**The effect of shared decision making on empowerment-related outcomes in psychosis: systematic review and meta-analysis**

Running head: Shared decision-making and psychosis

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**Abstract**

*Background*

In the UK, almost 60% of service users diagnosed with schizophrenia 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 service users with psychosis.

*Method*

We conducted a systematic review and meta-analysis of randomised controlled trials of shared decision-making for 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 randomised controlled trials. 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 to 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, $\infty$). No clear effects on treatment decision-making ability (3 RCTs) or the quality of the therapeutic relationship (8 RCTs) were 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*

A.P.M. is a member of two National Institute for Health and Clinical Excellence guideline development groups: Psychosis and Schizophrenia in Children and Young People, and Psychosis and Schizophrenia in Adults (partial update).

**Introduction**

*"The Commission believes 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."* [The Schizophrenia Commission, 2012; p.30 (1)]

Shared decision-making (SDM) in healthcare has been described as a process of supportive collaboration between clients and clinicians, drawing on evidence and the client's preferences and values to reach a consensus about treatment or care. (2, 3) It is seen as falling mid-way on a continuum between paternalistic decision-making practices by clinicians and autonomous, informed decision-making by clients.(4-7) Whilst a significant body of research exists demonstrating the benefits of SDM in physical healthcare,(8) research and practice in the area of SDM in relation to people with mental health problems is still at a formative stage.(9) SDM may be particularly relevant in psychosis, where increasing treatment-related empowerment and reducing use of coercion have been identified by service users as outcomes of intrinsic value (10-13). If clinical trials of SDM show it to be effective at improving these outcomes, then this would support existing recommendations that SDM be widely implemented with this group. (1, 14)

We conducted a systematic review and meta-analysis of randomised controlled trials of SDM in psychosis, with the overall aim of finding out whether enhancing SDM can improve treatment-related empowerment in this group, as judged by participants and indicated by objective measures. The effect of enhancing SDM on secondary outcomes of quality of service user/provider relationship (service user or observer-rated) and decision-making abilities and knowledge (clinician-rated) were also evaluated.

**Method**

*Search strategy*
The electronic databases, Medline (1946- ), PsychInfo (1806- ), EMBASE (1980- ), CINAHL (1937- ) and The Cochrane Central Register of Controlled Trials (CENTRAL) were searched by the DS and MP in August 2013 and January 2015, respectively, along with the references of two previous reviews of SDM interventions in mental health care. (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 available in the supplementary material. The search was not limited by date or publication status, but non-English studies were not included. Initial screening and data extraction was carried out by DS, and studies published between 2013 and 2015 were screened and extracted by MP. PH provided supervision of screening and extraction, and arbitration in the event of uncertainty.

*Inclusion and exclusion criteria*
Trials were included if they compared (1) a psychosocial intervention designed to enhance SDM in the planning of treatment for psychosis with (2) usual care or a non-specific control treatment. SDM was defined as a process of supportive collaboration between clients and clinicians, drawing on evidence and the client's preferences and values to reach a consensus about treatment or care (3, 15). Interventions to enhance SDM could be delivered either individually or in a group format, and could involve either current or future treatment

decisions (ie., joint crisis planning), but they had to share a focus on promoting SDM 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 SDM were excluded, as were studies where interventions were provided to family members or carers. We included trials where assessing the effects of promoting SDM was either a primary or secondary aim of the study.

*Participants*

We included studies where ≥50% of participants had a diagnosis of a schizophrenia-spectrum disorder. Studies where >50% 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: (1) subjective empowerment and (2) reduced objective coercion. For the first outcome, a scoping review of the literature suggested that few studies measured subjective empowerment directly. Several, however, 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 service user/provider interaction > reduced perceived coercion. The second primary outcome was reduced objective coercion as indicated by fewer admissions under mental health legislation. This would be the Mental Health Act (MHA) (2003/2007), where studies had taken place in the UK, or corresponding legislation within the country concerned, where studies had taken place elsewhere. We originally planned to analyse days spent in hospital under compulsory care for this outcome, however skewed or unavailable data meant we decided to analyse admission rates instead. Secondary outcomes were quality of service user/provider relationship (service user 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, 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.[16] In the absence of available continuous data, proportions were converted to SMDs using the Campbell Collaboration's Practical Meta-Analysis Effect Size Calculator (http://www.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 was assessed as part of the risk of bias assessment, but no tests of robustness of

estimates to changing assumptions around missing data were 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 (http://www.epigear.com) to derive the SMD and 95% confidence intervals, with Hedge's *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%).(16) Cohen's proposed criteria for interpretation of effect sizes (small = 0.2, moderate = 0.5, large = 0.8) (17) were used in the absence of more specific criteria for judging clinical significance of standardised mean differences. 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 >25% attrition.

*Pre-registration of review protocol*
The review protocol was registered in advance with PROSPERO (International Prospective Register of Systematic Reviews).(18)

*Risk of bias and study quality*
Risk of bias was assessed for each study using the Cochrane Collaboration Risk of Bias Tool.(19) Assessment of outcome quality was performed using the GRADE approach.(20) 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. Risk of publication bias using funnel plots was planned if there were sufficient studies (≥10).(21) GRADE ratings were used to determine overall confidence in the reliability of individual outcomes. Full details on the GRADE and Cochrane Risk of Bias assessments are provided in the supplementary material.

**Results**

*Study Selection*
The process of study selection is represented in the PRISMA diagram (see Figure 1). The titles and abstracts of 4676 papers were screened for eligibility. Of these, full-text reports were sought for 39. Three studies were not included because they were ongoing or could not be traced. A further 25 studies were excluded either because they did not report outcomes we could use (k=5), did not evaluate a treatment-related SDM intervention (k=11) were not randomised controlled trials (*k*=6), had an attrition rate of >50% (*k*=1), had <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 SDM in relation to future treatment (ie., joint crisis planning or facilitated advance directives).(22-26) The remaining seven RCTs examined interventions designed to

support SDM in relation to current treatment. Of these, four examined the effects of paper (27, 28) or web-based (29, 30) decision or communication aids, one evaluated a group SDM intervention for service users (31), another evaluated the effects of training clinicians in an SDM approach to medicines management (32), and another RCT evaluated the effects of client-focused case management where treatment-related SDM was emphasised (33). Details of interventions delivered are provided in Table 2, alongside other study characteristics. Baseline demographics of participants are provided in Table DS1.

*Risk of bias and GRADE*
Table 1 provides a summary of the results for each outcome and the GRADE ratings of outcome quality. The detail of the Cochrane risk of bias ratings and a detailed rationale for all the ratings is provided in the supplementary material.

Most (k=8) studies (22, 23, 26, 27, 29-33) had at least one judgement of unclear risk of selection bias. Risk of performance bias was high across all studies due to the 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 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)

*Outcomes (Table 1, Figures 2-5)*

*Primary outcomes*

*Indices of treatment-related empowerment (Figure 2)*
A small effect of SDM interventions on indices of subjective empowerment was observed (*k*=6, g=0.30, 95% CI 0.09, 0.51; low quality evidence). Six trials (25, 27, 29-31) involving a total of 843 participants provided data on this outcome. The quality of the evidence was downgraded due to its indirectness, with no study measuring subjective empowerment specifically, and 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 (27, 31) provided follow-up data. One (27) did not find a significant effect at hospital discharge (g=0.16, CI -0.27, 0.60), but data was missing from >25% of participants. For the other, (31) 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, CI 0.49, 1.69).

*Risk of compulsory treatment (Figure 3)*
Data from three studies, (24-26) involving a total of 872 participants suggested a trend towards shared decision-making for future treatment (ie., crisis planning) reducing the likelihood of future compulsory inpatient treatment over the subsequent 15-18 months, but the estimate was imprecise and inconsistent and did not exclude the possibility of no effect (RR 0.59, 95% CI 0.35, 1.02, RD -0.10, 95% CI -0.19, 0; NNT 10, 95% CI 5, ∞).

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*Sensitivity analysis*
Excluding two studies (27, 33) with >25% missing data from the empowerment analysis resulted in a smaller effect size (*k*=4, *g*=0.17, 95% CI 0.01, 0.32), as did using a fixed-effect analysis instead of random-effects (k=8, g=0.23, 95% CI 0.09, 0.38).

*Secondary outcomes*

*Relationship with clinician (Figure DS1)*
Overall, no significant effect of SDM interventions on patient or observer-rated relationship with clinician was found (*k*=8, *g*=0.14, 95% CI -0.05, 0.34). Eight studies with a total of 1200 participants contributed to this outcome (23, 25, 26, 28, 29, 31-33). 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 Hamann 2011 (31) (*g*=-0.62, 95% CI -1.13, -0.11) contributed particularly to the high heterogeneity. This study of a group in-patient SDM intervention differed from the others in measuring 'trust in physician' rather than 'alliance' or 'quality of communication'. Omitting this data suggested a small, statistically significant effect (*g*=0.21, 95% CI 0.07, 0.35; moderate quality evidence) favouring SDM, with a reduction in heterogeneity to 20%.

*Clinician-rated decision-making abilities (Figure DS2)*
Pooled data from three studies (22, 27, 31) involving a total of 520 participants, did not support the hypothesis that SDM interventions can enhance participant decision-making ability as rated by clinicians (*k*=3, *g*=0.27, 95% CI -0.24, 0.79, very low quality evidence). 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 (22) used a validated measure of decisional capacity.

*Sensitivity analyses*
Excluding four studies (25, 26, 32, 33) with >25% missing data from the analysis of service user-provider relationship reduced the overall effect size to 0.07 (-0.29, 0.42; k=4) but increased heterogeneity ($I^2$ 73%). Also removing the Hamann 2011 (31) study from this analysis increased the pooled effect size to 0.25 (0.08, 0.41; k=3) and reduced heterogeneity to 0%. Excluding one study (27) with >25% missing data from the analysis of decision-making ability reduced the effect size to 0.02 (-0.60, 0.65) but did not reduce heterogeneity ($I^2$ 83%).

**Discussion**

Collaborative decision-making around psychiatric treatment, with greater consideration of patient preferences and values, may help service users with 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 studies that measured treatment-related empowerment directly, our analysis of data from 6 RCTs (N=843) found that interventions which shared a focus on increasing SDM were associated with a small overall increase in indices of empowerment, including service users' subjective sense of involvement in treatment, self-efficacy and autonomy. There was also trend-level evidence from 3 RCTs (N=872) that applying a shared decision-making approach to decisions about future treatment may reduce by approximately 40% the

risk of service users experiencing compulsory care over a 15-18 month period, with a number needed to treat of approximately 10. Both primary outcomes were heavily influenced by the null results of a large multi-centre study,(25) however the ability of this trial to detect SDM-attributable benefits may have been compromised by what appeared to be poor implementation of SDM by participating clinicians (25, 34).

What is the clinical significance of a standardised mean difference of 0.3? If we accept the results of the 2014 National Schizophrenia Audit (35), that 59% of service users diagnosed with schizophrenia in the UK do not feel involved in treatment decision-making, then the observed SDM effect size of 0.3 would translate to a number needed to treat of 9 (95% CI 6, 26) (36). That is, SDM would need to be implemented with approximately 9 service users for 1 to experience greater empowerment. Given as many as 40-50% of clinicians do not regularly practice shared decision-making with service users with psychosis (35, 37), this is an important finding.

We did not find clear evidence that SDM can improve treatment-related decision-making ability of service users, 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 SDM might actually help *increase* decisional ability, however 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 SDM on the service user-provider relationship, but the pooled results were also heterogeneous. A significant negative finding from Hamann et al (2011) (31) seemed to account for this, and excluding it resulted in an overall small positive finding for the remaining trials. Hamann et al used the Trust in Physician scale, (38) 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 SDM can cause small improvements in working alliance and communication, whilst also stimulating greater questioning of physician 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. SDM 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 all people diagnosed with schizophrenia wish to be involved in treatment decisions (6, 39). 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 SDM 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 service users. 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 SDM, and we assumed they were successful in this regard. Our interest lay not in finding out what interventions are best-placed to increase SDM, rather we wanted to find out whether doing so led to improvements in empowerment. Our assumption that interventions were successful in increasing SDM is challenged by the Thornicroft et al study, where the particular context may have moderated SDM uptake by clinicians (34). It could also be argued that our definition of SDM was overly broad, and that pooling results from trials of SDM 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 timeframe of the decision to be made. Supporting this, the recent authors of the largest trial of joint crisis planning to date (25) have also described their approach as shared decision-making about future treatment (34).

There was some evidence that excluding trials with >25% missing 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 (40, 41). The limited number of studies for the primary outcome (k=6) 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 (42) - more trials are required to reduce uncertainty regarding the true effect.

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 service users regard greater treatment-related empowerment not *just* as a means to some further end, but also as having value in its own right (13, 43, 44). 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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**Table 1. Characteristis of included studies**

| Trial | Interventions | Treatment setting | Number randomised (*n* included in analysis) | Included primary outcome (measure) | Included secondary outcome (measure) | Number and location of sites |
|---|---|---|---|---|---|---|
| Hamann *et al* (2006)[20] | 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 |
| | Treatment as usual. | | 59 (Primary outcome: 45, secondary outcome: 52) | | | |
| Hamann *et al* (2011)[57] | 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)<br><br>Clinician- rated decision- making abilities & knowledge (idiosyncratic measure of capacity) | 1 Munich, Germany |
| | 5-session group cognitive training. | | 29 (29) | | | |
| Henderson *et al* (2004)[52] | 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 |
| | Provision of written material about mental health services, MHA etc. | | 80 (80) | | | |

| Trial | Interventions | Treatment setting | Number randomised (*n* included in analysis) | Included primary outcome (measure) | Included secondary outcome (measure) | Number and location of sites |
|---|---|---|---|---|---|---|
| Steinwachs *et al* (2011)[55] | 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 |
| | Video and written information about treatment for schizophrenia | | Total for both groups: 56 (26) | | | |
| Swanson *et al* (2006)[51] Elbogen *et al* (2007)[50] | 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 |
| | Written information re advance directives and signposting | | 206 (Swanson:186 Elbogen: 181) | | | |
| Thornicroft *et al* (2013)[53] | 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 |

| Trial | Interventions | Treatment setting | Number randomised (*n* included in analysis) | Included primary outcome (measure) | Included secondary outcome (measure) | Number and location of sites |
|---|---|---|---|---|---|---|
| | Treatment as usual under CPA | | 284 (MPCS: 245, Admission: 280, WAI: 240) | | | |
| Van Os *et al* (2004)[54] | 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 measuring quality of patient-clinician communication) | 7 centres across Europe: Maastricht Oviedo, Gijon Hamburg, Copen-hagen, Milan, Nice |
| | Treatment as usual | | 67 (NS) | | | |
| Woltmann *et al* (2011)[56] | 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 |
| | Care planning as usual. | | 40 (40) | | | |
| Ruchlewska *et al* (2015) | Clinician-facilitated crisis plan | Community | 70 (46 and 50 provided WAI data at 9 and 18 months) | Objective coercion (N admitted under court order) | Relationship with clinician (WAI) | 12 Assertive Community Teams and Illness Management & Recovery Teams in Rotterdam, Netherlands |
| | Patient advocate-facilitated crisis plan | | 69 (57 and 50 provided WAI data at 9 and 18 months) | | | |

| Trial | Interventions | Treatment setting | Number randomised (*n* included in analysis) | Included primary outcome (measure) | Included secondary outcome (measure) | Number and location of sites |
|---|---|---|---|---|---|---|
| | Usual care | | 73 (50 and 52 provided WAI data at 9 and 18 months) | | | |
| O'Donnell *et al* 1999 | 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 |
| | Client-focused case management plus peer advocacy (strong SDM focus) | | 45 (~27 provided data at 12 months) | | | |
| | Standard community case management | | 35 (~20 provided data at 12 months) | | | |
| Harris *et al* 2009 | Medication management training (strong SDM focus) | Community | 88 (72) | None | Relationship with clinician (working alliance) | 1, Manchester, England |
| | Waiting list for medication management training | | 81 (51) | None | | |

Note: COMRADE, Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness;[78] DSS, Decision Self-efficacy Scale;[79] TPS, Trust in Physician Scale;[60] JCP, Joint Crisis Plan; MPCS, MacArthur Perceived Coercion Scale;[81] 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;[82] WAI, Working Alliance Inventory;[83] DCAT-PAD, Decisional Competence Assessment Tool for Psychiatric Advance Directives.[84]

**Table 2 Summary of results**

| Outcome (Number of trials) | Number of participants: intervention (I), control (C) | Effect size (s) (95% CI) | Heterogeneity ($I^2$) and p- value | GRADE quality rating |
|---|---|---|---|---|
| Indices of subjective empowerment (k=6) | 843 (I: 423, C: 420) | g = 0.30 (0.09, 0.51) | $I^2$ = 35%, p = .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 =.08 | Low |
| Relationship with clinician (k=8) | 1261 (I: 577, C: 684) | g = 0.14 (-0.05, 0.34) | $I^2$ = 60%, p = .02 | Low |
| Relationship with clinician, excluding Hamann et al (2011) (k=7) | 1200 (I: 545, C: 655) | g = 0.21 (0.07, 0.35) | $I^2$ = 20%, p = .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 |

**Figure 1. PRISMA flowchart showing process of study selection**

```
┌─────────────────────────┐        ┌─────────────────────────┐
│ Number of records       │        │ Number or records       │
│ identified through      │        │ identified through      │
│ database searching:     │        │ other sources: 11       │
│ 4665                    │        │                         │
└───────────┬─────────────┘        └───────────┬─────────────┘
            │                                  │
            ▼                                  ▼
        ┌───────────────────────────────────────┐
        │ Number of irrelevant or               │
        │ duplicate records                     │
        │ excluded on basis of title            │
        │ or abstract: 4638                     │
        └─────────────────┬─────────────────────┘
                          │
                          ▼
        ┌──────────────────────────┐        ┌──────────────────────────────┐
        │ Number of full-text      │        │ Number of studies            │
        │ reports screened for     │───────▶│ excluded: 28                 │
        │ eligibility: 39          │        │                              │
        └────────────┬─────────────┘        │ Ongoing studies: 2           │
                     │                       │ Untraced reports: 1          │
                     ▼                       │ No usable outcomes: 5 Not    │
        ┌──────────────────────────┐        │ treatment SDM: 11            │
        │ Number of RCTs           │        │ Not RCT: 6                   │
        │ included in review: 11   │        │ >50% data missing: 1         │
        │                          │        │ >50% participants with       │
        │                          │        │ psychotic disorder: 1        │
        │                          │        │ Non-English: 1               │
        └──────────────────────────┘        └──────────────────────────────┘
```

**Figure 2: The effect of shared decision-making on indices of subjective empowerment**

| Study | Outcome | N SDM | N Control | N Total | | g (95% CI) | % Weight |
|---|---|---|---|---|---|---|---|
| Hamann 2006 | Perceived involvement | 30 | 45 | 75 | | 0.50 (0.03, 0.96) | 14.31 |
| Hamann 2011 | Decision self-efficacy | 32 | 29 | 61 | | 0.04 (-0.45, 0.54) | 13.02 |
| Steinwachs 2011 | Reduced clinician verbal dominance | 24 | 26 | 50 | | 0.60 (0.04, 1.16) | 10.93 |
| Thornicroft 2013 | Reduced perceived coercion | 213 | 245 | 458 | | 0.13 (-0.05, 0.32) | 35.56 |
| Woltmann 2011 | Perceived involvement | 40 | 40 | 80 | | 0.18 (-0.26, 0.62) | 15.67 |
| O'Donnell 1999 | 'have more say' | 84 | 35 | 119 | | 0.74 (0.17, 1.31) | 10.52 |
| | Total | 423 | 420 | 843 | | 0.30 (0.09, 0.51) | 100.00 |

Q=7.70, p=0.17, $I^2$=35%

0   g

Favours control        Favours SDM

**Figure 3: The effect of shared decision-making on risk of compulsory treatment**

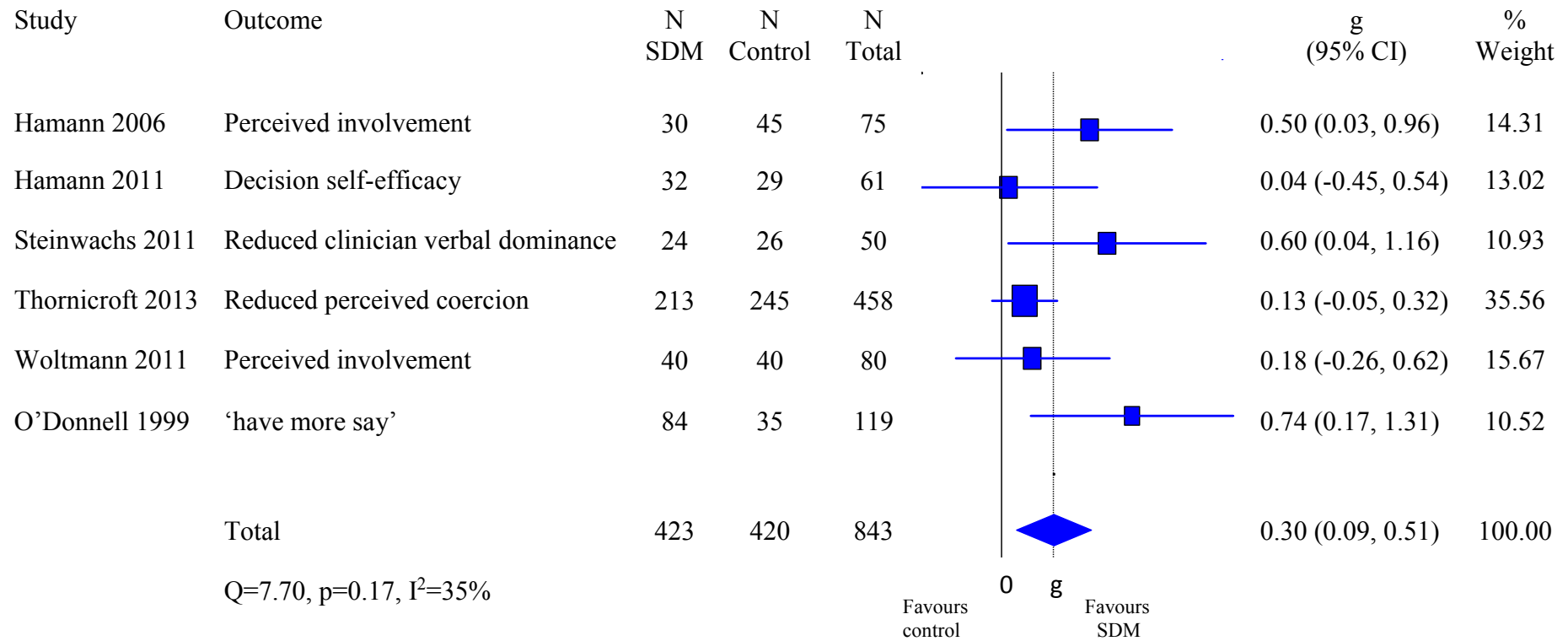| Study | Outcome | N Cases / N SDM | N Cases / N Control | N Total | | RR (95% CI) | % Weight |
|-------|---------|-----------------|---------------------|---------|--|-------------|----------|
| Henderson 2004 | Admission, MHA | 10/80 | 21/80 | 160 | | 0.48 (0.34, 0.96) | 29.37 |
| Thornicroft 2013 | Admission, MHA | 49/285 | 56/284 | 569 | | 0.87 (0.62, 1.23) | 45.65 |
| Ruchlewska 2015 | Admission, Court Order | 7/70 | 19/73 | 143 | | 0.38 (0.17, 0.86) | 24.99 |
| | Total | 66/435 | 96/437 | 872 | | 0.59 (0.36, 1.02) | 100.00 |

$Q=4.90, p=0.09, I^2=59\%$

RR      1

Favours SMD     Favours Control