. decision support system/

30. decision theory/

31. decision tree/

32. (treatment adj3 (option* or choice* or choos* or prefer*)).tw.

33. ((patient or user or consumer or carer or caregiver or care giver) adj (preference* or choice* or expectation* or understanding or involvement or participation)).tw.

34. or/18-33

35. human relation/ or employer/

36. doctor patient relation/

37. nurse patient relationship/

38. (family adj (cent?red or focus?ed)).tw.

39. patient participation/

40. consumer/

41. exp patient attitude/

42. exp cooperation/

43. or/35-42

44. 34 and 43

45. 17 or 44

46. 12 and 45

47. randomized controlled trial/

48. controlled clinical trial/

49. single blind procedure/ or double blind procedure/

50. crossover procedure/

51. random*.tw.

52. placebo*.tw.

53. ((singl* or doubl*) adj (blind* or mask*)).tw.

54. (crossover or cross over or factorial* or latin square).tw.

55. (assign* or allocat* or volunteer*).tw.

56. or/47-55

57. 46 and 56

58. limit 57 to yr="2009 -Current"

Appendix 3. Ovid MEDLINE search strategy

14 January 2020

1. mental health/

2. exp mental health services/

3. exp psychotherapy/

4. exp psychiatry/

5. psychiatric nursing/

6. community mental health centers/

7. hospitals, psychiatric/

8. substance abuse treatment centers/

9. exp mental disorders/

10. exp behavioral symptoms/

11. mentally ill persons/

12. ((mental* or psychiatric or emotion*) adj (ill* or disorder* or health*)).tw.

13. ((chronic* or severe*) adj mental*).tw.

14. (schizo* or psychos#s or psychotic* or neuros#s or neurotic* or depressive or depression or anxiety disorder*).tw.

15. px.fs.

16. or/1-15

17. ((shar* or join*) adj5 decision making).tw.

18. ((involv* or include* or inclusive* or inclusion or participat* or collaborat* or share? or sharing or join*) adj7 (decision* or decid*)).tw.

19. patient cent?red communication.tw.

20. or/17-19

21. exp decision making/

22. (decision* adj analys*).tw.

23. ((making or make or made or arriv*) adj5 decision*).tw.

24. decid*.tw.

25. (negotiat* or agreement or consensus or concordance or (shar* adj information) or (risk* adj communicat*)).tw.

26. ((understand* or understood) adj5 (check* or clarif* or ascertain*)).tw.

27. (problem* adj2 defin*).tw.

28. problem solving/

29. (decision aid* or decision support or checklist*).tw.

30. decision support techniques/

31. exp decision theory/

32. (treatment adj3 (option* or choice* or choos* or prefer*)).tw.

33. ((patient or user or consumer or carer or caregiver or care giver) adj (preference* or choice* or expectation* or understanding or involvement or participation)).tw.

34. or/21-33

35. professional patient relations/

36. physician patient relations/

37. professional family relations/

38. "Conflict (Psychology)"/

39. (family adj (cent?red or focus?ed)).tw.

40. exp community participation/

41. patient acceptance of health care/

42. exp consumer behavior/

43. cooperative behavior/

44. or/35-43

45. 34 and 44

46. 20 or 45

47. 46 and 16

48. randomized controlled trial.pt.

49. controlled clinical trial.pt.

50. randomized.ab.

51. placebo.ab.

52. drug therapy.fs.

53. randomly.ab.

54. trial.ab.

55. groups.ab.

56. or/48-55

57. exp animals/ not humans.sh.

58. 56 not 57

59. and/47,58

Appendix 4. PsycINFO search strategy

14 January 2020

1. mental health/

2. exp mental health services/

3. exp psychotherapy/

4. exp psychiatry/

5. psychiatric nursing/

6. community mental health centers/

7. hospitals psychiatric/

8. substance abuse treatment centers/

9. exp mental disorders/

10. exp behavioral symptoms/

11. mentally ill persons/

12. ((mental* or psychiatric or emotion*) adj (ill* or disorder* or health*)).tw.

13. ((chronic* or severe*) adj mental*).tw.

14. (schizo* or psychos#s or psychotic* or neuros#s or neurotic* or depressive or depression or anxiety disorder*).tw.

15. or/1-14

16. ((shar* or join*) adj5 decision making).tw.

17. ((involv* or include* or inclusive* or inclusion or participat* or collaborat* or share? or sharing or join*) adj7 (decision* or decid*)).tw.

18. patient cent?red communication.tw.

19. or/16-18

20. exp decision making/

21. (decision* adj analys*).tw.

22. ((making or make or made or arriv*) adj5 decision*).tw.

23. decid*.tw.

24. (negotiat* or agreement or consensus or (shar* adj information) or (risk* adj communicat*)).tw.

25. ((understand* or understood) adj5 (check* or clarif* or ascertain*)).tw.

26. (problem* adj2 defin*).tw.

27. problem solving/

28. (decision aid* or decision support or checklist*).tw.

29. decision support techniques/

30. exp decision theory/

31. (treatment adj3 (option* or choice* or choos* or prefer*)).tw.

32. ((patient or user or consumer or carer or caregiver or care giver) adj (preference* or choice* or expectation* or understanding or involvement or participation)).tw.

33. or/20-32

34. professional patient relations/

35. physician patient relations/

36. professional family relations/

37. (family adj (cent?red or focus?ed)).tw.

38. exp consumer participation/

39. patient acceptance of health care/

40. patient satisfaction/

41. cooperative behavior/

42. or/34-41

43. 33 and 42

44. 19 or 43

45. 44 and 15

46. random*.ti,ab,hw,id.

47. intervention.ti,ab,hw,id.

48. trial.ti,ab,hw,id.

49. placebo*.ti,ab,hw,id.

50. groups.ab.

51. ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.

52. (cross over or crossover).ti,ab,hw,id.

53. latin square.ti,ab,hw,id.

54. (assign* or allocat* or volunteer*).ti,ab,hw,id.

55. (control or controlled).ti,ab,hw,id.

56. treatment effectiveness evaluation/

57. mental health program evaluation/

58. exp experimental design/

59. "2100".md.

60. or/46-59

61. animal.po.

62. 60 not 61

63. 45 and 62

64. limit 63 to yr="2009 -Current"

WHAT'S NEW

Date	Event	Description
14 November 2022	Amended	Author name, Yoshikazu Takaesu, corrected

HISTORY

Protocol first published: Issue 3, 2008
Review first published: Issue 1, 2010

Date	Event	Description
11 November 2022	New search has been performed	This is the first update of this Cochrane Review, first published in 2010. We conducted new searches and updated other content. We added 13 new studies to the review, and four further studies are awaiting classification.
10 November 2022	New citation required and conclusions have changed	This update suggests that people exposed to SDM interventions may perceive greater levels of involvement immediately after an encounter compared with those in control groups.

CONTRIBUTIONS OF AUTHORS

2010 version of the review (Duncan 2010):

- Edward Duncan: conceived the review, wrote the title registration form and the protocol. Led and contributed to all further stages of the review.
- Catherine Best: conducted electronic searches of databases; assessed title and abstracts obtained from electronic and other searches, and contributed to the assessment of the methodological quality of the retrieved studies, the analysis of the results, and the drafting of the review.
- Suzanne Hagen: provided guidance on preparing the title registration form and protocol. Contributed to the assessment of methodological quality of retrieved studies, analysis of results, and critically read drafts of the review document.

2022 (current) version of the review:

- YA led the team with help from AE in coordinating the update.
- YA, YY, LS, MS, and TU screened studies; YA, YY, LS, and MS extracted data including the risk of bias assessment; TU and AE verified the data extracted and the risk of bias.
- YA and YY analysed the results.
- YA, TU, and YY conducted update search.
- YA drafted the review.
- YA, YY, TU, TY, NW, KW, ED, LS, MS, and AE contributed to the interpretation of results and the revision, and approved the final paper.

DECLARATIONS OF INTEREST

YA: co-authorship of the included study Aoki 2019a
YY: none declared
TU: has received lecture fees from Eisai.
YT: has received lecture fees from Otsuka Pharmaceutical, Meiji Seika Pharma, Eli Lilly, Eisai, Mitsubishi Tanabe Pharma, MSD, and Yoshitomi Pharmaceutical, and has received research funding from Otsuka Pharmaceutical, Meiji Seika Pharma, MSD, and Eisai; and co-authorship of the included study Aoki 2019a.
NW: has received royalties from Sogensha, Medical Review, and Akatsuki for writings.

KW: has received manuscript fees or speaker's honoraria from Daiichi Sankyo, Eisai, Eli Lilly, GlaxoSmithKline, Janssen Pharmaceutical, Kyowa Pharmaceutical, Meiji Seika Pharma, Mitsubishi Tanabe Pharma, MSD, Otsuka Pharmaceutical, Pfizer, Shionogi, Sumitomo Dainippon Pharma, Takeda Pharmaceutical, Yoshitomi, and has received research/grant support from Astellas Pharma, Daiichi Sankyo, Eisai, MSD, Mitsubishi Tanabe Pharma, Meiji Seika Pharma, Otsuka Pharmaceutical, Pfizer, Shionogi, Sumitomo Dainippon Pharma, and is a consultant of Eisai, Eli Lilly, Kyowa Pharmaceutical, Otsuka Pharmaceutical, Pfizer, Sumitomo Dainippon Pharma, Taisho Toyama Pharmaceutical, and Takeda Pharmaceutical; and co-authorship of the included study Aoki 2019a.
ED: none declared
LS: none declared
MS: none declared
AE: none declared

Those members of the review author team who co-authored the included study Aoki 2019a did not select, extract data, or appraise the risk of bias for this study. GRADE ratings for the assessment of the overall certainty of the evidence for each outcome were led by review authors other than YA, TY, and KW (authors on the Aoki 2019a trial).

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied, Other

  No sources of support supplied

External sources

- No sources of support supplied, Other

  No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are several differences between the original review and this update review.

Although the original review included controlled before-and-after studies (CBAs), interrupted time series (ITS) studies, and quasi-RCTs, this update review excluded study designs other than RCTs and cluster-RCTs because we were aware that there would be more literature in this area for this update.

Since the idea of recovery – which is a way of living a satisfying, hopeful, and contributing life even with limitations caused by the illness – has become more important in the last decade in this area, we have added recovery as an outcome in this update.

We planned to conduct narrative (descriptive) subgroup analyses in cases where it was not possible to pool data statistically to carry out subgroup analysis or there were too few included studies to warrant statistical subgroup analyses. However, there were not enough studies or differences across potential modifying factors, or both, to allow us to undertake this descriptive analysis.

We used GRADE tools to summarise our findings (see Summary of findings 1). Because we had two primary outcomes, each of which contained multiple items, instead of reporting secondary outcomes, we reported on each of the two primary outcomes in the summary of findings (SoF) table.

Since publishing the original review, two review authors have been removed (CB, SH) and nine new review authors added (YA, YY, TU, LS, MS, YT, KW, NW, and AE).

Regarding consumers' feedback to support our review, we are recruiting participants for this purpose. Thus, the next step will be to conduct one or several focus group discussions to explore the relevance of findings for practice.

INDEX TERMS

Medical Subject Headings (MeSH)

*Anxiety; Anxiety Disorders; Caregivers; Health Personnel; *Mental Health

MeSH check words

Adolescent; Adult; Child; Humans