BJPsych | The British Journal of Psychiatry (2016)
209, 23–28. doi: 10.1192/bjp.bp.114.158931

Review article

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

Diana Stovell, Anthony P. Morrison, Margarita Panayiotou and Paul Hutton

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.

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.

*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.

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

https://doi.org/10.1192/bjp.bp.114.158931 Published online by Cambridge University Press

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

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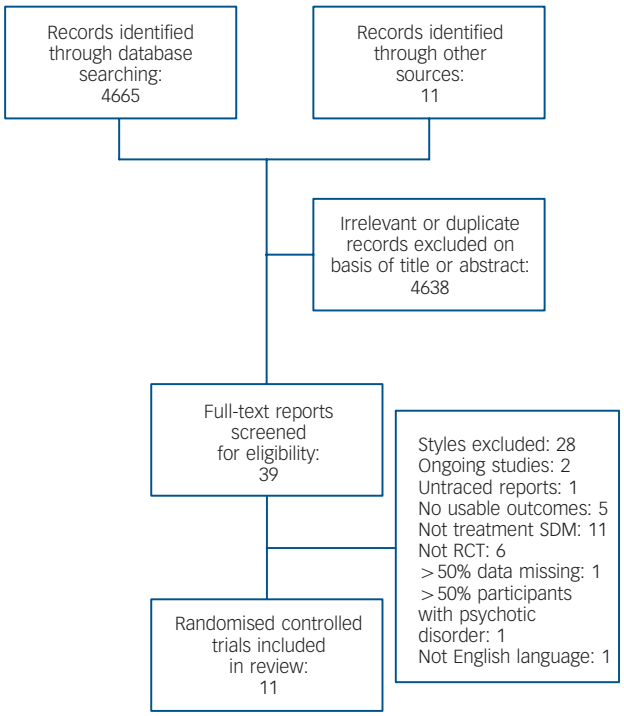

Fig. 1 Study selection process.

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 to1.69).[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 *n*	Effect size (95% CI)	Heterogeneity and *P* 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 *et al* (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.

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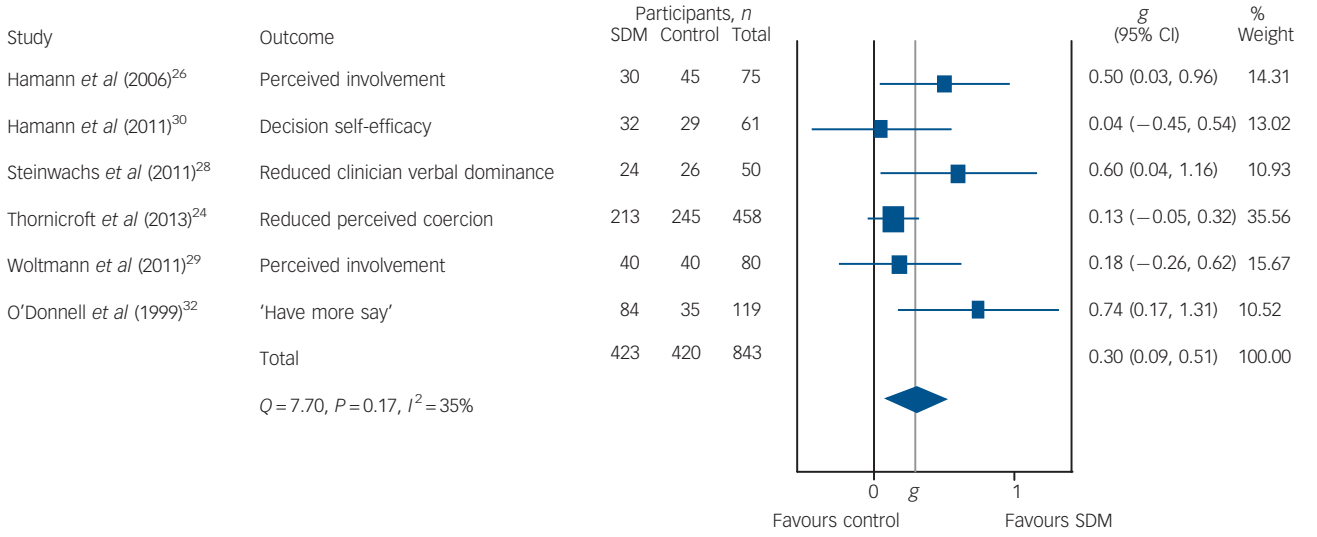

Fig. 2 Effect of shared decision-making (SDM) on indices of subjective empowerment.

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% CI 0.01 to 0.32),[26,32] as did using a fixed effect analysis instead of random effects ($k = 8$, $g = 0.23$, 95% CI 0.09 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% CI -0.05 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% CI −1.13 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% CI 0.07 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% CI −0.24 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

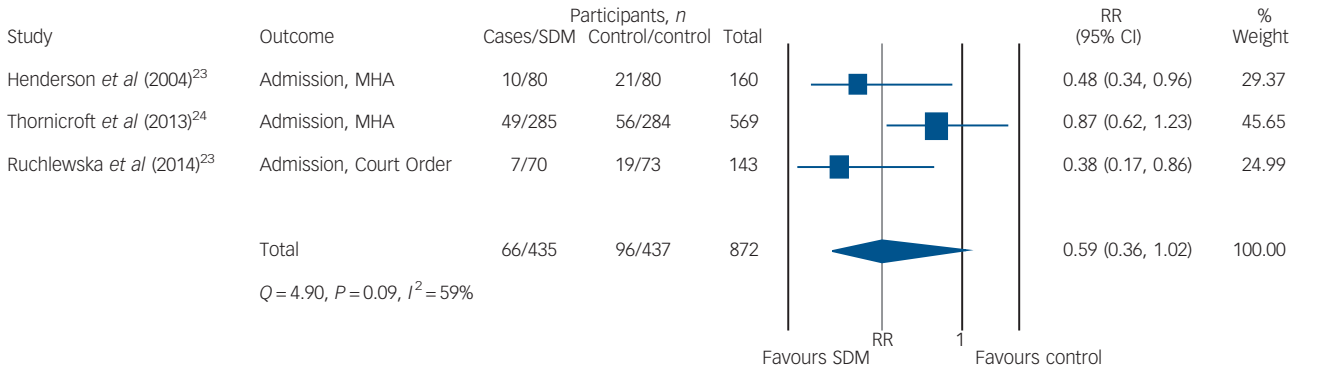

Fig. 3 Effect of shared decision-making (SDM) on risk of compulsory treatment.

MHA, Mental Health Act; RR, relative risk.

https://doi.org/10.1192/bjp.bp.114.158931 Published online by Cambridge University Press

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]

https://doi.org/10.1192/bjp.bp.114.158931 Published online by Cambridge University Press

Diana Stovell, ClinPsyD, **Anthony P. Morrison**, ClinPsyD, Division of Clinical Psychology, School of Psychological Sciences, University of Manchester, Manchester; **Margarita Panayiotou**, PhD, **Paul Hutton**, ClinPsyD, Section of Clinical Psychology, School of Health in Social Science, University of Edinburgh, Edinburgh, UK

Correspondence: Dr Paul Hutton, Section of Clinical Psychology, Doorway 6, Medical Building, Teviot Place, Edinburgh EH8 9AG, UK. Email: paul.hutton.cf@ed.ac.uk

First received 13 Oct 2014, final revision 1 Jun 2015, accepted 15 Aug 2015

Acknowledgements

We would like to thank all the original authors who helped answer our various queries, and we are also grateful to anonymous reviewers for their useful comments and suggestions.

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https://doi.org/10.1192/bjp.bp.114.158931 Published online by Cambridge University Press