Shared decision making interventions for psychosis: rationale & protocol for a systematic review and meta-analysis

ABSTRACT

Background: In recent years paternalistic practices by health professionals have been giving way to shared decision making between clinicians and service users. This shift has been notably more marked in physical than in mental health care. There has however been some progress towards shared decision making (SDM) in the care of those with mental health problems, and interventions have been developed to promote this. A relatively recent review of studies evaluating such interventions does not include the most recent work in this area. It also leaves open to question the extent to which the interventions empower service users. The current review will examine these as yet unaddressed areas. It will also differ from previous reviews in being specific to the area of psychosis.

Methods and design: Systematic searches shall be conducted of Medline, PsychInfo, EMBASE, CINAHL, The Cochrane Central Register of Controlled Trials (CENTRAL) and the references of previous reviews to identify randomised controlled trials evaluating the effectiveness of SDM interventions for psychosis, as compared with TAU or a control intervention. Primary outcomes will be service user empowerment and indices thereof. Secondary outcomes will be quality of service user-provider relationships and decision-making abilities as rated respectively by service users and clinicians.

Discussion: This review will provide information relating to the costs and benefits of SDM for service users, focusing on the extent to which SDM is associated with service user empowerment. Gaps in the evidence will be highlighted, and recommendations for future trial design will be made.
INTRODUCTION

Background

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 (Department of Health, 2012; Adams & Drake, 2006; Deegan, 2006). It is seen as falling mid-way on a continuum between paternalistic decision-making practices by clinicians and relatively autonomous informed decision-making by clients (Hamann, Leucht & Kissling, 2003; Duncan, Best & Hagen, 2010).

There is a significant body of research into SDM in physical healthcare and a number of benefits have been identified, such as improvements in functional and illness outcomes, greater client satisfaction and reduced psychological distress (Adams & Drake, 2006). SDM research and practice in the area of mental health however is at a very much less advanced stage (Schauer, Everett and del Vecchio, 2007). Schauer et al. suggest that the autonomy of individuals with mental health conditions is seen in psychiatry as being necessarily different to that of other patients due to generalised perceptions of reduced decisional capacity. This assertion resonates with a body of literature summarised by Fitzsimons and Fuller (2002) suggesting existence of a health service culture that is intrinsically disempowering for clients with serious mental health problems. Within such a culture it is perhaps unsurprising that progress towards SDM has been slow for this client group.

This culture however is at odds with strong policy initiatives which are detailed in the Department of Health publications, ‘Independence, choice and risk: a guide to best practice in supported decision making’ (DoH, 2007) and ‘Liberating the NHS: No decision about me, without me’ (DoH, 2012). These publications are 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’. It also cites contribution of the mental health charity, Mind to consultation on the document. Mind suggested that inclusion of service users’ expertise about their own well-being in decision-making about treatment increases efficiency of services and promotes recovery.

The view that SDM is bound up with recovery-oriented approaches to care is also expressed in the SDM literature (Schauer et al., 2007). Recovery-oriented approaches aim to prioritise service users’ goals (Pitt, Kilbride, Nothard, Welford & Morrison, 2007; Bellack, 2006) and SDM offers a vehicle through which these might become a central part of treatment decision-making. Where this is possible in the context of empathic, respectful relationships with clinicians, young service users with
psychosis have reported feeling empowered (Grealish, Tai, Hunter & Morrison, 2011), and empowerment itself is seen by service users as being a key element of recovery (Pitt et al., 2007; Neil et al., 2009; Bellack, 2006). Given that disempowerment is a particular issue for service users with psychosis (Vauth, Kleim, Wirtz & Corrigan, 2007; Kleim et al., 2008; Harrison & Gill, 2010), examination of the potential of SDM to empower this client group specifically would seem to be a worthwhile line of enquiry.

The literature on SDM in psychosis however has yet to be specifically reviewed. There exist only two reviews of studies looking at SDM in mental healthcare overall (Hamann et al., 2003; Duncan et al., 2010). These reviews found only three studies of SDM interventions and only two specifically for service users with psychosis, one of which was limited by having no control group. Neither review was able to draw firm conclusions overall or specifically in relation to SDM with psychosis.

Whilst there may be relatively few studies of SDM in mental healthcare due to research being at an early stage, these two reviews may have been limited by use of an overly stringent model of SDM. Both cite Charles’ (1997) model that defines SDM in terms of active sharing of information and participation by two parties in reaching a consensus about a particular decision. Both exclude studies of advance directives and studies evaluating interventions to improve service user/provider communication and relationships without reference to a particular treatment decision.

The nature of psychosis however, including its chronicity and potential for relapse, pervasive impacts on individuals’ lives and implications for how they might see their condition and relate to self and others all suggest that a broader model of SDM might be appropriate. Montori, Gafni and Charles (2006) recommend that SDM in long term conditions should encompass the ongoing relationship between the service user and their clinical team. ‘No decision about me, without me’ (DoH, 2012) advocates use of advance directives to support SDM where individuals’ decisional capacity might become compromised in the future. Chan and Mak (2012) suggest that a broader approach to enhancing the relationship between service users and providers may be needed due to the cognitive and communicative problems sometimes associated with psychosis. Thus it would seem appropriate to review studies evaluating a range of interventions, including those associated with particular decisions, those addressing broader negotiations between service users and providers about care, those empowering service users in their interactions with providers and those involving collaboration on joint crisis planning.

A review of SDM interventions specifically for service users with psychosis might also differ from existing reviews in terms of its outcomes. Duncan et al. (2010), in the only existing review of SDM in mental health to examine particular outcomes, looked primarily at global patient satisfaction and clinical and service related outcomes. Empowerment however might be an appropriate and more recovery and client-
centred choice of primary outcome for a further review of this area, given its importance to service users with psychosis and the seeming potential for its enhancement by SDM.

Objectives

Our key objective is to conduct a systematic review and meta-analysis of SDM interventions for people with a schizophrenia-spectrum diagnosis. The aim is to test the primary hypothesis that SDM will be significantly more effective than control interventions (e.g., treatment as usual, non-specific psychosocial treatments, information giving) on the primary outcome of empowerment, as judged by participants and indicated by objective measures. The effect of SDM on the secondary outcomes of quality of service user-provider relationship (service user-rated) and decision-making abilities and knowledge (clinician-rated) will also be evaluated.

METHODS

Inclusion and exclusion criteria

Population

Trials will be included only where ≥50% of participants have a diagnosis of schizophrenia, schizoaffective disorder or early psychosis. Studies where >50% participants have an established diagnosis of bipolar disorder or learning disability, a primary diagnosis of substance-induced psychosis or where psychosis results primarily from a general medical condition or organic pathology will be excluded. This is justified by the focus of the review on issues of empowerment. Research suggests that individuals with a schizophrenia-spectrum diagnosis are particularly susceptible to disempowerment associated with experience of stigma (Vauth et al., 2007; Kleim et al., 2008). Whilst other population groups, such as those diagnosed with a learning disability, may also be susceptible to disempowerment, its nature is likely to differ from that associated with experience of a schizophrenia–spectrum condition. The parameters of the population for the review are also in keeping with a precedent set by other reviews of interventions for people with a schizophrenia diagnosis such as Jones, Hacker, Cormac, Meaden and Irvings’ (2012) Cochrane Review. No limits will be placed on age of participants or severity or duration of illness.
**Interventions and comparators**

The interventions to be evaluated will be those seeking to promote collaboration between service users with psychosis and providers. Specifically they will seek to enhance shared decision-making in relation to current treatment, communication related to treatment or ongoing care and development of joint crisis plans. The interventions will be ones directed at service users or providers. All randomised controlled treatment trials comparing interventions of this nature with usual treatment, non-specific or specific control interventions will be included. Our emphasis is on empowerment through enhanced communication and collaboration between service users and providers. For this reason studies involving advance statements or care-planning where contribution of either party is absent or minimal will be excluded.

**Study design**

Inclusion will be limited to studies where there is random and concealed allocation of participants to treatment conditions. Single-blind and non-blind studies will be included. Observational studies, uncontrolled case series studies, crossover trials and cohort studies will be excluded.

**Outcomes**

In an initial scoping exploration of the literature only one study was found that measured empowerment directly. There are therefore two primary outcomes in the current review that cumulatively give an indication of empowerment. The first comprises subjective empowerment and indices of the same, namely decision self-efficacy, health locus of control, perceived patient involvement in decision-making, patient centeredness of service user/provider interaction and perceived coercion. The other primary outcome is objective coercion. Eligible reports must provide either continuous post-treatment data, on preferably a valid and reliable self-report or behavioural measure of subjective empowerment or of one of the listed indices of empowerment, or a measure of objective coercion (involuntary treatment under the Mental Health Act 2007).

The following empowerment-related secondary outcomes will also be examined: quality of service user-provider relationship (service user-rated) and decision-making abilities and knowledge (clinician-rated).

**Search strategy**

The references of previous reviews of SDM in mental healthcare (Hamann et al., 2003; Duncan et al., 2010) will be searched. Medline, PsychInfo, EMBASE, CINAHL and The Cochrane Central Register of Controlled Trials (CENTRAL) will also be
searched. Titles, abstracts and keywords will be searched in the publication databases using a strategy involving the term ‘shared decision making’ and related terms. These will include 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 will also include 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’. A full list of the terms will be included in the appendices to the report. No date limits will be placed on the search.

**Study selection**

Titles and abstracts will first be screened for relevance. Full-text reports of all potential studies will be accessed and the above-mentioned criteria used to assess their eligibility. Reasons for rejection of papers on basis of abstract or full-text will be documented and reported in a PRISMA flow-chart. Details of all electronic searches will be saved.

**Data extraction**

Predefined tables will be used to collate data (no of events, means, SDs) from relevant studies. Data extraction will also include study characteristics including type and object of intervention (e.g. SDM, joint crisis plan), duration of intervention, number of sessions offered, control condition, diagnosis, number of centres, baseline demographics (age, gender, symptom severity at baseline), follow-up data points and drop-out rates.

An initial scoping exploration of the literature revealed only one study that reported more than one of the indices of subjective empowerment comprising the first part of our primary outcome. Nonetheless a ‘data extraction hierarchy’ is needed to decide the order of preference for inclusion of our indices of subjective empowerment, should there be more than one measured in any given study. Construction of the hierarchy was based on closeness of the index concept to that of subjective empowerment. The hierarchy is as follows: decision self-efficacy > health locus of control > perceived patient involvement in decision making > patient-centerededness of interaction > perceived coercion.

For our second primary outcome of objective coercion, decisions about use of continuous data (e.g. number of days’ involuntary treatment under the MHA) or binary data (whether or not individuals were treated under the MHA) will depend on
data type across studies. The decision will be taken on the basis of potential for combining data in a meaningful way.

In the unlikely event that studies contain more than one measure of any of the indices of subjective empowerment, or of the secondary outcomes, decisions will be taken on a case by case basis about which to include, based primarily on the reliability and validity of the measure.

With all measures included, mean change scores will be preferable to endpoint scores.

Methodological quality

To ensure meaningful interpretation of included trials' effect sizes and conclusions, assessments of quality and risk of bias will be undertaken using, respectively, the GRADE approach (Guyatt et al., 2008) and the Cochrane Collaboration Risk of Bias Tool (Higgins et al., 2011a). This provides a categorical assessment of studies’ risk of bias by looking at selection and randomisation of participants, intervention concealment, attrition rates and reporting. Fidelity to study protocols will be assessed where possible and missing data sought through contact with authors.

The researcher will complete the GRADE online training (http://cebgrade.mcmaster.ca/). All decisions will be recorded with aim of providing greater transparency and giving indications as to the limits of the conclusions drawn.

Data synthesis and analysis

Meta-analytic calculations

For dichotomous data, a strict intention-to treat analysis will be employed, with the denominator in each case being the total numbers randomised to each group. Where participants fail to complete the intervention, it will be assumed that they had the unchanged outcome.

In the case of continuous outcomes, summary data produced using a mixed-model repeated measures imputation method will be used in preference to data based on last observation carried forward assumptions. For study data to be included, endpoint scores from 50% or more of those randomised will be required.

For binary data, calculations will include the relative risk (RR) of the unfavourable outcome, its 95% confidence intervals and the absolute risk difference (RD). The NNT will be calculated in two ways; (1) as the inverse of the RD and (2) as a product of the RR and a range of ‘assumed control risks’ (ACRs), following equations specified in section 12.5.4.3 of the Cochrane Handbook (Higgins, Green &
Collaboration, 2011b). For comparison of effect sizes, continuous data from different outcome measures will be combined to allow calculation of the standardised mean difference (SMD). Revman or Comprehensive Meta-Analysis software will be used to calculate the SMD and 95% confidence intervals (CI). Both adjust for small sample bias using the Hedges’ g. Two-tailed hypotheses will be tested throughout, and statistical significance will be assumed where p<.05.

A random-effects analysis will be used for both continuous and binary outcomes, but a secondary fixed-effects analysis will be performed where there is less than moderate heterogeneity. Where the I-squared statistic is 40% or more, moderate heterogeneity will be assumed (Higgins et al., 2011b).

Discussion

This proposed review will help clarify the benefits and costs of SDM interventions for service users with psychosis, focusing on the effect of SDM on subjective empowerment. The advance specification of hypotheses, scope and methodology outlined here will increase transparency and minimise the risk of bias (Stewart, Moher & Shekelle, 2012). Gaps in the evidence will be highlighted, and recommendations for future trial design will be made.

Currently available reviews may not have prioritised outcomes which are of value to service users, or outcomes which are relevant to service user definitions of recovery (Pitt et al., 2007; Grealish et al., 2011). The extent to which SDM interventions are underpinned by recovery-oriented values is also unclear. By examining outcomes of importance to service users, the results of this review may inform development of this promising area of intervention.

References


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