

Review article

Shared treatment decision-making and empowerment-related outcomes in psychosis: systematic review and meta-analysis

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Background

In the UK almost 60% of people with a diagnosis of schizophrenia who use mental health services say they are not involved in decisions about their treatment. Guidelines and policy documents recommend that shared decision-making should be implemented, yet whether it leads to greater treatment-related empowerment for this group has not been systematically assessed.

Aims

To examine the effects of shared decision-making on indices of treatment-related empowerment of people with psychosis.

Method

We conducted a systematic review and meta-analysis of randomised controlled trials (RCTs) of shared decision-making concerning current or future treatment for psychosis (PROSPERO registration CRD42013006161). Primary outcomes were indices of treatment-related empowerment and objective coercion (compulsory treatment). Secondary outcomes were treatment decision-making ability and the quality of the therapeutic relationship.

Results

We identified 11 RCTs. Small beneficial effects of increased

shared decision-making were found on indices of treatment-related empowerment (6 RCTs; $g=0.30$, 95% CI 0.09–0.51), although the effect was smaller if trials with >25% missing data were excluded. There was a trend towards shared decision-making for future care leading to reduced use of compulsory treatment over 15–18 months (3 RCTs; RR=0.59, 95% CI 0.35–1.02), with a number needed to treat of approximately 10 (95% CI 5–∞). No clear effect on treatment decision-making ability (3 RCTs) or the quality of the therapeutic relationship (8 RCTs) was found, but data were heterogeneous.

Conclusions

For people with psychosis the implementation of shared treatment decision-making appears to have small beneficial effects on indices of treatment-related empowerment, but more direct evidence is required.

Declaration of interest

None.

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The Schizophrenia Commission has stated that: ‘shared decision-making on medication choices is essential to improving outcomes [. . .]. This means practitioners discussing medication options fully with service users [and] providing them with quality information so that informed decisions can be made.’¹

Shared decision-making in healthcare has been described as a process of supportive collaboration between patients* and clinicians, drawing on evidence and the patient’s preferences and values to reach a consensus about treatment or care.^{2,3} It is seen as falling midway on a continuum between paternalistic decision-making practices by clinicians and autonomous, informed decision-making by patients.^{4–7} Although benefits have been reported for shared decision-making in physical healthcare,⁸ research and practice on this topic in relation to people with mental health problems are still at a formative stage.⁹ Shared decision-making may be particularly relevant in psychosis, where increasing treatment-related empowerment and reducing use of coercion have been identified by patients as outcomes of intrinsic value.^{10–13} If clinical trials of this approach show it to be effective at improving these outcomes, then this would support existing recommendations that shared decision-making be widely implemented with this group.^{1,14}

We conducted a systematic review and meta-analysis of randomised controlled trials (RCTs) of shared decision-making in psychosis, with the overall aim of finding out whether

enhancing shared decision-making can improve treatment-related empowerment in this group, as judged by participants and indicated by objective measures. The effects on secondary outcomes – quality of patient–provider relationship (patient- or observer-rated) and decision-making abilities and knowledge (clinician-rated) – were also evaluated.

Method

The electronic databases Medline (from 1946), PsycINFO (from 1806), EMBASE (from 1980), CINAHL (from 1937) and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched by two authors (D.S. and M.P.) in August 2013 and January 2015 respectively, along with the references of two previous reviews of shared decision-making interventions in mental healthcare.^{4,5} Titles, abstracts and keywords were searched using the terms ‘shared decision making’, ‘psychosis’ and ‘randomised controlled trial’, with related terms in each case. The full search strategy is given in online supplement DS1. The search was not limited by date or publication status, but only English-language studies were included. Initial screening and data extraction were carried out by D.S. and studies published between 2013 and 2015 were screened and extracted by M.P. Supervision of screening and extraction, and arbitration in the event of uncertainty, were provided by P.H.

Inclusion and exclusion criteria

Trials were included if they compared a psychosocial intervention designed to enhance shared decision-making in the planning of

*The literature reviewed refers to people with psychosis variously as ‘patients’, ‘service users’ and ‘clients’; ‘patients’ is used here for consistency and in accordance with *BJPsych* house style.

treatment for psychosis with usual care or a non-specific control treatment. Shared decision-making was defined as a process of supportive collaboration between patients and clinicians, drawing on evidence and the patient's preferences and values to reach a consensus about treatment or care.^{2,3} Interventions to enhance it could be delivered either individually or in a group format, and could involve either current or future treatment decisions (e.g. joint crisis planning), but they had to share a focus on promoting shared decision-making as defined above and they had to involve direct contact with patients or clinicians. Thus, studies of advance statements or care planning not involving promotion of shared decision-making were excluded, as were studies providing interventions to family members or carers. We included trials where assessing the effects of promoting shared decision-making was either a primary or a secondary aim of the study.

Participants

We included studies in which at least half of the participants had a diagnosis of a schizophrenia spectrum disorder. Studies where more than half of participants had a diagnosis of bipolar disorder or learning disability, or where psychosis was predominantly substance-induced or organic in origin, were excluded. We did not include participants at risk of developing psychosis, and we did not exclude participants on the basis of age or stage of established illness.

Outcomes

Two primary outcomes were chosen: first, subjective empowerment, and second, reduced objective coercion. For the first outcome a scoping review of the literature suggested that few studies measured subjective empowerment directly; however, several measured aspects of empowerment or closely related concepts. In order to include as many studies as possible a conceptual hierarchy was developed to specify in advance the order of preference for the data that would be extracted and analysed, based on its closeness to the concept of empowerment. The hierarchy was structured as follows: self-reported subjective empowerment > treatment decision-making self-efficacy > health-related locus of control > patient-perceived involvement in treatment decision-making > patient-centredness of patient-provider interaction > reduced perceived coercion. The second primary outcome was reduced objective coercion as indicated by fewer admissions under mental health legislation: the Mental Health Act 1983 for studies in England & Wales or corresponding legislation within the country concerned for studies that had taken place elsewhere. We originally planned to analyse days spent in hospital under compulsory care for this outcome, but skewed or unavailable data meant we decided to analyse admission rates instead. Secondary outcomes were quality of patient-provider relationship (patient- or observer-rated) and decision-making abilities and knowledge (clinician-rated). For all outcomes we included data derived from both validated and non-validated scales, although use of the latter was considered when assessing the quality of the individual outcome.

Data extraction

Summary data (means and standard deviations) were extracted where possible from relevant studies using a spreadsheet. Information on study characteristics was also collated. Authors were contacted where information was missing. When means and standard deviations were not reported and the authors were unable to supply this information, other parameters such as *F*

values, regression coefficients, *P* values and sample size were used to estimate the standardised mean difference (SMD) using equations specified in the *Cochrane Handbook*.¹⁵ In the absence of available continuous data, proportions were converted to SMDs using the Campbell Collaboration's Practical Meta-Analysis Effect Size Calculator (campbellcollaboration.org/resources/effect_size_input.php). Numbers randomised were used where appropriate methods for imputing missing data were reported, but limitation to use of *n* reported for the analysis was expected where this was not the case. Missing data were assessed as part of the risk of bias assessment, but no test of robustness of estimates to changing assumptions around missing data was planned or performed. For the binary outcome of compulsory admission, we assumed those randomised but unaccounted for had an unchanged outcome from randomisation.

Meta-analytic calculations

Continuous data were extracted and combined using MetaXL version 2.0 (epigear.com) to derive the SMD and 95% confidence intervals, with Hedges' *g* employed to adjust for small sample sizes. Statistical significance was inferred with *P* values of < 0.05, using two-tailed hypotheses. Analyses employed a random effects model although a fixed effect analysis was also performed where the *I*² statistic indicated less than moderate heterogeneity (defined *a priori* as 40%).¹⁵ Cohen's proposed criteria for interpretation of effect sizes (small 0.2, moderate 0.5, large 0.8) were used in the absence of more specific criteria for judging clinical significance of SMDs.¹⁶ For the binary outcome of objective coercion (compulsory admission) we computed the pooled relative risk of the unfavourable outcome, the risk difference and number needed to treat, each with 95% confidence intervals.

Sensitivity analyses

Sensitivity analyses were used to assess the effect of excluding studies with more than 25% attrition.

Registration of review protocol

The review protocol was registered in advance with the International Prospective Register of Systematic Reviews (PROSPERO) number CRD42013006161.¹⁷

Risk of bias and study quality

Risk of bias was assessed for each study using the Cochrane Collaboration risk of bias tool.¹⁸ Assessment of outcome quality was performed using the GRADE approach.¹⁹ Risk of performance bias was not used as a criterion for downgrading the quality of the evidence, since it is essentially unavoidable in trials of psychosocial interventions, and to downgrade on this basis was judged to be overly conservative. Assessment of risk of publication bias using funnel plots was planned if there were at least ten studies.²⁰ GRADE ratings were used to determine overall confidence in the reliability of individual outcomes. Full details of the assessment methods are provided in online supplements DS2 and DS3.

Results

The titles and abstracts of 4676 papers were screened for eligibility (Fig. 1). Of these, full-text reports were sought for 38. Three studies were not included because they were ongoing or could not be traced. A further 25 studies were excluded because they

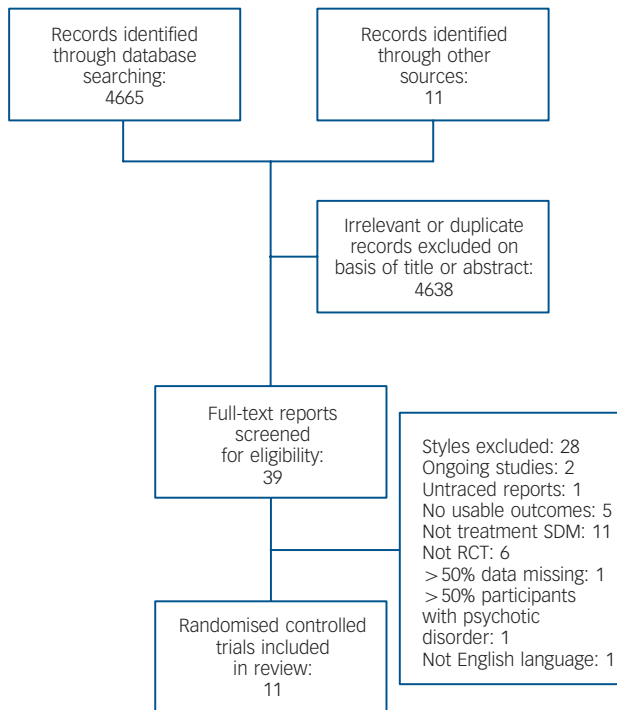


Fig. 1 Study selection process.

RCT, randomised controlled trial; SDM, shared decision-making.

did not report outcomes we could use ($k=5$), did not evaluate a treatment-related shared decision-making intervention ($k=11$), were not RCTs ($k=6$), had an attrition rate of $>50\%$ ($k=1$), had less than 50% participants with non-affective psychosis ($k=1$) or were not published in English ($k=1$). A total of 11 RCTs were therefore included. Of these, four evaluated interventions designed to support shared decision-making in relation to future treatment (joint crisis planning or facilitated advance directives).^{21–25} The remaining seven RCTs examined interventions designed to support shared decision-making in relation to current treatment. Of these, four examined the effects of paper-based or web-based decision or communication aids;^{26–29} one evaluated a group intervention;³⁰ another evaluated the effects of training clinicians in a shared decision-making approach to medicines management;³¹ and another evaluated the effects of patient-focused case management where treatment-related shared decision-making was emphasised.³² Details of interventions

delivered and baseline demography of the participants are given in online Table DS1; reasons for exclusions are summarised in online Tables DS2 and DS3.

Bias and quality assessment

Table 1 provides a summary of the results for each outcome and the GRADE ratings of outcome quality. The full risk of bias and quality ratings are provided in online Tables DS4 and DS5. Funding of the included studies is summarised in online Table DS6. Most ($k=8$) studies had at least one judgement of unclear risk of selection bias.^{21,22,25,26,28–32} Risk of performance bias was high across all studies owing to the nature of the interventions, which precluded masking (blinding). Insufficient information in reporting also led to unclear detection bias in seven studies,^{21,22,25–27,29,30,32} and one RCT stated no attempt to mask assessors was made.³¹ Risk of attrition bias was high or unclear on some post-intervention measures in just over half of the studies ($k=6$).^{24–27,31,32} Risk of selective reporting bias was largely unclear, although there was an indication that three RCTs did not report all their outcomes.^{21,25,32} There was unclear risk of other sources of bias in four trials, namely risk of recruitment bias due to cluster randomised design,^{26,29,31} and risk of cross-contamination due to in-patient research setting.³⁰

Primary outcomes

Treatment-related empowerment

A small effect of shared decision-making interventions on indices of subjective empowerment (Fig. 2) was observed ($k=6$, $g=0.30$, 95% CI 0.09 to 0.51; low-quality evidence). Six trials ($n=843$) provided data on this outcome.^{24,26,28–30} The quality of the evidence was downgraded owing to its indirectness, with no study measuring subjective empowerment specifically, and its imprecision, given that the 95% confidence interval included both trivial and moderate effects. There was, however, no evidence of undue heterogeneity ($I^2=35\%$). Two small studies provided follow-up data. One did not find a significant effect at hospital discharge ($g=0.16$, 95% CI -0.27 to 0.60), but data were missing for more than a quarter of participants.²⁶ For the other, ratings on an idiosyncratic measure of patient-perceived involvement were reported at 6-month follow-up, and suggested a large effect was maintained ($g=1.09$, 95% CI 0.49 to 1.69).³⁰

Compulsory treatment

Data from three studies ($n=872$) suggested a trend towards shared decision-making for future treatment (crisis planning) reducing the likelihood of future compulsory in-patient treatment

Table 1 Summary of results

Outcome (number of trials)	Participants <i>n</i>	Effect size (95% CI)	Heterogeneity and <i>P</i> value	Quality rating
Indices of subjective empowerment ($k=6$)	843 (I 423, C 420)	$g=0.30$ (0.09, 0.51)	$I^2=35\%$, $P=0.17$	Low
Risk of compulsory treatment ($k=3$)	872 (I 435, C 437)	RR = 0.59 (0.35, 1.02) RD = -0.10 (-0.19 , 0) NNT = 10 (5, ∞)	$I^2=61\%$, $P=0.08$	Low
Relationship with clinician ($k=8$)	1261 (I 577, C 684)	$g=0.14$ (-0.05 , 0.34)	$I^2=60\%$, $P=0.02$	Low
Relationship with clinician, excluding Hamann <i>et al</i> (2011) ³¹ ($k=7$)	1200 (I 545, C 655)	$g=0.21$ (0.07, 0.35)	$I^2=20\%$, $P=0.27$	Moderate
Clinician-rated decision-making abilities and knowledge ($k=3$)	520 (I 258, C 262)	$g=0.27$ (-0.24 , 0.79)	$I^2=83\%$, $P=0.003$	Very low

C, control; I, intervention; NNT, number needed to treat; RD, risk difference; RR, relative risk.

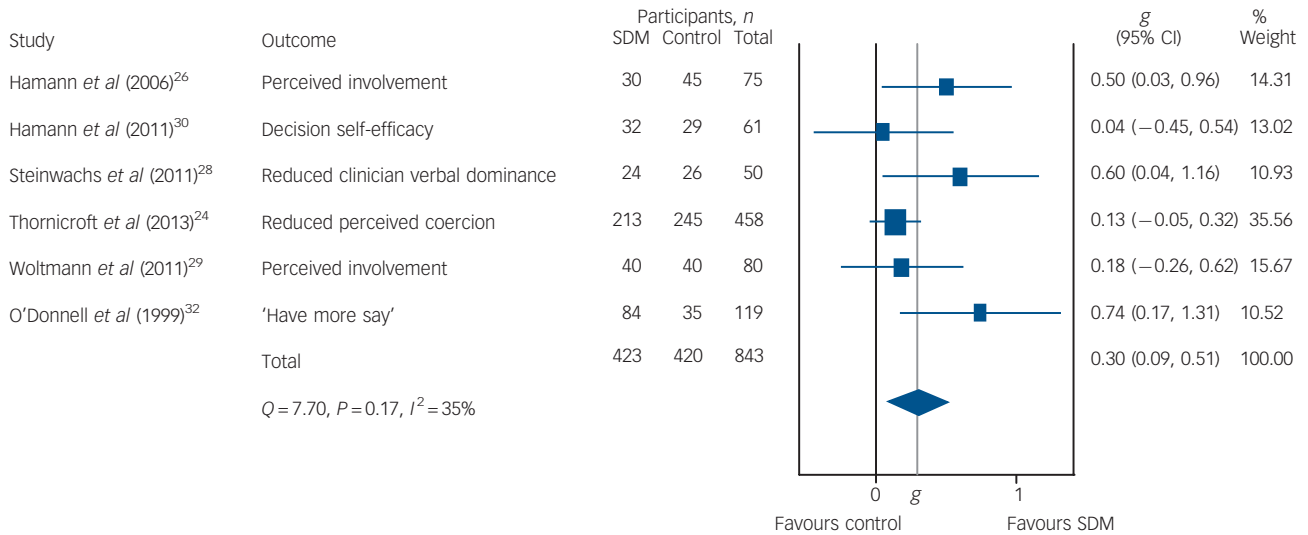


Fig. 2 Effect of shared decision-making (SDM) on indices of subjective empowerment.

over the subsequent 15–18 months (Fig. 3), but the estimate was imprecise and inconsistent and did not exclude the possibility of no effect (RR = 0.59, 95% CI 0.35 to 1.02; risk difference -0.10, 95% CI -0.19 to 0; NNT = 10, 95% CI 5 to ∞).^{23–25}

Sensitivity analysis

Excluding the two studies with more than 25% missing data from the empowerment analysis resulted in a smaller effect size ($k = 4, g = 0.17, 95\% \text{ CI } 0.01 \text{ to } 0.32$),^{26,32} as did using a fixed effect analysis instead of random effects ($k = 8, g = 0.23, 95\% \text{ CI } 0.09 \text{ to } 0.38$).

Secondary outcomes

Relationship with clinician

Overall, no significant effect of shared decision-making interventions on patient or observer-rated relationship with clinician was found ($k = 8, g = 0.14, 95\% \text{ CI } -0.05 \text{ to } 0.34$); see online Fig. DS1. Eight studies ($n = 1200$) contributed to this outcome.^{22,24,25,27,28,30–32} High heterogeneity ($I^2 = 60\%$) together with wide 95% confidence intervals (including both marginal negative effects and small positive effects) meant we rated the evidence as low quality. A moderate negative effect in the study by Hamann *et al* ($g = -0.62, 95\% \text{ CI } -1.13 \text{ to } -0.11$) contributed particularly to the high heterogeneity.³¹ This study of a group in-patient intervention differed from the others in measuring 'trust

in physician' rather than 'alliance' or 'quality of communication'. Omitting these data suggested a small, statistically significant effect ($g = 0.21, 95\% \text{ CI } 0.07 \text{ to } 0.35$; moderate-quality evidence) favouring shared decision-making, with a reduction in heterogeneity to 20%.

Clinician-rated decision-making abilities

Pooled data from three studies ($n = 520$) did not support the hypothesis that shared decision-making interventions can enhance participant decision-making ability as rated by clinicians ($k = 3, g = 0.27, 95\% \text{ CI } -0.24 \text{ to } 0.79$, very low-quality evidence); see online Fig. DS2.^{21,26,30} However, heterogeneity was high ($I^2 = 83\%$), as was imprecision, with a 95% confidence interval including both small negative and large positive estimates, and only one of the studies used a validated measure of decisional capacity.²¹

Sensitivity analyses

Excluding four studies with more than 25% missing data from the analysis of patient-provider relationship reduced the overall effect size to 0.07 (95% CI -0.29 to 0.42; $k = 4$) but increased heterogeneity ($I^2 = 73\%$).^{24,25,31,32} Also removing the Hamann study from this analysis increased the pooled effect size to 0.25 (95% CI 0.08 to 0.41; $k = 3$) and reduced heterogeneity to 0%.³⁰ Excluding one study with more than 25% missing data from the analysis of decision-making ability reduced the effect size to

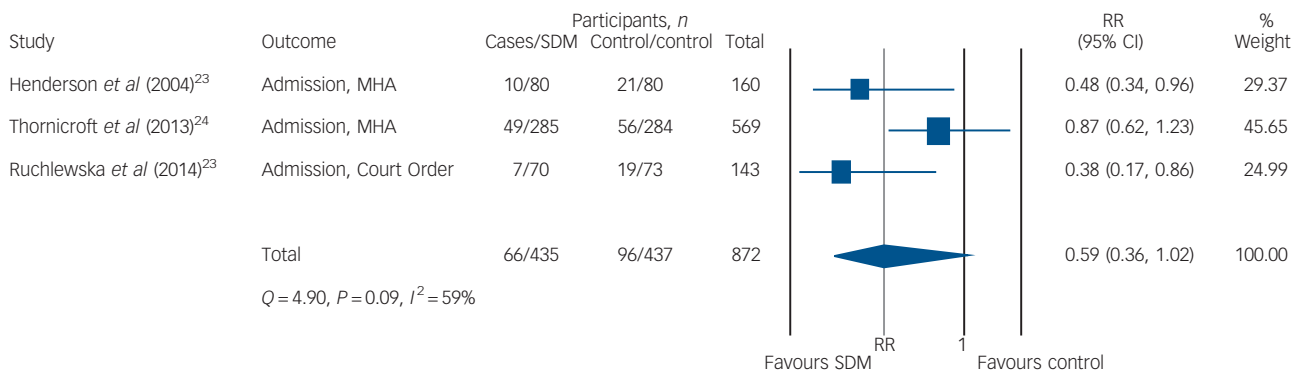


Fig. 3 Effect of shared decision-making (SDM) on risk of compulsory treatment.
MHA, Mental Health Act; RR, relative risk.

0.02 (95% CI -0.60 to 0.65) but did not reduce heterogeneity ($I^2 = 83\%$).²⁶

Discussion

Collaborative decision-making around psychiatric treatment, with greater consideration of patient preferences and values, may help people receiving treatment for psychosis experience greater empowerment and reduced coercion in relation to their care. We examined whether and to what extent this hypothesis is supported by findings from clinical trials. Although we did not find any study that measured treatment-related empowerment directly, our analysis of data from six RCTs ($n = 843$) found that interventions that shared a focus on increasing shared decision-making were associated with a small overall increase in indices of empowerment, including patients' subjective sense of involvement in treatment, self-efficacy and autonomy. There was also trend-level evidence from three RCTs ($n = 872$) that applying a shared decision-making approach to decisions about future treatment may reduce by approximately 40% the risk of patients experiencing compulsory care over a 15–18 month period, with an NNT of approximately 10. Both primary outcomes were heavily influenced by the null results of a large multicentre study;²⁴ however, the ability of this trial to detect benefits attributable to shared decision-making may have been compromised by what appeared to be poor implementation of shared decision-making by participating clinicians.^{24,33}

What is the clinical significance of a standardised mean difference of 0.3? If we accept the results of the 2014 National Audit of Schizophrenia that 59% of people with a diagnosis of schizophrenia using mental health services in the UK do not feel involved in treatment decision-making,³⁴ then the observed effect size of 0.3 would translate to an NNT of 9 (95% CI 6–26).³⁵ That is, shared decision-making would need to be implemented with approximately nine people for one to experience greater empowerment. Given that up to half of clinicians do not regularly practice shared decision-making when treating people with psychosis,^{34,36} this is an important finding.

We did not find clear evidence that shared decision-making can improve treatment-related decision-making ability of patients, but the data were heterogeneous and imprecise. This is unfortunate, because impaired treatment decisional ability has been identified by clinicians as a barrier to implementation of shared decision-making in psychosis, and it may also increase the risk of involuntary treatment. We tried to examine the hypothesis that shared decision-making might actually help increase decisional ability, but the very low quality of our findings prevented us from doing so. More rigorous studies investigating this question as a primary outcome would be welcome.

Eight trials provided usable data on the effect of shared decision-making on the patient–provider relationship, but the pooled results were also heterogeneous. A significant negative finding from Hamann *et al* seemed to account for this,³⁰ and excluding it resulted in an overall small positive finding for the remaining trials. Hamann *et al* used the Trust in Physician scale,³⁷ which conceptualises trust as agreement with statements such as, 'If my doctor tells me something is so, then it must be true'. It may be that shared decision-making can cause small improvements in working alliance and communication, while also stimulating greater questioning of clinician authority.

Study limitations

Our findings are limited by the absence of studies using direct measures of empowerment, and we were forced to consider more

indirect indices of empowerment instead. We think the conceptual overlap of the different data we extracted is sufficient to ensure the pooled estimate is meaningful and interpretable. Nonetheless, our findings should be interpreted with caution and, if we wish to understand how to reduce disempowerment in schizophrenia, future RCTs need to use valid and reliable measures of this construct. Shared decision-making is often assessed by its ability to improve treatment satisfaction, but clearly this is not the same thing as empowerment, since empowerment might involve feeling able to express dissatisfaction.

In interpreting our findings it should also be noted that not everyone diagnosed with schizophrenia wishes to be involved in treatment decisions.^{6,38} People who believe their decision-making ability is not good enough, or lack clear goals, may prefer to adopt a more passive role in their meetings with prescribers. We would argue that shared decision-making should be implemented in a thoughtful way, and that clinical judgement and case formulation will always be required when deciding what approach to take with particular individuals. Coercing unwilling patients to engage with treatment decision-making may be as much a threat to their autonomy as excluding them without consultation.

The interventions we included in our meta-analysis were varied. However, they all shared a focus on increasing the use of shared decision-making, and we assumed they were successful in this regard. Our interest lay not in finding out which interventions were best placed to increase shared decision-making, but rather in finding out whether doing so led to improvements in empowerment. Our assumption that interventions were successful in increasing shared decision-making is challenged by the study reported by Thornicroft *et al*,²⁴ where the particular context may have moderated uptake of shared decision-making by clinicians.³³ It could also be argued that our definition of shared decision-making was overly broad, and that pooling results from trials of shared decision-making and trials of joint crisis planning is misleading, since these interventions might have different aims. However, we argue the only real distinction between these interventions is the time frame of the decision to be made. Supporting this, in the most recent report of the largest trial of joint crisis planning to date, that by Thornicroft *et al*,²⁴ the authors have also described their approach as shared decision-making about future treatment.³³

There was some evidence that excluding trials missing more than a quarter of outcome data led to smaller estimates of benefit. We did not test whether the overall results were robust to making different assumptions about the outcomes of those who left early, but the overall rates of missing data were generally low and better than for other interventions in psychosis.^{39,40} The limited number of studies for the primary outcome (six) also contributed to increased imprecision in our estimate. Although this is not uncommon for healthcare interventions – for example, the median number of trials in Cochrane reviews across medicine is six – more trials are required to reduce uncertainty regarding the true effect.⁴¹

Implications of the study

Finally, it may be argued that empowerment has value only in so far as it facilitates other established outcomes, such as symptom reduction, lower cost or improved social outcomes. However, there is considerable evidence that people using mental health services regard greater treatment-related empowerment not just as a means to some further end, but also as having value in its own right.^{13,42,43} Indeed, some 80% of people with experience of psychosis believe that knowing a great deal about treatment options is an essential part of what it means to experience recovery.¹³

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Data supplement to Stovell et al. Shared decision-making and empowerment-related outcomes in psychosis: systematic review and meta-analysis. Br J Psychiatry doi: 10.1192/bjp.bp.114.158931

Supplement DS1

Search strategy

The references of previous reviews of SDM in mental healthcare were searched.^{24,31} Medline (1946-), PsychInfo (1806-), EMBASE (1980-), CINAHL (1937-) and The Cochrane Central Register of Controlled Trials (CENTRAL) (Issue 8 of 12, August 2013) were also searched in August 2013. Titles, abstracts and keywords were searched in the publication databases using a strategy involving the term ‘shared decision making’ and related terms. These included patient-oriented terms such as ‘patient participation’ and ‘patient autonomy’; process terms such as ‘decision making’ and ‘empower*’; technique-related terms such as ‘decision aid*’ and ‘communication training’; relational terms such as ‘communicat*’ and ‘working alliance’; and advance treatment planning-related terms such as ‘joint crisis plan*’ and ‘advance statement*’. The search strategy also included the term ‘psychosis’ and related terms such as ‘schizophrenia’ and ‘schizoaffective disorder’; and the term ‘randomized controlled trial’ and related terms such as ‘randomised clinical trial’ and ‘controlled trial’. The search terms are listed in full below. No limits were placed on the search with regard to date or publication status. Searches were updated in January 2015.

Shared decision-making terms

Patient-oriented terms

Patient participation
Consumer participation
Patient autonomy
Patient satisfaction
Consumer satisfaction
Patient involve*
Consumer involve*
Patient preference*
Consumer preference*
Patient centered
Client Participation
Client centered
Patient Centered Care

Process terms

Decision making
Informed decision making
Decision process
Informed choice
Empower*
Self-determination
Treatment preference
Self-manage*
Patient decision making
Decision making, clinical
Decision making, patient
Decision support systems, clinical

Technique terms

Decision aid*
Decision support technique*
Communication training
Communication aid*
Communication skill*
Decision support system*
Communication aid*
Communication skill*
Communication skills training

Relationship terms

Shared decision making
Communicat*
Collaborat*
Negotiat*
Working alliance
Therapeutic alliance
Partnership
Cooperat*
Consensus
Doctor patient relation*
Doctor patient communicat*
Nurse patient relation*
Physician patient relation*
Professional patient relation*
Professional client relation*

Advance planning terms

Joint crisis plan*
Advance statement*
Advance directive*
Advance care planning

Psychosis terms

Psychosis
Schizophrenia
Schizophrenic
Schizoaffective disorder
Schizoaffective psychosis
Psychotic disorder
Psychotic

Trial terms

RCT
Randomised Controlled Trial
Randomized Controlled Trial
Randomised Clinical Trial

Randomized Clinical Trial
Controlled Trial
Clinical Trial
Controlled Clinical Study
Controlled study
Controlled Clinical Comparison
Controlled Clinical Trial

Supplement DS2

Risk of bias assessment method

Assessment was carried out by DS and checked with PH, and vice versa, with disagreements being resolved through discussion. Risk of bias ratings are given in Table DS4. A judgement of unclear risk of selection bias was made where randomisation was referred to but described in insufficient detail to determine independent random sequence generation and allocation concealment. There was judged to be low risk of bias where these procedures were explicitly reported.

Blinding of participants and personnel was not possible due to the nature of the interventions, as is the case with trials of psychosocial interventions in general. This resulted in high risk of performance bias across studies. Detection bias was judged to be high where non-blinding of assessors was stated, unclear if no information was given and low if blinding was explicitly reported.

Where data for $\geq 25\%$ of those randomised was missing, judgement of high risk of attrition bias was made where no account of this was taken in analysis,⁷² and unclear risk of attrition bias where it was appropriately accounted for e.g. by controlling for variables associated with missing data. Selective reporting bias was judged to be unclear where there was no availability of a study protocol, and high where outcomes of interest in the review were reported incompletely so as to preclude full inclusion in the meta-analysis.

Risk of other sources of bias included that associated with cluster randomised design, where there might be potential for recruitment bias, and setting, where there might be possibility of cross-contamination through contact between participants in the different groups.

Overview

Most (k=8) studies had at least one judgement of unclear risk of selection bias.^{22,23,26,27,29,30-33} Risk of performance bias was high across all studies due to nature of the interventions, which precluded blinding. Insufficient information in reporting also led to unclear detection bias in seven studies,^{22,23,26-28,30,31,33} and one RCT stated no attempt to blind assessors was made.³² Risk of attrition bias was high or unclear on some post-intervention measures in just over half of the studies (k=6).^{25-28,32,33} Risk of selective reporting bias was largely unclear, although there was an indication that three of the RCTs did not report all their outcomes.^{22,26,33} There was unclear risk of other sources of bias in four trials, namely risk of recruitment bias due to cluster randomised design,^{27,30,32} and risk of cross-contamination due to in-patient research setting.³¹

Supplement DS3
GRADE assessment method

Assessment was carried out by DS and checked with PH, and vice versa, with disagreements being resolved through discussion. Results of the assessment are summarised in Table DS5. Outcome quality was downgraded by one point if at least one ‘high’ risk rating was present for $\geq 50\%$ studies contributing to an outcome within the Cochrane Risk of Bias assessment. Downgrading by two points occurred where $\geq 50\%$ relevant studies had at least two ‘high’ risk ratings. ‘High’ risk ratings of performance bias were however excluded from the total ‘high’ risk ratings for each outcome. Risk of performance bias is very commonly found in psychosocial interventions where blinding of participants and personnel is not possible. To rate down for this would be to imply reduced integrity in this body of research as a whole and, as such, was judged to be overly conservative. Furthermore downgrading occurred only where the risk of bias affected the particular outcome in question. For example, if a study had a high degree of missing data, or was at high risk of selective reporting bias, downgrading only occurred where missing data or selective reporting impacted directly the outcome in question.

Indirectness was assessed by considering the relevance of the outcome data to the construct of interest for each outcome, together with that of the study population, nature of the intervention under investigation and the control condition. Because there were fewer than ten studies contributing to each outcome, assessment of publication bias using funnel plots was not undertaken.²¹ With regard to inconsistency, downgrading by one point occurred if the I^2 statistic was $\geq 40\%$,¹⁶ indicating at least moderate heterogeneity, and by two points if the I^2 statistic was $\geq 75\%$, indicating high heterogeneity. With regard to imprecision, downgrading occurred where the outcome represented by either end of the 95% confidence interval might lead to different clinical decision-making.²⁰ Outcomes were also downgraded for imprecision where the sample size was insufficient to detect a clinically meaningful, small-moderate effect. Heterogeneity of outcome measures precluded possibility of calculating a meaningful Optimal Information Size.²⁰

Overall quality of the evidence for each outcome was rated down one level for each factor that had been down-graded, or by two levels where there were especially serious problems with one particular factor.¹⁶

Table DS1 Trial characteristics and baseline demographic details of participants										
Trial	Interventions	Treatment setting	Number randomised (n included in analysis)	Included primary outcome (measure)	Included secondary outcome (measure)	Number and location of sites	Baseline demographics			Timing of measures and available follow-up data
							Age, mean (s.d.)	Number female (%)	Number with schizophrenia-spectrum diagnosis (%)	
Hamann <i>et al</i> (2006) ²⁷	Nurse- supported use of paper-based decision aid (30-60 minutes), preparing for consultation with doctor. Training for nurses and doctors involved.	In-patient – acute	54 (Primary outcome: 30, secondary outcome: 36)	Patient-perceived involvement (COMRADE)	Clinician-rated decision-making abilities and knowledge (idiosyncratic measure)	1 Munich, Germany	35.5 (11.9)	20 (37)	54 (100)	Perceived involvement: post intervention and at discharge from ward. Decision-making ability: discharge only.
	Treatment as usual.		59 (Primary outcome: 45, secondary outcome: 52)				39.6 (10.8)	31 (53)	59 (100)	
Hamann <i>et al</i> (2011) ³¹	5-session group SDM intervention including motivational, behavioural and supportive elements.	In-patient – post acute phase	32 (32)	Decision self-efficacy (DSS)	Relationship with clinician (TPS) Clinician-rated decision-making abilities & knowledge (idiosyncratic measure of capacity)	1 Munich, Germany	39.78 (12.07)	Across groups: 38 (62)	32 (100)	Post-intervention, with perceived involvement measured also at 6 months.

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	5-session group cognitive training.		29 (29)				41.76 (11.36)	NS	29 (100)	
Henderson <i>et al</i> (2004) ²⁴	2-session shared facilitation of JCP, involving clinical team and possibly friend/advocate.	Community with hospital admission in previous 2 years	80 (80)	Objective coercion (N admitted under MHA)	None	7 CMHTs in South London and 1 in Kent, England	39.5 (12.1)	33 (41)	>50% (correspondence from last author)	Follow-up 15 months post-randomisation.
	Provision of written material about mental health services, MHA etc.		80 (80)				38.6 (10.6)	33 (41)	NS	
Steinwachs <i>et al</i> (2011) ²⁹	Tailored web-based intervention (average 20 minutes) to improve patients' use of consultations. Includes medical and psychosocial areas of care, and modelling of targeted communication skills.	Community & out-patient	Total for both groups: 56 (24)	Clinician-verbal dominance (ratio of clinician to patient statements)	Relationship with clinician (greater clinician engagement - rated by observers)	1 Baltimore, USA	49 (12)	9 (38)	24 (100)	Post-intervention.
	Video and written information about treatment for schizophrenia		Total for both groups: 56 (26)				50 (11)	8 (31)	26 (100)	

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Swanson <i>et al</i> (2006) ²³ Elbogen <i>et al</i> (2007) ²²	Research assistant-administered semi-structured interview, discussion and practical assistance to facilitate advance directive.	Community	213 (Swanson: 195 Elbogen: 190)	None	Relationship with clinician (WAI) Clinician-rated decision-making ability (DCAT-PAD)	1 North Carolina, USA	Across groups 42 (10.7)	Across groups 251 (60)	Across groups 247 (59)	1 month after baseline.
	Written information re advance directives and signposting		206 (Swanson: 186 Elbogen: 181)				NS *	NS*	NS*	
Thornicroft <i>et al</i> (2013) ²⁵	2-meeting joint facilitation of JCP. Facilitated by senior nurse. Involved clinical team and possibly family/friend.	Community	285 (MPCS: 213, Admission: 267, WAI: 106)	Perceived coercion (MPCS) Objective coercion (N admitted under MHA)	Relationship with clinician (WAI)	3 sites across England: Birmingham Manchester and Lancashire South London	40.0 (11.8)	146 (51)	210 (74)	Median 18.5 months.
	Treatment as usual under CPA		284 (MPCS: 245, Admission: 280, WAI: 240)				39.6 (12.1)	138 (49)	212 (75)	

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Van Os <i>et al</i> (2004) ²⁸	Use of problem checklist with brief guidance, covering medical, psychological/ emotional and psychosocial areas, prior to consultation with doctor to enhance communication.	Community	67 (NS)	None	Relationship with clinician (4-point rating on single question)	7 centres across Europe: Maastricht Oviedo, Gijon Hamburg, Copenhagen, Milan, Nice	40.3 (12.7)	35 (52)	67 (100)	Immediately post-intervention and 4-6 weeks later.
	Treatment as usual		67 (NS)				41.3 (12.5)	29 (43)	67 (100)	
Woltmann <i>et al</i> (2011) ³⁰	Electronic decision support system to facilitate synthesising perspectives in care planning for patients and case managers.	Community	40 (40)	Patient-perceived involvement (idiosyncratic measure)	None	1 Dartmouth, USA	47 (9)	15 (38)	24 (60)	Post-intervention.
	Care planning as usual.		40 (40)				46 (11)	12 (30)	24 (60)	
Ruchlewska <i>et al</i> (2014) ²⁶	Clinician-facilitated crisis plan	Community	70 (46 and 50 provided WAI data at 9 and 18 months)	Objective coercion (N admitted under MHA)	Relationship with clinician (WAI)	12 Assertive Community Teams and Illness Management & Recovery Teams in Rotterdam, Netherlands	40.6 (11.6)	24 (34.3)	45 (64.3)	0, 9, 18 months

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	Patient advocate-facilitated crisis plan		69 (57 and 50 provided WAI data at 9 and 18 months)				40.3 (10.9)	19 (27.5)	53 (76.8)	
	Usual care		73 (50 and 52 provided WAI data at 9 and 18 months)				39.4 (11.6)	24 (32.9)	56 (76.7)	
O'Donnell <i>et al</i> (1999) ³³	Client-focused case management (strong SDM focus)	Community	39 (~32 provided data at 12 months)	Patient-perceived involvement (N agreeing they 'had more say' on idiosyncratic measure)	Relationship with clinician (N reporting satisfaction with care manager on idiosyncratic measure)	1 Sydney, Australia	35 (8.1)	13 (28.8)	Across groups, 105 (88%) had schizophrenia-spectrum diagnoses	0, 12 months
	Client-focused case management plus peer advocacy (strong SDM focus)		45 (~27 provided data at 12 months)				36 (9.6)	23 (51.1)		
	Standard community case management		35 (~20 provided data at 12 months)				36 (11.7)	15 (42.9)		
Harris <i>et al</i> (2009) ³²	Medication management training (strong SDM focus)	Community	88 (72)	None	Relationship with clinician (working alliance)	1, Manchester, England	44 (13.8)	43 (49)	88 (100)	0, 9 months

Shared decision-making in psychosis: Supplementary material

	Waiting list for medication management training		81 (51)	None			41.4 (13.5)	30 (37%)	81 (100)	
<p>COMRADE, Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness; DSS, Decision Self-efficacy Scale; TPS, Trust in Physician Scale; JCP, Joint Crisis Plan; MPCS, MacArthur Perceived Coercion Scale; CPA, Care Plan Approach; MHA, Mental Health Act; CMHT, Community Mental health Team; NS, not specified; NS*, not specified – no significant difference between groups; RIAS, Roter Interaction Analysis System; WAI, Working Alliance Inventory; DCAT-PAD, Decisional Competence Assessment Tool for Psychiatric Advance Directives.</p>										

Table DS2 Studies excluded primarily on basis of outcomes (full-text reports)†	
Study	Outcomes
1. Hamann <i>et al</i> (2007) ⁴⁵	Hospitalisations, compliance, severity of illness, changes to antipsychotic
2. Malm <i>et al</i> (2003) ⁴⁶	Global and social functioning, symptoms and consumer satisfaction.
3. Priebe (1999) ⁴⁷	Patients' ratings of treatment and own condition and BPRS
4. Priebe <i>et al</i> (2007) ⁴⁸	Quality of life, unmet needs and treatment satisfaction
5. Van Dorn <i>et al</i> (2008) ⁴⁹	Reduction in patient-perceived PAD-related and external barriers to PAD completion
<p>BPRS, Brief Psychiatric Rating Scale; PAD, Psychiatric Advance Directive. †Studies or reports excluded on the basis of title or abstract alone are not given as there was a very large number. In general they covered conditions, interventions or outcomes other than those covered in the review, or were not RCTs.</p>	

Table DS3 Other excluded studies and reasons for exclusion (full-text reports)†	
Study	Reason for exclusion
1. Gray <i>et al</i> (2006) ⁵⁰	Intervention more about adherence than SDM
2. Hansson <i>et al</i> (2008) ⁵¹	Adjunct to RCT looking at moderators. Not included review outcomes
3. Hayward <i>et al</i> (2009) ⁵²	Intervention more about adherence than SDM
4. Henderson <i>et al</i> (2009) ⁵³	Not RCT: interview study
5. Li & Wan (2004) ⁵⁴	In Chinese – no funds for translation
6. Mittal <i>et al</i> (2009) ⁵⁵	Intervention more about adherence than SDM
7. Rogers <i>et al</i> (2007) ⁵⁶	Intervention not sufficiently about treatment-related SDM
8. Sells <i>et al</i> (2006) ⁵⁷	SDM not main group difference; primary substance misuse
9. Staring <i>et al</i> (2010) ⁵⁸	Intervention more about adherence than SDM
10. Tondora <i>et al</i> (2010) ⁵⁹	Outcome data not available (not SDM)
11. Woltmann & Whitley (2010) ⁶⁰	Not RCT
12. Farrelly <i>et al</i> (2014) ⁴³	Not RCT
13. Jørgensen <i>et al</i> (2014) ⁶¹	Not SDM
14. Van Oenen <i>et al</i> (2013) ⁶²	Not SDM
15. Papageorgiou <i>et al</i> (2002) ⁶³	Not SDM
16. Martino & Strejilevich (2014) ⁶⁴	Not RCT
17. Kilbourne <i>et al</i> (2014) ⁶⁵	<50% participants with non-affective psychosis
18. Dow <i>et al</i> (1991) ⁶⁶	Not RCT (sequential allocation)
19. Van der Krieke <i>et al</i> (2013) ⁶⁷	>50% missing data
20. Priebe <i>et al</i> (2013) ⁶⁸	Ongoing trial
21. Ishii <i>et al</i> (2014) ⁶⁹	Ongoing trial
22. Rogers <i>et al</i> (2003) ⁷⁰	Untraced
23. Slade <i>et al</i> (2015) ⁷¹	Not SDM
†Studies or reports excluded on the basis of title or abstract alone are not given as there was a very large number. In general they covered conditions, interventions or outcomes other than those covered in the review, or were not RCTs.	

Table DS4 Risk of bias in included studies – Cochrane Risk of Bias Tool							
Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias (blinding of participants and personnel)	Detection bias (blinding of assessments)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias (e.g. recruitment bias, contamination)
Hamann <i>et al</i> (2006) ²⁷	Unclear: insufficient information about randomisation of matched pairs of wards: <i>‘Selection of the wards was made so as to ensure that there were six pairs of wards, with one member of each pair being randomly assigned to the control or to the interventional condition.’</i>	Unclear: insufficient information about allocation concealment of wards: <i>‘Selection of the wards was made so as to ensure that there were six pairs of wards, with one member of each pair being randomly assigned to the control or to the interventional condition.’</i>	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Unclear: No information about blinding assessors.	High: for patient-perceived involvement - >25% of those randomised did not complete perceived involvement measure. No account taken of missing data in analysis. Unclear: for knowledge about medication – 22% did not complete knowledge about medication measure. No account taken of missing data in analysis.	Unclear: unavailability of protocol.	Unclear: paired cluster randomised design might introduce recruitment bias. <i>‘... patients were sent to that ward of a pair that had free beds available.’</i> No information on participant allocation where beds available on both wards of a pair.

Table DS4 Risk of bias in included studies – Cochrane Risk of Bias Tool							
Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias (blinding of participants and personnel)	Detection bias (blinding of assessments)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias (e.g. recruitment bias, contamination)
Hamann <i>et al</i> (2011) ³¹	Unclear: insufficient information about randomisation: 'Patients were recruited until group size was reached and then randomly assigned to the intervention or control condition.'	Low: 'numbered closed-allocation concealment envelopes were prepared before the study.'	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Unclear: no information about blinding of assessors.	Low: on post measures – no report of missing data. Unclear: at follow-up – perceived involvement measure only completed by 79% - attrition evenly spread across groups but no reasons given. No account of imputation of missing data.	Unclear: unavailability of protocol. Reporting on only one idiosyncratic measure at follow-up raises questions about selective reporting.	Unclear: insufficient information to assess risk of cross-contamination in in-patient research setting.

Table DS4 Risk of bias in included studies – Cochrane Risk of Bias Tool							
Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias (blinding of participants and personnel)	Detection bias (blinding of assessments)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias (e.g. recruitment bias, contamination)
Henderson <i>et al</i> (2004) ²⁴	Low: <i>'The allocation sequence was generated by using minimisation, stratified by team and by severity of the patients.'</i>	Low: <i>'When a patient was recruited, the project worker requested allocation by email, which was returned by a statistician... Allocation was not revealed to the investigator.'</i>	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Low: <i>'One investigator (CH) collected follow-up data and was blinded to treatment group.'</i>	Low: <i>'Information on use of the Mental Health Act was available for 77/80 of each group (total 154/160 = 96%).'</i> Low attrition rate and ITT analysis resulted in low risk of bias.	Unclear: unavailability of protocol.	Low: study appears to be free of other sources of bias.
Steinwachs <i>et al</i> (2011) ²⁹	Unclear: insufficient information about sequence generation: <i>'Patients were randomly assigned to the intervention or to a control group.'</i>	Unclear: no method of concealment described: <i>'Patients were randomly assigned to the intervention or to a control group.'</i>	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Low: <i>'The two coders were not aware of study hypotheses or patients' intervention status.'</i>	Low: data missing for 11% due to technical failure. No account of handling of missing data but unlikely to cause undue bias.	Unclear: unavailability of protocol.	Low: study appears to be free of other sources of bias.

Table DS4 Risk of bias in included studies – Cochrane Risk of Bias Tool							
Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias (blinding of participants and personnel)	Detection bias (blinding of assessments)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias (e.g. recruitment bias, contamination)
Swanson <i>et al</i> (2006) ²³ Elbogen <i>et al</i> (2007) ²²	Unclear: insufficient information about sequence generation: <i>'each participant was randomly assigned to either the facilitated psychiatric advance directive intervention or the control group.'</i>	Unclear: no method of concealment described: <i>'each participant was randomly assigned to either the facilitated psychiatric advance directive intervention or the control group.'</i>	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Unclear: no information about blinding of assessors.	Low: attrition of 10%. No account of imputation of missing data – mitigated by relatively low attrition rate and even distribution of missing data between groups.	Unclear: for patient-rated relationship with clinician due to unavailability of protocol. High: for decision-making ability – data only available for subscale of measure where there was a significant effect.	Low: study appears to be free of other sources of bias.

Table DS4 Risk of bias in included studies – Cochrane Risk of Bias Tool							
Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias (blinding of participants and personnel)	Detection bias (blinding of assessments)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias (e.g. recruitment bias, contamination)
Thornicroft <i>et al</i> (2013) ²⁵	Low: ‘we stratified participants by site and randomly allocated them... The allocation sequence was generated by the independent clinical trials unit at the study coordinating centre.’	Low: ‘The JCP facilitators at each site were notified by an automatic email from the clinical trials unit of participants at their Trust who were allocated to the intervention or control.’	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Low: ‘Investigators, research assistants (who did the follow-up), and trial statisticians were masked to allocation.’	Low: For primary outcomes. Missing data: 4% for admission data, 20% for perceived coercion. Unclear: For relationship with clinician: 39% missing data. Attrition mitigated by ‘analysis done under ITT principles’ and controlling for variables associated with missing data.	Low: protocol available and outcomes reported in the pre-specified way.	Low: study appears to be free of other sources of bias.

Table DS4 Risk of bias in included studies – Cochrane Risk of Bias Tool							
Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias (blinding of participants and personnel)	Detection bias (blinding of assessments)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias (e.g. recruitment bias, contamination)
Van Os <i>et al</i> (2004) ²⁸	Low: <i>‘Patients were randomised centrally by an independent, non-investigator agency using a predetermined random sequence.’</i>	Low: concealment ensured by central allocation.	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Unclear: no information on blinding of assessors.	Unclear: no report of missing data and this is likely to be unrealistic.	Unclear: unavailability of protocol.	Low: study appears to be free of other sources of bias.
Woltmann <i>et al</i> (2011) ³⁰	Unclear: insufficient information about randomisation of case managers: <i>‘Case managers from three clinics were randomly assigned to the intervention group or treatment as usual.’</i>	Unclear: insufficient information about concealment of allocation of case managers: <i>‘Case managers from three clinics were randomly assigned to the intervention group or treatment as usual.’</i>	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Unclear: no information about blinding of research assistants facilitating assessment.	Low: no report of missing data. Missing data reported on other outcomes, so likely this is realistic.	Unclear: unavailability of protocol.	Unclear: insufficient information to judge risk of recruitment bias with cluster randomised design. Process of identifying clients unclear. However, low intra-cluster correlation (ICC=0.10) on outcome of interest.

Table DS4 Risk of bias in included studies – Cochrane Risk of Bias Tool							
Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias (blinding of participants and personnel)	Detection bias (blinding of assessments)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias (e.g. recruitment bias, contamination)
Ruchlewska <i>et al</i> (2014) ²⁶	Unclear: insufficient information about randomisation: <i>‘Randomisation was stratified by treatment team... the principal investigator allocated participants randomly into one of the three conditions..’</i>	Unclear: <i>“we used envelopes containing 12 lots per team...”</i>	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Unclear: no information about blinding of assessors.	Low: minimal missing data for N admitted High: >25% missing data for WAI data	High: a number of outcomes pre-specified in protocol not reported, including health-related Locus of Control scores	Low: study appears to be free of other sources of bias.

Table DS4 Risk of bias in included studies – Cochrane Risk of Bias Tool							
Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Performance bias (blinding of participants and personnel)	Detection bias (blinding of assessments)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias (e.g. recruitment bias, contamination)
O'Donnell <i>et al</i> (1999) ³³	Unclear: insufficient information about randomisation: “ <i>subjects who agreed to participate in the study were randomly allocated to one of three groups</i> ”.	Unclear: insufficient information about randomisation: “ <i>subjects who agreed to participate in the study were randomly allocated to one of three groups</i> ”.	High: risk of bias with potential for knowledge of allocation to influence behaviour.	Unclear: no information about blinding of assessors.	High: >25% missing data for empowerment and relationship outcomes at 12 months.	High: 6-month data not reported. Admission data not reported in usable way. Empowerment and relationship data not clearly reported. No protocol publicly available.	Low: study appears to be free of other sources of bias.
Harris <i>et al</i> (2009) ³²	Unclear: insufficient information about randomisation given	Unclear: insufficient information about randomisation given	High: risk of bias with potential for knowledge of allocation to influence behaviour.	High: “ <i>There was no ‘blind’ assessment of service user level outcomes. The principle investigator was not ‘blind’ to the allocation of experimental and control groups.</i> ”	High: >25% missing data for relationship outcomes at 9 months.	Unclear: unavailability of protocol.	Unclear: cluster randomised design might introduce recruitment bias.

Table DS5 GRADE assessment of outcomes – detail of assessment								
Outcome	Included studies and outcome	Quality	Inconsistency	Indirectness	Imprecision	Other factors	Overall	Comments
Subjective empowerment	<p>Hamann <i>et al</i> (2006):²⁷ patient-perceived involvement</p> <p>Hamann <i>et al</i> (2011):³¹ decision self-efficacy</p> <p>Steinwachs <i>et al</i>:²⁹ reduced verbal dominance by clinician (observer rated)</p> <p>Thornicroft <i>et al</i>:²⁵ reduced perceived coercion</p> <p>Woltmann <i>et al</i>: patient-perceived involvement</p> <p>O'Donnell <i>et al</i>:³³ N agreeing they 'have more say' in treatment decisions</p>	0	0	-1	-1	0	Low	Rating down for indirectness occurred due to absence of direct measures of empowerment. Rating down for imprecision occurred due to span of 95% CI: trivial to moderate effects.

Table DS5 GRADE assessment of outcomes – detail of assessment								
Outcome	Included studies and outcome	Quality	Inconsistency	Indirectness	Imprecision	Other factors	Overall	Comments
Reduction in objective coercion	<p>Henderson <i>et al.</i>²⁴ admissions under section of MHA</p> <p>Thornicroft <i>et al.</i>²⁵ admissions under section of MHA</p> <p>Ruchlewska <i>et al.</i>²⁶ admissions under Court Order</p>	0	-1	0	-1	0	Low	Significant heterogeneity (albeit in context of clear direction of effect) and wide confidence intervals for pooled estimate reduces quality of outcome to low.

Table DS5 GRADE assessment of outcomes – detail of assessment								
Outcome	Included studies and outcome	Quality	Inconsistency	Indirectness	Imprecision	Other factors	Overall	Comments
Relationship with clinician	<p>Hamann <i>et al</i> (2011):³¹ trust in physician</p> <p>Swanson <i>et al</i>:²³ working alliance</p> <p>Thornicroft <i>et al</i>:²⁵ working alliance</p> <p>Van Os <i>et al</i>:²⁸ patient-rated quality of communication</p> <p>Ruchlewska <i>et al</i>:²⁶ working alliance</p> <p>Steinwachs <i>et al</i>:²⁹ greater clinician engagement</p> <p>O'Donnell <i>et al</i>:³³ satisfaction with care manager</p> <p>Harris <i>et al</i>:³² working alliance</p>	0	-1	0	-1	0	Low	Judgements of inconsistency and imprecision due to moderate negative effect in Hamann <i>et al</i> (2011). ⁵⁷

Table DS5 GRADE assessment of outcomes – detail of assessment								
Outcome	Included studies and outcome	Quality	Inconsistency	Indirectness	Imprecision	Other factors	Overall	Comments
Relationship with clinician – Hamann <i>et al</i> (2011) ³¹ excluded	<p>Swanson <i>et al.</i>²³ working alliance</p> <p>Thornicroft <i>et al.</i>²⁵ working alliance</p> <p>Van Os <i>et al.</i>²⁸ patient-rated quality of communication</p> <p>Ruchlewska <i>et al.</i>²⁶ working alliance</p> <p>Steinwachs <i>et al.</i>²⁹ greater clinician engagement</p> <p>O'Donnell <i>et al.</i>³³ satisfaction with care manager</p> <p>Harris <i>et al.</i>³² working alliance</p>	0	0	0	-1	0	Moderate	Imprecision due to 95% CI spanning trivial to low-to-moderate effects.

Table DS5 GRADE assessment of outcomes – detail of assessment								
Outcome	Included studies and outcome	Quality	Inconsistency	Indirectness	Imprecision	Other factors	Overall	Comments
Clinician-rated decision-making abilities of knowledge	<p>Hamann <i>et al</i> (2006):²⁷ knowledge about disease and medication</p> <p>Hamann <i>et al</i> (2011):³¹ decisional capacity</p> <p>Elbogen <i>et al</i>:²² decisional capacity (reasoning only)</p>	-1	-2	-2	-1	0	Very low	Quality down-rated due to risk of attrition bias in Hamann <i>et al</i> (2006) ²⁰ and reporting bias in Elbogen <i>et al</i> . ⁵⁰ High heterogeneity and wide 95% CI led to down-rating for inconsistency and imprecision. Judgement of indirectness due to partial, selective and idiosyncratic measurement and reporting of decision-making abilities.

Table DS6 Funding sources of included studies	
Study	Funding source
Harris <i>et al</i> (2009) ³²	North West Regional Training Fellowship, England, UK
Hamann <i>et al</i> (2006) ²⁷	German Ministry of Health and Social Security
Hamann <i>et al</i> (2011) ³¹	German-Israeli Foundation for Research and Development
Henderson <i>et al</i> (2004) ²⁴	Medical Research Council
O'Donnell <i>et al</i> (1999) ³³	Innovative Grants Program of the Australian National Mental Health Strategy
Ruchlewska <i>et al</i> (2014) ²⁶	Dutch organization for health research and development (ZonMw) and BavoEuroport.
Steinwachs <i>et al</i> (2011) ²⁹	National Institute of Mental Health, USA
Swanson <i>et al</i> (2006) and Elbogen <i>et al</i> (2007) ^{22,23}	National Institute of Mental Health, USA; MacArthur Foundation Research Network on Mandated Community Treatment
Thornicroft <i>et al</i> (2013) ²⁵	Medical Research Council, UK
Van Os <i>et al</i> (2004) ²⁸	Astra Zeneca
Woltmann <i>et al</i> (2011) ³⁰	West Family Foundation; Segal Family Foundation

Fig. DS1 Forest plots for secondary outcomes: relationship with clinician.

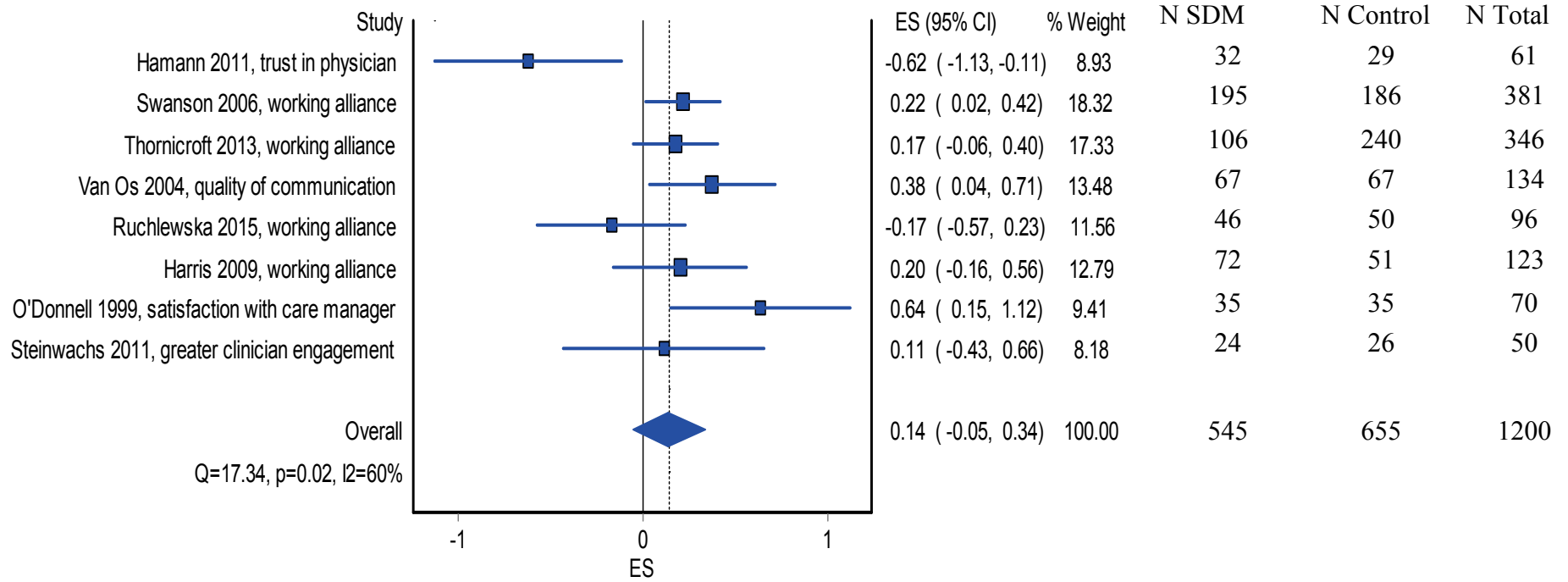
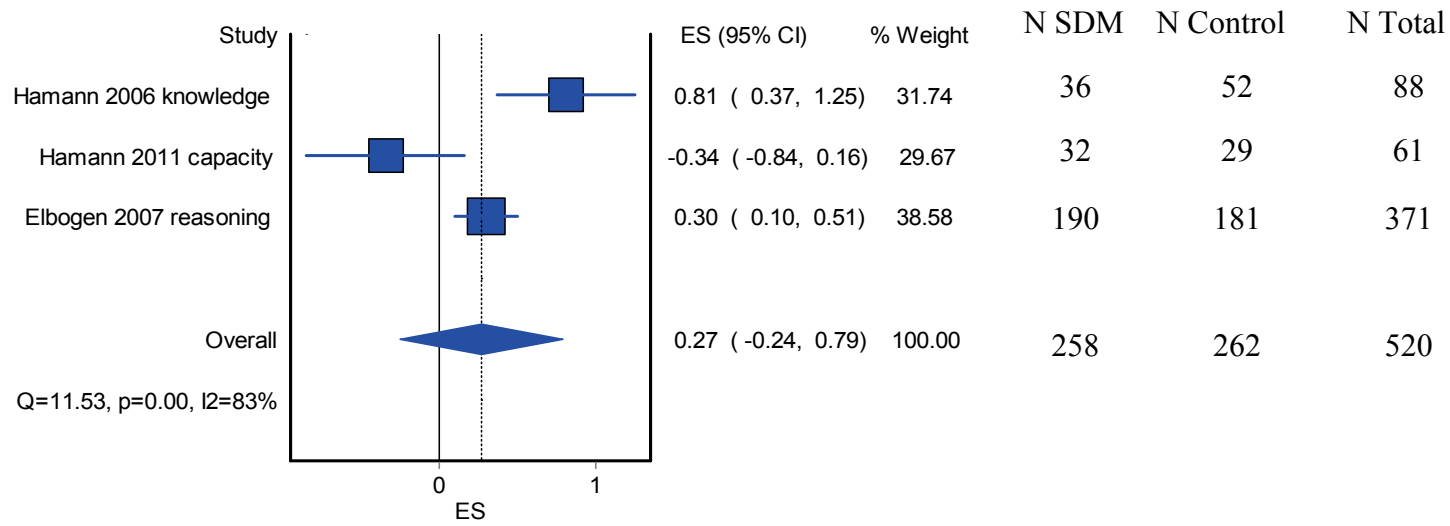


Fig. DS2 Forest plots for secondary outcomes: clinician-rated treatment decision-making ability



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