Decision-making about treatment for psychosis

A Thesis Submitted to the University of Manchester for the Degree of Doctor of Clinical Psychology in the Faculty of Medical and Human Sciences

2014

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Abstract

Decision-making about treatment for psychosis
A Thesis Submitted for the Degree of Doctor of Clinical Psychology
Diana Stovell, University of Manchester, 2014

This thesis investigated treatment decision-making (TDM) in psychosis, where people might experience distress and impairments to functioning associated with positive symptoms (hallucinations; delusions; disordered thinking or behaviour) and negative symptoms (flattened affect, avolition).

Paper 1 reports a systematic review and exploratory meta-analysis of shared decision-making (SDM) interventions for psychosis. Eight randomised controlled trials were included that compared an intervention to enhance SDM around treatment or care for psychosis with a control intervention. Empowerment-related outcomes were examined and the quality of the evidence evaluated. Small, statistically significant positive effects of SDM were found on indices of subjective empowerment and aspects of patient-clinician relationships. No significant effects on indices of objective coercion or participants’ decision-making abilities were found. The quality of the evidence was generally low. It was concluded that higher-quality studies are needed that include outcomes of importance to service users.

Paper 2 reports a qualitative study that employed Interpretative Phenomenological Analysis (IPA) to explore the experiences of TDM of seven service users with psychosis. Of interest was how participants’ experience might relate to ways of promoting service users’ values and goals in TDM, with particular reference to issues of treatment decision-making capacity (TDMC), or abilities to make a particular decision about treatment. Four themes were identified, linked by an overarching theme of empowerment. They concerned not being listened to; influence of psychosis-related experience; being inadequately informed and supported; and influence of a Recovery orientation, wherein service users’ values and goals are of primary concern. The importance of listening closely to service users with psychosis and of awareness of power dynamics in TDM was identified, along with the need to develop more comprehensive models of TDMC.

Paper 3 reflects on the thesis context; the process of project planning and design; the quality of the work; the merits and limitations of the line of enquiry; clinical, theoretical and research implications; and the author’s experience of completing the work in the context of her background and values. The paper seeks a cohesive overview of the thesis, the process of its production and its contribution to the literature.
Declaration

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Acknowledgements

To the individuals who participated in this research I would like to say thank you for sharing your experience so generously. It was a privilege to meet with each of you.

Thank you also to my supervisors, Paul Hutton, Tony Morrison and Alison Wearden for your expert guidance and generous support.

Finally, I would like to thank my family and friends. Your unstinting and ever-generous support has been invaluable in enabling me to complete this work and all that led up to it. Thank you.
The effect of shared decision making interventions on empowerment-related outcomes in psychosis: systematic review and exploratory meta-analysis

Prepared in accordance with author guidelines for
The British Journal of Psychiatry
(see Appendix 1)

Word Count: 5,067 words, excluding tables, figures, figure legends and references
Abstract

Background
The small body of evidence around treatment-related shared decision-making (SDM) interventions for psychosis has yet to be appropriately reviewed.

Aims
We aimed to conduct a systematic review and exploratory meta-analysis of randomised controlled trials (RCTs) evaluating the efficacy of SDM interventions in empowering service users with psychosis.

Method
Pooled effect sizes for empowerment-related outcomes were derived from eight RCTs of SDM interventions for psychosis. The quality of the evidence was evaluated.

Results
Small, statistically significant positive effects of SDM were found on indices of subjective empowerment ($g = 0.23$, 95% CI 0.05-0.41, $P = 0.014$) and aspects of patient-clinician relationships ($g = 0.23$, 95% CI 0.09-0.37, $P = 0.001$). No significant effects on objective coercion ($g = 0.30$, 95% CI -0.36 to 0.96, $P = 0.373$) or participants’ decision-making abilities ($g = 0.27$, 95% CI -0.24 to 0.79, $P = 0.300$) were found. The quality of the evidence was generally low.

Conclusions
SDM may empower individuals with psychosis, but higher-quality research is needed.

Declaration of interest
None.
1.1 Introduction

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. It is seen as falling mid-way on a continuum between paternalistic decision-making practices by clinicians and autonomous, informed decision-making by clients.

1.1.1 SDM in mental healthcare

There is a significant body of research into SDM in physical healthcare, and a number of benefits have been identified to patients’ physical, functional and psychological well-being. However, SDM research and practice in the area of mental health is still at a formative stage. Review findings have suggested that health service culture is intrinsically disempowering for clients with serious mental health problems, and assumptions of decisional incapacity are purportedly common. Within such a culture it is perhaps unsurprising that progress towards SDM has been slow.

This culture, however, is at odds with the strong policy initiatives detailed in numerous Department of Health publications such as ‘Liberating the NHS: No decision about me, without me’. Such publications make clear that the drive towards a culture of shared decision-making in health and social care should encompass mental health services. ‘No decision about me, without me’ emphasises professionals’ obligation under the Mental Capacity Act (2005) to ‘take all practicable steps’ to help people make their own decisions ‘even where they have a mental impairment’. The mental health charity, Mind, in contributing to this policy, suggested that treatment decision-making
informed by service users’ expertise about their own well-being may increase the effectiveness of treatment and promote recovery.\textsuperscript{1}

1.1.2 SDM, Recovery and empowerment

The congruence of SDM with Recovery-oriented approaches to mental health is highlighted also in the SDM literature.\textsuperscript{5} Such approaches aim to prioritise service users’ goals,\textsuperscript{7,8} and SDM offers a vehicle whereby these might become a central part of treatment decision-making. In the context of empathic, respectful relationships with clinicians, young service users with psychosis have reported feeling empowered by SDM.\textsuperscript{9} Empowerment, in turn, is itself seen by service users as being central to recovery.\textsuperscript{7,8,10} Given that disempowerment is a particular issue for service users with psychosis,\textsuperscript{11-13} examination of the potential of SDM to empower this client group specifically would seem to be a worthwhile line of enquiry.

1.1.3 SDM with psychosis

The literature on SDM in psychosis has yet to be specifically reviewed. There exist only two reviews of studies examining SDM in mental healthcare overall.\textsuperscript{2,3} These included just three studies and only two relating to psychosis, with neither review able to draw firm conclusions. Whilst this may reflect the early stage of research into SDM in mental healthcare, use of a highly stringent model of SDM in these reviews may also have limited their findings. Both cited Charles’\textsuperscript{14} model where SDM is defined as active collaboration by two parties in reaching a consensus about a particular decision. Both excluded studies of advance directives and those with an emphasis on improving patient-clinician communication without reference to a particular treatment decision.

The nature of psychosis, however, with its potentially chronic, pervasive impacts on individuals’ lives, perceptions and ways of relating to self and others, suggests that a broader model of SDM might be appropriate. Focus on the ongoing relationships between service users and clinicians in SDM has been advocated both in relation to long-term conditions\textsuperscript{15} and specifically
psychosis, where cognitive and communication problems may undermine them. Meanwhile, ‘No decision about me, without me’ advocates the use of advance directives to support SDM where there is potential for future loss of capacity. Thus, in relation to psychosis, it would seem appropriate to review studies evaluating a range of interventions, focusing variously on particular decisions; broader care issues; enhancement of patient-clinician relationships and communication; and collaboration on joint crisis planning.

Similarly important is to examine outcomes of particular relevance to individuals with psychosis. The one existing review of SDM in mental healthcare to examine specific outcomes focused on patient satisfaction and clinical and service-related outcomes. Empowerment might, however, be a more appropriate choice of Recovery-oriented and client-centred primary outcome, given its importance to service users with psychosis and the seeming potential for its enhancement by SDM.

1.1.4 Objectives
We conducted a systematic review and exploratory meta-analysis of SDM interventions for people with a schizophrenia-spectrum diagnosis. The aim was to test the hypothesis that SDM is significantly more effective than control interventions on the primary outcome of increasing empowerment, as judged by participants and indicated by objective measures. The effect of SDM on secondary outcomes of quality of service user/provider relationship (service user-rated) and decision-making abilities and knowledge (clinician-rated) were also evaluated.

1.2 Method
1.2.1 Search strategy
The electronic databases, Medline (1946-), PsychInfo (1806-), EMBASE (1980-), CINAHL (1937-) and The Cochrane Central Register of Controlled Trials (CENTRAL) (Issue 8 of 12, August 2013) were searched in August 2013, along with the references of two previous reviews of SDM.
interventions in mental health care. 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 (Appendix 2). The search was not limited by date, language or publication status.

1.2.2 Inclusion and exclusion criteria

Studies were included that compared an active psychosocial intervention designed to enhance shared decision-making in relation to current or future treatment for psychosis with a control intervention (e.g. usual care or a non-specific control treatment). Further requirements were random allocation to conditions and that interventions be directed primarily at service users with psychosis. Included interventions could be individual or group treatments directed either at the process of shared decision-making itself, at improving the communication between service users and clinicians or at facilitating generation of advance directives or crisis plans. Studies were included only where the emphasis of the intervention was on improving the collaboration between service users and providers. Studies of advance statements or care planning where this emphasis was absent were therefore excluded.

To ensure the results were generalisable to service users with primarily non-affective psychosis, studies were included only 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.

1.2.3 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, an a priori 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-centeredness of service user/provider interaction > reduced perceived coercion. The second primary outcome was reduced objective coercion as indicated by fewer days’ involuntary treatment 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. Secondary outcomes were quality of service user/provider relationship (service user-rated) and decision-making abilities and knowledge (clinician-rated).

1.2.4 Data extraction
Summary data (means, standard deviations) were extracted where possible from relevant studies using a spreadsheet. Information on study characteristics was also collated including type of intervention (e.g. shared decision-making/joint crisis plan), mode of delivery (individual/group), medium of intervention (e.g. use of communication/decision aids), duration of intervention, treatment setting (e.g. inpatient/community), number of sessions offered, control condition, diagnosis, number of centres, baseline demographics (age, gender), availability of follow-up data and attrition rates. Authors were contacted where data or other 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 using equations specified in the Cochrane Handbook. 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.
1.2.5 Meta-analytic calculations
Continuous data was extracted and combined using Comprehensive Meta-Analysis Version 2 for Windows (Biostat, NJ, USA; see http://www.meta-analysis.com/index.php) to derive the standardised mean difference 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. A one-tailed analysis would have provided greater power to detect either a positive or a negative effect. Given, however, the relative novelty of the area of intervention under review, and associated uncertainty as to the direction of effect, the more conservative choice of a two-tailed hypothesis was judged appropriate. Analyses employed a random-effects model although, where the \(I^2\) statistic indicated less than moderate heterogeneity,\(^\text{17}\) a fixed-effect analysis was also performed and reported. Cohen’s proposed criteria for interpretation of effect sizes (small = 0.2, moderate = 0.5, large = 0.8)\(^\text{18}\) were used in the absence of more specific criteria for judging clinical significance of mean differences.

1.2.6 Sensitivity analyses
Sensitivity analyses were used to assess the effect of excluding two studies with respectively >25%\(^\text{19}\) and >50%\(^\text{20}\) attrition. The effect of including a relevant older study,\(^\text{21}\) which had been excluded from the main analysis on grounds of non-random allocation, was similarly assessed. This latter study was included in the sensitivity analysis, where other non-RCTs were not, because it compared an intervention and control group on an intervention and outcomes of interest, but fell short of RCT methodological standards, with group allocation being on the basis of admission date. Other studies excluded on the basis of design departed in much more substantial ways from RCT methodology, being either interview or qualitative studies.

1.2.7 Pre-registration of review protocol
The review protocol was registered in advance with PROSPERO (International Prospective Register of Systematic Reviews).\(^\text{22}\)
1.2.8 Risk of bias and study quality

Risk of bias was assessed for each study using the Cochrane Collaboration Risk of Bias Tool.23 Assessment of outcome quality was performed using the GRADE approach.24 Risk of performance bias was excluded 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).25 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 (Appendix 2).

1.3 Results

1.3.1 Study Selection

The process of study selection is represented in the PRISMA diagram (see Fig. 1). Of the 3904 papers initially identified, 294 were judged potentially relevant on the basis of title. For six of these, published reports were unavailable. Two authors reported that data is not yet available,26,27 and four did not respond to requests for further information.28-31 A further 260 studies were excluded on the basis of information provided in the abstract. Full-text publications were sought for the remaining 28 studies. Of these, 19 were excluded either because they did not report usable outcomes (k=6),32-37 did not evaluate an SDM intervention as defined in the protocol (k=6),38-43 were not randomised controlled trials (k=4),21,44-46 did not provide outcome data (k=1),47 had an attrition rate of >50% (k=1)20 or were not published in English (k=1).48 A total of 8 studies were included. One of these was the subject of two reports.49,50

Of the included studies, three evaluated interventions to support service users in joint crisis planning or completion of an advance psychiatric directive.49-52 Four examined interventions involving supported use of external aids in SDM or communication with clinicians. Two of these were
paper-based\textsuperscript{19, 53} and two were web-based.\textsuperscript{54, 55} A further trial\textsuperscript{56} evaluated a group SDM intervention. The included trials, their characteristics and baseline demographics are given in Table 1.
Fig. 1 PRISMA flowchart showing process of study selection

Number of records identified through database searching: **3894**

Number of irrelevant/duplicate records excluded on basis of title: **3610**

Number of records screened (abstract/description): **294**

Published reports unavailable – data not yet available: **2**
Authors did not respond to requests for additional information: **4**

Number of records excluded: **260**

Number of full-text reports screened for eligibility: **28**

Number of full-text reports excluded: **19**
Not included outcomes: **6**
Not SDM: **5**
SDM not main group difference/primary substance misuse: **1**
Not RCT: **4**
Outcome data not yet available: **1**
>50% data missing: **1**
In Chinese: **1**

Number of studies included in meta-analysis: **8**
(one study was the subject of two reports)

Number or records identified through other sources: **10**
Table 1  Trial characteristics and baseline demographics

<table>
<thead>
<tr>
<th>Trial</th>
<th>Interventions</th>
<th>Treatment setting</th>
<th>Number randomised <em>(n included in analysis)</em></th>
<th>Included primary outcome (measure)</th>
<th>Included secondary outcome (measure)</th>
<th>Number and location of sites</th>
<th>Baseline demographics</th>
<th>Number female (%)</th>
<th>Number with schizophrenia-spectrum diagnosis (%)</th>
<th>Timing of measures and available follow-up data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamann et al (2006)†</td>
<td>Nurse-supported use of paper-based decision aid (30-60 minutes), preparing for consultation with doctor. Training for nurses and doctors involved.</td>
<td>In-patient – acute</td>
<td>54 (Primary outcome: 30, secondary outcome: 36)</td>
<td>Patient-perceived involvement (COMRADE)</td>
<td>Clinician-rated decision-making abilities and knowledge (idiosyncratic measure)</td>
<td>1 Munich, Germany</td>
<td>35.5 (11.9)</td>
<td>20 (37)</td>
<td>54 (100)</td>
<td>Perceived involvement: post intervention and at discharge from ward. Decision-making ability: discharge only.</td>
</tr>
<tr>
<td>Treatment as usual.</td>
<td></td>
<td></td>
<td>59 (Primary outcome: 45, secondary outcome: 52)</td>
<td></td>
<td></td>
<td></td>
<td>39.6 (10.8)</td>
<td>31 (53)</td>
<td>59 (100)</td>
<td></td>
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<tr>
<td>Trial</td>
<td>Interventions</td>
<td>Treatment setting</td>
<td>Number randomised (n included in analysis)</td>
<td>Included primary outcome (measure)</td>
<td>Included secondary outcome (measure)</td>
<td>Number and location of sites</td>
<td>Age, mean (s.d.)</td>
<td>Number female (%)</td>
<td>Number with schizophrenia-spectrum diagnosis (%)</td>
<td>Timing of measures and available follow-up data</td>
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<td></td>
<td>Health locus of control (MHLCS)</td>
<td>Clinician-rated decision-making abilities &amp; knowledge (idiosyncratic measure of capacity)</td>
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<td></td>
<td>Patient-perceived involvement in decision-making (idiosyncratic measure)</td>
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<tr>
<td></td>
<td>5-session group cognitive training</td>
<td></td>
<td>29 (29)</td>
<td></td>
<td></td>
<td></td>
<td>41.76 (11.36)</td>
<td>NS</td>
<td>29 (100)</td>
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<tr>
<td>Henderson et al (2004)⁵¹</td>
<td>2-session shared facilitation of JCP, involving clinical team and possibly friend/advocate.</td>
<td>Community with hospital admission in previous 2 years</td>
<td>80 (80)</td>
<td>Objective coercion (days’ treatment under MHA)</td>
<td>None</td>
<td>7 CMHTs in South London and 1 in Kent, England</td>
<td>39.5 (12.1)</td>
<td>33 (41)</td>
<td>&gt;50% (correspondence from last author)</td>
<td>Follow-up 15 months post-randomisation.</td>
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<td>Trial</td>
<td>Interventions</td>
<td>Treatment setting</td>
<td>Number randomised (n included in analysis)</td>
<td>Included primary outcome (measure)</td>
<td>Included secondary outcome (measure)</td>
<td>Number and location of sites</td>
<td>Baseline demographics</td>
<td>Timing of measures and available follow-up data</td>
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<tr>
<td></td>
<td>Provision of written material about mental health services, MHA etc.</td>
<td></td>
<td>80 (80)</td>
<td></td>
<td></td>
<td></td>
<td>38.6 (10.6)</td>
<td>33 (41)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Steinwachs et al (2011) 54</td>
<td>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.</td>
<td>Community &amp; out-patient</td>
<td>Total for both groups: 56 (24)</td>
<td>Patient-centredness of interaction (RIAS)</td>
<td>None</td>
<td>1 Baltimore, USA</td>
<td>49 (12)</td>
<td>9 (38)</td>
<td>24 (100)</td>
<td>Post-intervention.</td>
</tr>
<tr>
<td></td>
<td>Video and written information about treatment for schizophrenia</td>
<td></td>
<td>NS (26)</td>
<td></td>
<td></td>
<td></td>
<td>50 (11)</td>
<td>8 (31)</td>
<td>26 (100)</td>
<td></td>
</tr>
<tr>
<td>Trial</td>
<td>Interventions</td>
<td>Treatment setting</td>
<td>Number randomised (n included in analysis)</td>
<td>Included primary outcome (measure)</td>
<td>Included secondary outcome (measure)</td>
<td>Number and location of sites</td>
<td>Age, mean (s.d.)</td>
<td>Number female (%)</td>
<td>Number with schizophrenia-spectrum diagnosis (%)</td>
<td>Timing of measures and available follow-up data</td>
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<tr>
<td>Swanson et al (2006)⁵⁰</td>
<td>Research assistant-administered semi-structured interview, discussion and practical assistance to facilitate advance directive.</td>
<td>Community</td>
<td>213 (Swanson:195 Elbogen: 190)</td>
<td>None</td>
<td>Patient-rated relationship with clinician (WAI)</td>
<td>1 North Carolina, USA</td>
<td>Across groups 42 (10.7)</td>
<td>Across groups 251 (60)</td>
<td>Across groups 247 (59)</td>
<td>1 month after baseline.</td>
</tr>
<tr>
<td>Elbogen et al (2007)⁴⁹</td>
<td>Written information re advance directives and signposting</td>
<td>Community</td>
<td>206 (Swanson:186 Elbogen: 181)</td>
<td>NS *</td>
<td>NS *</td>
<td>NS *</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Trial</td>
<td>Interventions</td>
<td>Treatment setting</td>
<td>Number randomised (n) included in analysis</td>
<td>Included primary outcome (measure)</td>
<td>Included secondary outcome (measure)</td>
<td>Number and location of sites</td>
<td>Age, mean (s.d.)</td>
<td>Number female (%)</td>
<td>Number with schizophrenia-spectrum diagnosis (%)</td>
<td>Timing of measures and available follow-up data</td>
</tr>
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</tr>
<tr>
<td>Van Os et al (2004) (^5^3)</td>
<td>Use of problem checklist with brief guidance, covering medical, psychological/emotional and psychosocial areas, prior to consultation with doctor to enhance communication.</td>
<td>Community</td>
<td>67 (NS)</td>
<td>None</td>
<td>Patient-rated relationship with clinician (4-point rating on single question)</td>
<td>7 centres across Europe: Maastricht, Oviedo, Gijon, Hamburg, Copenhagen, Milan, Nice</td>
<td>40.3 (12.7)</td>
<td>35 (52)</td>
<td>67 (100)</td>
<td>Immediately post-intervention and 4-6 weeks later.</td>
</tr>
<tr>
<td>Treatment as usual</td>
<td></td>
<td></td>
<td>67 (NS)</td>
<td></td>
<td></td>
<td></td>
<td>41.3 (12.5)</td>
<td>29 (43)</td>
<td>67 (100)</td>
<td></td>
</tr>
</tbody>
</table>

Baseline demographics

- **Trial**: Treatment as usual under CPA
- **Number randomised (n included in analysis)**: 284 (MPCS: 245, MHA: 280, WAI: 240)
- **Included primary outcome (measure)**: None
- **Included secondary outcome (measure)**: Patient-rated relationship with clinician (4-point rating on single question)
- **Number and location of sites**: 7 centres across Europe: Maastricht, Oviedo, Gijon, Hamburg, Copenhagen, Milan, Nice
- **Age, mean (s.d.)**: 39.6 (12.1)  
- **Number female (%)**: 138 (49)  
- **Number with schizophrenia-spectrum diagnosis (%)**: 212 (75)  
- **Timing of measures and available follow-up data**: Immediately post-intervention and 4-6 weeks later.
<table>
<thead>
<tr>
<th>Trial</th>
<th>Interventions</th>
<th>Treatment setting</th>
<th>Number randomised (n) included in analysis</th>
<th>Included primary outcome (measure)</th>
<th>Included secondary outcome (measure)</th>
<th>Number and location of sites</th>
<th>Baseline demographics</th>
<th>Timing of measures and available follow-up data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Woltmann et al (2011)(^{55})</td>
<td>Electronic decision support system to facilitate synthesising perspectives in care planning for patients and case managers.</td>
<td>Community</td>
<td>40 (40)</td>
<td>Patient-perceived involvement (idosyncratic measure)</td>
<td>None</td>
<td>1 Dartmouth, USA</td>
<td>Age, mean (s.d.) 47 (9)</td>
<td>Number female (%) 15 (38)</td>
</tr>
<tr>
<td>Care planning as usual.</td>
<td>40 (40)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>46 (11)</td>
<td>12 (30)</td>
<td>24 (60)</td>
</tr>
</tbody>
</table>

**Trials excluded from main analysis due to sequential rather than true random allocation\(^*\) and high attrition,\(^*\) but included in post hoc analysis:**

<p>| Dow et al (1991)(^{51}) | 5-session group communication and access skills programme over 2.5 weeks covering doctor-patient interactions. Included video, role play, discussion and problem solving. | In-patient – intensive residential treatment for chronically mentally ill patients | Total for both groups: 51 (48) | Health locus of control (HLCS) | Clinician-rated decision-making abilities and knowledge (idosyncratic behavioural measures) | 1 Florida, USA | Across groups 31.3 (NS), range 19-58 (46) | Across groups 22 (58) | Across groups 28 (58) | Pre- and post-intervention. |</p>
<table>
<thead>
<tr>
<th>Trial</th>
<th>Interventions</th>
<th>Treatment setting</th>
<th>Number randomised ((n\text{ included in analysis}))</th>
<th>Included primary outcome (measure)</th>
<th>Included secondary outcome (measure)</th>
<th>Number and location of sites</th>
<th>Age, mean ((s.d.))</th>
<th>Number female (%)</th>
<th>Number with schizophrenia-spectrum diagnosis (%)</th>
<th>Timing of measures and available follow-up data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Van der Kriek et al (2013)(^{55})</td>
<td>5-session group medication education programme over 2.5 weeks.</td>
<td>Community</td>
<td>124 (40)</td>
<td>Patient-perceived involvement in decision making (COMRADE)</td>
<td>None</td>
<td>1 Leeuwarden, Netherlands</td>
<td>37 (12.35)</td>
<td>13 (33)</td>
<td>124 (100)</td>
<td>Post-intervention.</td>
</tr>
<tr>
<td></td>
<td>Web-based information and decision tool with exploration of needs (medical and psychosocial) and treatment module options. Printout for use in consultation Facilitation optional.</td>
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</tr>
<tr>
<td>Care as usual</td>
<td></td>
<td></td>
<td>126 (33)</td>
<td></td>
<td>40 (13.47)</td>
<td>21 (64)</td>
<td>126 (100)</td>
<td></td>
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</tbody>
</table>

Note: COMRADE, Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness;\(^57\) DSS, Decision Self-efficacy Scale;\(^58\) MHLCS, Multi-Dimensional Health Locus of Control Scale;\(^59\) TPS, Trust in Physician Scale;\(^60\) JCP, Joint Crisis Plan; MPCS, MacArthur Perceived Coercion Scale;\(^61\) 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;\textsuperscript{62} WAI, Working Alliance Inventory;\textsuperscript{63} DCAT-PAD, Decisional Competence Assessment Tool for Psychiatric Advance Directives\textsuperscript{64}; HLCS, Health Locus of Control Scale\textsuperscript{65}
1.3.2 Risk of bias and GRADE

Table 2 summarises risk of bias ratings for the included studies. Table 3 provides a summary of the results for each outcome and the GRADE ratings of outcome quality. A detailed rationale for the ratings is provided in the supplementary material (Appendix 2).

A global issue identified by the risk of bias assessment was a high risk of performance bias since, as is generally the case with trials of psychosocial interventions, blinding of participants and personnel was not possible. Knowledge of group allocation may therefore have influenced behaviour, with potential to affect outcomes. Risk of attrition bias was rated respectively as high in Hamann et al (2006)\(^{19}\) and unclear on a secondary outcome in Thornicroft et al,\(^{52}\) with only the latter taking due account of the missing data in analysis. Meanwhile, Elbogen et al's\(^{49}\) partial reporting of an outcome of interest resulted in a judgement of high risk of reporting bias. Insufficiently explicit reporting led to judgements of unclear risk of selection bias where procedures for random sequence generation and allocation concealment were not specified,\(^{19, 49, 50, 54-56}\) detection bias where masking of assessors was not explicitly reported\(^{19, 49, 50, 53, 55, 56}\) and recruitment bias where influence of cluster randomised design was unaccounted for.\(^{19, 55}\)
<table>
<thead>
<tr>
<th>Study</th>
<th>Random sequence generation (selection bias)</th>
<th>Allocation concealment (selection bias)</th>
<th>Performance bias (blinding of participants and personnel)</th>
<th>Detection bias (blinding of assessments)</th>
<th>Incomplete outcome data (attrition bias)</th>
<th>Selective reporting (reporting bias)</th>
<th>Other bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamann <em>et al.</em> (2006)(^{19})</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>High: for patient-perceived involvement.</td>
<td>Unclear</td>
<td>Unclear</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Unclear: for knowledge about disease and medication.</td>
<td></td>
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</tr>
<tr>
<td>Hamann <em>et al.</em> (2011)(^{56})</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
<td>Unclear</td>
<td>Low: post</td>
<td>Unclear</td>
<td>Unclear</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Unclear: at follow-up</td>
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<tr>
<td>Henderson <em>et al.</em> (2004)(^{51})</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td>Study</td>
<td>Random sequence generation (selection bias)</td>
<td>Allocation concealment (selection bias)</td>
<td>Performance bias (blinding of participants and personnel)</td>
<td>Detection bias (blinding of assessments)</td>
<td>Incomplete outcome data (attrition bias)</td>
<td>Selective reporting (reporting bias)</td>
<td>Other bias</td>
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<tr>
<td>Steinwachs et al (2011) $^{54}$</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
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<tr>
<td>Swanson et al (2006) $^{50}$</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear for patient-rated relationship with clinician</td>
<td>Low</td>
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<tr>
<td>Elbogen et al (2007) $^{19}$</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>High for clinician-rated decision-making abilities and knowledge</td>
<td>Low</td>
</tr>
<tr>
<td>Study</td>
<td>Random sequence generation (selection bias)</td>
<td>Allocation concealment (selection bias)</td>
<td>Performance bias (blinding of participants and personnel)</td>
<td>Detection bias (blinding of assessments)</td>
<td>Incomplete outcome data (attrition bias)</td>
<td>Selective reporting (reporting bias)</td>
<td>Other bias</td>
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<tr>
<td>Thornicroft et al (2013)</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>Low for primary outcomes</td>
<td>Unclear for patient-rated relationship with clinician</td>
<td>Low</td>
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<td>Unclear</td>
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<tr>
<td>Woltmann et al (2011)</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear</td>
<td>Unclear</td>
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</table>
### Table 3  Summary of results and GRADE assessment of outcomes

<table>
<thead>
<tr>
<th>Outcome and number of studies</th>
<th>Studies and index measured</th>
<th>Number of participants: intervention (I), control (C)</th>
<th>Effect size and P-value</th>
<th>95% CI for effect size</th>
<th>Heterogeneity ($I^2$) and P-value</th>
<th>GRADE overall quality rating</th>
</tr>
</thead>
</table>
| Subjective empowerment: 5 studies | Hamann et al (2006):\(^{19}\) patient-perceived involvement  
Hamann et al (2011):\(^{56}\) decision self-efficacy  
Steinwachs et al:\(^{54}\) patient-centredness of interaction  
Thornicroft et al:\(^{52}\) perceived coercion  
Woltmann et al:\(^{55}\) patient-perceived involvement | 724 (I: 339, C: 385) | $g = 0.23, P = 0.014$ | (0.05-0.41) | $I^2 = 16.85, P = 0.307$ | -2 (low) |
<table>
<thead>
<tr>
<th>Outcome and number of studies</th>
<th>Studies and index measured</th>
<th>Number of participants: intervention (I), control (C)</th>
<th>Effect size and P-value</th>
<th>95% CI for effect size</th>
<th>Heterogeneity ($\hat{I}^2$) and P-value</th>
<th>GRADE overall quality rating</th>
</tr>
</thead>
</table>
| Reduction in objective coercion: 2 studies | Henderson et al.51 days’ treatment under section of MHA  
Thornicroft et al.52 days’ treatment under section of MHA | 707 (I: 347, C: 360) | $g = 0.30, P = 0.373$ | (-0.36 to 0.96) | $\hat{I}^2 = 92.64$, $P<0.001$ | -3 (very low) |
Swanson et al.50 working alliance  
Thornicroft et al.52 working alliance  
Van Os et al.53 patient-rated quality of communication | 922 (I: 400, C: 522) | $g = 0.10, P = 0.462$ | (-0.17 to 0.38) | $\hat{I}^2 = 72.59$, $P = 0.012$ | -2 (low) |
<table>
<thead>
<tr>
<th>Outcome and number of studies</th>
<th>Studies and index measured</th>
<th>Number of participants: intervention (I), control (C)</th>
<th>Effect size and P-value</th>
<th>95% CI for effect size</th>
<th>Heterogeneity ($I^2$) and P-value</th>
<th>GRADE overall quality rating</th>
</tr>
</thead>
</table>
| Patient-rated relationship with clinician, reduced 'trust' excluded: 4 studies | Hamann et al (2011)\(^{56}\) trust in physician   
Swanson et al\(^{50}\) working alliance   
Thornicroft et al\(^{52}\) working alliance   
Van Os et al\(^{53}\) patient-rated quality of communication | 922 (I: 400, C: 522) | $g = 0.26, \ P<0.001$ | (0.12-0.39) | $\hat{I}^2 = 2.56, \ P = 0.380$ | -1 (moderate) |
| Clinician-rated decision-making abilities and knowledge: 3 studies | Hamann et al (2006)\(^{19}\) knowledge about disease and medication   
Hamann et al (2011)\(^{56}\) decisional capacity   
Elbogen et al\(^{49}\) decisional capacity (reasoning only) | 520 (I: 258, C: 262) | $g = 0.27, \ P = 0.300$ | (-0.24 to 0.79) | $\hat{I}^2 = 82.62, \ P = 0.003$ | -3 (very low) |
1.3.3 Outcomes

1.3.4 Primary outcome (i) – subjective empowerment (see Fig. 2)

Low-quality evidence suggested a small, statistically significant effect of SDM interventions on subjective empowerment \((k = 5, \ g = 0.23, \ 95\% \ CI \ 0.05-0.41, \ P = 0.014)\). Five trials,\(^{19,52,54-56}\) involving a total of 724 participants, provided data on this outcome. Of these, one was a group SDM intervention for in-patients,\(^{56}\) two were community, web-based interventions,\(^{54,55}\) one was an individual, in-patient SDM intervention involving use of a paper-based decision aid\(^{19}\) and one provided community-based facilitation of joint crisis plans.\(^{52}\) The quality of the evidence was downgraded due to its indirectness, with no study measuring subjective empowerment specifically. Downgrading also occurred due to imprecision, given that the 95% confidence interval included both trivial and moderate effects, and the combined sample size was only just sufficient to detect a small effect.\(^{66}\) There was, however, no evidence of undue heterogeneity \((I^2 = 16.85, \ P = 0.307)\).

There were two studies\(^{19,54}\) that, despite the small effect size overall, showed statistically significant moderate effect sizes \((g = 0.50, \ 95\% \ CI \ 0.03-0.96, \ P = 0.035; \ g = 0.64, \ CI \ 0.08-1.20, \ P = 0.026)\). Both studies were small however, and the 95% confidence intervals wide, reducing confidence in the magnitude of these individual effects.\(^{67}\)

Only two studies\(^{19,56}\) provided follow-up data. One\(^{19}\) reported a small, statistically non-significant effect at hospital discharge \((g = 0.16, \ CI -0.27 \ to \ 0.60, \ P= 0.463)\). Data was missing from >25% of participants however and no account of this was taken in analysis. For the other,\(^{56}\) the index of subjective empowerment included as the post-intervention measure (decisional self-efficacy) was not repeated at 6-month follow-up, suggesting a risk of selective reporting bias. Instead, it was necessary to include an idiosyncratic measure of patient-perceived involvement. Although the outcome estimate of effect was large \((g = 1.09, \ CI 0.49-1.69, \ P<0.001)\), it
was judged to be imprecise due to the small sample \((n = 48)\) and wide 95% confidence interval.

1.3.5 Sensitivity analysis
Excluding a study\(^1\) that had an attrition rate of >25% that was unaccounted for in analysis gave a marginally smaller, yet still statistically significant effect size \((k = 4, g = 0.17, 95\% \text{ CI 0.01-0.33}, P = 0.035)\). Including in turn data from studies that had been excluded from the main analysis for reasons of sequential rather than true random allocation\(^2\) and a high rate of attrition (>50\%)\(^3\) also had little effect on the overall estimate of effect, respectively \((k = 6, g = 0.20, 95\% \text{ CI 0.06-0.34}, P = 0.005)\) \((k = 6, g = 0.20, 95\% \text{ CI 0.06-0.33}, P = 0.006)\).
### Indices of subjective empowerment

<table>
<thead>
<tr>
<th>Model</th>
<th>Study name</th>
<th>Statistics for each study</th>
<th>Sample size</th>
<th>Hedges’s g and 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hedges’s g</td>
<td>Standard error</td>
<td>Lower limit</td>
</tr>
<tr>
<td>Fixed</td>
<td></td>
<td>0.499</td>
<td>0.237</td>
<td>0.034</td>
</tr>
<tr>
<td>Random</td>
<td></td>
<td>0.226</td>
<td>0.092</td>
<td>0.045</td>
</tr>
</tbody>
</table>

#### Fig. 2 Indices of subjective empowerment

Note: perc injvlt, patient-perceived involvement; self effic, decision self-efficacy; pat cent int, patient-centred interaction; perc coerc, perceived coercion.
1.3.6 Primary outcome (ii) – reduction in objective coercion (see Fig. 3)

Very low-quality evidence from two studies,\textsuperscript{51,52} involving a total of 707 participants suggested a small, statistically non-significant effect of joint crisis planning on number of days’ involuntary treatment under the MHA (1983/2007) ($k = 2$, $g = 0.30$, 95% CI -0.36 to 0.96, $P = 0.373$). Heterogeneity was high ($I^2 = 92.64$, $P < 0.001$) and precision low, given a 95% confidence interval including zero, spanning a negative through to a large effect. The evidence was consequently downgraded on grounds of inconsistency and imprecision in GRADE. Other quality indicators, however, suggested that the individual studies were of high quality and provided direct measures of objective coercion.
### Reduction in objective coercion

<table>
<thead>
<tr>
<th>Model</th>
<th>Study name</th>
<th>Outcome</th>
<th>Statistics for each study</th>
<th>Sample size</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hedges's $g$ and 95% CI</td>
<td></td>
</tr>
<tr>
<td>Henderson</td>
<td>Obj coerc</td>
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<td>0.000</td>
<td>80</td>
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<tr>
<td></td>
<td></td>
<td>0.162</td>
<td>0.162</td>
<td>80</td>
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<td></td>
<td>0.333</td>
<td>1.000</td>
<td>160</td>
</tr>
<tr>
<td>Thornicroft</td>
<td>Obj coerc</td>
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<td>95.000</td>
<td>267</td>
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<td></td>
<td></td>
<td>0.085</td>
<td>-0.023</td>
<td>280</td>
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<tr>
<td></td>
<td></td>
<td>-0.191</td>
<td>0.085</td>
<td>547</td>
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<tr>
<td>Random</td>
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<td>1.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.336</td>
<td>1.000</td>
<td></td>
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<tr>
<td></td>
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<td>-0.360</td>
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<td></td>
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<td>0.959</td>
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<td></td>
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<td>0.373</td>
<td>1.000</td>
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</tbody>
</table>

**Fig. 3 Reduction in objective coercion**

Note: obj coerc, objective coercion.
1.3.7 Secondary outcome (i) – patient-rated relationship with clinician (see Fig. 4)

Analysis of very low-quality evidence did not find that there was a significant effect of SDM interventions on patient-rated relationship with clinician ($k = 4$, $g = 0.10, 95\% \text{ CI} -0.17 \text{ to } 0.38, P = 0.462$). Four studies\textsuperscript{50, 52, 53, 56} with a total of 922 participants contributed to this outcome. One study examined the effect of a group in-patient SDM intervention,\textsuperscript{56} two evaluated respectively facilitation of advance directives and joint crisis plans\textsuperscript{50, 52} and one assessed community-based, checklist-mediated support in communication with clinicians.\textsuperscript{53} Since the 95\% confidence interval included both negative and small-moderate positive effects, confidence in the precision of the estimate of effect was reduced. Heterogeneity was also high ($I^2 = 72.59, P = 0.012$).

A moderate negative effect in one study\textsuperscript{56} ($g = -0.62, 95\% \text{ CI} -1.13 \text{ to } -0.11, P = 0.017$) contributed particularly to the high heterogeneity. This study of a group in-patient SDM intervention differed from the other studies in measuring ‘trust in physician’ rather than ‘alliance’ or ‘quality of communication’. Omitting this result suggested a small, statistically significant effect ($g = 0.23, 95\% \text{ CI} 0.09-0.37, P = 0.001$), favouring intervention, for the remaining three studies (see Fig. 5). In this analysis, heterogeneity was low ($I^2 = 0.00, P = 0.626$). The estimate of effect lacked precision, however, given a 95\% confidence interval spanning a trivial to low-to-moderate effect. The evidence produced by this analysis was therefore considered to be of moderate quality.
## Patient-rated relationship with clinician

<table>
<thead>
<tr>
<th>Model</th>
<th>Study name</th>
<th>Outcome</th>
<th>Statistics for each study</th>
<th>Sample size</th>
<th>Hedges's $g$ and 95% CI</th>
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<tr>
<td></td>
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<td>Hedges's Standard Lower Upper</td>
<td>Control Total</td>
<td>p-Value SDM</td>
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<td></td>
<td></td>
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<td>$g$ error limit limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hamann 11 Trust</td>
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<td>Trust</td>
<td>-0.622 0.259 -1.130 -0.113 0.017</td>
<td>32 29</td>
<td>61</td>
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<td>Alliance</td>
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<td>195 186</td>
<td>381</td>
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<tr>
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<td>Alliance</td>
<td>0.174 0.117 -0.054 0.403 0.135</td>
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<tr>
<td>Van Os Commun</td>
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<td>0.375 0.173 0.035 0.714 0.031</td>
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<td>0.104 0.142 -0.174 0.382 0.462</td>
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</tbody>
</table>

**Fig. 4 Patient-rated relationship with clinician**

Note: trust, trust in physician; alliance, working alliance; commun, patient-rated quality of communication.
Patient-rated relationship with clinician - 'trust' excluded

<table>
<thead>
<tr>
<th>Model</th>
<th>Study name</th>
<th>Outcome</th>
<th>Statistics for each study</th>
<th>Sample size</th>
<th>Hedges's g and 95% CI</th>
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<td>0.228</td>
<td>0.070</td>
<td>0.090</td>
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</tbody>
</table>

Note: alliance, working alliance; commun, patient-rated quality of communication.

Fig. 5 Patient-rated relationship with clinician - 'trust' excluded
1.3.8 Secondary outcome (ii) – clinician-rated decision-making abilities and knowledge (see Fig. 6)

Very low-quality evidence from three studies,\textsuperscript{19, 49, 56} involving a total of 520 participants, suggested a small, but statistically non-significant effect of SDM interventions on clinician-rated decision-making abilities and knowledge \((k = 3, g = 0.27, 95\% \text{ CI} -0.24 \text{ to } 0.79, P = 0.300)\). Two studies\textsuperscript{19, 56} examined respectively individual and group in-patient SDM interventions. The third\textsuperscript{49} evaluated an intervention supporting facilitation of advance directives. Heterogeneity was high \((I^2 = 82.62, P = 0.003)\), as was imprecision, with a 95\% confidence interval including both negative and moderate-to-large, positive effect sizes. Only one of the studies\textsuperscript{49} used a validated measure of decisional capacity, resulting in evidence that lacked directness, and from this study only statistically significant results were comprehensively reported, introducing a risk of reporting bias.

1.3.9 Sensitivity analysis

Including data from a study that had been excluded from the main analysis due to sequential rather than true random allocation\textsuperscript{21} gave a slightly larger, though still statistically non-significant effect, with a similarly wide 95\% confidence interval \((k = 4, g = 0.34, 95\% \text{ CI} -0.07 \text{ to } 0.76, P = 0.103)\).
# Clinician-rated decision-making abilities and knowledge

<table>
<thead>
<tr>
<th>Model</th>
<th>Study name</th>
<th>Outcome</th>
<th>Statistics for each study</th>
<th>Sample size</th>
<th>Hedges’s g and 95% CI</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td>Hedges’s g</td>
<td>Standard error</td>
<td>Lower limit</td>
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<td></td>
<td></td>
<td>0.274</td>
<td>0.264</td>
<td>-0.244</td>
</tr>
</tbody>
</table>

**Fig. 6 Clinician-rated decision-making abilities and knowledge**

Note: knowlg, knowledge about disease and medication; capacity, decisional capacity.
1.4 Discussion

1.4.1 Summary of findings
Results from the eight randomised controlled trials in this review provide some promising indications that psychosocial interventions may empower patients with a diagnosis of a schizophrenia-spectrum disorder in communication and collaborative treatment-related decision-making with clinicians. Most notably, results of our main primary outcome suggested significant, albeit small, benefits on indices of patients’ subjective empowerment.

Improvements in patients’ experience of their relationship with their clinician were also suggested by the collective results of three studies.\textsuperscript{50, 52, 53} This finding was, however, at odds with that of a further study\textsuperscript{56} that differed from the others in measuring ‘trust in physician’ rather than ‘alliance’ or ‘quality of communication’, and in reporting a moderate negative effect on this outcome. The low scores on the Trust in Physician Scale reported\textsuperscript{60} might indicate reduced tendencies to passivity and adoption of a ‘sick role’,\textsuperscript{68} since a number of the items on this measure appear to reflect a conceptualisation of ‘trust’ tending toward ‘unquestioning acceptance of the physician’s authority’. As such, low scores on this measure might be seen as a positive indicator of empowerment. The pooled estimate of effect, excluding this study, suggested a small, though significant positive effect of SDM interventions on patients’ experienced relationship with their clinicians.

Although these results from post-intervention measures were promising, the longer-term effects of SDM interventions were unclear. The data from follow-up measures was limited in scope and difficult to interpret. Although there were indications of sustained benefits to subjective empowerment,\textsuperscript{19, 56} confidence in these effects was diminished by small sample sizes and large amounts of missing data. Also unclear was the effectiveness of future-oriented SDM interventions in reducing the duration of involuntary treatment. One study found a moderate positive effect\textsuperscript{51} that was then not replicated in
a further trial. Meanwhile, no significant effect of SDM interventions on treatment-related decision-making abilities was found.

1.4.2 Limitations and recommendations for future research

1.4.3 Study selection
Completion of the review as part of a Clinical Psychology Doctorate thesis placed limitations on the cross-checking of papers that was possible. Whilst consultation with supervisors on matters of inclusion took place, full duplication of study selection and associated negotiation in cases of disagreement was not possible.

1.4.4 Numbers of studies and design issues
The numbers of studies included in the meta-analyses were low. With use of random-effects analysis, this gives cause for uncertainty as to the between-studies variance and, as such, the results should be treated with caution. The results on our main primary outcome of ‘subjective empowerment’ and secondary outcome, ‘clinician-rated decision-making abilities and knowledge’, need also to be interpreted with caution due to inclusion of studies with cluster randomised design. This may have led to unrealistically precise estimates of effect for these trials and a possibility that they contributed disproportionately to the overall estimate of effect.

1.4.5 Quality of the evidence
Quality of the evidence was generally rated as low or very low due to imprecision in the estimate of effect, statistical heterogeneity and indirectness. Unclear or high risk of bias was also present in a number of areas. Improvements in the quality of future studies might therefore include rigorous and transparently reported procedures for randomising participants to treatment arms, concealing participant allocations, blinding assessors and accounting for effects of cluster randomisation. Trials also need to recruit samples of sufficient size to detect small to moderate effects and report clearly their methods of imputing missing data. Attention to gathering
adequate follow-up data would also contribute to more reliable, informative results.

Study quality was not downgraded due to risk of performance bias, since this is a pervasive and largely unavoidable issue in trials of psychosocial interventions. Nonetheless, trials might reduce the likelihood of this risk being compounded through provision of an adequate comparator condition, so controlling for the possibility that benefits of the SDM intervention are attributable to the increased input from professionals that participants might receive.

Publication bias was not formally assessed due to the small number of studies. Nonetheless, the non-response of four authors of unpublished studies to requests for information may have indicated a heightened risk of publication bias with possibility that our estimates of effect were inflated.

1.4.6 Heterogeneity
Some of the heterogeneity in our findings was almost certainly attributable to diversity in the types of SDM interventions evaluated, outcome measures employed, populations, treatment settings and control conditions. This heterogeneity reflects both the exploratory nature of our review in this emerging area of research, and the broad model of SDM that it has been argued is necessary to meeting the needs of individuals with psychosis. As the body of research into SDM interventions for psychosis develops, reviews of particular areas of intervention with greater specificity may be possible and helpful.

Heterogeneity notwithstanding, however, all the included studies shared a focus on enhancing the patient-clinician relationship through improved communication, with the ultimate aim of promoting collaborative decision-making around care and treatment for psychosis. This common focus would seem to be crucially important given patient preferences for working in partnership with clinicians on treatment decision-making and evidence to
suggest that there may be considerable barriers to this. Colombo et al\textsuperscript{68} found that patients and clinicians frequently espouse contrasting models of mental disorder, posing a threat to reciprocity in decision-making.

1.4.7 Social and service-level influences

Such models are likely to be embedded in the social and service contexts within which this body of research is developing. Thornicroft et al\textsuperscript{62} concluded from qualitative data in their study that the service context may have contributed to its failure to replicate the findings of Henderson et al\textsuperscript{51} exploratory trial. It appeared that implementation of their joint crisis plan intervention was undermined by low levels of staff understanding and sense of ownership. Hamann et al (2006)\textsuperscript{19} suggested similarly that physicians in their study may have struggled to integrate SDM with what was described as their ‘paternalistic role’. It seems that SDM may represent a significant challenge to the implicit medical model within which it has been suggested that many mental health professionals operate.\textsuperscript{68} Recommendations in Thornicroft et al’s study of measures to support and train staff, and take account of the organisational context, are ones that might apply across SDM interventions. They resonate with Fitzsimons and Fullers\textsuperscript{6} assertion that empowerment interventions need to operate at different levels within a system to be effective.

1.4.8 Service user/provider relationship

Whilst SDM interventions appear to empower service users, they might also introduce discord into the relationship with clinicians where ‘trust in physician’ is reduced.\textsuperscript{56} As discussed above, however, the nature of a number of the items on the ‘Trust in Physician Scale’,\textsuperscript{60} suggests an underlying conceptualisation of ‘trust’ that tends toward ‘unquestioning acceptance of the doctor’s authority’. Measurement based on a more collaborative conceptualisation of the construct might be appropriate when evaluating the efficacy of SDM interventions. Attention may be needed, nonetheless, to the potential for SDM interventions to destabilise service user/provider relationships. Hamann et al (2011)\textsuperscript{56} reported findings suggesting that
intervention participants in their study were more skeptical about treatment than controls and that physicians found them more stressful to treat. There was consequently suggestion in this study also that provision of training for clinicians engaged in SDM may be helpful. It is possible that service users, likewise, might benefit from support to adjust to an altered dynamic in the relationship with clinicians resulting from SDM intervention.

1.4.9 Empowerment and decisional capacity
Within this relatively new area of research, our focus on empowerment seems to have been particularly novel. Direct evidence on this outcome did not exist; we found no completed study that measured empowerment directly. Given that involvement in decision-making is an important aspect of empowerment to service users and that empowerment is, in turn, so central to service users’ ideas about Recovery, this might seem surprising. It may be that the most widely accepted existing measures of empowerment are limited in their usefulness to evaluate SDM interventions. It has been suggested that the Empowerment Scale may be insufficiently sensitive to change. The Mental Health Confidence Scale, meanwhile, may be unsuited to capturing the social aspects of empowerment that might be addressed by SDM associated with psychosocial interventions. Research to develop and evaluate appropriate measures of empowerment may therefore be helpful alongside that investigating SDM.

The low level of direct measurement of decisional capacity was also unexpected, given prominence of the issue in healthcare policy. Hamann et al (2006) identified pressures of service context as a reason for not including a validated measure of capacity in their study. Given failings in implementation of the Mental Capacity Act (2005) identified by a House of Lords Special Committee Report, it seems likely that routine assessment of capacity is not generally part of service culture. The developing body of research into SDM with psychosis might therefore have an important part to play in much needed culture change. This might be more readily effected where studies are able to demonstrate improvement on validated measures
of decisional capacity such as the MacArthur Competence Assessment Tool-Treatment (MacCAT-T).\textsuperscript{79} Commentators\textsuperscript{80} and patient perspectives\textsuperscript{81, 82} have, however, suggested limitations to the way that capacity is conceptualised and measured, with neglect of patients' emotions, values, life experience and of contextual factors. Continuing development of SDM research might therefore benefit from parallel work to develop a more comprehensive understanding of decisional capacity.

Overall, the promising results of this review need to be treated with some caution, given the low quality of the evidence. However, with studies of improved quality that support participants appropriately and take account of the service context, there is scope for SDM research to be part of a sea change in the treatment of individuals with psychosis. Together with development and implementation of appropriate measures of decisional capacity, empowerment and service user/provider relationships, there is potential to effect change in the paternalistic culture that seems to persist within mental health services,\textsuperscript{83, 84} and to address outcomes of primary importance to service users.

References


‘You’re ill, you need treatment and you may never get better’. Service users’ experience of treatment decision-making with psychosis: a qualitative study

Prepared in accordance with the author guidelines for Social Science and Medicine
(see Appendix 3)

Word Count: 8,409 words including references; 7,500 words excluding references

62
Abstract

Individuals with psychosis are frequently judged to have reduced treatment decision-making capacity (TDMC) and consequently may suffer adverse effects of involuntary treatment. The conceptualisation of capacity contained in the Mental Capacity Act (2005), and on which assessments are based, has been judged to be limited, with suggestion that insufficient weight is given to the role of emotions, values, experience and situational context. To date there is little research into the concept of decisional capacity with psychosis. Our study sought to develop understandings of TDMC with psychosis by exploring in depth service users’ experiences of treatment decision-making (TDM) situations using Interpretative Phenomenological Analysis (IPA). We conducted semi-structured interviews with seven service users with experience of treatment for psychosis in the Northwest of England. Four themes were identified, connected by an overarching theme of empowerment. They concerned not being listened to; influence of psychosis-related experience; being inadequately informed and supported; and influence of a Recovery orientation. Disempowerment seemed to exist at multiple levels from the intra-psychic to the socio-political. The need to listen closely to individuals with psychosis during TDM, with awareness of unequal power dynamics and unhelpful, taken-for-granted meanings around psychosis, is recommended. Further qualitative and quantitative research is needed to extend models of TDMC and explore the implications for intervention.

2.1 Introduction

Mental capacity is a legal/philosophical term that refers to the ability to make a particular decision, which may be impaired with illness, injury or disability. Assessment of capacity under the Mental Capacity Act (MCA, 2005) involves determining abilities to understand, retain, weigh up and communicate information relevant to the decision. In cases of incapacity, others may act without the individual’s consent ‘in their best interest’. Professionals must
first, however, make all reasonable efforts to help the person increase their decision-making capacity (Mental Capacity Act 2005: Code of Practice, 2007).

Capacity may be compromised with experience of psychosis, which might include positive symptoms (hallucinations; delusions; disordered thinking or behaviour) and negative symptoms (flattened affect; avolition). Psychotic symptoms may be associated with a number of diagnoses, one of the most common being schizophrenia. This frequently involves significant impairments to social and occupational functioning, and more than 50% of psychiatric in-patients with this diagnosis have been judged to lack capacity (Okai et al., 2007). Decisions to undertake compulsory treatment in such cases may involve negotiation of complex and challenging issues.

Nonetheless, patients may experience negative outcomes such as feelings of disempowerment (McDaid & Delaney, 2011), perceived coercion and social disadvantage (Priebe et al., 2011).

Whilst treatment decision-making capacity (TDMC) is a relevant issue in the treatment of psychosis, the scope of research into its meaning, determinants and related intervention is limited. One focus has been identification of correlates of reduced capacity in schizophrenia, which include positive and negative symptoms, medication non-adherence or refusal and poor ‘insight’ (Candia & Barba, 2011; Okai et al., 2007). Research has also evaluated educative interventions associated with a range of conditions and treatments, finding some benefits (Desplenter, 2006; Dunn & Jeste, 2001; Xia, Merinder, & Belgamwar, 2011). Few studies, however, have focused specifically on understanding TDMC in psychosis, although findings from one recent study suggested that group metacognitive training might improve cognitive processing of treatment-related information (Naughton et al., 2012). Individuals’ appreciation of the personal impacts of treatment decisions, however, remained unchanged.
Similarly, in the broader TDMC literature, the role of emotions, values and beliefs in TDMC has yet to be fully investigated (Eyler & Jeste, 2006). Conceptualisations of capacity in the academic literature, which inform standardised assessment tools, are generally cognitive in focus. For example, Breden and Vollmann’s (2004) critique of the MacArthur Competence Assessment Tool-Treatment (MacCAT-T) (Grisso & Appelbaum, 1995), which measures competencies analogous to those assessed under the MCA, noted an emphasis on de-contextualised, rational cognitive abilities.

Arguably, a cognitive orientation could be helpful when considering the decisional capacity of individuals with psychosis, given the prevalence of systematic reasoning biases (Broome et al., 2007). Long established models of psychosis, however, emphasise the interaction of cognitive disturbance with emotional distress and adverse social experience, impacting on ways in which individuals make sense of the world (e.g. Garety, Kuipers, Fowler, Freeman, & Bebbington, 2001). Broadening conceptualisations of capacity to incorporate a wider range of influences may, therefore, be helpful for service users with psychosis.

This view is supported by research into service users’ experiences and values. Wharne, Langridge and Motzkau’s (2012) study, exploring experiences of individuals with psychosis in the healthcare system, suggested the need to consider how their history of adversity might influence their decision-making, experience of trauma being common (Mueser, Lu, Rosenberg, & Wolfe, 2010; Varese et al., 2012). Service users have also highlighted the influence of the TDM context on their TDMC, including situational stress and emotions, the quality of professionals’ interactions and the range of treatment options available (McDaid & Delaney, 2011). This perspective exemplifies a social model, where TDMC is seen as emerging from the interaction of the person and their environment, rather than residing predominantly within the individual (McDaid & Delaney, 2011). Meanwhile, the importance of considering individuals’ values in TDM is highlighted with
consideration of a Recovery perspective, as conceptualised by service users. This emphasises the pursuit of valued life goals and personal priorities in treatment (Pitt, Kilbride, Nothard, Welford, & Morrison, 2007; Wood, Price, Morrison, & Haddock, 2010).

Progress toward more holistic conceptualisations of TDMC with psychosis would therefore seem to be helpful, as has been recognised within psychological guidelines (British Psychological Society, 2006). Colombo et al (Colombo, Bendelow, Fulford, & Williams, 2003) suggest, however, that a Medical Model tends frequently to dominate treatment for psychosis, within which problems are conceptualised as ‘symptoms’ within the person to be ‘treated’ by ‘experts’. In this context TDMC is more likely to be seen as a within-person, cognitively oriented ability, with the risk that influence of the individual’s emotions, values and lived experience and the TDM context may be neglected. Paradoxically, medical treatment with antipsychotic medications may affect TDMC by dampening both cognitive abilities and individuals’ emotional experience and motivation (Moncrieff, Cohen, & Mason, 2009). Tan et al (Tan, Hope, Stewart, & Fitzpatrick, 2006) have highlighted also how experience of particular mental health problems might influence TDMC in idiosyncratic ways. It seems important therefore to explore specifically, and in depth, experiences of TDM among those with psychosis in seeking a more comprehensive understanding of TDM and TDMC for this population.

Interpretative Phenomenological Analysis (IPA), a qualitative method that uses in-depth, semi-structured interviews, would seem highly suited to this purpose. It seeks a detailed ‘insider perspective’ on the phenomenon of interest (Conrad, 1987) and recognises the contribution of cognition, affect and the social context to individuals’ sense-making (Smith, Flowers, & Larkin, 2009). Whilst IPA is an idiographic approach, it does not preclude generalisation (Smith et al., 2009). It conceptualises idiographic enquiry as being a study of the particular phenomenon rather than necessarily the individual, and the person as being intrinsically interconnected to others and
the world, which allows for drawing of tentative generalisations. Using IPA, the present study seeks to investigate how service users with psychosis experience TDM situations. In-depth exploration of their reflections on this experience may yield helpful insights into possible influences on TDMC and ways of promoting the prioritisation of service users’ values and goals in TDM.

2.2 Method

Ethical approval was obtained from the National Research and Ethics Service and from the Research and Development Departments of two National Health Service (NHS) Trusts in the Northwest of England. (Appendix 4.)

2.2.1 Design

IPA was employed to explore service users’ experience in relation to TDM. This method involves the researcher’s interpretative perspective in making sense of the participants’ sense-making (Smith & Osborn, 2003). Information about the researcher’s background may therefore be helpful. Prior to training in Clinical Psychology she undertook a Psychology degree with the Open University where there is an orientation towards critical social psychology. This background inspired a particular interest in how human experience might be situated within, and shaped by, social discourses and practices, and their associated power relations (Holloway, 2007). The researcher also worked in an acute in-patient psychology service that prioritised Recovery-oriented ways of working. This involved particular emphasis on patients’ empowerment through promotion of choice and control in relation to how they sought to make sense of and manage their mental health-related experience. Collectively, these influences on the researcher engendered a particular interest in issues of empowerment around treatment for psychosis.
2.2.2 Recruitment and Participants

In keeping with IPA methodology, a small homogenous sample was sought (Smith et al., 2009). Inclusion criteria were being 18-65 years old, having experience of treatment for a schizophrenia-spectrum condition and the ability to share in-depth reflections on this experience in English. Exclusion criteria were being currently in crisis or receiving in-patient care, experiencing psychosis that was primarily organic in origin or substance-induced, having a moderate-to-severe learning disability and lacking capacity to consent to take part.

Eleven individuals with experience of treatment for psychosis were recruited, but the interviews of only seven were analysed (see below). Of the participants whose interviews were included in the analysis, all were white British. There were four males and three females with a mean age of 49.1, range 38 to 58 years. Six were involved with a Community Mental Health Team (CMHT) and one was receiving only out-patient psychiatric care. None was in paid employment and all but one were single. Five had been hospitalised with psychosis at least once. (See Table 4.)

CMHTs were prioritised in recruitment with a view to achieving a homogenous sample with a wealth of TDM experience. Also approached, however, were an Early Intervention in Psychosis Team (EIT), voluntary mental health organisations and researchers on other NHS-approved, psychosis-related projects in the relevant Trusts. Referrers, both care coordinators and researchers, were informed about the project and provided with participant information sheets, which were also distributed to voluntary organisations, along with posters. The researcher visited several CMHTs and one voluntary organisation in person, presenting on the aims of the study, detailing the inclusion/exclusion criteria and answering people’s questions about the project. Decisions about which CMHT service users might be approached thereafter were at the discretion of care coordinators. Possibilities to visit particular teams or organisations depended on managers’ responses to requests to arrange this. Researchers on other
relevant NHS-approved projects were informed about the study by email and/or approached informally by one of the researcher’s supervisors. Referrers sought the consent of interested potential participants to be contacted by the researcher. Self-referrals were invited from the voluntary organisations. Each participant gave written, informed consent and received £10 to cover expenses and inconvenience. (Appendix 5.)

2.2.3 Procedure
The researcher conducted a semi-structured interview lasting one-to-two hours with each participant, either at their home or on NHS premises. In developing the interview schedule she considered topic areas of seeming importance to service users with psychosis, derived from the findings of a service user focus group on TDMC and her own experience of talking with service users about TDM. Literature relating IPA philosophy and epistemology to interview methods (Smith, Flowers & Larkin, 2009), and experienced qualitative researchers were consulted. The interview schedule was piloted and further refined with the help of a service user researcher who has experience of IPA methodology. It consisted of open-ended questions about participants’ experience of TDM situations, where they had had both greater and lesser degrees of input. It included questions about their feelings; sense-making; coping; influence of symptoms; helpful and unhelpful aspects of experience; and sense of self and others. A summary interview schedule was used flexibly, so allowing participants to elaborate on aspects of experience of importance to them. (Appendix 6.)

The interviews were recorded and transcribed verbatim by a university administrative assistant, leaving wide margins for analysis. The researcher kept a reflective diary throughout the research process.

2.2.4 Analysis
It was necessary to exclude two interviews due to participants’ inability to provide in-depth reflections on their experience of TDM: the responses of one bore very little relation to the topic of TDM about which he was being
asked, and the responses of the other were very minimal indeed. A further participant was excluded because he had virtually no experience of TDM for psychosis; he had only very recently been referred to the EIT. The quality of such data as there was from this participant was further impoverished by many distracting interruptions during the interview. These three participants, therefore, did not fully meet two of the inclusion criteria, namely, having experience of treatment for a schizophrenia-spectrum condition and the ability to share in-depth reflections on this experience. A fourth interview was excluded due to insufficient clarity of speech for transcription.

IPA analysis requires that researchers immerse themselves in participants’ narratives (Smith et al., 2009). Beginning with the first participant, therefore, the researcher listened to the recorded interview and read the transcript a number of times. The wide margins were then used for initial commenting on any points or features of seeming significance, followed by noting of emergent themes. These were printed out on separate pieces of paper and iteratively grouped and re-grouped until clusters of themes emerged that seemed to capture the essence of the participant’s meanings. These were then organised under super-ordinate theme headings. The super-ordinate themes and sub-themes were arranged in a table and files of transcript excerpts illustrating each theme were constructed.

This process was repeated with each participant’s transcript. Incrementally, participants’ tables of themes were combined, initially using colour coding, to distinguish between participants, and processes of grouping, abstraction and subsumption. Areas of similarity and difference were sought, along with connections and patterns at different levels of abstraction. Illustrative quotations, colour coded to distinguish between participants, were also included in this process. In-depth, three-way discussions with supervisors, using these materials, were part of the process of distillation and refinement of the themes. Their number was gradually reduced and their names negotiated to reflect the essential meanings and messages thought to be emerging from the analysis. Ultimately, a table of super-ordinate themes and sub-themes was generated for the group as a whole. Each theme was
illustrated with colour-coded quotations, drawn from transcripts from across the participant group. (See Appendix 7 for examples of materials illustrating the process of analysis).

IPA methodology advocates moving iteratively between the part and the whole of participants’ narratives (Smith et al., 2009). The researcher therefore returned at intervals to re-reading complete transcripts, checking that the analysis remained grounded in participants’ experience. To ensure transparency in the analysis, decision-making and analytic procedures were recorded throughout. Validity of the analysis was supported, as above, through detailed discussions in supervision, and reference was made to guidelines for promoting the integrity of qualitative research (Elliott, Fischer, & Rennie, 1999).
<table>
<thead>
<tr>
<th>Participant number</th>
<th>Age</th>
<th>Gender</th>
<th>Ethnic background</th>
<th>Marital status</th>
<th>Employment status</th>
<th>Current level of care</th>
<th>Duration of psychosis (years)</th>
<th>Experience of mental health system</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50</td>
<td>Male</td>
<td>White-British</td>
<td>Single</td>
<td>Unemployed</td>
<td>CMHT</td>
<td>30</td>
<td>3 hospitalisations, (one very lengthy), experience of 4 antipsychotics, community care for past 10 years.</td>
</tr>
<tr>
<td>4</td>
<td>46</td>
<td>Male</td>
<td>White-British</td>
<td>Single</td>
<td>Unemployed</td>
<td>CMHT</td>
<td>20</td>
<td>Never hospitalised, experience of 6 antipsychotics.</td>
</tr>
<tr>
<td>5</td>
<td>38</td>
<td>Male</td>
<td>White-British</td>
<td>Single</td>
<td>Unemployed</td>
<td>CMHT</td>
<td>12</td>
<td>3 hospitalisations, all under section, 1 antipsychotic throughout.</td>
</tr>
<tr>
<td>6</td>
<td>58</td>
<td>Male</td>
<td>White-British</td>
<td>Single</td>
<td>Unemployed</td>
<td>CMHT</td>
<td>30</td>
<td>8-9 hospitalisations, 2 under section.</td>
</tr>
<tr>
<td>7</td>
<td>46</td>
<td>Female</td>
<td>White-British</td>
<td>Single</td>
<td>Unemployed</td>
<td>Psychiatric out-patient</td>
<td>24</td>
<td>Service involvement for 14 years, 2 hospitalisations, both under section.</td>
</tr>
<tr>
<td>8</td>
<td>51</td>
<td>Female</td>
<td>White-British</td>
<td>Single</td>
<td>Unemployed</td>
<td>CMHT</td>
<td>6</td>
<td>2 hospitalisations when young, service involvement since with different diagnoses.</td>
</tr>
<tr>
<td>10</td>
<td>55</td>
<td>Female</td>
<td>White-British</td>
<td>Married</td>
<td>Unemployed</td>
<td>CMHT</td>
<td>22</td>
<td>Never hospitalised, experience of numerous antipsychotics.</td>
</tr>
</tbody>
</table>
2.3 Results

Four themes resulted from the analysis, which were linked by an overarching theme of empowerment. The four themes were:

1. ‘Listen and engage with my experience. Respect and empower the person that I am.’
2. Experience of psychosis, its treatment and social meanings: ‘How I might be disempowered in TDM.’
3. ‘Empower me with knowledge, support and enablement to self-expression.’
4. ‘Support my Recovery through TDM.’

Each theme comprised between three and five sub-themes (Appendix 8).

Key for quotations: / denotes a second-long pause; underlining denotes emphasis.

2.3.1 Theme 1: ‘Listen, engage with my experience. Respect and empower the person that I am.’

Nearly all participants described feelings of disempowerment arising from a sense of not having been listened to with respect and compassion during TDM, and some had had similar experiences in relation to TDM systems and processes. By contrast, participants spoke very positively of experiences that stood out for them where they had felt heard and validated, often in their more recent treatment history.

Sub-theme 1(i): Importance of listening, validating and engaging with experience.

Participants’ experiences of disempowerment included feeling that professionals weren’t listening to them, didn’t believe them, didn’t take their distress seriously and ignored their viewpoint. Participant 8’s seeming experience of invalidation and denigration was typical:
I think he [psychiatrist] saw me as nothing, like a, like a / like I was just saying it // saying that like when I see things and he was like trying to make it out as if I wasn’t really… (Participant 8)

A number of participants noted the positive contrast when they did feel heard. Participant 10’s emphasis here reinforces this, with even a sense of incredulity:

...what a difference, what a difference. He used to consult about me medication...ask me how I’d found it, and he, he seemed as though he genuinely cared and was interested.... (Participant 10)

Sub-theme 1(ii): Need for respect, compassion and empathy.
All participants described TDM situations where they had experienced professionals as lacking in compassion. It seemed possible, at times, that the demands of the situation had reduced clinicians’ capacities for empathy, leaving participants feeling variously isolated, neglected, dismissed, degraded and even devastated on occasion. Respect and seeking a ‘human connection’ were seen as fundamentally important, with some valuing ongoing relationships with clinicians as the ideal context for TDM. The stress and sense of isolation described by Participant 1 typified experiences of situations where compassion was seemingly absent:

...they were just making decisions. // There were no warmth...there were just no emotion... it was stressful you know, very stressful...sometimes I just felt like a // like an effigy, you know in the corner… (Participant 1)

Sub-theme 1(iii): Counter disempowerment by system and process.
A number of the participants recounted feelings of disempowerment through being subsumed within what they experienced as a de-humanising treatment system. Some felt that their autonomy and rights were undermined. Participants said variously that they felt ‘insignificant’, ‘like being in a lost parcel department’, like ‘some alien patient in the corner’ and ‘an outcast’ (respectively, Participants 1, 6 and 4). Participant 8 captures the essence of this seemingly felt sense of disempowerment:
...sent pillar to post, you know like that was going here, trying to get help there and they were sending me back there and he wasn't listening to me and then I was sent to somewhere, and I, I thought, I don't know what, what's going on. (Participant 8)

Sub-theme 1(iv): Counter feelings of subjective disempowerment.
Most participants described having experienced a profound sense of subjective disempowerment within TDM situations. The most notable examples were in descriptions of tribunals, being sectioned or having been turned away from services when feeling suicidal. Participants described feelings variously of fear, intimidation, isolation, bewilderment and withdrawal, with some even reporting that their experience had felt abusive. Some described over-estimation of their coping resources to the extent that they were left feeling hopeless and dangerously vulnerable. As participants struggled to make sense of this, some described clinicians seemingly at the limits of their personal and professional resources. Participant 7’s description of her response to being sectioned typifies the felt sense of devastation evoked by these experiences:

Erm, so, I coped in the hospital with feeling of // being sort of like, bashed over the head and told I’m hopeless at living life, that’s how it felt, and I withdrew, and I became numb. (Participant 7)

2.3.2 Theme 2: Experience of psychosis, its treatment and social meanings: ‘How I might be disempowered in TDM.’
Experience of psychosis seemed to affect TDM situations for participants both directly, via symptoms and medication; and indirectly, with influence of past treatment experiences and beliefs, negative social meanings around psychosis, a sense of low self-worth and a sense of being negatively judged by others.
Sub-theme 2(i): Reduction in agency and self-efficacy with distressing psychosis.

Direct influences of psychosis that seemed to reduce participants’ agency and self-efficacy in TDM situations included the severity of their distress, undermining influence of hallucinations, feeling physically unwell and effects of medication. Striking examples of participants’ apparent sense of disempowerment included those where psychotic experience seemed to compound other vulnerabilities. Participant 8’s hallucinatory experience, for example, appeared to exacerbate a felt sense of invalidation that seemingly pervaded much of her TDM experience:

…he [auditory hallucination] used to say, he [psychiatrist] don’t believe you… I was getting upset about it, ‘cos I thought, is this really happening and no one believes me… (Participant 8)

Elsewhere, the effects of medication appeared paradoxically to compromise individuals’ capacity to influence further treatment decisions:

I was on powerful medication… it just took away me emotions… I just had eyes, you know, that’s all I had…, I’d lost me body, you know, lost me everything, just me eyes looking… there were no feeling, there were no, no reaction, no push and pull… (Participant 1)

Sub-theme 2(ii): Influence of treatment-related experiences and beliefs.

Participants’ approach to TDM seemed frequently to be influenced by their past experiences of, and beliefs about, treatment. These included aversive, even traumatic treatment experiences; beliefs about the nature of symptoms and the appropriateness of treatment; and experience of limited treatment options. The links between participants’ experience and approach to TDM in some instances seemed clear, such as where past trauma seemed to undermine trust in professionals. With some, however, there appeared more complexity. Participant 4, for example, expressed ambivalence about starting Clozapine, seemingly associated with a paradoxical mix of resignation, resistance and desperation.
I suppose they have saved me life in many respects, but I don’t know, anti-psychotics, they’re not brilliant. They talk about putting us on Clozapine...I’m not anti it...anything that take away some of them symptoms...but it’s really quite hard hitting drug, so you’re into all the reservations to some degree...I’m quite happy to go with the flow...I just want to be better really. (Participant 4)

Close engagement with the sub-text of Participant 4’s broader narrative was necessary in seeking to understand this. He suggested throughout that services did not meet his needs, but there were many indications also that he struggled with the assertiveness needed to address this. The seeming conflict expressed here between acquiescence and tentative resistance seems characteristic of this participant’s relationship with services.

Sub-theme 2(iii): Power of negative constructions of mental illness.

Participants articulated many ‘taken-for-granted’ meanings or social constructions concerning the nature of psychosis, which might have a disempowering influence within TDM. They made associations between psychosis and being ‘not normal’, a ‘basket case’, a ‘nutter’ and ‘a danger’ (Participants 4, 10 and 7). In some instances, there seemed clear disempowering consequences of such constructions. Participant 8’s diagnosis, for example, deterred her from raising her concerns about treatment, believing that her ‘label’ would preclude them from being taken seriously. The disempowering effects of social constructions seemed more insidious, however, where their taken-for-granted nature might mean that they would go un-noticed and unchallenged. Participant 10, for example, seemed to experience as positively noteworthy her psychiatrist treating her with the respect that he would afford anybody else. This might suggest an implicit low baseline of expectation with regard to collaborative TDM.

I think he thought I wasn’t a basket case and I did have some sort of intelligence... and erm, we just conversed, er, like you know with someone you meet on the street. (Participant 10)

Having a sense of low self-worth might seem unsurprising where individuals are subject to such social constructions. There seemed discernable influence of this at different levels on TDM for most participants. Notable, however, was that it was much more immediately apparent for some than others. For Participant 8, for example, it seemed to have very clear impacts on her low level of assertiveness in pursuing the treatment she needed.

...I don't want to be a burden, I don't want to be where they've got to come and they don't really want to talk to me. And then I just say, oh leave it then, and I just have to cope with it meself. (Participant 8)

In contrast, for Participant 1, a seeming deep level of shame associated with psychosis was much slower to emerge. He delayed considerably discussing a decision to seek treatment, which he described as having reinforced a shaming illness identity that he felt was undermining of his recovery. Unsurprisingly, he described having been reluctant to seek treatment. There also appeared to be a complex relationship between an apparent sense of low self-worth and TDM with Participants 4 and 10. Both seemed to value very much social aspects of their encounters with professionals and to be keen to present a confident persona. Only late in their interviews did they reveal fundamental unmet needs that they had expressed only tentatively or not at all in clinical encounters, such as Participant 4’s wish to discuss psychotherapy:

R: You've mentioned a few times about not being offered psychotherapy...and that sounds like it's quite important to you...

P: Well, you see the thing is, I've mentioned it a few times, not like banged on any doors, but I've mentioned, it's never been offered, it's never really been discussed... (Participant 4)

It seemed that the presence of avoidance and defenses linked to stigma and a sense of low self-worth may have impeded these participants in getting their needs met in TDM.
Sub-theme 2(v): Sense of being negatively judged by others.
Suggested influence of negative social constructions seemed latent also in participants’ perceptions of professionals’ judgements about them. Some participants described a sense of being negatively judged in relation to their actions, choices and capabilities associated with TDM. There were suggestions that what might be seen otherwise as ‘normal’ choices were pathologised due to the presence of psychosis. Conversely, psychosis-induced action seemed to have been judged by the same standards as that not so influenced. Such perceived judgements, perhaps interacting with a sense of low self-worth, seemed adversely to affect some participants’ confidence and feelings towards clinicians during TDM. Of particular pertinence was Participant 7’s implied suggestion that decisional incompetence might be assumed in someone experiencing psychosis.

I think on first meeting someone, erm, a more thorough investigation should be done into what their belief system is and whether or not they // they are coherent. I was coherent, I was just, erm, psychotic at the same time as well. (Participant 7)

2.3.3 Theme 3: ‘Empower me with knowledge, support and enablement to self-expression.’
There was a sense among participants’ narratives that a source of disempowerment in TDM lay in being inadequately informed or supported, and in difficulties communicating their needs to clinicians. This appeared to exist in the context of unequal power dynamics that, whilst suggesting a possible contributory factor to the problem, might also make it difficult to address.

Sub-theme 3(i): Power dynamics in TDM from the implicit to the coercive.
Suggestion of unequal power dynamics emerged at a number of different levels within the narratives. Participants expressed variously the view that psychiatrists hold immutable power, have authority over their patients, are of
higher status and are the main drivers of TDM. Participant 1 said, for example:

...that's the decision they make. You can't influence 'em, or else, there'd be corruption wouldn't there? (Participant 1)

As with the social constructions of psychosis described above, some sense of these dynamics came through implicitly in participants' language use. This suggested their operation at unconscious levels such that they might go unnoticed and unchallenged. Participant 4’s tentative tone below, for example, suggested that he might feel any input he had in TDM to be a concession.

I go and see Dr [psychiatrist]...and they're nice with me...almost with a bit of like, you know, like you've got a bit of input if necessary...So you've got almost like some sort of influence.... (Participant 4)

Elsewhere, however, these dynamics were described as having been experienced at an explicit level. There was mention variously of 'that barrier with the doctor'; being 'palmed off'; being 'overridden'; being 'completely at your [psychiatrists'] mercy'; being 'dictated to'; and that 'doctors are supposed to know best' (respectively, Participants 1, 8, 7, 6, 4 and 5). Three participants also described experience of coercion, as typified by Participant 7:

...it was either [participant's name] you've got three days, it's either an injection or you take your medication, so I took it... (Participant 7)

Sub-theme 3(ii): Disempowerment with knowledge imbalance and lack of support.

Against this seeming background of multi-layered, unequal power dynamics there was a sense of participants being disempowered specifically through a lack of information and support. Knowledge that they felt was kept from them included the content of multi-disciplinary discussions about them; the rationale for decisions; and information about psychosis, medication and other treatment options. Contributory factors to this seemed on the one hand to include the protocol of formal TDM situations, invalidation of participants’ concerns about treatment and assumption of the primacy of doctors’
knowledge over participants’ expertise about themselves. On the other hand, there were factors that seemingly undermined participants’ possibilities for accessing further information. These factors included fear and agitation on the part of participants, unquestioning trust in professionals and apparently taken-for-granted acceptance of not being fully informed about treatment. Thus a disempowering knowledge imbalance appeared woven into the very fabric of TDM encounters. It seemed to operate both at implicit, taken-for-granted levels and at levels whereby it was keenly felt:

I thought, really they should be saying we think you need this medication. Not go and pick your own …I didn’t know what psychosis was, didn’t know what antipsychotic drugs was, didn’t know any of that. I still don’t really know what antipsychotic drugs are. (Participant 8)

Sub-theme 3(iii): Importance and challenge of self-representation.
Most participants’ narratives contained suggestion that being able to communicate their needs to clinicians in TDM situations was very important, but also frequently challenging. Apparent reasons for this difficulty included distress associated with symptoms of psychosis, effects of medication, low levels of assertiveness and difficulties with self-expression, associated possibly with curtailed life chances. The spectrum of associated difficulties for participants ranged from misunderstandings about treatment preferences to problems communicating distress and suicidality. In the context of unequal power dynamics, however, discerning cause and effect in problems of communication seemed difficult. Two participants spoke of being turned away from services repeatedly when in crisis, a problem that was ameliorated by having someone else speak for them in each case. The reasons for the greater credibility afforded to their advocates were probably multiple and complex. Unambiguous, however, were the devastating consequences of failed communication for one participant particularly:

R: What’s it like ...?
P: To be turned away?
R: Mmm
P: Well, you’re pretty much at a loss really/// I tried to commit suicide...
(Participant 6)
2.3.4 Theme 4: ‘Support my Recovery through TDM.’

A notable dimension on which participants seemed to vary in their approach to TDM was in their degree of Recovery orientation, that is, in how far they sought autonomy, looked beyond purely medical solutions to their problems, prioritised their values and goals and maintained a hopeful outlook.

Sub-theme 4(i): Negotiating barriers to autonomy.
All participants expressed preferences for at least some level of autonomy in their treatment. Where they varied greatly was in their approach to, and effectiveness in, bringing this about. Two participants had a particularly strong Recovery orientation. Participant 7 had a like-minded psychiatrist who supported her choice of primarily non-medical options in pursuit of well-being. Participant 1, meanwhile, exercised considerable autonomy in pursuit of Recovery-oriented life goals. He had had no say, however, in medical intervention over a long treatment history, during which he had experienced considerable constraint. The extent to which this had limited his perceptions of possibilities for seeking agency in his medical treatment was unclear. Participants 4 and 8, meanwhile, seemed constrained in their pursuit of Recovery-oriented intervention by low levels of assertiveness and support. Participant 10 differed from the others in prioritising exercise of autonomy within the medical system whilst showing little interest in pursuit of Recovery-oriented life goals. Despite this heterogeneity, experience that seemed common to a number of participants was that of disempowerment where TDM was out of step with their preferences for managing their well-being, as was the case for Participant 7 when she was sectioned:

*I prefer independence and, taking some form of action to resolve and feel comfortable with me, within myself, and // all of that was ignored.* (Participant 7)

Sub-theme 4(ii): Power of the Medical Model
A key influence on participants’ level of subjective empowerment appeared to be their relationship to the Medical Model. Two participants had seemed,
at times, to share with their psychiatrists an assumption that medication was an appropriate default option for managing distress. Participant 10 seemed to find a sense of security within the medical framework. She expressed priorities in life to feel ‘warm’ and ‘safe’ and spoke positively of a psychiatrist who ‘looked after’ her. Participant 8’s narrative, however, suggested that she was prone to low self-efficacy and had become accustomed to turning to medics to manage her distress. Whilst she had expressed interest in psychosocial intervention, services had been slow to respond, seemingly disempowering her through failing to support a Recovery orientation. Generally it appeared that the Medical Model prevailed unless participants exercised considerable personal resources to resist. For those who perceived limitations to the Medical Model but struggled to summon such resources, there was potential for frustration and hopelessness:

...what can you achieve with an half hour chat with somebody who’s like really medically qualified?...It’s handy to have that safety net, but in terms of actually making you better // it isn’t really is it? (Participant 4)

Sub-theme 4(iii): Seeking treatment congruent with values and goals
All participants spoke about their values and goals in relation to TDM. Here again their level of subjective empowerment appeared to be related to the degree to which services took account of them. Some participants reported their preferences having been seemingly completely overridden in in-patient settings. In contrast, Participant 1 described a sense of considerable empowerment achieved through being supported by services to realise his goals. This seemed to have involved some measured weighing of his needs and strengths against the risks:

I passed me English language...it’s best thing I’d ever done...for the staff to let me // express meself and for them to put faith in me to go to college...it’s that freedom again..... (Participant 1)
Sub-theme 4(iv): Hope, an influence and an outcome in TDM

...when you’re crumbling //...you don’t need to receive the message that it’s always going to be the status quo, where you are now...everybody’s got the ability to get better, really, and it would be nice to be told that... (Participant 7)

All participants reported feelings of hopelessness within their experience of TDM. These were induced variously by highly restrictive decisions made entirely by others, negative messages imparted by clinicians (as above), non-delivery of a promised support worker to enable community access, limited intervention options and persistently being offered treatment that was antithetical to the participant’s understanding of his experience. Participant 7 (as above) had clearly found ways to counteract this hopelessness and other participants varied in the degree to which this seemed to be the case. Participant 6 noted how hopelessness, induced by traumatic treatment experiences, had been an influence on subsequent encounters with clinicians, with potential to influence TDM. Conversely, positive clinical encounters had induced hope in Participant 4 that it was possible for him to recover. Sadly, however, he described also hope as being limited by paucity of offered intervention options.

... [sigh] at the moment, services, it’s like damage limitation really...[sigh] I’m under no illusions that I might [inaudible] and recover or get better... (Participant 4)

Hope seemed therefore crucial, yet vulnerable to a host of influences within TDM.

2.4 Discussion

2.4.1 Summary of findings relating to participants’ experience

Empowerment emerged as an over-arching theme from the analysis. All participants described experiences of disempowerment where they felt that they were not listened to, validated or treated with compassion and respect. Exceptions to this stood out in sharp relief, with participants describing very positively times when they had felt heard. Generally, however, participants’
experiences seemed embedded in unhelpful and disempowering social constructions of psychosis, and in unequal power dynamics wherein they might have little say, be insufficiently informed or supported and, at worst, experience feelings of being neglected, abused or coerced. In such instances, experience of disempowerment was explicitly expressed. At other times, however, disempowering social influences emerged implicitly in participants’ use of language, such that they might go unseen and unchallenged. Effects of psychosis and medication seemed also to disempower participants where their abilities to communicate their needs were compromised.

Historic experiences of this kind seemed to have had a lasting psychological influence on TDM experiences, feeding variously into stigma, shame, a sense of low self-worth and trauma, with potential to affect adversely participants’ engagement with professionals. One participant, however, seemingly drew a sense of security from close engagement with the medical system. There were also stories of seeking empowerment with a Recovery orientation. This manifested in different ways and to different degrees, seemingly influenced by participants’ goals and values, past experience, relationships with clinicians, degree of support, levels of self-efficacy and relationship to the Medical Model.

2.4.2 Relationship of findings to study aims and existing literature
The rationale for the present study included dissatisfaction, expressed in the literature (e.g. Breden & Vollmann, 2004), with limitations to existing conceptualisations of TDMC. This literature draws attention to the importance of emotions, values, lived experience, and the TDM context in issues of TDMC, alongside considerations of cognition and rationality. Whilst the current study did not address issues of capacity directly, the findings are consistent with the view that models of TDMC might be enhanced with a more holistic approach. It added to the findings from previous studies, however, by suggesting that issues of power may also be important. It may be that the concept of TDMC in psychosis needs to be extended even...
beyond the social model advocated by McDaid and Delaney (2011) to encompass the power dynamics operating within the social context of TDM situations.

Examination of the ways in which our findings map onto conceptualisations of empowerment in the mental health literature suggests the considerable extent to which it may be necessary to broaden the MCA conceptualisation of TDMC beyond its predominant focus on within-person cognitive abilities. These conceptualisations of empowerment are variously multi-dimensional (e.g. Rogers, Chamberlin, Ellison, & Crean, 1997; Segal, Silverman, & Temkin, 1995), taking in intrapsychic, interpersonal and socio-political levels. Participants in our study appeared to experience disempowerment in TDM related to all three levels, reflected respectively in signs of a sense of low self-worth and self-efficacy; feeling not listened to; and with influence of unequal power dynamics and negative social constructions of psychosis.

Whilst there have been many policy initiatives seeking to empower patients in TDM at the socio-political level (e.g. Department of Health, 2012), our findings suggested, as have others’ (e.g. Hui & Stickley, 2007), that effects of these initiatives are not reflected in service users’ experience. Disempowering use of language (Hui & Stickley, 2007) and models of mental health problems espoused by service users and professionals (Colombo et al., 2003), both operating at implicit levels, have been suggested as contributory factors to service users’ continued experience of disempowerment. The apparent implicit influence of disempowering dynamics and social constructions found in our study seemed to accord with these findings.

A further contributory factor to levels of subjective empowerment experienced in TDM seemed to be the degree of congruence between participants’ and clinicians’ respective orientation to a Recovery or Medical model. Dominance of the Medical Model seemed to be experienced as disempowering where those who appeared inclined towards a Recovery
orientation were unsupported by clinicians and seemed to struggle to pursue their Recovery goals unaided. These findings accord with those of Colombo et al (2003) who found heterogeneity in the implicit models of mental health problems espoused by service users. Where their models were at odds with those of clinicians, service users seemed to experience disempowerment due to dominance of the Medical Model, generally espoused by psychiatrists, and to possibilities only for ‘soft resistance’ that was frequently pathologised and ultimately ineffective in changing the ‘status quo’.

2.4.3 Clinical implications
The need to listen very closely to patients during TDM was the principle message emerging from the analysis. Discernment of the disempowering influence on TDM of psychotic symptoms, past experiences, difficulties with self-representation and sense of low self-worth might require detailed, sustained engagement with their narratives. Close attention and responsiveness to service users’ degree of Recovery orientation may also be particularly important. Service users have reported that such responsiveness is, of itself, a source of empowerment and an aid to recovery (Grealish, Tai, Hunter, & Morrison, 2011).

It seemed from our study and others’ (Colombo et al., 2003) that clinicians themselves may be susceptible to the implicit influence of unequal power dynamics and negative social constructions of psychosis. Thus close listening to service users in TDM may require clinicians to question their preconceptions around psychosis. Principles of phenomenological enquiry may be helpful in this. Heidegger (1962/1927) advocates first paying close attention to the ‘thing itself’ and then considering the influence of our preconceptions. Meeting and engaging with the person first would seem to be an approach much in accordance with participants’ expressed needs. Doing so might then assist clinicians in stepping back from their assumptions.
Whilst work to integrate these ideas with formal models of capacity has yet to be done, their essence might usefully be incorporated informally into clinical practice.

2.4.4 Limitations and implications for research
Arguably, our study may have lacked specificity with regard to issues of decision-making capacity. This may have been a consequence of participants having had limited exposure to the concept within their experience of care. Given the primary aim of IPA to privilege participants’ experience (Smith & Osborn, 2003), emphasis on their issues of concern, such as not feeling listened to, seemed appropriate.

It was not possible, however, to include all participants’ interviews in the analysis and one included participant was under-represented in the write-up due to his minimal manner of expression. IPA assumes human capacities to share reflections on experiences of personal significance (Smith et al., 2009). It seems necessary to hold in mind those for whom this might not be possible, if their seemingly already-heightened propensity for disempowerment is not to be compounded by being rendered further invisible.

Our findings might also be argued to lack generalisability, given the study’s individual, qualitative focus. Resonance with findings in the empowerment literature, however, expands the case made above for the appropriateness of drawing tentative generalisations, based on IPA philosophy and epistemology. Nonetheless, given the highly homogenous sample and inclusion in the analysis of social meanings, the study’s cultural specificity should be acknowledged.

It is possible that the research adhered insufficiently to IPA principles. The researcher’s academic and clinical background may have contributed to a particular interest in implicit workings of power and psychological influences on TDM, at the expense of participants’ phenomenological experience. She
was aware of being very much moved by participants’ reported experiences of disempowerment, and of a sense that this was a fundamentally incapacitating influence for them within TDM. Balance in the analysis was sought, however, in supervision with two expert IPA researchers, respectively from the disciplines of health and clinical psychology, who read some of the transcripts and advised on the emerging analysis. IPA literature was also consulted where there is support both for taking account of the influence of social construction of human experience (Ashworth, 2003), and for use of one’s ‘interpretative resources’ (Smith, Jarman, & Osborn, 1999). Reflexiveness and returning iteratively to participants’ transcripts also supported attempts to remain appropriately grounded in their experience.

Overall, our findings supported views expressed in the literature that development of models of TDMC might helpfully take account of individuals’ emotions, values, experience and the TDM context. They suggested, in addition, the importance of recognising the power dynamics and taken-for-granted meanings within TDM situations. Methodologies such as Foucauldian Discourse Analysis and Grounded Theory might be employed in development of models that integrate these factors with existing cognitive conceptualisations of TDMC. Quantitative methods, meanwhile, might support the development of a self-report measure, reflecting the key themes to have emerged from the present study, with a view to assessment and enhancement of TDM experience for service users with psychosis.

References


Critical Reflection

Word Count: 6226 words, excluding references
3.1 Thesis context

Treatment decision-making (TDM) with psychosis is a subject area in relation to which there have been some significant legal and policy initiatives in the past decade. The Mental Capacity Act (MCA) (2005) brought into legislation practice to protect the rights and welfare of persons vulnerable to loss of decisional capacity. Shared decision-making (SDM) has also loomed large on the healthcare policy agenda (Department of Health, 2007, 2012). It seems, however, that neither development has delivered for service users with psychosis in ways that might have been hoped. A recent House of Lords Select Committee Report concluded that adherence to the practices set out in the MCA (2005) has been poor (House of Lords Select Committee on the Mental Capacity Act 2005, 2014). Progress in promoting SDM, meanwhile, has been very much slower in mental health than in physical healthcare (Schauer, Everett, del Vecchio, & Anderson, 2007).

This might seem unexpected given a context where the service user-led Recovery movement has continued to promote the empowerment of service users with psychosis in seeking support congruent with their values and goals (Pitt, Kilbride, Nothard, Welford, & Morrison, 2007). Adoption of Recovery-oriented practice can, however, introduce significant challenges to services, necessitating organisational and cultural change, and posing a threat to traditional power relationships (Shepherd, Boardman, & Slade, 2008). Prospects with regard to TDM in psychosis might nonetheless seem to be brightening currently with extension of Increased Access to Psychological Therapies (IAPT) into the area of serious mental illness, and introduction of new National Institute for Health and Care Excellence (NICE) guidelines for psychosis and schizophrenia (National Institute for Health and Care Excellence, 2014). Such developments might bring to prominence issues of TDM with psychosis and broaden treatment options. These changes, however, might also meet with some challenges, given those encountered previously with implementation of NICE guidelines for schizophrenia (Berry & Haddock, 2008).
The reasons for these collective challenges are likely to be multi-faceted and complex, and suggest the need for innovative thinking around potential underlying issues in TDM for psychosis. One avenue of exploration is to consider the appropriateness of the models and assumptions on which research and clinical practice are based, an approach that has been central to this thesis. I have argued that the very particular nature of psychosis, with its potential chronicity and likely influence on TDM of an array of disempowering psychosocial influences, necessitates much broader models both of SDM and treatment decision-making capacity (TDMC) than have been employed previously. It might be necessary to broaden the focus of SDM to take in not only discreet decisions, but also the ongoing collaborative relationship between service users and clinicians. Consideration of TDMC, meanwhile, might need to look beyond individuals’ powers of rational calculation to their emotions, values, lived experience and the power relations that may impact on TDM at multiple levels. Consistent with a service user-oriented approach to outcome measurement (Haddock et al., 2011), I have also made a case for evaluation of Recovery-oriented outcomes with the choice of a primary outcome of empowerment in my literature review.

Such an emphasis on innovative thinking has come at a cost, introducing considerable heterogeneity of interventions and outcome measures in my literature review, and possibly contributing to a necessarily broad-brush approach to thinking about clinical and research implications in my empirical paper. Nonetheless, given seeming need of a paradigm shift in the area of TDM with psychosis, it would appear that research that pushes at existing parameters may be helpful.

### 3.2 Project planning and design

#### 3.2.1 Empirical paper

The original project plan was to generate a model of treatment decision-making capacity in psychosis (TDMC), and to design and test a Cognitive
Behavioural Therapy- (CBT) based intervention to improve TDMC and subjective empowerment for this client group. Aside from this being ambitious for a Clinical Psychology Doctorate (ClinPsyD) project, I started to have doubts early on about what the model of TDMC might look like. These doubts emerged as I became familiar with the MCA (2005) model of capacity and with the MacArthur Competence Assessment Tool-Treatment (MacCAT-T) (Grisso & Appelbaum, 1995), which would likely form a key part of the outcome evaluation of any intervention. Both seemed to resonate very much with the within-person focus of a Medical Model, with neglect of social influences that I felt would very likely impact considerably on TDMC.

My thoughts about this were influenced partly by what I knew of service users’ views and experiences. I had encountered these as an assistant psychologist working in an acute in-patient service, later with access to the findings of a service user focus group about TDMC, and personally through two acquaintances who had had experience of being sectioned with psychosis. What emerged from some of these perspectives was the experience of having no voice, and of the concept of capacity seemingly having no relevance, given that the possibility of individuals having a say in their treatment had simply not arisen. With reflection on this, influences of critical social psychology from my undergraduate studies with the Open University started also to come to the fore, notably Foucauldian ideas about the operation of power in healthcare (Foucault, 1973).

It was with these influences that I started to move towards qualitative methodology that has been described as a ‘democratic endeavour’ that might ‘provide a hearing for the voices of the excluded’ (Ashworth, 2003). This rationale seemed to accord with what I knew at that point of service users’ experience of TDM with psychosis. The choice of method posed a dilemma however. Foucauldian Discourse Analysis might have been a possibility, given my interest in the workings of power. I had an interest also in generating a model of TDMC, which might suggest suitability of Grounded Theory. I felt, however, that my priority should be with seeking to make
service users’ experiences visible before applying a theoretical framework to them, or focusing directly on associated power relations. Thus IPA, with its capacity to privilege participants’ experience (Smith & Osborn, 2003), was the method of choice. The method’s holistic model of the person, taking account of cognition, affect, embodiment, intrinsic connectedness to others and concern with valued goals also seemed to address many of the facets of TDM that have been identified in the literature as having been neglected within existing conceptualisations (Breden & Vollmann, 2004; Eyler & Jeste, 2006; McDaid & Delaney, 2011; Wharne, Langdrridge, & Motzkau, 2012).

3.2.2 Literature review
Unsurprisingly, my interest in empowerment extended to thinking about my literature review. A meta-synthesis around issues of empowerment of service users with psychosis might have been a possibility, though a focus on TDM with this was unlikely to have been possible. I was also keen to broaden the methodological palate of my thesis. Laugharne and Priebe (2006) suggest that an interest in topics such as empowerment tends towards a postmodern stance and that there may exist a tension where one seeks to research them using methodologies in the modern tradition. My view is, however, that promoting more permeable boundaries between paradigms gives greater potential for development and change. In reviewing randomised controlled trials (RCTs) of SDM interventions for psychosis, I had the opportunity to give an overview of an emerging field where the policy-driven potential for such change seems considerable.

Operationalising this with a primary outcome of empowerment, however, posed some very real practical challenges. A scoping review of the literature revealed only one, as yet incomplete, study that had measured empowerment directly. I was therefore forced to develop a hierarchy of related concepts to guide data extraction. This was based on findings from the scoping review, and guided largely by considerations of face validity. The resulting hierarchy did, however, find resonance with Rogers’ (Rogers, Chamberlin, Ellison, & Crean, 1997) model of empowerment. Similarly, as I
examined existing reviews of SDM in mental health (Duncan, Best, & Hagen, 2010; Hamann, Leucht, & Kissling, 2003), with a view to developing inclusion/exclusion criteria, I found their model of SDM to be limited. I based my broader model on what I considered to be the particular needs of service users with psychosis in light of insights from policy (Department of Health, 2012) and the SDM literature (Chan & Mak, 2012; Montori, Gafni, & Charles, 2006).

This commitment to focusing on a model suited to the needs of service users with psychosis and on outcomes of likely importance to them seemed to add potential for particular complexity to the review. Rigour of approach was therefore especially crucial, starting with the publication of a detailed protocol (Prospero International Register of Systematic Reviews, 2013) to guide the review, enhance transparency and reduce potential for bias (Stewart, Moher, & Shekelle, 2012). Such rigour seemed helpful also in imparting the implicit message that this is an important area of research that warrants maximum attention to quality.

3.2.3 Reflections on design across papers
The contrasted design of my two papers would allow me to look at TDM in psychosis from two very different angles, one working with subjective experience and the other seeking maximum objectivity. Arguably, my choice of subjective empowerment as my primary outcome in the literature review bridged the gap in a way that might make appraisal of the collective findings more meaningful.

3.3 Evaluation of what was done
My use of contrasting methodologies in the two papers meant that it was appropriate to use different quality guidelines to appraise each. For the IPA study I made reference to Elliott et al’s (1999) and Yardley’s (2000) guidelines for appraising qualitative research. I evaluated the literature review against A Measurement Tool to Assess Systematic Reviews
(AMSTAR) (Shea et al., 2007), an instrument focusing on methodological quality. From these assessments, both papers appeared to be of high quality. The literature review scored 9/11 on the AMSTAR (see Appendix 10). The authors of qualitative guidelines recommend a nuanced, flexible approach to their use (Elliott et al., 1999) whereby derivation of a ‘score’ is neither possible nor seen as desirable.

Elliott et al (1999) include alongside their qualitative guidelines those that might apply across qualitative and quantitative methodologies and these seemed useful as a framework for an initial broad assessment across the two papers.

3.3.1 Joint assessment of both papers against Elliott et al’s (1999) publishability guidelines for qualitative and quantitative research

Explicit scientific context and purpose. Both papers laid out clearly the context and identified the gaps in existing knowledge that they were seeking to address. It seemed particularly necessary to establish coherent links with what had gone before, given the early stage of a seemingly important line of enquiry in both instances.

Appropriate methods. The method I used in the literature review was appropriate to the question asked, namely, whether SDM interventions for psychosis empower service users. Given, however, the degree of compromise demanded with use of analogue measures of empowerment, it seemed important to acknowledge limitations to the directness with which the research question was answered.

I might also have achieved a more nuanced answer to the question with addition of elements of a narrative approach to the synthesis. Meta-analysis and approaches where there is emphasis is on summary tabulation have been criticised for being unduly descriptive with neglect of explanatory theory (Evans, 2002; Shadish, 1996). Narrative description might have allowed for
greater exploration of the heterogeneity in our studies; the relationships between their characteristics and outcomes; and generation of ideas about ‘what works, for whom, and in what circumstances’ (Popay et al., 2006). Given the nature of the studies in our review however, this would likely have given a confusing and misleading picture. They were few in number, of generally poor quality and with cross-cutting patterns of heterogeneity e.g. in interventions, participants, settings and outcomes. Detailed narrative analysis might therefore have produced spurious and ungeneralisable findings and detracted from the study’s aim to provide a clear, uncluttered overview of the state of the research into SDM interventions for psychosis, with close attention to study quality.

In the IPA study meanwhile, I shifted my focus, at the point of generating the research question, somewhat away from the original topic of interest, namely TDMC. A service user focus group had expressed the view, seemingly rooted in their experience, that capacity was not a meaningful concept to them. I felt that, by asking the question of how service users experienced TDM situations, I might learn about issues of capacity indirectly. The method was very much suited to this question.

It should be noted, however, that the question was answered in relation to a highly homogenous sample in terms of demographic characteristics. Research with ethnic minority communities has found individuals’ possibilities for accessing support with mental illness to be seemingly compromised by services’ cultural unresponsiveness, coupled with particularly high levels of experienced stigma (Knifton, 2012). Given especially the seeming influence on TDM of social constructions of psychosis that we found in our study, and the likely cultural specificity of these, it seems important to recognise potential limits to the generalisability of the findings.

*Respect for participants.* I paid close attention to issues of respect for participants in the IPA study, specifically in relation to matters of informed consent, confidentiality and participants’ welfare. A number of participants
also spoke of having found the interview experience helpful and an antidote to not having been heard during TDM encounters. My close engagement with participants’ narratives, noted by some during the interviews, continued also throughout the analysis.

‘Respect for participants’ might seem to be less applicable as an evaluative dimension with the literature review. With attention, however, to employing an appropriate model of SDM and to outcomes of value to service users with psychosis, I feel that I demonstrated respect for this client group as a whole.

**Specification of methods.** I specified the methods I used with as much precision as possible in each paper. It is easy to under-estimate, however, the remaining margin for subjectivity in the literature review. Given, arguably, a less clear-cut model of SDM and less clearly defined outcomes than in previous SDM reviews, replicability might be lower than expected.

**Appropriate discussion.** I discussed the findings of each study in the context of their contribution to the literature. In the case of the IPA study, I related the findings to the literature on empowerment, this being the overarching theme to emerge from the analysis. This was, however, a significant departure from my focus on the capacity literature within the introduction. Such a shift is in keeping with IPA methodology (Smith, Flowers, & Larkin, 2009). It gives pause for reflection, however, as to the nature of knowledge production in IPA, with consideration of the relative contributions of participants and researcher to this shift.

**Clarity of presentation and contribution to knowledge.** Clarity of presentation is for the reader to judge. It seemed as if both studies made a helpful contribution to knowledge in currently salient topic areas. The literature review gave a useful overview of the state of the literature on SDM for psychosis. It highlighted the need for higher-quality studies and, with findings of small, and in some instances conflicting effects, cautioned against complacency in this field. Careful documentation of the reasons for exclusion
of studies broadened this picture to reveal priority given to outcomes other than empowerment within the literature on SDM for psychosis (Hamann, Cohen, Leucht, Busch, & Kissling, 2007; Malm, Ivarsson, Allebeck, & Falloon, 2003; O'Donnell et al., 1999; Priebe, 1999; Priebe et al., 2007; van Dorn, Swanson, Swartz, Elbogen, & Ferron, 2008). Studies focusing on adherence in intervention, rather than SDM, seemed to be further distanced from the aim of empowerment (Gray et al., 2006; Hayward et al., 2009; Mittal et al., 2009; Staring et al., 2010).

More broadly, it is perhaps important to remember that SDM research in mental health is an emerging field and there were some soon-to-be-completed studies that were not included. The results of the review therefore provided a summary overview at a particular moment in time that is likely to change relatively rapidly.

The IPA study, meanwhile, made visible experiences of service users with psychosis within TDM where it seems that, through not being heard, they have been very much disempowered. It added to a small body of literature making a case for broadening of the concept of TDMC, suggesting that issues of power may be important to consider. With adherence to the MCA having recently been found to be poor (House of Lords Select Committee on the Mental Capacity Act 2005, 2014) and treatment options increasing for service users with psychosis (National Institute for Health and Care Excellence, 2014), these findings seem as if they might be a timely addition to the literature.

3.3.2 Evaluative reflections on the literature review in light of assessment against AMSTAR criteria (Shea et al., 2007) (Appendix 10)

The design of this review was somewhat complex due to our specificity of purpose to evaluate a model of SDM tailored to the needs of service users with psychosis, and to evaluate outcomes of importance to them. The quality of reporting in some of the studies also necessitated a considerable amount of work and consultation to derive statistics that could be entered into the
meta-analytic software. As a result, the subjective experience of completing the review was that of a project that felt somewhat ‘messy’. Completing the AMSTAR was thus a helpful evaluative experience, reminding me that I had completed the work with a considerable degree of rigour and thoroughness. It allowed me to appreciate many areas of strength in the study including provision of an a priori design; conducting a comprehensive search; appropriate documentation of included and excluded studies; due assessment of study quality and its impacts on conclusions; and consideration of publication bias and conflict of interest. This was a useful learning experience, confirming the value of a disciplined approach in deriving credible and useful findings, even where the body of research is at a formative stage.

The AMSTAR did, however, highlight some areas of concern. One of these resulted from the review’s completion as part of a ClinPsyD thesis, due to which it was not possible to duplicate study selection and data extraction for purposes of verification. Nonetheless, the study was very closely overseen by a supervisor who has considerable experience in conducting systematic reviews. Another area of some concern was in my approach to the grey literature. Although I did not exclude grey literature from my database searches, and considered the possible impacts on my conclusions of being unable to access information about a number of possibly relevant studies, I might have been able to give a clearer indication of publication bias had I searched designated sources of grey literature.

Another key issue is whether the methods that I used to combine the studies were appropriate. The AMSTAR (Shea et al., 2007) implies that a test of homogeneity to evaluate whether studies are combinable should be done a priori. In my review, I assessed heterogeneity only during the process of combining the results as part of the meta-analytic calculation, where I duly took it into account in interpretation of the findings. The AMSTAR does, however, suggest that the use of a random-effects model might mitigate heterogeneity, and clinical appropriateness should be considered in
decisions about whether to combine data. Both were included in the process of completing my review.

The issue of heterogeneity, as was present in my review, is sometimes raised more generally as a reason not to conduct a meta-analysis. Borenstein’s (2009) view is that the research question should guide this decision. If one is interested in the combined effect of a number of different kinds of intervention, he advocates the use of meta-analysis to provide this global picture. This was the case in my review, where I was seeking to provide a broad overview of the state of the research into SDM interventions for psychosis, with a necessarily broad model of SDM and likely heterogeneity resulting from the early stage of development of the research area.

The small number of studies in my review, however, might also have been a reason not to perform a meta-analysis. Borenstein (2009) highlights how uncertainty as to the between-studies variance may introduce considerable uncertainty as to the estimates of effect from meta-analyses using a random-effects model with very few studies. He also emphasises, however, that, where outcomes from studies are not combined statistically, there is a strong tendency in readers intuitively to combine the results in an ad hoc way that may be highly misleading. He deems preferable statistical combination where it is possible to be transparent as to the degree of uncertainty in the estimates of effect.

3.3.3 *Evaluative reflections on the IPA study in light of Yardley’s (2000) guidelines for evaluating qualitative research*

Yardley (2000) sets out four broad dimensions for evaluation of qualitative research: ‘sensitivity to context’, ‘commitment and rigour’, ‘transparency and coherence’ and ‘impact and importance’. These are elaborated by Smith *et al* (2009) in relation specifically to IPA. There is some overlap, both between Yardley’s dimensions, and with Elliott *et al*’s (1999) guidelines discussed
above. There follows discussion on some issues in my IPA paper, as yet unaddressed, stimulated by the guidelines as a whole.

**Thoroughness of the study, transparency and coherence:** The study seems to have some clear strengths in terms of a cogent rationale supplied for my use of IPA, an appropriately homogenous sample with rich experience of the phenomenon of interest, some well conducted interviews yielding some very rich data and an analysis that provides a rich, nuanced account of experiences of TDM situations with psychosis. I described clearly the stages of the research and the themes cohere to tell a story that makes sense, taking due account of conflicting ideas and narratives.

Being new to the methodology, I was careful to draw actively on the considerable expertise available to me, namely through supervision by two Professors of Psychology with a wealth of collective experience of IPA and psychosis research, attendance at qualitative seminars at the University of Manchester and consultation with other researchers undertaking doctoral IPA research in psychosis.

**Approach to sampling:** It was not possible to use interviews from all the participants recruited. In essence, those it was necessary to exclude had been referred with insufficient attention to inclusion/exclusion criteria. This raised questions as to whether screening participants in some way might have been helpful. On reflection, it seemed perhaps not. Meeting those I was unable to include gave me first-hand experience of the limitations of the method to access the experience of those perhaps most likely to be disempowered in TDM. It sat uncomfortably with me, however, being unable to represent the experience of all those who took part.

**Interview technique and attention to interactional issues:** It is perhaps important to question whether my inexperience in conducting research interviews might have accounted for difficulties eliciting sufficiently rich data from two participants, resulting in exclusion of their interviews from analysis.
A researcher highly experienced in IPA research with psychosis read one of the transcripts and thought not, and the ordering of rich and less-rich interviews suggested likewise.

There were, however, challenges in conducting the interviews. One of these was adapting my approach from that used in my more usual clinical role. There was potential for influencing participants’ meaning-making through summarising what they had said or showing undue empathy. It helped to pre-empt with participants that my interest was in their experience above all else and that this might result in an unusually one-sided conversation. I was always aware, however, of needing to strike a balance such that participants felt comfortable enough to discuss their experience openly. This balance between neutrality and being ‘human’ was most difficult to maintain when participants told me about very distressing or difficult TDM experiences. I was aware that I showed empathy and, at times, that I was saddened and shocked by their account of how they had been treated. I feel that this was appropriate, given that not having been heard or held in mind by others was almost invariably at the heart of the adversity and distress they were describing. It is possible, however, that this influenced the meanings that emerged in the data.

There was a sense, however, in which the influence of my clinical background was useful. In my reflective journal I found myself considering how an individual might come across in a clinical encounter and how this might impact on the process of TDM for them.

**Integrity of approach to analysis:** In analysis, Smith et al (2009) advocate ‘immersive and disciplined attention to the unfolding account of the participant and what can be gleaned from it’. Aspiring to this as a novice IPA researcher was overwhelming and rewarding in equal measure with my first participant. He gave me a huge amount of fantastically rich, vivid material. I was very much moved by his story of maintaining hope and seeking empowerment against a background of having experienced, at times, very
high levels of disempowerment, and was keenly motivated to do his experience justice.

The danger was that his narrative might dominate the analysis. The issue of power came very strikingly to the fore within his account and I wondered how far this might shape my reading of the other transcripts. As I worked through the others, however, I felt as if I got to know and was moved by each of them as individuals. The issue of power did indeed remain sharply in focus throughout, but I felt as if I was looking at it through a different lens with each of my participants. Similarly, there were indications of a very strong Recovery orientation in the narratives of the two participants whose interviews I analysed first, and it seems possible that this, influenced also by my background and beliefs, coloured my sense-making with the others. The variety of ways in which the theme of Recovery seemed to manifest, however, played back into the over-arching theme of empowerment in a way that seemed very much to bring further coherence to the story as a whole.

Smith et al (2009) also suggest that there should be a good number of verbatim extracts from participants, demonstrating that the analysis is grounded in their experience, and that these should be evenly distributed across participants. This even distribution was not possible, given the minimal style of expression of one of my participants. His experience seemed to be captured within the themes, but his utterances did not capture their essence. This raises questions again about IPA’s assumption of individuals’ capacity to share the richness of their phenomenological experience through language. For this participant it was the paucity of his expression of forcibly held and highly unusual beliefs, which seemed to have created an impasse in TDM with his clinical team, that was so moving.

A very different challenge was posed by the narratives of a number of the other participants. Their apparent thinking and means of expression were often far from straightforward, frequently requiring engagement with a lengthy section of narrative to derive the essence of their experience.
Together with the rich complexity of meaning that emerged with analysis, it was simply not possible to include numerous verbatim quotations, but instead necessary to be highly selective.

*Balance between participants’ phenomenological experience and interpretation.* IPA seeks depth of understanding of the phenomenon of interest through participants’ ‘insider perspective’ (Conrad, 1987), coupled with the researcher’s interpretative reflections (Smith & Osborn, 2003). The integrity of the research would seem to rely very much on the balance between the two. The central theme of this study concerned issues of power. Much of participants’ sense of disempowerment was manifestly expressed. Some, however, was also implicit, and questions arise as to how far I strayed from participants’ phenomenological experience and ‘true’ IPA methodology. I was very much aware of the influence on my interpretation of both my clinical formulatory skills and my interest in Foucauldian ideas about the exercise of power in healthcare.

A number of factors might bear consideration with this. It could be argued that some aspects of my analysis reflected a deeper level of phenomenological experience, possibly akin to that referred to by Husserl as the pre-reflective, ‘natural attitude’ (Husserl, 1927). Whilst he suggested that conscious, reflective experience should be the subject of phenomenological enquiry, he worked from a first-person philosophical perspective with little exploration of application of the method to psychological investigation of others’ experience (Smith et al., 2009). Such investigation might arguably offer more scope for exploration of aspects of phenomenological experience less immediately accessible to subjective consciousness, so long as it is duly grounded in the narrative of the participant as a whole. Furthermore, writers on IPA methodology support consideration of the influence of social construction on human experience (Ashworth, 2003), and use by researchers of their ‘interpretative resources’ (Smith, Jarman, & Osborn, 1999).
3.4 Evaluation of the line of enquiry as a whole: merits and limitations

Research into TDM with psychosis would seem to be an important line of enquiry as it concerns the empowerment of a client group that has been very much disempowered (Harrison & Gill, 2010; Kleim et al., 2008; Vauth, Kleim, Wirtz, & Corrigan, 2007). This would seem to be all the more so given challenges that seem to have arisen in implementation of legal and policy initiatives that might have been expected to promote this empowerment (Berry & Haddock, 2008; House of Lords Select Committee on the Mental Capacity Act 2005, 2014; Schauer et al., 2007).

Limitations to the line of enquiry would seem to lie in the challenges and constraints that exist in pursuing it. Complex practical issues arose when evaluating the effectiveness of SDM interventions in empowering service users with psychosis. One such issue was the early stage of the research, which resulted in there being only a small number of highly heterogeneous studies. Another was the limited nature of existing models of SDM relative to the needs of service users with psychosis. Measurement of outcomes of importance to service users in SDM research was similarly limited. Engaging with these issues resulted in a high degree of complexity in my literature review and contributed to the necessity of advocating caution in interpretation of its results.

The constraints in pursuing this line of enquiry with regard to TDMC, meanwhile, would seem to lie in the wider context of knowledge production. There was the risk, with my IPA study, that the predominant emerging narrative, concerning service users’ disempowerment in TDM, might be challenging to the point of being ‘unpalatable’ to those who might be best placed to bring about change, most notably psychiatrists. This gives pause for reflection about the power structures within which knowledge is produced. It is as if, for knowledge to have potential to contribute to change, it must remain within a ‘zone of proximal development’ (Vygotsky, 1978), whereby
there is sufficient overlap with the conceptual frameworks espoused by those who might mediate its influence to motivate their engagement with it.

There were seemingly related practical issues concerning the potential dissemination of the IPA paper. Despite its message being highly relevant to psychiatrists, the word count would preclude its submission to suitable psychiatric journals. There would seem to be broader implications here. It appears possible that lines of enquiry such as this, which present a challenge to prevailing ideas in psychiatry, and which might be more likely to advance through the ‘democratic endeavour’ of qualitative methodology (Ashworth, 2003), might be limited in their possibilities for appropriately targeted dissemination. They might be forced to take an indirect approach through submission to more sympathetic journals, or to present their findings in a reduced form that could place limits on the communication of their message. There are, of course, readily discernable, prosaic reasons for limited word counts in psychiatric journals. Foucault, however, might see them as an example of ways in which power circulates unseen through systems of knowledge production and use, maintaining the privileged position of some forms of knowledge over others (Foucault, 1988).

3.5 Implications for theory, practice and research

In considering the implications of this thesis research, it seems helpful to return to the question of why a number of key legal and policy initiatives have failed to deliver in empowering service users with psychosis in TDM in recent years. This would seem to indicate the need for some fundamentally different thinking about the assumptions and models on which research and practice are based. This thesis has taken up that challenge in suggesting the need for broader models both of SDM and TDMC in relation to psychosis.

With SDM in psychosis, however, much needs yet to be done to develop explanatory models of the workings of interventions. By improving both the quantity and quality of effectiveness studies, it may be possible to conduct
reviews with more potential to generate explanatory theory about ‘what works, for whom, and in what circumstances’ (Popay et al., 2006), which was not possible in our review.

Findings in the IPA study, meanwhile, suggested the need for development of models of TDMC extending beyond the social model suggested by McDaid and Delaney (2011), to encompass the workings of power at different levels around TDM with psychosis. Research using Foucauldian Discourse Analysis might illuminate further the workings of power in TDM situations. Meanwhile, Grounded Theory in its full form (Willig, 2001), possibly employing triangulation of data from interviews with service users and clinicians, and analysis of TDM encounters, might usefully generate explanatory theory about the processes involved in TDM, including those implicated in the maintenance of unequal power dynamics. Development of more appropriately comprehensive models of TDMC might then inform outcome measurement and enhance evaluation of SDM interventions, where assessment of capacity seems not to have been a priority thus far.

Measurement of empowerment was also found not to have been a priority in evaluation of SDM interventions to date. In much the same way as has been done in relation to general and Recovery-related outcomes in psychosis (Haddock et al., 2011; Neil et al., 2009), it seems important in SDM to use outcome measures of constructs, such as empowerment, that reflect the priorities of service users (Pitt et al., 2007). Were measures of empowerment to be employed, they would need to be sufficiently sensitive to change and would need to take account of the construct’s intrapsychic, interpersonal and socio-political aspects.

Outcome measurement in TDM more generally might also be enhanced with quantitative research, following on from my IPA study. Development of a measure of TDM experience, reflecting key themes to have emerged from the analysis, such as feeling listened to and having one’s values and goals taken into account, might allow for monitoring and enhancement of the TDM
experience of service users with psychosis. More broadly, this too might contribute to a seemingly valuable emerging trend of prioritising the values and experience of service users with psychosis in outcome measurement (Haddock et al., 2011; Neil et al., 2009).

Turning to clinical implications, the key recommendation to emerge from the IPA study was that clinicians should listen much more closely to service users with psychosis during TDM, taking account of the possible influence of their treatment history, undermining effects of psychotic symptoms, sense of low self-worth and difficulties with self-representation. Engagement with the individual’s level of Recovery orientation seemed also particularly important. Heightened awareness, on clinicians’ part, of their position of power and of the influence of taken-for-granted meanings around psychosis was a further important implication.

These findings might question the predominant focus on the service user in SDM interventions. Thornicroft et al’s (2013) qualitative findings and Hamann et al’s (2011) recommendations, suggesting the need for preparation, training and support for clinicians delivering SDM interventions, resonate also with the idea that the focus of intervention may need to be much broader. It seems that a broader model of TDMC, that makes explicit the potentially multi-layered processes enabling TDM or otherwise, may usefully inform SDM interventions as well.

3.6 Closing reflections

Engaging with fundamental questions as to the nature of TDMC with psychosis is a weighty topic, and I feel that the process of research has been a real journey for me. The starting point was thinking about development of a CBT-related intervention to improve TDMC and subjective empowerment in psychosis. With the study’s completion, it seems to me that the nature of service users’ experiences of TDM-related disempowerment necessitates considerable expansion to thinking about what capacity is. Related
intervention might need to encompass the wider system, so contributing to much-needed culture change. This feels daunting, but the seeds of change are there. It feels important to be authentic in one’s view of the direction in which research and clinical practice might usefully develop, but also to maintain a compassionate stance toward those deeply embedded within the system as it stands. In this way, supportive encouragement to different ways of thinking may be possible.

With reflection on my approach to the project as a whole, I think perhaps that formative academic and clinical experiences may have oriented me, from the outset, toward the direction that I have followed. I feel that values and beliefs, rooted in critical social psychology, and experience of work in an in-patient psychology team, steeped in a Recovery perspective, were guiding influences. These, together with immersion in the deeply moving accounts of TDM experience so generously shared by my participants, kept me motivated on the journey.

References


Appendices
Appendix 1

Author guidelines for the British Journal of Psychiatry

- Excerpts from the *BJP* instructions for authors
- Excerpts from the House Style Guide for the *BJP*
- Excerpts from the House Style Guide for the *RCPsych*
- Notes on implementation of *BJP* author guidelines
Excerpts from the *BJP* instructions for authors

**Title and authors**

The title should be brief and relevant. Subtitles should not be used unless they are essential. Titles should not announce the results of articles and, except in editorials, they should not be phrased as questions.

**Structure of manuscripts**

**Papers**

A structured abstract not normally exceeding 150 words should be given at the beginning of the article, incorporating the following headings: Background; Aims; Method; Results; Conclusions; Declaration of interest. The abstract is a crucial part of the paper and authors are urged to devote some care to ensuring that all the important findings are within the word limit.

Introductions should normally be no more than one paragraph; longer ones may be allowed for new and unusual subjects. This should be followed by Method, Results and Discussion sections. The Discussion should always include limitations of the paper to ensure balance. Use of subheadings is encouraged, particularly in Discussion sections. A separate Conclusions section is not required.

The article should normally be between 3000 and 5000 words in length (excluding references, tables and figure legends) and normally would not include more than 25 essential references beyond those describing statistical procedures, psychometric instruments and diagnostic guidelines used in the study. All large tables (exceeding half a *Journal* page) will be published only in the online version of the *Journal* (see Online data supplements, below). Authors are encouraged to present key data within smaller tables for print publication. This applies also to review articles and short reports.

**Review articles**

Review articles should be structured in the same way as regular papers, but the length of these may vary considerably, as will the number of references. Systematic reviews are preferred and narrative reviews will be published only under exceptional circumstances. Reviews done for the Cochrane Collaboration, the National Institute for Health and Clinical Excellence and other groups likely to be published, or already published, elsewhere, should have the submitted paper accompanied by the latest version of the parent review and its status so that an informed decision can be made about the added value of the submitted paper.

**References**

Authors are responsible for checking all references for accuracy and relevance in advance of submission. Reference lists not in the correct style will be returned to the author for correction. From January 2008, all references should be numbered in the
order in which they appear in the text and listed at the end of the article using the Vancouver style (see below), in which the names and initials of all authors are given after the appropriate reference number. If there are more than six authors, the first six should be named, followed by 'et al'.

The authors' names are followed by the full title of the article; the journal title abbreviated (in italics) according to the style of Index Medicus; the year of publication; the volume number (in bold type); and the first and last page numbers. References to book or book chapters should give the titles of the book (and the chapter if selected), names of any authors, name of publisher, names of any editors, and year. Examples are shown below.


**Tables**

Tables should be numbered and have an appropriate heading. The tables should be mentioned in the text but must not duplicate information. The heading of the table, together with any footnotes or comments, should be self-explanatory. The desired position of the table in the manuscript should be indicated. Do not tabulate lists, which should be incorporated into the text, where, if necessary, they may be displayed.

Authors must obtain permission from the original publisher if they intend to use tables from other sources, and due acknowledgement should be made in a footnote to the table.
**Figures**

Figures should be clearly numbered and include an explanatory legend. Avoid cluttering figures with explanatory text, which is better incorporated succinctly in the legend. 3-D effects should generally be avoided. Lettering should be parallel to the axes. Units must be clearly indicated and should be presented in the form quantity (unit) (note: ‘litre’ should be spelled out in full unless modified to ml, dl, etc.). All figures should be mentioned in the text and the desired position of the figure in the manuscript should be indicated.

Authors must obtain permission from the original publisher if they intend to use figures from other sources, and due acknowledgement should be made in the legend.

Colour figures may be reproduced if authors are able to cover the costs.

**Statistics**

Methods of statistical analysis should be described in language that is comprehensible to the numerate psychiatrist as well as the medical statistician. Particular attention should be paid to clear description of study designs and objectives, and evidence that the statistical procedures used were both appropriate for the hypotheses tested and correctly interpreted. The statistical analyses should be planned before data are collected and full explanations given for any post hoc analyses carried out. The value of test statistics used (e.g. \( t \), \( F \)-ratio) should be given as well as their significance levels so that their derivation can be understood. Standard deviations and errors should not be reported as ± but should be specified and referred to in parentheses.

Trends should not be reported unless they have been supported by appropriate statistical analyses for trends.

The use of percentages to report results from small samples is discouraged, other than where this facilitates comparisons. The number of decimal places to which numbers are given should reflect the accuracy of the determination, and estimates of error should be given for statistics.

A brief and useful introduction to the place of confidence intervals is given by Gardner & Altman (1990, *British Journal of Psychiatry*, **156**, 472–474). Use of these is encouraged but not mandatory.

Authors are encouraged to include estimates of statistical power where appropriate. To report a difference as being statistically significant is generally insufficient, and comment should be made about the magnitude and direction of change.

**Online data supplements**

Material related to a paper but unsuitable for publication in the printed journal (e.g. large tables) may be published as a data supplement to the online *Journal* at the Editor’s discretion. For very large volumes of material, charges may apply.
**Abbreviations, units and footnotes**

All abbreviations must be spelt out on first usage and only widely recognised abbreviations will be permitted.

The generic names of drugs should be used.

Generally, SI units should be used; where they are not, the SI equivalent should be included in parentheses. Units should not use indices: i.e. report g/ml, not gml$^{-1}$.

The use of notes separate to the text should generally be avoided, whether they be footnotes or a separate section at the end of a paper. A footnote to the first page may, however, be included to give some general information concerning the paper.

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**Excerpts from the House Style Guide for the British Journal of Psychiatry**

**Structure of papers**

**Summary**
Except for editorials and short reports, all papers must have a summary structured into the following headings: Background, Aims, Method, Results, Conclusions, Declaration of interest. The summary should not normally exceed about 150 words.

**Introduction**
Papers and short reports should begin with an introductory paragraph (with no heading). Every effort should have been made before the paper’s acceptance to encourage the author to restrict this to a single paragraph. If, however, the introduction exceeds two paragraphs, B-level subheadings may be used to break it up.

**Title**
The title of any paper should be brief and relevant. If the author has chosen a cute title that is not obvious, add a few explanatory words. Titles may have colons in them, if necessary. Subtitles should not be used unless they are essential. Try to remove (with AQ to author) inessential parochial detail such as “the East London Psychosis Study”. Remove article (a/the) after colon if possible: ‘Psychosocial interventions for eating disorders: systematic review’ Excerpt for editorials, a paper title may not end with a question mark and must be neutral (i.e. the title must not anticipate the authors’ conclusions – so ‘Hippocampal structure and schizophrenia’ is permissible, ‘Hippocampal structural abnormalities are associated with schizophrenia’ is not).

**Tables**
- Data presented in a figure should not be repeated in a table, and *vice versa*. 

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124
Data in a table should not be repeated in large part in the text, but may be discussed there.

In all papers (including review articles and short reports) large tables (exceeding half a Journal page portrait or landscape) are published only in the online version of the Journal (see Online/data supplements, below). Key data should be presented in smaller tables for print publication.

Tables may be one or two text-columns wide.

Each table should be comprehensible in isolation, so define all abbreviations used and structure the table for optimum clarity.

Do not include citations of references for psychometric instruments in the title or footnote, unless the instrument is not cited in the body of the paper.

Rules:
- insert full-width rule below table title and below final row of data (above footnotes)
- insert full-width rule below the table column heads, with spanners or part-rules as required within the column heads
- in the body of the table use horizontal rules to separate main rows, and indent 'subrows'; italic may be used to clarify structure only if unavoidable

Footnotes should be indicated using superscript lower case letters (a, b, c, ...) in the body of the table (and baseline lower case letters, followed by a full point, in the footnote). Each numbered footnote should start on a new line. When a footnote serves only to define the abbreviations used in the table, these definitions may run-on (each separated by a semicolon), do not require numbering and should be defined in the order in which they appear in the table itself.
- Standard asterisk notation may be used to signify P-values (single asterisk means <0.05, double asterisk means <0.01, triple asterisk means <0.001; use further symbols (see general house style guide for hierarchy) to indicate alternative comparisons).
- Footnotes should appear in the following order: definitions; numbered footnotes; explanation of significance. A footnote showing all of these features is show below.

HRSD, Hamilton Rating Scale for Depression; GAD, generalised anxiety disorder.

Data unavailable for three participants.

Calculated according to the method of Molotov et al.25

*P<0.05, **P<0.01 v. control group; †P<0.05, †††P<0.001 v. first-onset group.

References

References should be numbered in the order in which they appear in the text and listed at the end of the article using the Vancouver style (see below). In the text make reference numbers superscripts, positioned after any punctuation except for parentheses. If the reference refers to text in parentheses, it should appear within them: ‘(35% in the UK)’. References appearing for the first time in Tables or Figures should be numbered sequentially as if they were in the text.

Online supplements

References that appear in both the print text and an online supplement should be numbered and listed as normal in the print
text, and the same numbers shown in the supplement; the reference list need not be repeated in the supplements. If online-only (data supplement) material such as tables includes references not cited in the reference list in the full (printed) text, number these additional references to run on from the last text-reference number. Then list only these additional references in the supplement, under the A-heading 'Additional references'.

- **Example 1**
  A paper has two online tables, DS1 and DS2. Table DS1 introduces two additional references, and Table DS2 introduces a further three. If the text references end at number 52, the Table DS1 references will be numbered 53 and 54, and the Table DS2 ones will be numbered 55, 56 and 57. Since both tables will appear in a single data supplement only one 'Additional references’ list is needed (after Table DS2), showing refs 53–57.

- **Example 2**
  A paper has two Data supplements: Data supplement 1 comprises three paragraphs of text and a related graph (Fig. DS1); and Data supplement 2 comprises an interview checklist. The paper’s text references end at number 34. In Data supplement 1 the three paragraphs introduce two additional references (which become 35 and 36) and Fig. DS1 introduces a further one (37); this data supplement will have an ‘Additional references’ list showing refs 35–37. Data supplement 2 introduces yet another reference: this will be numbered 38 and will appear as an ‘Additional reference’ at the end of the checklist.

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**Excerpts from the House Style Guide of the Royal College of Psychiatry**

- **Citing software in all College product**
  For the software packages most commonly used (any Microsoft product, SPSS and Stata) we just require the product name, version (or release year) and platform to be cited in the text, for example ‘Analyses were performed using Stata version 9 for Windows’. No reference is required in the reference list.

- **For any other (necessarily more obscure) software**, we need the above information along with the name and location of the manufacturer and a URL where the product may be downloaded or purchased (i.e. enough information for a reader who is unfamiliar with the software to easily find out more). This is best presented within the text, rather than as a reference. For example: ‘...data from each study were entered into the RevMan 4.2 for Windows program (Cochrane Collaboration, Oxford, UK; see http://www.cc-ims.net/RevMan/current.htm)’

  We have sometimes presented software details as a reference in the reference list – this is no longer acceptable (unless removal would require extensive renumbering in numbered reference lists).

- **Reference lists**
  Documents available online should be treated in the same way as published sources, giving the full URL in place of publisher or journal name/volume/page number details.

- **Tables and Figures**
  For all College product, use ‘Fig. 1’ not ‘Figure 1’, both in the text citation and in the figure legend (unless the text citation is the start of a sentence, in which case spell ‘Figure’ in full).
• Save figures at final size.
• Column alignment
  o Columns of text: left-align column heading and entries.
  o Columns of numerals: decimal-align single numerical entries and
    centre column heading.
  o Mixture of numerals and words or numerical entries of greatly
    varying magnitude: centre entries and column heading.

• Cochrane publications
Cochrane references are usually to the Cochrane Database of Systematic
Reviews or the Cochrane Library, two different products from the
Cochrane Collaboration (http://www.cochrane.org/). CD numbers can be
found on PubMed. Reference them as:
dysfunction due to antipsychotic drug therapy. Cochrane Database of Systematic
Reviews, issue 1: CD003546.

Notes on implementation of the British Journal of Psychiatry guidelines

Length of introduction
Introductions of not more than one paragraph are generally recommended.
Longer ones may however be permitted for ‘new and unusual subjects’. It
was felt that a longer introduction was justified for the literature review, given
the novelty of the model of shared decision-making being investigated, and
the need to give a clear rationale for examining empowerment-related
outcomes, which involved a degree of complexity.

Tables
Large tables are published only in the online version of the journal. Some of
the tables in the literature review might fall into this category, but have been
included in the main paper for ease of navigation within the thesis.

References
Whilst the guidance states the expectation that the number of essential
references in ‘papers’ will not exceed 25, ‘beyond those describing statistical
procedures, psychometric instruments and diagnostic guidelines used in the
study’, it suggests that the number in ‘review articles’ is expected to ‘vary
considerably’. This guidance was interpreted as meaning that a considerably
greater number of references might be permissible within a review.
Additionally, a number of the references in the review do relate to statistical procedures and psychometric instruments used in the included studies.

Reporting of statistics
Where specific advice was not given in the *BJP* author guidelines e.g. on reporting of 95% confidence intervals, reviews published recently in the *BJP* were used as a guide. Reporting practices departed in some instances from *APA* guidelines.
A. Search strategy

The references of previous reviews of SDM in mental healthcare\(^2\textsuperscript{-3}\) were searched. 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.

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 communica*
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
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

**B. Excluded studies**

Below in tables DS1 and DS2 are listed studies or reports excluded on the basis of reading the full-text report. 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 DS1 Studies excluded primarily on basis of outcomes**

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamann et al. (2007)</td>
<td>Hospitalisations, compliance, severity of illness, changes to antipsychotic</td>
</tr>
<tr>
<td>O’Donnell et al. (1999)</td>
<td>Functioning, disability, quality of life, burden of care and service satisfaction</td>
</tr>
</tbody>
</table>
### Study Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priebe (1999)</td>
<td>Patients’ ratings of treatment and own condition and BPRS</td>
</tr>
<tr>
<td>Priebe et al (2007)</td>
<td>Quality of life, unmet needs and treatment satisfaction</td>
</tr>
<tr>
<td>van Dorn et al (2008)</td>
<td>Reduction in patient-perceived PAD-related and external barriers to PAD completion</td>
</tr>
</tbody>
</table>

Note: BPRS, Brief Psychiatric Rating Scale; PAD, Psychiatric Advance Directive

### Table DS2 Other excluded studies and reasons for exclusion

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gray et al (2006)</td>
<td>Intervention more about adherence than SDM</td>
</tr>
<tr>
<td>Hansson et al (2008)</td>
<td>Adjunct to RCT looking at moderators. Not included review outcomes</td>
</tr>
<tr>
<td>Haywood et al (2009)</td>
<td>Intervention more about adherence than SDM</td>
</tr>
<tr>
<td>Henderson et al. (2009)</td>
<td>Not RCT: interview study</td>
</tr>
<tr>
<td>Li &amp; Wan (2004)</td>
<td>In Chinese – no funds for translation</td>
</tr>
<tr>
<td>Mittal et al (2009)</td>
<td>Intervention more about adherence than SDM</td>
</tr>
<tr>
<td>Rogers et al (2007)</td>
<td>Intervention not sufficiently about treatment-related SDM</td>
</tr>
<tr>
<td>Sells et al (2006)</td>
<td>SDM not main group difference; primary substance misuse</td>
</tr>
<tr>
<td>Staring et al (2010)</td>
<td>Intervention more about adherence than SDM</td>
</tr>
<tr>
<td>Tondora et al (2010)</td>
<td>Outcome data not available</td>
</tr>
<tr>
<td>Woltmann and Whitley (2010)</td>
<td>Not RCT: qualitative study</td>
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</tbody>
</table>

### C. Risk of bias assessment

**Method**

Assessment was carried out by the author and checked with a supervisor, with disagreements being resolved through discussion. Risk of bias ratings are given in Table DS3. 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 ≥25% of those randomised was missing, judgement of high risk of attrition bias was made where no account of this was taken in analysis, 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**

With regard to selection bias, five studies had at least one judgement of unclear risk of bias, the remainder of judgements being of low risk of bias. Risk of performance bias was high across studies due to nature of the interventions, which precluded blinding. Insufficient information in reporting also led to unclear detection bias in five studies. Risk of attrition bias was high or unclear on some post-intervention measures in
three studies.\textsuperscript{19, 52, 53} Risk of selective reporting bias was largely unclear. One study,\textsuperscript{49} however, reported an outcome of interest incompletely, resulting in high risk of selective reporting bias. There was unclear risk of other sources of bias in three studies, namely risk of recruitment bias due to cluster randomised design\textsuperscript{19, 55} and risk of cross-contamination due to in-patient research setting.\textsuperscript{56}
## Table DS3  Risk of bias ratings – detail of assessment

<table>
<thead>
<tr>
<th>Study</th>
<th>Random sequence generation (selection bias)</th>
<th>Allocation concealment (selection bias)</th>
<th>Performance bias (blinding of participants and personnel)</th>
<th>Detection bias (blinding of assessments)</th>
<th>Incomplete outcome data (attrition bias)</th>
<th>Selective reporting (reporting bias)</th>
<th>Other bias (e.g. recruitment bias, contamination)</th>
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<tbody>
<tr>
<td>Hamann <em>et al</em> (2006)&lt;sup&gt;19&lt;/sup&gt;</td>
<td>Unclear: insufficient information about randomisation of matched pairs of wards: ‘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.’</td>
<td>Unclear: insufficient information about allocation concealment of wards: ‘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.’</td>
<td>High: risk of bias with potential for knowledge of allocation to influence behaviour.</td>
<td>Unclear: No information about blinding assessors.</td>
<td>High: for patient-perceived involvement - &gt;25% of those randomised did not complete perceived involvement measure. No account taken of missing data in analysis.</td>
<td>Unclear: unavailability of protocol.</td>
<td>Unclear: paired cluster randomised design might introduce recruitment bias. ‘... patients were sent to that ward of a pair that had free beds available.’ No information on participant allocation where beds available on both wards of a pair.</td>
</tr>
<tr>
<td>Study</td>
<td>Random sequence generation (selection bias)</td>
<td>Allocation concealment (selection bias)</td>
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<tr>
<td>Hamann et al (2011)&lt;sup&gt;56&lt;/sup&gt;</td>
<td>Unclear: insufficient information about randomisation: ‘Patients were recruited until group size was reached and then randomly assigned to the intervention or control condition.’</td>
<td>Low: ‘numbered closed-allocation concealment envelopes were prepared before the study.’</td>
<td>High: risk of bias with potential for knowledge of allocation to influence behaviour.</td>
<td>Unclear: no information about blinding of assessors.</td>
<td>Low: on post measures – no report of missing data. <strong>Unclear</strong>: 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.</td>
<td>Unclear: unavailability of protocol. Reporting on only one idiosyncratic measure at follow-up raises questions about selective reporting.</td>
<td>Unclear: insufficient information to assess risk of cross-contamination in in-patient research setting.</td>
</tr>
<tr>
<td>Study</td>
<td>Random sequence generation (selection bias)</td>
<td>Allocation concealment (selection bias)</td>
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<td>Henderson et al (2004)</td>
<td>Low: 'The allocation sequence was generated by using minimisation, stratified by team and by severity of the patients.' Evidence found of legitimacy of randomisation technique.</td>
<td>Low: '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.'</td>
<td>High: risk of bias with potential for knowledge of allocation to influence behaviour.</td>
<td>Low: 'One investigator (CH) collected follow-up data and was blinded to treatment group.'</td>
<td>Low: 'Information on use of the Mental Health Act was available for 77/80 of each group (total 154/160 = 96%).' Low attrition rate and ITT analysis resulted in low risk of bias.</td>
<td>Unclear: unavailability of protocol.</td>
<td>Low: study appears to be free of other sources of bias.</td>
</tr>
<tr>
<td>Steinwachs et al (2011)</td>
<td>Unclear: insufficient information about sequence generation: 'Patients were randomly assigned to the intervention or to a control group.'</td>
<td>Unclear: no method of concealment described: ‘Patients were randomly assigned to the intervention or to a control group.’</td>
<td>High: risk of bias with potential for knowledge of allocation to influence behaviour.</td>
<td>Low: 'The two coders were not aware of study hypotheses or patients' intervention status.'</td>
<td>Low: data missing for 11% due to technical failure. No account of handling of missing data but unlikely to cause undue bias.</td>
<td>Unclear: unavailability of protocol.</td>
<td>Low: study appears to be free of other sources of bias.</td>
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<tr>
<td>Study</td>
<td>Random sequence generation (selection bias)</td>
<td>Allocation concealment (selection bias)</td>
<td>Performance bias (blinding of participants and personnel)</td>
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<tr>
<td>Swanson et al (2006)⁵⁰</td>
<td>Unclear: insufficient information about sequence generation: ’each participant was randomly assigned to either the facilitated psychiatric advance directive intervention or the control group.’</td>
<td>Unclear: no method of concealment described: ’each participant was randomly assigned to either the facilitated psychiatric advance directive intervention or the control group.’</td>
<td>High: risk of bias with potential for knowledge of allocation to influence behaviour.</td>
<td>Unclear: no information about blinding of assessors.</td>
<td>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.</td>
<td>Unclear: for patient-rated relationship with clinician due to unavailability of protocol.</td>
<td>Low: study appears to be free of other sources of bias.</td>
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<td>Elbogen et al (2007)⁴⁹</td>
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<td>Allocation concealment (selection bias)</td>
<td>Performance bias (blinding of participants and personnel)</td>
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<td>Incomplete outcome data (attrition bias)</td>
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<tr>
<td>Thornicroft et al (2013)</td>
<td>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.'</td>
<td>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.'</td>
<td>High: risk of bias with potential for knowledge of allocation to influence behaviour.</td>
<td>Low: 'Investigators, research assistants (who did the follow-up), and trial statisticians were masked to allocation.'</td>
<td>Low: For primary outcomes. Missing data: 4% for MHA 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.</td>
<td>Low: protocol available and outcomes reported in the pre-specified way.</td>
<td>Low: study appears to be free of other sources of bias.</td>
</tr>
<tr>
<td>Study</td>
<td>Random sequence generation (selection bias)</td>
<td>Allocation concealment (selection bias)</td>
<td>Performance bias (blinding of participants and personnel)</td>
<td>Detection bias (blinding of assessments)</td>
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<td>Van Os et al (2004)53</td>
<td>Low: ‘Patients were randomised centrally by an independent, non-investigator agency using a predetermined random sequence.’</td>
<td>Low: concealment ensured by central allocation.</td>
<td>High: risk of bias with potential for knowledge of allocation to influence behaviour.</td>
<td>Unclear: no information on blinding of assessors.</td>
<td>Unclear: no report of missing data and this is likely to be unrealistic.</td>
<td>Unclear: unavailability of protocol.</td>
<td>Low: study appears to be free of other sources of bias.</td>
</tr>
<tr>
<td>Woltmann et al (2011)55</td>
<td>Unclear: insufficient information about randomisation of case managers: ‘Case managers from three clinics were randomly assigned to the intervention group or treatment as usual.’</td>
<td>Unclear: insufficient information about concealment of allocation of case managers: ‘Case managers from three clinics were randomly assigned to the intervention group or treatment as usual.’</td>
<td>High: risk of bias with potential for knowledge of allocation to influence behaviour.</td>
<td>Unclear: no information about blinding of research assistants facilitating assessment.</td>
<td>Low: no report of missing data. Missing data reported on other outcomes, so likely this is realistic.</td>
<td>Unclear: unavailability of protocol.</td>
<td>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.</td>
</tr>
</tbody>
</table>
D. GRADE assessment

Method
Assessment was carried out by the author and checked with a supervisor, with disagreements being resolved through discussion. Results of the assessment are summarised in Table DS4. Outcome quality was downgraded by one point if at least one ‘high’ risk rating was present for ≥50% studies contributing to an outcome within the Cochrane Risk of Bias assessment. Downgrading by two points occurred where ≥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. With regard to inconsistency, downgrading by one point occurred if the $\hat{I}^2$ statistic was ≥40%, indicating at least moderate heterogeneity, and by two points if the $\hat{I}^2$ statistic was ≥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. 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.\textsuperscript{66}

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 particularly serious problems with the factor in question.\textsuperscript{17}
Table DS4  GRADE assessment of outcomes – detail of assessment

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Included studies and index of outcome</th>
<th>Quality</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other factors</th>
<th>Overall</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective empowerment</td>
<td>Hamann et al (2006):19 patient-perceived involvement</td>
<td>0</td>
<td>0</td>
<td>-1</td>
<td>-1</td>
<td>0</td>
<td>-2 (low)</td>
<td>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.</td>
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<td></td>
<td>Hamann et al (2011):56 decision self-efficacy</td>
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<td></td>
<td>Steinwachs et al:54 patient-centredness of interaction</td>
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<td></td>
<td>Thornicroft et al:52 perceived coercion</td>
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<td></td>
<td>Woltmann et al:55 patient-perceived involvement</td>
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<td>Outcome</td>
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<td>Reduction in objective coercion</td>
<td>Henderson <em>et al.</em>[^31] days’ treatment under section of MHA</td>
<td>0</td>
<td>-2</td>
<td>0</td>
<td>-2</td>
<td>0</td>
<td>-3</td>
<td>(very low) There being only two studies with widely divergent results afforded a high level of heterogeneity and imprecision, resulting in very low quality evidence.</td>
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<tr>
<td></td>
<td>Thornicroft <em>et al.</em>[^52] days’ treatment under section of MHA</td>
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<tr>
<td>Patient-rated relationship with clinician</td>
<td>Hamann <em>et al.</em> (2011):[^56] trust in physician</td>
<td>0</td>
<td>-1</td>
<td>0</td>
<td>-1</td>
<td>0</td>
<td>-2</td>
<td>(low) Judgements of inconsistency and imprecision due to moderate negative effect in Hamann <em>et al.</em> (2011).[^56]</td>
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<td></td>
<td>Swanson <em>et al.</em>[^56] working alliance</td>
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<td></td>
<td>Thornicroft <em>et al.</em>[^52] working alliance</td>
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<td></td>
<td>Van Os <em>et al.</em>[^53] patient-rated quality of communication</td>
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<td>Outcome</td>
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<tr>
<td>Patient-rated relationship with clinician – ‘trust’ excluded</td>
<td>Hamann <em>et al.</em> (2011): trust in physician</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-1</td>
<td>0</td>
<td>-1 (moderate)</td>
<td>Imprecision due to 95% CI spanning trivial to low-to-moderate effects.</td>
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<td></td>
<td>Swanson <em>et al.</em> working alliance</td>
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<td></td>
<td>Thornicroft <em>et al.</em> working alliance</td>
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<td></td>
<td>Van Os <em>et al.</em> patient-rated quality of communication</td>
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<td>Outcome</td>
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<td>Other factors</td>
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<tr>
<td>Clinician-rated decision-making abilities of knowledge</td>
<td>Hamann <em>et al.</em> (2006):¹⁹ knowledge about disease and medication</td>
<td>-1</td>
<td>-2</td>
<td>-2</td>
<td>-1</td>
<td>0</td>
<td>3</td>
<td>Quality down-rated due to risk of attrition bias in Hamann <em>et al.</em> (2006)¹⁹ and reporting bias in Elbogen <em>et al.</em> ⁴⁹ 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.</td>
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<tr>
<td>Hamann <em>et al.</em> (2011):⁵⁶ decisional capacity</td>
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<tr>
<td>Elbogen <em>et al.</em>:⁴⁹ decisional capacity (reasoning only)</td>
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</table>
E. Funding sources of included studies

Table DS5 gives the funding sources of the included studies. The authors of six studies\textsuperscript{51-56} reported explicitly there being no conflict of interest, and there was none apparent in the remaining two studies.\textsuperscript{19, 49, 50}

Table DS5  Funding sources of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Funding source</th>
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<tbody>
<tr>
<td>Hamann et al (2006)\textsuperscript{19}</td>
<td>German Ministry of Health and Social Security</td>
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<tr>
<td>Hamann et al (2011)\textsuperscript{56}</td>
<td>German-Israeli Foundation for Research and Development</td>
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<tr>
<td>Henderson et al\textsuperscript{51}</td>
<td>Medical Research Council</td>
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<tr>
<td>Steinwachs et al\textsuperscript{54}</td>
<td>National Institute of Mental Health, USA</td>
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<tr>
<td>Swanson et al\textsuperscript{50} and Elbogen et al\textsuperscript{49}</td>
<td>National Institute of Mental Health, USA; MacArthur Foundation Research Network on Mandated Community Treatment</td>
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<tr>
<td>Thornicroft et al\textsuperscript{52}</td>
<td>Medical Research Council</td>
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<tr>
<td>Van Os et al\textsuperscript{53}</td>
<td>Astra Zeneca</td>
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<tr>
<td>Woltmann et al\textsuperscript{55}</td>
<td>West Family Foundation; Segal Family Foundation</td>
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F. Additional references


Appendix 3
Author guidelines for Social Science and Medicine
Excerpts from author guidelines
Guidelines for qualitative papers
Excerpts from author guidelines for SSM

Journal Policies
The journal publishes the following types of contribution:
1) Peer-reviewed original research articles and critical analytical reviews in any area of social science research relevant to health and healthcare. These papers may be up to 8000 words including abstract, tables, and references as well as the main text. Papers below this limit are preferred.

Formatting requirements
There are no strict formatting requirements but all manuscripts must contain the essential elements needed to convey your manuscript, for example Abstract, Keywords, Introduction, Materials and Methods, Results, Conclusions, Artwork and Tables with Captions.
If your article includes any Videos and/or other Supplementary material, this should be included in your initial submission for peer review purposes.
Divide the article into clearly defined sections.

Figures and tables embedded in text
Please ensure the figures and the tables included in the single file are placed next to the relevant text in the manuscript, rather than at the bottom or the top of the file.

Text
In the main body of the submitted manuscript this order should be followed: abstract, main text, references, appendix, figure captions, tables and figures. Author details, keywords and acknowledgements are entered separately during the online submission process, as is the abstract, though this is to be included in the manuscript as well. During submission authors are asked to provide a word count; this is to include ALL text, including that in tables, figures, references etc.

Title
Please consider the title very carefully, as these are often used in information-retrieval systems. Please use a concise and informative title (avoiding abbreviations where possible). Make sure that the health or healthcare focus is clear.

Abstract
An abstract of up to 300 words must be included in the submitted manuscript. An abstract is often presented separately from the article, so it must be able to stand alone. It should state briefly and clearly the purpose and setting of the research, the principal findings and major conclusions, and the paper's contribution to knowledge. For empirical papers the country/countries/locations of the study should be clearly stated, as should the methods and nature of the sample, the dates, and a summary of the findings/conclusion. Please note that excessive statistical details should be avoided, abbreviations/acronyms used only if essential or firmly established, and that the abstract should not be structured into subsections. Any references cited in the abstract must be given in full at the end of the abstract.

Research highlights
Research highlights are a short collection of 3 to 5 bullet points that convey an article’s unique contribution to knowledge and are placed online with the final article. We allow 85 characters per bullet point including spaces. They should be supplied as a separate file in the online submission system (further instructions
will be provided there). You should pay very close attention to the formulation of the Research Highlights for your article. Make sure that they are clear, concise and capture the reader's attention. If your research highlights do not meet these criteria we may need to return your article to you leading to a delay in the review process.

Keywords
Up to 8 keywords are entered separately into the online editorial system during submission, and should accurately reflect the content of the article. Again abbreviations/acronyms should be used only if essential or firmly established. For empirical papers the country/countries/locations of the research should be included. The keywords will be used for indexing purposes.

Methods
Authors of empirical papers are expected to provide full details of the research methods used, including study location(s), sampling procedures, the date(s) when data were collected, research instruments, and techniques of data analysis. Specific guidance on the reporting of qualitative studies are provided.

References
Reference formatting
There are no strict requirements on reference formatting at submission. References can be in any style or format as long as the style is consistent. Where applicable, author(s) name(s), journal title/book title, chapter title/article title, year of publication, volume number/book chapter and the pagination must be present. Use of DOI is highly encouraged. The reference style used by the journal will be applied to the accepted article by Elsevier at the proof stage. Note that missing data will be highlighted at proof stage for the author to correct. If you do wish to format the references yourself they should be arranged according to the following examples:

Reference style

List: references should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.

Examples:
Reference to a journal publication:

Reference to a book:

Reference to a chapter in an edited book:

Supplementary data
Elsevier accepts electronic supplementary material to support and enhance your research. Supplementary files offer the author additional possibilities to publish supporting applications, accompanying videos describing the research, more detailed tables, background datasets, sound clips and more.

**Guidelines for Qualitative Papers**

There is no one qualitative method, but rather a number of research approaches which fall under the umbrella of ‘qualitative methods’. The various social science disciplines tend to have different conventions on best practice in qualitative research. However SS&M has prepared the following general guidance for the writing and assessment of papers which present qualitative data (either alone or in combination with quantitative methods). General principles of good practice for all research will also apply.

**Fitness for purpose**

Are the methods of the research appropriate to the nature of the question(s) being asked, i.e.

- Does the research seek to understand social processes or social structures &/or to illuminate subjective experiences or meanings?
- Are the settings, groups or individuals being examined of a type which cannot be pre-selected, or the possible outcomes not specified (or hypothesised) in advance?

**Methodology and methods**

- All papers must include a dedicated methods section which specifies, as appropriate, the sample recruitment strategy, sample size, and analytical strategy.

**Principles of selection**

Qualitative research is often based on or includes non-probability sampling. The unit(s) of research may include one or a combination of people, events, institutions, samples of natural behaviour, conversations, written and visual material, etc.

- The selection of these should be theoretically justified e.g. it should be made clear how respondents were selected
- There should be a rationale for the sources of the data (e.g respondents/participants, settings, documents)
- Consideration should be given to whether the sources of data (e.g people, organisations, documents) were unusual in some important way
- Any limitations of the data should be discussed (such as non response, refusal to take part)

**The research process**

In most papers there should be consideration of

- The access process
- How data were collected and recorded
- Who collected the data
- When the data were collected
- How the research was explained to respondents/participants
Research ethics

- Details of formal ethical approval (i.e. IRB, Research Ethics Committee) should be stated in the main body of the paper. If authors were not required to obtain ethical approval (as is the case in some countries) or unable to obtain ethical approval (as sometimes occurs in resource-poor settings) they should explain this. Please anonymise this information as appropriate in the manuscript, and give the information when asked during submission.
- Procedures for securing informed consent should be provided

Any ethical concerns that arose during the research should be discussed.

Analysis

The process of analysis should be made as transparent as possible (notwithstanding the conceptual and theoretical creativity that typically characterises qualitative research). For example

- How was the analysis conducted
  - How were themes, concepts and categories generated from the data
  - Whether analysis was computer assisted (and, if so, how)
  - Who was involved in the analysis and in what manner
- Assurance of analytic rigour. For example
  - Steps taken to guard against selectivity in the use of data
  - Triangulation
  - Inter-rater reliability
  - Member and expert checking
  - The researcher’s own position should clearly be stated. For example, have they examined their own role, possible bias, and influence on the research (reflexivity)?

Presentation of findings

Consideration of context

The research should be clearly contextualised. For example

- Relevant information about the settings and respondents/participants should be supplied
- The phenomena under study should be integrated into their social context (rather than being abstracted or de-contextualised)
- Any particular/unique influences should be identified and discussed

Presentation of data:

- Quotations, field notes, and other data where appropriate should be identified in a way which enables the reader to judge the range of evidence being used
- Distinctions between the data and their interpretation should be clear
- The iteration between data and explanations of the data (theory generation) should be clear
- Sufficient original evidence should be presented to satisfy the reader of the relationship between the evidence and the conclusions (validity)
- There should be adequate consideration of cases or evidence which might refute the conclusions

Amended February 2010
Appendix 4

Approval letters

University Research Sub Committee
Research Ethics Committee
Research and Development Departments
Diana Stowell
41 Moorside Road
Heaton Moor
Stockport
SK4 4DS

29th November 2012

Dear Diana,

Re: Feedback from Research Sub-committee - 19th November 2012

Thank you for your revised research proposal which was considered by the Research Sub-Committee Meeting on 19th November 2012. The committee were satisfied that the revisions made were appropriate and in accordance with the feedback from the meeting of 19th October 2012. You may now proceed with the research project as set out in your final proposal.

For the purposes of ethical scrutiny by relevant NHS and/or University bodies, this letter may be taken as confirmation that your research proposal has been independently reviewed and that it is considered to meet necessary scientific and methodological standards.

On behalf of the Research Subcommittee, we wish you good luck with your research work.

Yours sincerely,

[Signature]

Dr Dougal Hare
Lecturer in Clinical Psychology
Panel A Chair, Research Sub-Committee

C: Anthony Morrison, Alison Weardale and Paul Hatton
Research Ethics Committee

NRES Committee North West - Greater Manchester East
3rd Floor, Beetham House
4 Minshull Street
Manchester
M1 3DZ

19 April 2013

Ms Diana Stovell
41 Moorside Road
Heaton Moor
Stockport
SK4 4DS

Dear Ms Stovell

Study title: Making decisions about treatment for psychosis: A qualitative study of service users' experiences.
REC reference: 13/NW/0244
IRAS project ID: 120956

The Research Ethics Committee reviewed the above application at the meeting held on 16 April 2013. Thank you for attending the meeting to discuss the application.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of the favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator, Elaine Hutchings, nrescommittee.northwest-gmeast@nhs.net.

Discussion

With regard to capacity, you confirmed that this will be appropriately assessed and if there were any doubts about capacity, the service user would not be included in the study or would be withdrawn, and any data obtained so far relating to the participant concerned would not be included in the study.

The telephone number given in the poster and the information sheet was queried and you advised that this was a work number and not a personal number.

On the question of seeking consent for you as the researcher to liaise with healthcare professionals regarding any factors which might affect the service user's participation in the study, you said that this is to provide an extra check if necessary. You were asked to be clearer on this point in the information sheet and consent form.
It was pointed out that it will not be possible to delete data relating to a participant who wishes to withdraw from the study once the data has been anonymised. You mentioned that this issue had also been raised by the Greater Manchester West Mental Health NHS Foundation Trust and would be addressed.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see ‘Conditions of the favourable opinion’ below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Participant information sheet

a. The information sheet should say that the study is being conducted for the purposes of obtaining an educational programme and give contact details for your supervisor.

b. Under the heading ‘Can I withdraw from the study if I change my mind?’, it should explain that data and information obtained in the study can be withdrawn up to the time of removing personal details and pooling of the data taken from all participants; after this time, it will not be possible to identify and remove an individual’s data.

c. It should say that you will liaise with healthcare professionals as well as notify them about the service user’s participation where necessary.

d. Under the heading ‘Who has reviewed the study?’, the name of the reviewing Research Ethics Committee should be given.

Consent form

a. Point 6 of the form should reflect the position stated in point ii above.

b. A separate point should be included to seek consent for the use of anonymised quotations in your study report.

c. Point 8 should include consent for liaison with healthcare professionals as per point iii above.
Suggestions

- The phrase 'treatment-related decision-making' in the poster is rather technical and could be changed or removed.

- References to 'tapes' could be replaced by 'recordings' as tapes are no longer in common use.

Please notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ('R&D approval') should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ('participant identification centre'), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertisement</td>
<td>Version 1</td>
<td>27 January 2013</td>
</tr>
<tr>
<td>Covering Letter</td>
<td></td>
<td>20 March 2013</td>
</tr>
<tr>
<td>Evidence of insurance or indemnity</td>
<td></td>
<td>11 March 2013</td>
</tr>
<tr>
<td>Interview Schedules/Topic Guides</td>
<td>Version 3</td>
<td>03 March 2013</td>
</tr>
<tr>
<td>Investigator CV</td>
<td>Diana Stovell</td>
<td>31 December 2012</td>
</tr>
<tr>
<td>Letter from Sponsor</td>
<td></td>
<td>11 March 2013</td>
</tr>
<tr>
<td>Other: Referrer Information Sheet</td>
<td>Version 1</td>
<td>28 December 2012</td>
</tr>
<tr>
<td>Other: Letter to healthcare provider</td>
<td>Version 1</td>
<td>27 January 2013</td>
</tr>
<tr>
<td>Other: Letter from Chair of University of Manchester Research Sub Committee</td>
<td>29 November 2012</td>
<td></td>
</tr>
<tr>
<td>Other: Summary of Protocol in Non-Technical language</td>
<td>Version 1</td>
<td>02 January 2013</td>
</tr>
<tr>
<td>Other: Summary Interview Topic Guide</td>
<td>Version 1</td>
<td>03 March 2013</td>
</tr>
<tr>
<td>Other: CV - Anthony Paul Morrison</td>
<td>18 March 2013</td>
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</tr>
<tr>
<td>Other: CV - Alfon Warden</td>
<td>18 March 2013</td>
<td></td>
</tr>
<tr>
<td>Other: CV - Dr Paul Hutton</td>
<td>18 March 2013</td>
<td></td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>Version 2</td>
<td>03 March 2013</td>
</tr>
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<td>Participant Information Sheet</td>
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<td>03 March 2013</td>
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<tr>
<td>REC application</td>
<td>120855/426197/1.23</td>
<td>08 March 2013</td>
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Membership of the Committee

The members of the Ethics Committee present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review
We are pleased to welcome researchers and R&D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

[Signature]

Mr Francis Chan
Chair

Email: nrescommittee.northwest-gmeast@nhs.net

Enclosure: List of names and professions of members present at the meeting

“After ethical review – guidance for researchers”

Copy to:

Ms Lynne McRae, University of Manchester

Ms Sandra Igbodo,

Greater Manchester West Mental Health NHS Foundation Trust Research and Development Office
25 April 2013

Ms Diana Stovell
41 Moonside Road
Heaton Moor
Stockport
SK4 4DS

Dear Ms Stovell

Study title: Making decisions about treatment for psychosis: A qualitative study of service users' experiences.

REC reference: 13/NW/0244
IRAS project ID: 120856

Thank you for your letter of 23 April 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 19 April 2013.

Documents received

The documents received were as follows:

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<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertisement</td>
<td>Version 2</td>
<td>23 April 2013</td>
</tr>
<tr>
<td>Covering Letter</td>
<td></td>
<td>23 April 2013</td>
</tr>
<tr>
<td>Participant: Consent Form</td>
<td>Version 5</td>
<td>23 April 2013</td>
</tr>
<tr>
<td>Participant: Information Sheet</td>
<td>Version 4</td>
<td>23 April 2013</td>
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</tbody>
</table>

Approved documents

The final list of approved documentation for the study is therefore as follows:

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<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertisement</td>
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</tr>
<tr>
<td>Evidence of insurance or indemnity</td>
<td></td>
<td>11 March 2013</td>
</tr>
</tbody>
</table>
You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to H&D offices at all participating sites.

13/NW/0244 Please quote this number on all correspondence

Yours sincerely

Signed on behalf of
E. Hutchings (Mrs)
Committee Coordinator

E-mail: nreccommittee.northwest-qmasl@nhs.net

Copy to: Ms Lynne MacRae – fmhusethicsapps@manchester.ac.uk

Ms Sandra Igboho - Greater Manchester West Mental Health NHS Foundation
Trust Research and Development Office

A Research Ethics Committee established by the Health Research Authority
Research and Development Departments

Greater Manchester West NHS Mental Health NHS Foundation Trust

Standardised Process for Electronic Approval of Research

29 April 2013

Ms Diana Stovell
Division of Clinical Psychology
2nd Floor, Zochosics Building
University of Manchester
Brunswick Street
Manchester M13 9PL

Research & Development Office
Room F336, Hanna House
Bury New Road
Prestwich
Manchester M25 3BL

Tel: 0161 772 3591/3594/3492/2933
Email: kathryn.bannock@gmw.nhs.uk
jennifer.hughes@gmw.nhs.uk
sandra.igboho@gmw.nhs.uk
aura.o.brien-kling@gmw.nhs.uk

Information for ID Badge if required:
Research Project Ref No: 774
Expiry Date: 30 June 2014
You must take this letter with you.

Dear Ms Stovell

Re: NHS Permission for Research

Project Reference: 774
Unique SPEAR Identifier: 1217
CSP Reference Number: N/A
IRAS/REC Reference Number: 13/NW/0244
Sponsor: University of Manchester
Protocol Version and Date: Version 3.0, 8 March 2013
Project Title: Making decisions about treatment for psychosis: A qualitative study of service users’ experiences
Date of Permission: 29 April 2013

Further to your request for permission to conduct the above research study at this Trust, we are pleased to inform you that this Trust has given NHS permission for the research. Your NHS permission to conduct research at this site is only valid upon receipt of a signed ‘Conditions for NHS Permission Reply Slip’ which is enclosed.

Please take the time to read the attached conditions for NHS permission. Please contact the R&D Office should you require any further information. You will need this letter as proof of NHS permission. Please note when contacting the R&D office about your study you must always provide the project reference numbers provided above.

NHS permission for the above research has been granted on the basis described in the IRAS application form, Protocol and supporting documentation.

Sincerely,

Research & Development Office
Greater Manchester West Mental Health NHS Foundation Trust, Trust HQ, Bury New Road, Prestwich, Manchester M25 3BL Tel: 0161 773 9121

Chair: Alan Maden
Chief Executive: Bov Humphrey

164
The documents reviewed were:

Protocol: Version 3.0, 8 March 2013
Participant Information Sheet: Version 4.0, 23 April 2013
Participant Consent Form: Version 5.0, 23 April 2013
R&D Form: 19 March 2013
SSI Form: 15 March 2013
REC letter giving favourable ethical opinion: Dated 25 April 2013

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework and N-I-S Trust policies and procedures. Permission is only granted for the activities for which a favourable opinion has been given by the Ethics Committee.

Permission covers all locations within the Trust, however, you should ensure you have liaised with and obtained the agreement of individual service/ward managers before commencing your research.

We would like to point out that hosting research studies incurs costs for the Trust such as: staff time, usage of rooms, arrangements for governance of research. We can confirm that in this instance we will not charge for these. However we would like to remind you that Trust costs should be considered and costed at the earliest stage in the development of any future proposals.

May I wish you every success with your research.

Yours sincerely

[Signature]

Dr Stephen Colgan
Medical Director and R&D Lead

cc: Sponsor, University of Manchester

Enc: Approval Conditions Leaflet
      Induction & ID Badge Information, TrustTECH Leaflet
Dear Diana,

Research and Development amendment approval letter: Amendment: 1  
Re: Study title: Making decisions about treatment for psychosis: A qualitative study of service users’ experiences  
Pennine Care reference: 13 A 03-A  
REC reference: 13/NW/0244  
IRAS reference: 120859

Thank you for notifying us of an amendment to your research project, and submitting the necessary documentation to support this. These changes have been reviewed by the Research and Development (R&D) Department in regards to the project's continuing impact and suitability for the Trust. As previously, we have also verified the relevant documentation and approvals from all necessary regulatory agencies.

On this basis, we are able to grant approval for this amendment and hence to continue to endorse your project at Pennine Care NHS Foundation Trust, subject to the revised terms and conditions listed below:

- The currently approved protocol is now Version 4 dated 30th November 2013 and the approved documents, including the Participant Information Sheet and Informed Consent Form, are those listed in the Research Ethics Committee's favourable opinion letter for this amendment dated 20th January 2013. These must be the only versions in use.
- The research must continue to meet all of the other terms and conditions detailed in the original project approval letter dated 17th May 2013.
- Any further project specific conditions as detailed below:

Thank you again for submitting details of this amendment. If you need any further assistance, then please feel free to contact the R&D Department via the contact details at the top of this letter.

Research and Development amendment approval letter: Amendment: 1  
Re: Study title: Making decisions about treatment for psychosis: A qualitative study of service users’ experiences  
Pennine Care reference: 12 A 03-A  
REC reference: 12/NW/0244  
IRAS reference: 120859

Name: Reigan Birkh  
Role: Associate Director of Quality Assurance and Research, Pennine Care NHS Foundation Trust

Project Amendment Approval Letter v1.0, 010May14
Appendix 5

Recruitment materials

Information for referrers

Poster

Participant information sheet

Consent form

Letter to healthcare provider
We are looking for participants who have experienced treatment for psychosis to take part in a research study. The study forms part of a research project for a Clinical Psychology Doctorate.

We would be grateful if you might consider whether any individuals on your caseload are suitable.

**Referring people to the study should involve minimal extra work. Please see the section below on how to refer.**

**Background and overview of the research**

Since introduction of the Mental Capacity Act (MCA, 2005), treatment decision-making capacity has been a salient issue in health services. It is conceptualised as the ability to understand, retain, weigh up and communicate information relevant to a decision about treatment. Under the MCA clinicians are obliged to try and help an individual improve their treatment decision-making capacity, where this is compromised, before ‘acting in their best interest’.

This is of particular concern for people with psychosis who are frequently judged not to have capacity and who might, in consequence, be treated involuntarily. However there is little direct evidence to suggest what might help in supporting people with psychosis to improve their treatment decision-making capacity. Such evidence as exists suggests possible influence on decision-making processes of numerous aspects of individuals’ social, psychological and emotional experience.

The current study aims to explore such experiences further by conducting in-depth interviews with people with psychosis about their experience of treatment decision-making situations. These experiences might relate to decisions about treatment that they have made themselves and/or those that have been made by others on their behalf. It is hoped that detailed analysis of these accounts might help inform development of interventions to improve treatment decision-making capacity in people with psychosis, where this is compromised.

**Characteristics of suitable participants**

We are inviting people to take part in the research who have experience of receiving treatment for psychosis. In total we aim to recruit 6-8 participants.

**Inclusion criteria**

- Aged 18-65
- Diagnosis of non-affective psychosis e.g. schizophrenia, brief psychotic disorder, psychosis NOS and/or receiving treatment from an Early Intervention Team for psychosis.
- Experience of treatment for a psychosis spectrum disorder.
- Ability to reflect on and talk in depth about personal experiences.
- Command of English sufficient to engage in an in-depth interview.

Exclusion criteria

- In crisis or receiving inpatient care.
- Immediate risk to self or others.
- Organic basis to psychosis.
- Primary diagnosis of alcohol or substance dependence.
- Moderate to severe learning disability.
- Lacks capacity to consent.

What will be involved for participants

Individuals agreeing to take part in the study will be asked to meet with the researcher for one in-depth interview of about 30-60 minutes. This will involve talking about experiences of situations where decisions have been made about their treatment for psychosis. The kinds of things they will be asked about might include what happened and what it was like for them, how other people seemed to them at the time, how they felt about themselves and what helped or made things more difficult. However participants will not be asked to talk about anything that they don’t feel comfortable to.

How to refer people to the study

- Please approach the individual and ask if they might be interested in taking part.
- If so, please give them a Participant Information Sheet (copies supplied).
- If still interested, please ask for their consent to have the researcher contact them.
- Please contact Diana Stovell with their details on 07599933469 or diana.stovell@postgrad.manchester.ac.uk

What would happen next

- The researcher would make contact with the individual to give more information as needed.
- The individual would have at least 48 hours between this contact and being asked whether they wish to take part.
- If they agree to participate, a time and place would be arranged for the research interview, taking account of any risk issues and following lone working protocols.
- Their permission would be sought to inform their Care Coordinator or GP that they are taking part.
- Permission would also be requested to ask their Care Coordinator or GP about any factors that might affect their participation in the study. Any issues concerning their well-being or risk would be of primary concern.
- Contact details for the Care Coordinator or GP would be noted for all participants.
- Time would be allowed to go through the Participation Information Sheet before seeking written informed consent at the time of the interview.
Answers to possible concerns that individuals might have about taking part

Choice about participation

- Individuals are free to choose to take part or not.
- Participants are free to withdraw from the study at any time without giving a reason.
- A decision not to take part, or to withdraw from the study, will have no adverse consequences for the individual and will not affect their care in any way.

Advantages and disadvantages of taking part

- Advantages of taking part might include:
  - Having an opportunity to talk through personally meaningful experiences related to treatment for psychosis.
  - Having opportunity to contribute to research that might help people have more say in their treatment in the future.
- A disadvantage of taking part is that the interview may bring to mind distressing experiences. The researcher is a Trainee Clinical Psychologist who, by drawing on experience, training and supervision, will be able to respond sensitively if individuals become distressed.

Confidentiality

- Individuals’ participation would be kept confidential and strict protocols adhered to with regard to security of data.
- Confidentiality would only be breached in the event of concerns about risk to the participant or others.

Responsibility for the research

- The research is sponsored, funded and overseen by the University of Manchester and. It has been approved by an NHS Research Ethics Committee and by the local NHS Research and Development Department.
- The project forms part of a doctoral research project and is supervised by Professor Anthony Morrison and Dr Paul Hutton (GMW NHS Trust & University of Manchester) and Professor Alison Wearden (University of Manchester).
- Formal channels of communication and procedures exist to manage any complaints about the research or legal claims for compensation arising from it.

The results of the study

- A copy of the results will be passed to the University of Manchester Library. Participants will be invited to request a copy of any publications arising from the study.

Ethical considerations and management of risk
There may be some potential for participants to become distressed through talking about their experiences. A distress protocol is included within the research protocol to pre-empt and help manage this possibility. Key features of the protocol are offering to pause or end the interview in the event of a participant becoming distressed, allowing time for debriefing, providing assistance to seek support and sharing any concerns about risk with appropriate health professionals. Potential limits to confidentiality where there are concerns about risk will have been discussed at time of seeking participants’ consent, and the Care Coordinator’s or GP’s contact details will have been noted.

**Further information and contact details**

If you require any further information you can contact:

Diana Stovell  
Trainee Clinical Psychologist  
Email: diana.stovell@postgrad.manchester.ac.uk  
Tel: 07599933469

Dr Paul Hutton  
Research Clinical Psychologist  
Email: paulhutton@nhs.net  
Tel: 0161 772 4642

Prof. Anthony Morrison  
Professor of Clinical Psychology  
Email: tony.morrison@manchester.ac.uk  
Tel: 0161 772 4642
Participant information sheet

**Participant Information Sheet**

**Title of project:** Making decisions about treatment for psychosis: A qualitative study of service users’ experiences.

We would like to invite you to take part in a research study. This research is being carried out as part of a Doctorate in Clinical Psychology at the University of Manchester. Before you decide whether you would like to participate you need to understand why this particular piece of research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. If you are interested in taking part we will go through this information with you and answer any questions you might have.

**What is this research about?**

‘Psychosis’ is a term used to describe a range of experiences, such as hearing distressing voices or holding very distressing beliefs about being harmed by others. Sometimes it may be necessary to provide treatment to help with the distress associated with these experiences.
However, when experiencing psychosis, people may find it difficult to make decisions about their treatment. Clinicians are required to help people in this situation improve their decision-making abilities. They must do this before treating them without their consent.

For clinicians to know how to help, evidence of what it is like to be in these kinds of situations is needed. The aim of this research is to explore people’s experiences of situations where they and/or other people have made decisions about their treatment for psychosis. This might give clinicians useful information about how to help people have more say in their treatment.

**Why have I been invited to take part?**

We are inviting people to take part in the research who have experience of receiving treatment for psychosis. In total we aim to recruit 6-8 participants.

**What will it involve for me?**

If you agree to take part in the study, you will be asked to meet and talk with the researcher about your experiences of situations where decisions have been made about your treatment for psychosis. These may be situations where others made the decisions or where you had more say. The kinds of things you will be asked about might include what happened and what it was like for you, how other people seemed to you at the time, how you felt about yourself and what helped or made things more difficult. However we don’t have to discuss anything you don’t feel comfortable talking about. It will be like a conversation about your experience and will probably last between 30 minutes and an hour.

This will be audio taped so that the researcher can look for any common themes. The recordings will be transcribed, the transcripts stored securely and the voice recordings then destroyed. The researcher’s supervisors, Professors Anthony Morrison and Alison Wearden and Dr Paul Hutton may read some of the transcripts in order to aid analysis.

For purposes of monitoring and auditing the quality of the research, it is possible that personnel from the University of Manchester, regulatory authorities or NHS might have access to interview material.

**Expenses and payments**

You will receive a payment of £10 for the interview session to cover any travel costs, and to compensate you for any inconvenience caused by taking part.

**What will this mean for my treatment or support?**

If you are currently receiving treatment or support, you can access this in the usual way, via your care team. Your decision about whether to take part in this research will not affect your treatment or care in any way.

**Advantages and disadvantages of taking part**

It is hoped that your account of your experiences will add to understandings of how to help individuals with psychosis who might find it difficult to make decisions about their treatment. This is important to people having more say in how they are treated.

The hope is also that the study will give participants the opportunity to talk about their personal experiences in a non-judgemental, empathic environment.

However it is possible that talking about your personal experiences may cause you some distress. The person interviewing you will be sensitive to this and has previous experience of working with people who have had similar kinds of experiences. You will have the opportunity to discuss any concerns at the end of interview. You are also free to withdraw from the project at any point without this affecting any treatment you are receiving.
Do I have to take part?

It is up to you to decide. If you are interested in taking part, we will go through this information sheet with you. We will explain anything that is not clear and answer any questions you may have. We will also give you a copy to keep. You may wish to discuss whether or not to take part with someone who supports you, such as your Care Coordinator. Additionally, the Patient Advice and Liaison Service (PALS) is able to provide independent general advice about taking part in research. Their web address is http://www.pals.nhs.uk/ and their telephone number is 0161 945 7973.

If you decide you would like to participate we will then ask you to sign a consent form. This will show that you have agreed to take part. However you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

Can I withdraw from the study if I change my mind?

If you decide to take part you are still free to withdraw at any point, without giving a reason. You can choose for your data to be withdrawn from the study up to the point at which your personal details are removed from it and it is pooled with other participants’ data. However after this time it will not be possible to identify and remove individual participants’ data.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of any care that you receive.

Will my taking part in this study be kept confidential?

Your participation in the study will be kept confidential and all data recorded will be made anonymous. This will be done by storing all information about your identity separately from data gathered during the study. All participants will be assigned an identification number. This will be used to identify participants’ interview data instead of their name and personal details. Some direct quotations from respondents will be included in the final publication of the research. These will be completely anonymous. All data will be stored securely either in paper documents that are kept locked away, or in password-protected computer documents. Personal data will not be kept any longer than 12 months, and will be destroyed by this time. Completely anonymous copies of people’s responses may be retained in secure University storage for up to 5 years after the study.

We will ask your permission to inform your Care Coordinator or GP that you are participating in the study. We will also seek your permission to ask them about anything that might affect your participation in the study. This is to provide an additional safeguard with respect to your well-being. Additionally, if we were to become concerned about your well-being, or that of others, during the study we would ask for your permission to tell a health professional who knows you. This might be your Care Coordinator or GP. Due to our duty of care to you, in extreme cases, it may be necessary to breach the confidentiality of this study. If you were to express specific intent to hurt yourself or others, we would need to inform your management team or a suitable professional.

What will happen to the results of the research study?
A copy of the results of the study will be passed on to the University of Manchester Library. There are also plans to submit the results for publication in an academic journal. If you are interested in receiving a copy of any publications from this study, please tell the researcher at the interview.

Who is organising and funding the research?

The researcher is undertaking this project as part of a Doctorate in Clinical Psychology at the University of Manchester. The contact details for the researcher’s academic and clinical supervisors are provided below.

The research is sponsored by The University of Manchester.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of appropriately qualified people, called a Research Ethics Committee. Their job is to see that the research will not threaten your safety, rights, wellbeing or dignity. This study has been reviewed by the NRES Committee North West - Greater Manchester East.

What if there is a problem?

Complaints

- If you have concerns about any aspect of this study, you should ask to speak to the researcher who will do their best to answer any questions. If they are unable to resolve your concern, or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator. They can be reached on 0161 275 7583 or 0161 275 8093, or by email at Research.Complaints@Manchester.ac.uk
- You can also seek independent advice from The Patient Advice and Liaison Service (PALS) on 0161 945 7973.

Harm

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or NHS Trusts but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Further information and contact details

If you require any further information you can contact:

Diana Stovell
Trainee Clinical Psychologist
Email: diana.stovell@postgrad.manchester.ac.uk
Tel: 07599933469

Dr Paul Hutton (Clinical Supervisor)
Research Clinical Psychologist
Email: paulhutton@nhs.net
Tel: 0161 772 4642

**Prof. Anthony Morrison (Academic Supervisor)**

Professor of Clinical Psychology

Email: tony.morrison@manchester.ac.uk

Tel: 0161 772 4642

**Prof. Alison Wearden (Academic Supervisor)**

Professor of Health Psychology

Email: alison.wearden@manchester.ac.uk

Tel: 161 275 2588
CONSENT FORM

Client Identification Number for this study:

Title of Project: Making decisions about treatment for psychosis: A qualitative study of service users’ experiences.

Name of Researcher: Diana Stcvell

1. I confirm that I understand the nature of the study proposed, having read and understood the information sheet provided. I have had opportunity to ask questions, and I am satisfied with the answers I received.

2. I understand that my participation is voluntary, and that I am free to withdraw from the study at any time. Should I wish to withdraw, I understand that I can do so without giving reason, and without my medical care or legal rights being affected.

3. I agree that you may audio record the interview.

4. I agree that the project supervisors Professors Morrison and Waarden and Dr Hutton may read a transcript of the tape to aid data analysis.

5. I understand that data collected during the study may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.

6. I agree that, if I decide to withdraw from the study, then the researchers can continue to use the data and information I have already given them unless I ask for this to be destroyed. However I recognise that if I withdraw some time after my interview, when my data has been pooled with that of other participants, it may not be possible to withdraw my data.

7. I agree to take part in the study.

8. I agree to have the researcher inform a suitable healthcare professional about my participation in the study. This will be my Care Coordinator if I have one, or my GP if not. I also give my permission for the researcher to ask my Care Coordinator or GP if there is anything that might affect my involvement in the study.

9. I understand that the final publication of the study will include direct quotations from respondents. Those will be completely anonymous. I give consent for data from my interview to be presented in this way.

Participant Name: ........................................ Date: ........................................ Signature: ........................................

Researcher: ........................................ Date: ........................................ Signature: ........................................
Dear

Re:

I write to inform you that your patient/client has agreed to take part in a piece of research about experiences of individuals who have had treatment for psychosis.

The research forms part of a doctoral research project and is supervised by Professor Anthony Morrison and Dr Paul Hutton (Greater Manchester West NHS Foundation Trust & University of Manchester) and Professor Alison Wearden (University of Manchester).

Participation will involve meeting with the researcher for an interview of up to an hour. Questions will be related to experiences of treatment-related decision-making. These might be associated with decisions made by the individual themselves about treatment or situations where others made decisions on their behalf.

If you have any questions or concerns about this, please do not hesitate to contact me or my supervisors. Dr Hutton and Professor Morrison can be reached on 0161 772 4642.

Yours sincerely

Diana Stovell, Trainee Clinical Psychologist
Appendix 6

Interview topic guides

Detailed interview topic guide

Summary interview topic guide
Detailed interview topic guide

Making decisions about treatment for psychosis: A qualitative study of service users’ experiences

Background information

- Can you tell me a bit about yourself?
  - How would you describe yourself?
  - What sorts of things do you enjoy?
- Can you tell me about your current situation?

Experience of treatment

- I know from the information you’ve already given me that you’ve had x treatment for psychosis. What’s that been like for you?

Questions about salient treatment decision-making experiences

- Can you tell me about a time that stands out for you when you and/or other people made a decision about your treatment for psychosis?
  - How did that decision-making situation come about/what happened?
    - What was going on for you/ how were you feeling in yourself at the time?
    - How did you and other people respond to what was happening?
  - What was it like to be in that situation where you were making that decision/that decision was being made for/about you?
    - How did you feel? How did you manage that?
  - How did you make sense of that situation where other people were making decisions for and about you?
    - What did you think was going through their mind?
• What made that situation easier or harder to manage?

OR

• How did you go about making the decision?
  ▪ What was involved for you?
  ▪ What made it easier or harder to make the decision?

• How do you think that your experience of symptoms affected what that situation was like for you?
  ▪ What effect did they have on how you saw the situation and felt about it?
  ▪ What effect might they have had on your ability to think about your situation and talk to other people about it?
  ▪ What effects might they have had on how you felt about decision-making – whether you wanted to make decisions about your treatment/how far you were able to/how happy you were for other people to/whether you wanted to stick to the decision afterwards?

• How were you feeling about yourself at the time?
  ▪ What was that like for you/how did you manage that?
  ▪ How do you think feeling that way about yourself contributed to how you went about making the decision/copied with that situation?

• What were things like with the people around you at the time? (MH professionals, family, partner etc).
  ▪ How much/what kind of contact did you have?
  ▪ How did you feel about your MH team/family/partner etc?

• How did you feel at the time about the decision that you/was made?
  ▪ What kinds of impacts did you think it would have on your life?
  ▪ What was that like for you/how did you manage that?

• What was your experience of the treatment/not having treatment that resulted from your/that decision?
  ▪ What was the effect on your quality of life?
  ▪ How did it affect how you felt about yourself and others?

• How do you feel now about that time and the decision that you/was made, looking back on it?
  ▪ How do you feel about yourself and the other people involved now as you look back on that decision?
  ▪ What impact has that decision had on you over time?

• What might have helped you have more involvement in this decision/what might have helped you in your decision-making?
  ▪ What might it have been like had this been offered/available?
Where a participant has talked about a situation where the treatment decision was made predominantly by them, they would then be asked about a situation where the decision had been made by others and vice versa:

**You’ve just told me about a situation where you/other people had most of the say in the decision that was made about your treatment. Can you tell me now about a different situation when you/other people were the one(s) making the decision?**

The same questions as those above would then be used as appropriate to elicit information about this situation.

- You’ve told me about two different kinds of decision-making situation. One where you had a lot of say in what treatment you had and one where other people made the decision on your behalf.
- Which kind of situation would you choose?
  - What is it about that kind of situation that is more helpful for you?
  - What is unhelpful or difficult about the other kind of situation?
  - What would be the ideal kind of treatment decision-making situation for you?
    - What might this be like?
    - In what ways might it be better for you than situations you’ve experienced in the past?
- Have you ever experienced a situation where the decision about your treatment was shared between you and others? If yes, What was this like?
  - How did this situation make you feel?
  - How was it helpful or unhelpful for you?
  - What was involved in coming to the decision?
  - How did this situation differ from other experiences you’ve had where the decision wasn’t shared?
- If no, What do you think this might be like?
  - How do think a situation like this might make you feel?
  - How might this be helpful or unhelpful for you?
  - What do you think might be involved in coming to the decision?
  - How do think this situation might differ from other experiences you’ve had where the decision wasn’t shared?

**Question about potential intervention to improve treatment decision-making capacity.**
• If some kind of therapy were developed to help with people with difficulties, making decisions about treatment for psychosis, what sort of thing do think would be helpful?
• What else do you think might help improve treatment decision-making situations for people with psychosis?

**Ending/omissions/debriefing**

• Is there anything that I have not raised that you would like to tell me about?
• People can sometimes be affected by talking about things from the past. What’s it been like for you talking to me today?
• Has there been anything particularly difficult or distressing that you feel you might need additional support to manage?

**Summary interview topic guide**

**Making decisions about treatment for psychosis: A qualitative study of service users’ experiences**

**Background information**

• Can you tell me a bit about yourself?
• Can you tell me about your current situation?

**Experience of treatment**

• What has your experience of treatment for psychosis been like?

**Questions about salient treatment decision-making experiences**

• Can you tell me about a time that stands out for you when you and/or other people made a decision about your treatment for psychosis?
• How did your experience of symptoms affect what that situation was like for you?
• How were you feeling about yourself at the time?
• What were things like with the people around you?
• What was helpful or unhelpful in that situation? What would have been helpful? What might be helpful in the future?
• What was it like for you after the decision was made and in the time following on from that?

If decision discussed was made by others, ask about one made with more autonomy and vice versa.
• What kind of situation do you find most helpful and why?

**Ending/omissions/debriefing**

• Is there anything that I have not raised that you would like to tell me about?
• What’s it been like for you talking to me today? Is there anything that you’d like support with?
Appendix 7

Examples of materials from the process of data analysis

Original themes and sub-themes from Participants 1 and 7
Example of diagrammatic representation of early provisional analysis
Example of early provisional combined themes and sub-themes
Example of illustrative quotations in early provisional analysis
Example of illustrative quotations for one of the final sub-themes
Original themes and sub-themes from Participants 1 and 7, grouped under provisional super-ordinate headings

Recovery Orientation

P1 Recovery orientation
- Autonomy associated with Recovery decisions
- Personal significance of Recovery decisions
- Recovery decisions are person-centred
- Involvement in recovery decisions
- Recovery orientation inspires hope
- Empowerment through Recovery-oriented opportunity

P7 Recovery orientation
- Seeking autonomy in managing well-being
- Support for Recovery-oriented autonomy
- Hope with Recovery-oriented perspective

The Person in the System

P1 The person in the system
- Decision-making in an impersonal system
- Threats to personhood
- Hope suppressed by system and process
- Importance of validating, person-centred support with decision-making
- Importance of values in treatment decision-making situations

P7 Regard for the person
- Seeking validation
- Value of person-centred engagement
**P7 Sublimation of the person**

Non-engagement with experience
Non-engagement with personal values
Capabilities overlooked
Subject to intrusive scrutiny
Person-antithetical decision-making
Disempowerment with felt sublimation of personhood
Unempathic approach

**Communication, information and issues of power**

**P1 Meaningful communication and its absence**

Absence of direct, meaningful communication
No clear rationale for decisions
Disempowerment with knowledge imbalance
Importance and challenge of self-representation
Empowerment through self-expression

**P7 Disempowerment with psychiatric practices**

Psychiatric perspective simplistic and disempowering
No rationale
Disempowerment with lack of information
Hopelessness from psychiatric perspective

**Power: dynamics, discourses & structures**

**P1 Discourses and structures of power**

Power of an unresponsive system
Collusive power of system
Marginalised within system
Power relations defined by role
Internalised discourses of power
Ultimate, immutable power
Experiential structures of power
Systemic structures of power

**P7 Power dynamics**
Autonomy within unequal power dynamics
Positivity within unequal power dynamics
Shortcomings invisible within power dynamics
Marginalised within process
Disempowered by systemic post-decision inertia

**Feelings of disempowerment**

**P1 Feelings of disempowerment**
Feeling abused and worthless
Feelings of incarceration
Limited agency
Learned helplessness
Feeling isolated within process
Felt sense of threat of coercion

**P7 Feelings of disempowerment**
Autonomy denied
Experience feels abusive
Felt sense of coercion
Felt sense of capacity reduced with coercion
Psychological and physiological influences

P1 Influence of mental and physical well-being
Loss of autonomy to psychosis
Destabilisation and distortion
Stabilising support
Effects of medication
Mind/body inter-relationship

P7 Felt sense of derogation
Felt sense of derogation by professionals
Vulnerability to self-derogation
History of derogation by others

P7 Psychological mindedness in treatment decision-making
Self awareness
Seeking understanding

Emotion and absence of emotion

P1 Emotion and absence of emotion
Absence of emotion
Emotions inspire decisions
Power of the system over emotions
Fear
Support with emotions in treatment decision-making
Emotions are part of Recovery decisions
P7 Induced negative affective response
Struggle to cope
Anger
Fear
Withdrawal

Relationship to constructions of mental illness

P1 Negotiating constructions of mental illness
Disempowerment with stigma and shame
Recovery and empowerment through resistance of mental illness construct
Negative constructions of psychosis-induced action
Recovery decisions in presence of symptoms and side effects
Seeking normalisation of experience
Agency about fit with constructions of ‘normality’
Sense of self in decision-making self shaped by social practices and discourses

P7 Relationship to social constructions around psychosis
Pejorative constructions of psychosis
Alternative constructions of ‘illness’/’normality’
Seeking normalisation
Life choices pathologised
Culture of over-pathologisation
Seeking agency with conformity to constructions of ‘normality’
Negotiating with discourses around medication
Challenge to traditional ‘expertise’
Relationship to traditional treatment

P1 Ambivalence about traditional treatment
Little sense of involvement or purpose on treatment
Influence of negative treatment experiences
Acquiescent trust in professionals’ decisions

P7 Relationship to medication
Medication can be helpful
Over-tranquilising effects of medication
Pathologisation of reasonable concerns about medication
Disempowerment with psychiatric attitudes to medication
Example of diagrammatic representation of early provisional analysis: Participants 1, 7 and 8

- Communication, information & support
- Psychological, physiological & mental health influences
- Negotiations of social constructions
- Feelings of disempowerment
- Power in systems, discourses & social constructions
- Person-centredness

Denotes later subsumption of themes into others.
Example of early provisional combined themes and sub-themes: Participants 1, 7 and 8

**Person-centredness**

Seeking person-centred support with TDM
Importance of listening and engaging with experience
Importance of validation
Need of compassion and empathy
Emotion, absence of emotion and need of emotional support
Sublimation of personhood
Respect for the person
Importance of relationship
Importance of responsiveness to need
Services and staff over-stretched or deficient
Inaccurate appraisal of coping and capabilities

**Recovery orientation**

Autonomy
Personal significance
Involvement and motivation
Hope
Importance of values
Medical model orientation
Power in systems, dynamics and social constructions

Stigma and shame
Power of social constructions of ‘mental illness’
Pathologisation of life choices and actions
Systemic power dynamics
Subjectively experienced power dynamics
Marginalisation
Taken-for granted power
Paternalistic medical model
Disempowering system and process
Coercion

Negotiating social constructions
Seeking agency with conformity to social constructions
Seeking normalisation
Alternative constructions
Resistance of social constructions

Feelings of disempowerment
Feeling abused
Issues of agency
Isolation
Struggle to cope
Fear and withdrawal
Feeling degraded
Communication, information and support

Disempowerment with knowledge imbalance
No rationale for decisions
Psychiatric approach feels dismissive and disempowering
Disempowering response to concerns about medication
Lack of support around TDM
Importance and challenge of self-representation
Need of another's voice

Psychological, physiological and mental health influences

Sense of self-worth
Psychological mindedness
Influence of subjective and objective distress from psychosis
Impact of psychosis on others’ perceptions of the person
Reduction in agency and self-efficacy with psychosis
Impact of medication on experience of TDM situations
Influence of treatment –related experiences and beliefs
Influence of life stressors
Trust
Influence of physical state
Example of illustrative quotations for one sub-theme in early provisional analysis – Participants 1, 7 and 8.

Power in systems, dynamics and social constructions

*Power of social constructions of mental illness*

P1 p39(956-965)

..it was that barrier what’s built up between being mentally ill and out of it, out of society, dropped out of society and then there was this, this opportunity to, to be part of society and get involved

P7 p37(920)-p39(950)

…with paranoid schizophrenia, erm, with all the publicity that it gets, the general idea is that treatment should always be given…I know that my psychiatrist can override me at any point if she thinks I’m going to become a danger, but because (sigh) // I think because I’m proactive with me own wellbeing, and she’s prepared to support that.

P8 p39(942-952)

…when a person has a mental illness, erm, a professional doesn’t really listen to ‘em, because you’ve got this label of, that you’re mentally ill, erm, and if something is worrying you…they think it’s just part of your illness…

P56(1367-1372)

…this is why I think I get the help really now, is because that doctor at (unit) told Dr (psychiatrist) that I had, had schizophrenia, I was a bit of a schizophrenic. From that day, of him saying that, I started getting help.
Example of illustrative quotations for one of the final sub-themes

Theme 3: Empower me with knowledge, support and enablement to self-expression

Sub-theme 3(i): Power dynamics in TDM – from the implicit to the coercive

Felt sense of power dynamics

P1 p35b(857-861)
…it’s the power thing in’t it? It’s the // you’re the mental patient and the system, you know, you’re against the system…

P1 P44-45(1086-1107)
…it’s that barrier, with the doctor… You trust, you trust the doctor don’t you? Cos it’s the doctor’s decision. // all I can, all I can say is, from my point of view, you know, this is how I feel, what I want… and all they can do is analyse me, and say, yeah, he’s ok or no he’s mentally ill or in pain or something, you know. It’s their decision in’t it, at the end of the day…

P8 p38(926-931)
I feel like it’s difficult to raise because they’re professionals, erm, I’m an ill person, with a mental illness, erm, and if I do, I think if I do raise it, I wont get anywhere anyway. They just palm you off with sommat..

P7 p38(994-950)
..I know that my psychiatrist can override me at any point if she thinks I’m going to become a danger, but because (sigh) // I think because I’m proactive with me own wellbeing, and she’s prepared to support that.

P6 p15d(363-374)
...you’re working with extremely vulnerable people, who .. are completely at your mercy...and that puts the psychiatrist ...gives them enormous power over people’s lives.....That is a tremendous responsibility that should never be down-played.

P4 p39(956-962)
...I’m a psychiatrist...I’m an expert in the field, // you...come here as some sort of like...some mentally ill person, and I’m there to decide for you...’cos you’re sort of incapable....and you sort of got dictated to...
...ask whether that person thinks that this medication is doing them any good and er, .. or whether it’s not, or, their personal opinion, but I suppose the doctors are supposed to know best aren’t they...

_Felt sense of coercion_

P1 p43(1044-1050)

They’ve got this control over me where, I had no say, and if I do say anything, they’d section me or put me in hospital, there’s that threat.

P7 p5(121-131)

...when I did get onto the ward, it was either (participant) you’ve got three days, it’s either an injection or you take your medication, so I took it. …when he threatened me with a section in the interview room, erm, I said // I think I said, I’ll go in voluntarily and he told me it was too late.

P6 p7d(175-182)

I was put under the care of the crisis team ...they...told me that, erm, if I didn’t stop going on about what had happened, then I’d probably find myself back in there, and....they didn’t mince their words...

_ Implicit power dynamics_

P1 p11b-12b(272-275)

P: ….that’s the decision they make. You can’t influence ‘em, or else, there’d be corruption wouldn’t there?

P7 p29(714-722)

…my psychiatrist now is very good, she’s all for, me getting new experiences, and going to therapy, erm, I have a certain amount of autonomy with the taking of my drugs…She did once offer to say, I’m willing to let you not have any medication…

P8 p23(556-565)

…it made me feel like .. I shouldn’t be doing that, you know, I, I don’t know what medication…I thought, I shouldn’t be doing that, you should be, you’re the doctor.
...the psychiatrist that I have got on, are treating me like a decent human being, treating me like an equal...and it’s just like having a normal conversation.

I go and see Dr (psychiatrist)...and they’re nice with me...almost with a bit of like, you know, like you’ve got a bit of input if necessary...So you’ve got almost like some sort of influence... it does lift me mood.
Appendix 8

Table of themes and sub-themes

To be included as supplementary material in submission to *SSM*
| 1. | ‘Listen, engage with my experience. Respect and empower the person that I am.’ |
|    | (i) Importance of listening, validating and engaging with experience |
|    | (ii) Need for respect, compassion and empathy |
|    | (iii) Counter disempowerment by system and process |
|    | (iv) Counter feelings of subjective empowerment |

| 2. | Experience of psychosis, its treatment and social meanings: ‘How I might be disempowered in TDM.’ |
|    | (i) Reduction in agency and self-efficacy with distressing psychosis |
|    | (ii) Influence of treatment-related experiences and beliefs |
|    | (iii) Power of negative social constructions of mental illness |
|    | (iv) Stigma, shame and low sense of self-worth |
|    | (v) Sense of being negatively judged by others |

| 3. | ‘Empower me with knowledge, support and enablement to self-expression.’ |
|    | (i) Power dynamics in TDM – from the implicit to the coercive |
|    | (ii) Disempowerment with knowledge imbalance and lack of support |
|    | (iii) Importance and challenge of self-representation |

| 4. | ‘Support my Recovery through TDM.’ |
|    | (i) Negotiating barriers to autonomy |
|    | (ii) Power of the medical model |
|    | (iii) Seeking treatment congruent with values and goals |
|    | (iv) Hope: an influence and an outcome in TDM |
Appendix 9
‘Research highlights’ and key words
To be included in online submission to *SSM*
IPA research highlights

- Reduced treatment decision-making capacity may disempower people with psychosis.
- Conceptualisations of decisional capacity may focus unduly on cognitive abilities.
- Emotions, values, experience and decision-making contexts may also affect capacity.
- An IPA study explored service users’ experience of treatment decision-making (TDM).
- This revealed also pervasive influence of power dynamics on TDM with psychosis.

Key words

UK, psychosis, decision-making, treatment, capacity, Interpretative Phenomenological Analysis, empowerment, recovery
Appendix 10
AMSTAR evaluation of literature review
AMSTAR - a measurement tool to assess the methodological quality of systematic reviews.

1. Was an 'a priori' design provided?
The research question and inclusion criteria should be established before the conduct of the review.

   | Yes | No | Can't answer | Not applicable |
---|-----|----|--------------|----------------|
   |     |    |              |                |

   Note: Need to refer to a protocol, ethics approval, or pre-determined/a priori published research objectives to score a "yes."

2. Was there duplicate study selection and data extraction?
There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

   | Yes | No | Can't answer | Not applicable |
---|-----|----|--------------|----------------|
   |     |    |              |                |

   Note: 2 people do study selection, 2 people do data extraction, consensus process or one person checks the other's work.

3. Was a comprehensive literature search performed?
At least two electronic sources should be searched. The report must include years and databases used (e.g., Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

   | Yes | No | Can't answer | Not applicable |
---|-----|----|--------------|----------------|
   |     |    |              |                |

   Note: If at least 2 sources + one supplementary strategy used, select "yes" (Cochrane register/Central counts as 2 sources; a grey literature search counts as supplementary).

4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

   | Yes | No | Can't answer | Not applicable |
---|-----|----|--------------|----------------|
   |     |    |              |                |

   Note: If review indicates that there was a search for "grey literature" or "unpublished literature," indicate "yes." SIGLE database, dissertations, conference proceedings, and trial registries are all considered grey for this purpose. If searching a source that contains both grey and non-grey, must specify that they were searching for grey/unpublished lit.

5. Was a list of studies (included and excluded) provided?
A list of included and excluded studies should be provided.

   | Yes | No | Can't answer | Not applicable |
---|-----|----|--------------|----------------|
   |     |    |              |                |

   Note: Acceptable if the excluded studies are referenced. If there is an electronic link to the list but the link is dead, select "no."

6. Were the characteristics of the included studies provided?
In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g., age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

   | Yes | No | Can't answer | Not applicable |
---|-----|----|--------------|----------------|
   |     |    |              |                |

   Note: Acceptable if not in table format as long as they are described as above.
7. Was the scientific quality of the included studies assessed and documented?
   A priori methods of assessment should be provided (e.g., for effectiveness studies if the
   author(s) chose to include only randomized, double-blind, placebo-controlled studies, or
   allocation concealment as an inclusion criterion); for other types of studies distinctive items
   will be relevant.
   Note: Can include use of a quality scoring tool or checklist, e.g., Jadad scales, risk of bias,
   sensitivity analysis, etc., as a description of quality items, with some kind of result for
   EACH study (“low” or “high”) is fine, as long as it is clear which studies scored “low” and
   which scored “high”; a summary score/range for all studies is not translated.
   
   
   
   8. Was the scientific quality of the included studies used appropriately in
   formulating conclusions?
   The results of the methodological rigor and scientific quality should be considered in the
   analysis and the conclusions of the review, and explicitly stated in formulating
   recommendations.
   Note: Might say something such as “the results should be interpreted with caution due to
   poor quality of included studies.” Cannot score “yes” for this question if scored “no” for
   question 7.
   
   
   
   9. Were the methods used to combine the findings of studies appropriate?
   For the pooled results, a test SHOULD be done to ensure the studies were combinable,
   assess their homogeneity (i.e., Chi squared test for homogeneity, F), if heterogeneity
   exists a random effects model should be used and/or the clinical appropriateness of
   combining should be taken into consideration (i.e., is it possible to combine?).
   Note: Indicate “yes” if they mention or describe heterogeneity, i.e., if they explain that
   they cannot pool because of heterogeneity/variability between interventions.
   
   
   
   10. Was the likelihood of publication bias assessed?
   An assessment of publication bias should include a combination of graphical aids (i.e.,
   funnel plot, other available tests) and/or statistical tests (i.e., Egger regression test,
   Hedges-Owen).
   Note: If the test values or funnel plot included, score “yes”. Score “yes” if mentions that
   publication bias could not be assessed because there were fewer than 10 included
   studies.
   
   
   
   11. Was the conflict of interest included?
   Potential source of support should be clearly acknowledged in both the systematic
   review and the included studies.
   Note: To get a “yes,” must indicate source of funding or support for the systematic
   review AND for each of the included studies.
   
   
   
   Additional notes (in italics) made by Michelle Wold, John Berman, and Carolyn Wayne based on
   conversations with Ben Shin and/or Trinity Theodore in June and October 2003 and July and
   September 2010.