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Consumer-providers in the delivery of mental health services

TITLE

A systematic review of consumer-providers' effects on client outcomes in statutory mental health services: the evidence and the path beyond

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ABSTRACT

BACKGROUND

The past several decades has seen a steady increase in consumer-provider involvement in the delivery of mental health services, however the effects on client and service outcomes have remained unclear.

OBJECTIVES

The objectives of this paper are to 1) provide a summary of a Cochrane review of consumer-providers' effects on client outcomes in statutory mental health services, and 2) discuss several key issues that could be addressed to strengthen evidence in this area.

METHODS

We searched *The Cochrane Library*, MEDLINE, EMBASE, PsycINFO, CINAHL, and Current Contents until March 2012 to identify relevant studies. Studies were eligible for inclusion if they randomised adult clients to statutory mental health services delivered with and without consumer-provider involvement.

RESULTS

Eleven studies were included with two separate comparison groups: 1) studies comparing consumer-providers with professionals employed to do the same role within a mental health service (5 studies); and 2) studies comparing mental health services with and without consumer-providers as an adjunct to the service (6 studies). Limited outcome data available from the studies indicated there was no difference in quality of life, function, social relations, mental health symptoms, client satisfaction, or attrition in those receiving services from consumer-providers compared to those who did not. None of the included studies reported any adverse outcomes for clients. Key issues that could be addressed to strengthen the evidence include core outcome measures, appropriate study design for evaluating complex interventions, minimising cross-contamination of treatment groups for community-based

interventions, improved trial reporting, and the use of systematic reviews to inform the future research agenda.

MESH KEYWORDS:

Community Mental Health Services; Mental Health Services; Consumer Participation; Social Work, Psychiatric.

INTRODUCTION

This paper outlines the findings of a Cochrane systematic review comparing mental health services with and without consumer-provider involvement, and considers the implications of the review's findings for service delivery and future research. Mental health is a leading health priority area across the globe (Department of Health, 2011; Mental Health Commission of Canada, 2012; The Australian Federal Government, 2009; The Carter Center Mental Health Task Force, 2003; World Health Organization, 2004). Several international policies outlining the needs and objectives for mental health services place emphasis on consumers as key stakeholders in service provision, and the importance of modifying services in response to consumers' needs (Keating, Samele, Furnish, & Greatley, 2006; Wallcraft & Bryant, 2003 ; World Health Organization, 2004). It has been assumed that involving service users in the planning and delivery of mental health services is intrinsically worthwhile. As Nilsen pointed out, consumer involvement can promote "participative democracy, public accountability and transparency...Consumers may offer different and complementary perspectives to those of professionals" (Nilsen, Myrhaug, Johansen, Oliver, & Oxman, 2006). However there may be both positive and negative effects for *clients* (service recipients), care providers, and health services.

In response to policy directives, the past several decades has seen a slow but steady increase in the involvement of *consumer-providers* (past or present consumers of mental health services employed to provide care for other clients) in service delivery. This has been facilitated by consumer participation and self-help movements encouraging user involvement in mental health services (Doughty & Tse, 2011; Wright-Berryman, McGuire, & Salyers, 2011).

Consumer-providers are involved in adult mental health services in various ways. They can be employed in specifically designated roles such as peer support specialists or peer interviewers (Lecomte, Wilde, & Wallace, 1999; Mowbray et al., 1996; Pfeiffer, Heisler, Piette, Rogers, & Valenstein, 2011; Salzer, 2010). Consumer-providers can also be appointed to other core positions within services such as case management or outreach roles (Fisk, Rowe, Brooks, & Gildersleeve, 2000; Sherman & Porter, 1991). For example, a hospital in the US recruited consumer-providers from vocational training and peer advocacy programs to provide social support to severely ill inpatients and work alongside professional staff providing conventional therapy and crisis management. The consumer-providers built relationships with clients and fostered relationships between their clients in home and community settings, as well as contributing to treatment planning with professional staff (Rivera, Sullivan, & Valenti, 2007). Programmes facilitated by consumer-providers may also be integrated into the mental health system and closely linked with professional services, for example drop-in centres (Brown, Wituk, & Meissen, 2010), or social support programmes for service users discharged from hospital (Chinman, Weingarten, Stayner, & Davidson, 2001; Kaufmann, Ward-Colasante, & Farmer, 1993). Data are limited on how widespread this practice is (Crawford et al., 2003; Geller, Brown, Fisher, Grudzinskas, & Manning, 1998), but there are indications that the consumer-provider workforce continues to grow (Salzer, 2010) and is spurred on by government funding and advocacy organisations that support

service provision by peers (Segal, Silverman, & Temkin, 2011). Importantly, the overall benefits and harms of consumer-providers for client and service outcomes have been unclear. While a systematic review was undertaken in 2002 examining the effect of involving consumer-providers in the delivery, training and evaluation of mental health services (Simpson & House, 2002), most of the included studies were low quality quasi-randomised trials. Since publication of the review by Simpson et al, several randomised controlled trials (RCTs) have been conducted. It was therefore timely to evaluate the current evidence for consumer-provider involvement in mental health service delivery.

Systematic reviews are a valuable tool to inform evidence-based policy-making and practice, and also help to inform the future research agenda for specific areas of health care. These reviews are systematic in terms of identifying, assessing and synthesising evidence from trials assessing the effects of interventions. Features of a systematic review that distinguish them from a narrative or traditional review include the publication of a protocol outlining *a priori* how the review will be undertaken, the transparency about what evidence will be included, and the methods that are used to assess quality of this evidence and minimise bias in the synthesis of the data. Cochrane systematic reviews are renowned for their rigorous methodology as described in *The Cochrane Handbook for Systematic Reviews of Interventions* (Higgins & Green).

We conducted a Cochrane systematic review of all RCTs comparing statutory mental health services with and without consumer-provider roles integrated as part of the service. We assessed the effect of consumer-provider involvement on client outcomes using standardised measures for psychosocial outcomes (eg quality of life, function, social relations) and mental health symptoms, as well as assessing client satisfaction with services, attrition, and any reported adverse effects. The full technical report has been published in *The Cochrane Library* (Pitt et al., 2013).

Delivery of mental health services to clients typically involves a combination of interventions to improve the client's condition. Mental health services can therefore be classified as complex interventions comprising different components that can vary between different services. There are several important considerations when undertaking a systematic review of a complex intervention. Identifying the specific question being asked by the review is essential (eg what effect do consumer-providers have on outcomes for adult clients of mental health services?) and can help to simplify a review and the sources of complexity that need to be considered when evaluating the intervention (Squires, Valentine, & Grimshaw, 2013). Applying systematic review methods to reviews of complex interventions presents a number of challenges (Petticrew, Anderson, et al., 2013), some of which we discuss within the context of our review. Importantly, methodological approaches to understanding the harms and benefits of complex interventions is an area of ongoing research, as highlighted recently in a series of methodological articles on considering complexity in systematic reviews of interventions (Noyes et al., 2013).

The objectives of this article are: 1) to provide a summary of the findings of the Cochrane review, and 2) discuss several key issues we identified while undertaking the review that, if addressed, would serve to strengthen markedly the body of evidence in this area. Based on our review, we demonstrate how systematic reviews might be used to inform the future research agenda and evidence-based decisions for policy-making in areas of health care such as mental health services.

METHODS

The systematic review was conducted according to methods described in the *Cochrane Handbook* (Higgins & Green) and the preferred reporting items for systematic reviews and

meta-analyses (PRISMA) guidelines (Moher, Liberati, Tetzlaff, Altman, & Prisma Group., 2009).

ELIGIBILITY CRITERIA

Studies were included in the review if they randomised clients of mental health services to receive care from either the usual health service employees or consumer-providers. We defined the term *clients* as individuals aged 18 years and over with a diagnosed mental health condition that were recipients of mental health services described in the studies. We defined *consumer-providers* as individuals with previous or current experience of receiving mental health services that were acting as mental health service employees in a paid or unpaid capacity. Consumer-providers have also been described as consumer-survivors, peer educators, peer specialists, consumer-employees, user-employees and prosumers. We used the term *professional* to describe staff members employed within mental health services. We only considered studies involving *statutory* mental health services meaning public services, those services required by statute or law, or public services involving statutory duties. We did not include studies of consumer-operated services or consumer-operated service providers, which are independent organisations providing peer run services delivered according to a 'self-help' framework. Nor did we include studies of social services, befriending services, or services in which consumer involvement was limited to service planning or policy committees.

SEARCH

We searched the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library* 2012, Issue 3), MEDLINE (OvidSP) (1950 to March 2012), EMBASE (OvidSP) (1988 to March 2012), PsycINFO (OvidSP) (1806 to March 2012), CINAHL (EBSCOhost)

(1981 to March 2009), Current Contents (OvidSP) (1993 to March 2012), and reference lists of relevant articles. The search strategies for each database have been published (Pitt et al., 2013) and the MEDLINE strategy is provided as supplementary material. Studies were not limited by language or date of publication. Grey literature sources were considered if they were cited in the reference lists of relevant articles, however no systematic searching of grey literature was undertaken.

STUDY SELECTION

Two authors independently screened the search results to identify studies that met the eligibility criteria, and a third author acted as arbiter for any discordant decisions that could not be resolved through discussion.

DATA COLLECTION

Data were collected from each included study by one author using a data collection form specifically designed for the purposes of the review. A second author was responsible for checking all of the data and any discrepancies identified were discussed between the two authors until agreement was reached about the final data entered.

Data items for collection included study design; numbers of participants in each treatment group; characteristics of trial participants (including diagnoses and demographics of clients); description of the service or setting of consumer-provider involvement; characteristics of consumer-providers (number involved, diagnoses, demographics); the mechanism of involving consumer-providers (role description, training provided, support available); details of mental health service provided to the intervention and comparison groups; and outcomes (list of outcomes assessed, tools used, information regarding validity of tools, time points assessed, outcome data).

RISK OF BIAS

Each of the included studies were assessed independently by two authors for risk of bias using the Cochrane Risk of Bias tool (Higgins, Altman, & Sterne). Specifically, we assessed whether studies used adequate methods for randomisation and concealment of allocation when assigning participants to treatment groups in order to minimise selection bias. We examined whether outcome assessors within studies were blind to participant allocation, in order to assess the risk of detection bias. Selective outcome reporting was assessed by comparing the proposed outcome measures described in the methods of trials with the final outcomes reported, including whether outcome data were provided in full, incomplete, or only described narratively. We also assessed losses to follow up, comparability of groups at baseline, and the risk of contamination between treatment groups.

The risk of bias assessments for each of the elements described above were summarized across all of the included studies *<insert figure 1 near here>*. The summary was used to guide decisions about the overall risk of bias for each outcome of the review based on the combination of studies contributing to the results. For each separate outcome, we considered there was an overall low risk of bias if the combined studies had a low risk of bias for randomization, allocation concealment, blinding, and outcome assessment as there is empirical evidence indicating these domains can significantly impact the size and direction of effects of interventions (Higgins et al.). If any of the combined studies had a high or unclear risk of bias in any of these four domains, we considered there was an overall moderate risk of bias for that outcome. If all of the studies contributing to an outcome were at high risk of bias for most of these domains, we considered there was an overall high risk of bias for that outcome.

Finally, we considered the potential impact of any publication bias on the overall size and direction of effect in each of the included studies. This was based on a subjective assessment of the number of studies and number of participants with outcome data that could not be combined in the overall summary estimate of effect and what, if anything, these studies reported about the size of the effect. For example, an outcome with data missing from a large study or a study that (narratively) reported a large effect size could be expected to have a significant impact on the summary estimate, potentially increasing the precision of the estimate or increasing the size of the estimate respectively.

ANALYSIS

We analysed data separately for the two types of comparisons identified in studies included in our review:

- 1) Consumer-providers versus professionals employed to do the same role within a mental health service;
- 2) Mental health services with and without consumer-providers as an adjunct to the service.

The full review assessed both client outcomes (psychosocial, mental health, and adverse effects) and outcomes related to service provision (service use and patterns in service provision). This paper focuses on client outcomes only. Importantly, we preferentially report participant-rated outcome data over clinician assessments for any outcomes where data were available from both participant and clinician assessments (such as quality of life and depression scales).

Where possible, we pooled results of separate studies in a meta-analysis. Continuous outcomes were pooled using an inverse variance statistical method and a random-effects model. If studies used the same tool to measure continuous outcomes, the overall effect

estimate was expressed as mean difference (MD). Where different tools were used across studies to assess the same continuous outcome, the overall effect estimate was calculated as a standardised mean difference (SMD) that was then re-expressed as a MD for one of the scales used by the studies (to facilitate interpretation of results). Dichotomous outcomes were pooled using the Mantel-Haenszel statistical method and a random-effects model and expressed as a risk ratio (RR). All effect estimates were calculated with a 95% confidence interval (CI). We used Review Manager 5 to conduct our analyses .

IDENTIFYING KEY AREAS FOR IMPROVING THE BODY OF EVIDENCE

To address the second objective of this paper, we considered the limitations of the review and aspects of the review process or individual studies we felt could be addressed to strengthen the review findings in subsequent updates. The review authors discussed limitations based on our observation of the characteristics and risk of bias in the included studies and important sources of heterogeneity we had identified in the body of evidence. We then prioritized the issues based on the overall impact we felt each issue had on the review findings as well as the potential for strengthening the body of evidence if the issue were addressed in future updates of the review. The issues were considered by the author team until five key issues were agreed upon to be discussed as part of the second objective of this paper.

RESULTS

An overview of the search results and the selection of studies for inclusion in our review is presented in Figure 2.<insert figure 2 near here>. Overall, we identified 11 RCTs involving 2796 participants. Nine of these studies were conducted in the US, one in Australia and one in the UK. Clients receiving services in the 11 studies all had severe mental health diagnoses including psychotic illnesses and major mood disorders. In four studies consumer-providers

were involved as case managers, in one study as facilitators of mutual support group therapy or cognitive behavioural therapy sessions, in four studies consumer-providers assumed mentoring or advocacy roles, and in two studies clients were referred to consumer-operated services integrated with statutory mental health services in addition to usual care.

Several studies were excluded because the groups compared in the studies differed in more aspects than the consumer-provider alone. This was identified as one of the key challenges of reviewing a complex intervention such as mental health service delivery as it is not possible to disentangle the effects of a consumer-provider if two different services, comprising different interventional components, are being compared.

The 11 included studies were classified based on the type of comparison groups they used to assess the effects of consumer-providers. Five studies assessed the effects of consumer-providers by focusing on a specific role within mental health teams that was held by a consumer-provider in one group or a professional in the other group (Bright, Baker, & Neimeyer, 1999; Clarke et al., 2000; Rivera et al., 2007; Sells, Davidson, Jewell, Falzer, & Rowe, 2006; Solomon & Draine, 1995). Six studies assessed the effect of consumer-providers as an adjunct to existing services (Craig, Doherty, Jamieson-Craig, Boocock, & Attafua, 2004; Gordon, Edmunson, Bedell, & Goldstein, 1979; Kaufmann, Schulberg, & Schooler, 1995; O'Donnell et al., 1999; Rogers et al., 2007; Sledge et al., 2011). A detailed description of the characteristics of included studies has been provided as supplementary material.

Tables 1 and 2 present client outcomes assessed in the review including standardised measures of psychosocial outcomes (eg quality of life, function, social relations), standardised measures of mental health (eg general symptoms, depression), and client satisfaction with services. Overall, the results indicate that employing past or present

consumers of mental health services as providers of mental health services achieves psychosocial, mental health symptom and satisfaction outcomes that are no better or worse than those achieved through standard care. Furthermore, there were no adverse outcomes reported for clients in any of the included studies therefore no evidence was identified that involving consumer-providers is harmful to clients. *<insert table 1 and table 2 near here>*.

A key challenge identified during the analysis and synthesis of findings was the heterogeneity of outcomes measured across studies. The included studies were inconsistent in the type of outcomes they measured, with only one outcome in the review (client attrition) reported by all of the studies. Even when more than one study did measure the same outcome, pooling results was challenging because different studies had employed different tools to measure the same outcome (see 'Measurement tools' column in Tables 1 and 2). None of the studies reported any adverse effects on clients. A small number of studies included qualitative assessment of impacts on the consumer-providers themselves, but there was no comparable assessment of impact on professionals fulfilling the same role in these studies.

There was an overall moderate to high risk of bias in the results of studies included in the review, as indicated in Figure 1. Although most of the studies described 'random' assignment of participants to treatment groups, there was limited reporting of the methods of randomisation or concealment of allocation. It is therefore unclear whether adequate methods were used across the studies to minimise the risk of selection bias.

It is often difficult to blind participants and care providers to treatment allocation in studies involving behavioural interventions. Participant awareness of the consumer status of the consumer-provider is actually an important part of the intervention in this case. Whether participants felt they achieved better outcomes based on the knowledge they had received care from a consumer-provider is considered an effect of the intervention rather than a source of bias in these studies. Although participants and care providers were not blinded, it is still

possible to blind outcome assessors in these studies for outcomes not assessed by the participants themselves. Only one study employed outcome measures assessed by clinicians or trained interviewers and the assessors were not blind to the intervention status of participants (Solomon & Draine, 1995). However, the study by Solomon et al did not report group comparison data that could be used in a meta-analysis, therefore the contribution of this study and its potential bias to the overall body of evidence is limited.

Contamination of treatment groups was identified as a key limitation in several of the studies included in the review. Some studies comparing consumer-providers and professionals within the same role in the mental health service described both parties interacting on the same treatment teams, attending the same meetings and able to share practice activities. This may explain the lack of differences between groups if the consumer-providers and professionals consequently adopted similar behaviours to each other in these studies. For studies comparing services with consumer-providers as an adjunct to care, at least two studies described clients accessing the intervention who were initially assigned to the control group, as well as a lack of uptake by clients assigned to the intervention group. The contamination of treatment groups in these studies meant the proportion of clients accessing the intervention was similar in both the control and treatment groups, therefore compromising the study design and undermining the purpose of the trial which was to detect whether a difference in outcomes could be attributed to the intervention alone.

Selective outcome reporting was a significant source of potential bias in our review. For individual studies, outcome data that are missing or incomplete can bias the overall findings reported for a trial. This impacts the results of systematic reviews as it limits the data available for a meta-analysis and summary effect estimates could be misleading if the impact of reporting and publication bias is not considered carefully. Table 1 and 2 highlight the issue of selective reporting for each outcome with the number of studies (and participants) that

assessed an outcome but were not included in the meta-analysis because outcome data were missing or incomplete. The potential impact of including missing data in a meta-analysis is also considered in the description of results (last column).

Based on the limitations of studies included in the review and challenges faced throughout the review process that are described above, the review authors discussed the implications of these limitations and how they might be addressed in order to strengthen the body of evidence in this area. Five key issues were agreed upon as areas that, if improved upon in future studies and subsequent updates of the review, would markedly improve the strength of evidence regarding consumer-provider involvement in the delivery of mental health services. The selected key issues included: outcome measurement, study design and evaluation of complex interventions, cross-contamination of treatment groups for community-based interventions, and trial reporting. In addition, the authors observed there had been no apparent improvement in these issues over time, indicating a lack of cumulative learning from previous trials to improve upon research conducted in this area. The use of systematic reviews to inform future research and strengthen the body of evidence was therefore identified as the final key issue for discussion as part of the second objective of this paper.

DISCUSSION

WHAT BENEFITS OR HARMS ARE WE LOOKING FOR AND HOW SHOULD WE MEASURE THEM?

In this review and in many reviews of mental health interventions there was heterogeneity in the types of outcomes measured across separate trials as well as a varied range of tools used to measure those outcomes. When different tools or scales are used to measure a common underlying construct (eg quality of life) statistical approaches are available to standardise and combine treatment effects based on these different scales. These treatment effects are pooled

based on the standardised mean difference, but this statistic can be difficult to interpret and needs to be transformed back to units of a commonly-used scale to give more meaningful information about the size and clinical significance of the results.

A greater challenge was the difference in the type of constructs that were measured across separate trials. For example, when we were looking at mental health as an outcome for the review, some trials measured general psychological symptoms while others measured more specific constructs like symptoms of depression. Partly this was due to the fact that this subset of trials looked at more narrowly-defined groups within mental health. Given the broad population covered by the review (ie clients of statutory mental health services) we felt it was important to present the most broadly applicable outcomes for this population rather than focusing on condition-specific outcomes.

Finally, none of the studies in our review reported any adverse effects on clients when consumer-providers were part of the mental health service, but studies that incorporated qualitative assessment did identify a range of less desirable or unintended outcomes.

Although the intervention may not have had any harmful effects on clients, several studies reported potential harms for the consumer-providers themselves (eg workload pressure and managing their own illness, implications of employment on the government benefits they received) or their colleagues (eg increased workload to compensate for the reduced workload taken on by the consumer-providers) (Clarke et al., 2000; Craig et al., 2004; O'Donnell et al., 1999; Sells et al., 2006). As in many RCTs, adverse effects of interventions may not be readily identified and other trial designs may be needed to provide insight about potential harms. Further to this, evaluation of complex interventions is likely to involve exploration of the evidence beyond understanding the quantitative effectiveness of the intervention alone (Petticrew, Rehfuss, et al., 2013). In the context of mental health, longer-term observational studies that capture rates of relapse in both clients and consumer-providers, and qualitative

studies exploring both client and provider experiences could help to build a richer contextual understanding of the benefits and harms of interventions presented in systematic reviews.

The heterogeneity of outcome measures across studies in mental health could be improved if there was agreement about which outcomes are the most important when determining the potential benefits and harms of interventions in this field. This approach has been reported previously for mental health services (Clifford, 1998) and has been notably achieved in other disciplines such as rheumatology (Tugwell et al.). It is also the subject of a large project called the core outcome measures in effectiveness trials (COMET) initiative (Williamson et al.). The aim is to develop core outcome sets that must be measured and reported in all trials for specific conditions. Engagement with consumers to explore their views on research priorities and outcomes that are important to them is an essential part of this process.

Underpinning all of this is a systematic assessment of the validity of tools used to measure core outcomes. International efforts to identify and promote core outcome sets for studies in mental health will provide important guidance to trialists and ensure their research has impact through measuring the most relevant outcomes with the most reliable tools as well as facilitate meta-analysis across multiple studies of the same intervention. In the meantime, authors of systematic reviews of mental health interventions could approach the issue of outcome heterogeneity by establishing a hierarchy of outcome measures *a priori* (Hazell, O'Connell, Heathcote, & Henry, 2002; Hetrick, McKenzie, Cox, Simmons, & Merry, 2012).

A 'SERVICE' IS A COMPLEX INTERVENTION: HOW CAN WE TELL WHAT PARTS OF THE SERVICE WORK TO IMPROVE CLIENT OUTCOMES?

In our review we set out to assess the effects of employing consumer-providers as part of a mental healthcare service. All health services differ in what they offer clients. To evaluate the effectiveness of one element of the service, it is important that it is only this element that

differs between the groups being compared. In our review, this meant comparing services where the only difference between them was the presence of a consumer-provider. We identified two approaches used by trialists to compare the effect of the consumer-provider: 1) through substitution or 2) by addition. The first approach involved employing a consumer-provider as a substitute to do the role in one service that was carried out by a professional in another comparable service. The second approach was to compare the effect of a mental health service with or without the addition of a consumer-provider. The research question we were interested in was not always aligned with the objectives of some of the individual studies. Indeed, we had to exclude eleven trials that were otherwise relevant to our review, because they compared one mental health service involving a consumer-provider role with a different type of health service that did not involve a consumer-provider role. We excluded these studies as it would not be possible to disentangle the effects attributable to a consumer-provider in studies comparing interventions that differed on more than the consumer-provider role.

Study design in the field of mental health service provision could be improved by ensuring that guidelines for the evaluation of complex interventions are followed (Craig et al., 2008). Ryan and colleagues write that “complex interventions are so called because of the dynamic, multifaceted, interacting and socially contingent nature of the interventions and their application” (Ryan, Kaufman, & Hill, 2009). It is important that complex mental health interventions are based on theory and empirical evidence about the key drivers of change, thus establishing a causal pathway. The impact of the intervention along this causal pathway can then be examined, including testing the impact of the intervention on the proposed drivers of change (Eccles et al., 2009; Michie, Fixsen, Grimshaw, & Eccles, 2009; Michie et al., 2005). If each intervention and its components are carefully specified with regard to how each component theoretically addresses the proposed mechanism of change, then we can

measure each of these mechanisms and determine whether each individual component is effective. Alternatively, multi-arm trials are required to compare the whole intervention with each of the individual components in order to test how components might modify the size of effect for an intervention; however this type of study design requires larger sample sizes. This approach to designing interventions is consistent with the United Kingdom Medical Research Council guidance (Craig et al., 2008) for developing and evaluating complex interventions, specifying the ‘active ingredients’ of interventions and theorising the pathways to change (Craig et al., 2008; Michie et al., 2009; Michie, Webb, & Sniehotta, 2010).

Lack of detailed reporting and a description of the components of each intervention was a notable gap in the research identified in our review. As such, trialists should prepare a study manual with a detailed description of the intervention and its components, the proposed drivers of change, how it is delivered, who is involved in delivering it, as well as any training or supervision requirements, and provide the manual as supplementary information when study results are made available (Craig et al., 2008; Schulz, Altman, & Moher, 2010a).

Assessment and reporting of the quality and fidelity of interventions is also necessary in order to adequately consider clinical and statistical heterogeneity across trials in a systematic review (Herbert & Bo, 2005). Taking heed of the above guidance will help ensure that the effects of complex interventions such as employing consumers in care provider roles can be ‘disentangled’ from the overall effects of services for clients.

CHALLENGES FOR COMMUNITY-BASED RCTS

Interventions that are readily available within the community pose specific challenges when conducting RCTs. In particular, contamination of the treatment group can occur when the intervention is accessed by individuals assigned to the control group. Three studies included in our review involved community-based mental health services with consumer-provided

programmes that were ultimately accessible to participants in both groups (Craig et al., 2004; Kaufmann et al., 1995; Rogers et al., 2007). When up to 17% of the participants randomised to the control arm in these studies independently chose to attend the community-based programs, the integrity of the controlled parallel group trial design was compromised. The significance of this issue is highlighted in the study by Kaufmann et al where poor uptake in the intervention group resulted in a similar proportion of participants being exposed to the intervention across both treatment groups, therefore cancelling out the randomised assignment to intervention or control groups (Kaufmann et al., 1995). Similarly in a study by Craig there was the potential for 'leakage' of interventions between groups, as clients from the standard care arm also attended the social events run by the consumers (Craig et al., 2004).

The consequence of contamination occurring during a trial is that any real benefit of the intervention may be diluted, and as a result no difference will be observed between control and intervention groups. When comparing interventions that are readily accessible to individuals in the community setting and therefore to participants in both groups, one solution is for trialists to use the setting as the unit of randomisation rather than the individual client. Cluster randomisation assigns groups of participants in a designated setting to either the intervention or control arm. The benefit of a cluster-RCT is that separate geographical settings can be used to compare regions where participants have access to community-based interventions with regions where participants do not have access to the intervention (Giraudeau & Ravaud, 2009).

While cluster randomisation is a potential solution, it is not without limitations such as the possibility of recruitment bias. Where there is evidence of recruitment bias, such as differences in participant or cluster level covariates between the randomised groups, this can be addressed with hierarchical or multi-level models that adjust for identified confounders

(Hahn, Puffer, Torgerson, & Watson, 2005). However, this requires larger numbers of clusters and participants. In some cases, even if the potential for contamination is high or contamination has occurred at a high rate (e.g. 20%), it may still be more feasible to conduct an RCT rather than a cluster RCT in terms of the sample size required thus accepting there will be a potentially diluted effect size (Torgerson, 2001). Trialists also need to consider whether there are significant geographical distances required to protect groups from exposure to other treatments being tested, which may not be feasible, particularly in smaller trials with limited resources.

THE ROLE OF TRIALISTS TO MINIMISE BIAS

Incomplete reporting of trial procedures and outcomes in studies included in this review hampered our ability to pool data across studies in a meta-analysis and accurately assess the potential biases in study results. Trialists conducting future RCTs of consumer-providers in mental health services should familiarise themselves with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement to ensure a robust study design and minimal likelihood of bias in the study findings (Chan et al., 2013). Specific items include ensuring participants are truly randomised to the intervention or comparison group by employing appropriate methods to generate a random sequence, and concealing allocation so that assignments can not be predicted in advance. Trialists should endeavor to blind outcome assessors and consider whether it is possible to blind participants and care providers to the purpose of the study.

Selective outcome reporting by trialists was a significant limitation for our review. This would appear a greater problem when dealing with trials that pre-date clinical trial reporting guidelines provided in the CONSORT statement (Schulz, Altman, & Moher, 2010b). Current and future trialists should make all outcome data available in full, either in trial publications,

as supplementary material, or online. The prospective registration of trials goes some way towards ensuring that potential biases such as those identified within the current review are minimised. The benefits of doing so include independent peer review of the protocol which may limit the potential impact of any conflict of interest held by the trialists, whilst promoting full disclosure of outcome data following trial completion.

USING SYSTEMATIC REVIEWS AS A ROADMAP FOR FUTURE RESEARCH

Based on our systematic review, this paper identifies the various strengths and weaknesses across the existing body of evidence regarding consumer-provider involvement in statutory mental health services, and seeks to highlight how future trials might improve the evidence base for policy decisions in this area. Our review demonstrates there is a long-standing research base in the consumer provision of mental health services, with one of the studies published almost 35 years ago (Gordon et al., 1979). A concerning observation across the included studies was that, over time, it is not apparent that subsequent research in this area has systematically built on, or even consistently demonstrated awareness of, earlier quantitative studies. The importance of situating any new trial within the existing evidence base has been strongly advocated, and journals are increasingly insisting that authors of trials provide a summary of previous research and describe the impact their trial has on this summary (Young & Horton). Our review provides the most comprehensive and up-to-date summary of RCTs in this area to date, and should be considered an essential resource for trialists interested in assessing the impact of consumer-provider involvement in mental health services on client outcomes.

Importantly, our review identified a number of issues that future research in this area should consider such as the use of agreed core outcome sets and tools validated for use in mental health populations. A systematic assessment of adverse client outcomes as well as exploring

potential harms to consumer-providers themselves is also required in order to consider both potential benefits and harms of involving consumer-providers in mental health services. This includes determining the cost effectiveness of any potential benefits and considering these in the context of any harms identified for clients or consumer-providers.

CONCLUSION

Our Cochrane systematic review on consumer-provision of mental health services showed there was no overall difference in clients' quality of life, mental health symptoms, and satisfaction with services between those receiving care from consumer-providers and those who did not. A systematic assessment of potential harms of the intervention, that includes both observational and qualitative study designs, is warranted. Evidence from studies conducted in this area of mental health services research could be strengthened by having an agreed core outcome set and ensuring complete reporting of all outcome data. It is hoped that systematic reviews such as ours will contribute to building a 'roadmap' for research in the area of mental health services, and will inform research priorities and targeting of limited resources to areas of greatest need. In this way, researchers, care providers, policy makers, and clients can benefit from research that is likely to have the most impact on driving improvements in client outcomes.

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TABLES

Table 1. Client outcomes for mental health services with a consumer-provider in a professional role (5 studies)

Outcome	Studies with data for meta-analysis (N participants)	Studies with incomplete data (N participants)	Measurement tools	Estimate of effect (95%CI)	Risk of bias and interpretation of findings
Quality of Life	1 (130) (Rivera et al., 2007)	2 (233) (Sells et al., 2006; Solomon & Draine, 1995)	Lehman Quality of Life (QOLI); Client assessed life satisfaction subscale	MD -0.30 (-0.80, 0.20)	One study with moderate risk of bias showed there was no overall significant difference in client rated life satisfaction for clients managed by consumer-providers compared to professional staff. The range of values for which we can be reasonably sure that the true effect actually lies between is a 0.8 point reduction up to a 0.2 point increase on a scale of 7 points (higher scores indicate greater life satisfaction). Inclusion of missing data (Sells et al., 2006; Solomon & Draine, 1995) is likely to increase the precision of the result there is no significant difference between groups.
Function	1 (130) (Rivera et al., 2007)	2 (233) (Sells et al., 2006; Solomon & Draine, 1995)	Lehman Quality of Life (QOLI); Client assessed daily activities	MD 0.0 (-0.07, 0.07)	One study with moderate risk of bias indicated consumer-providers did not change client reported function for daily activities on a scale of 7 points (higher scores indicate greater function for daily activities). The range of values for which we can be reasonably sure that the true effect actually lies between is a 0.07 point reduction up to a 0.07 point increase. Inclusion of missing data (Sells et al., 2006; Solomon & Draine, 1995) is likely to increase the precision of the result there is no significant difference between groups.
Social relations	1 (130) (Rivera et al., 2007)	2 (233) (Sells et al., 2006; Solomon & Draine, 1995)	Lehman Quality of Life (QOLI); Client assessed social relations	MD -0.10 [-0.48, 0.28]	One study with moderate risk of bias showed there was no overall significant difference in client rated social relations for clients managed by consumer-providers compared to professional staff. The range of values for which we can be reasonably sure that the true effect actually lies between is a 0.28 point reduction up to a 0.48 point increase on 7 point scale (higher scores indicate better social relations). Inclusion of missing data (Sells et al., 2006; Solomon & Draine, 1995) is likely to increase the precision of the result there is no significant difference between groups.
Mental Health Symptoms	2 (197) (Bright et al., 1999; Rivera et al., 2007)	1 (96) (Solomon & Draine, 1995)	Hopkins Symptoms Checklist (HSCL)-58 (Bright et al., 1999); Brief Symptom Inventory (BSI)(Rivera et al., 2007); Brief Psychiatric Rating scale (BPRS)(Solomon & Draine, 1995)	SMD -0.24 (-0.52, 0.05)	Two studies with moderate to high risk of bias showed there was no overall significant difference in client rated symptoms for those managed by consumer-providers compared to professional staff. The range of values for which we can be reasonably sure that the true effect actually lies between is a 0.06 point reduction and a 0.57 point increase on the BSI 5 point scale (higher scores are favourable). Inclusion of missing data (Solomon & Draine, 1995) is likely to increase the precision of the result there is no significant difference between groups.

Depression	1 (67) (Bright et al., 1999)	1 (96) (Solomon & Draine, 1995)	Beck Depression Inventory (BDI)(Bright et al., 1999); BPRS subscale(Solomon & Draine, 1995)	MSG: MD 3.61 (-1.37, 8.59); CBT: MD -5.57 (-12.9, 1.76)	One small study with a high risk of bias indicated there was no overall significant difference in client assessed symptoms for depression for clients managed by consumer-providers compared to professional staff. A subgroup receiving mutual support group therapy (MSG) had a range of values indicating the true effect lies between a 1.37 point reduction and an 8.59 point increase on 63 point scale (higher scores indicate worse symptoms. Another subgroup in the same study receiving cognitive behavioural therapy (CBT) had a range of values indicating the true effect lies between a 12.9 point reduction and a 1.76 point increase. Inclusion of missing data (Solomon & Draine, 1995) is likely to increase the precision of the result there is no significant difference between groups.
Satisfaction with treatment	2 (213) (Rivera et al., 2007; Solomon & Draine, 1995)	-	Behavioural Health Care Rating of Satisfaction (BHCRS)(Rivera et al., 2007); Satisfaction with treatment rating (Solomon & Draine, 1995)	SMD -0.22 (-0.69, 0.25)	Two studies with moderate to high risk of bias indicated there was no overall significant difference in client satisfaction with treatment for clients managed by consumer-providers compared to professional staff. The range of values for which we can be reasonably sure that the true effect actually lies between is 0.45 points lower and 0.16 points higher on the BHCRS 6 point scale (higher scores indicate greater satisfaction).
Attrition	3 (333) (Bright et al., 1999; Sells et al., 2006; Solomon & Draine, 1995)	2 (250) (Clarke et al., 2000; Rivera et al., 2007)	Number of dropouts	RR 0.80 (0.58, 1.09)	Based on data from three out of five studies, there was an absolute risk reduction of losing 6 less people out of 100 from dropping out in the group treated by consumer-providers. The range of values for which we can be reasonably sure that the true effect actually lies between is 13 less people and up to 3 more people than those lost in groups treated without consumer-provider involvement. The impact of missing data on comparative attrition rate is unclear, as we were unable to determine whether losses were balanced across treatment groups however, the attrition rate in these studies ranged from 11 to 20% (Clarke et al., 2000; Rivera et al., 2007).

CI= confidence interval; MD= mean difference; SMD= standardised mean difference; MSG = Mutual support group therapy, CBT = Cognitive behavioural therapy

Table 2. Client outcomes for mental health services with a consumer-provider as an adjunct to care (6 studies)

Outcome	Studies with data for meta-analysis (N participants)	Studies with incomplete data (N participants)	Measurement tools	Estimate of effect (95%CI)	Risk of bias and interpretation of findings
Quality of Life	-	1 (84) (O'Donnell et al., 1999)	Modified version of the Quality Of Life Index for Mental Health	NE	One study with a high risk of bias showed there was no overall significant difference in client rated quality of life for clients managed by consumer-providers compared to professional staff, although insufficient data were reported to calculate a summary estimate.

			(QOLIMH)		
Function	1 (45) (Craig et al., 2004)	2 (208) (Kaufmann et al., 1995; Sledge et al., 2011)	Life Skills Profile (LSP) (Craig et al., 2004); Global Function Impairment (Sledge et al., 2011)	MD 3.00 (-5.75, 11.75)	One study with a moderate risk of bias showed there was no overall significant difference in client rated function for clients managed by consumer-providers compared to professional staff. The range of values for which we can be reasonably sure that the true effect actually lies between incorporates clinically important differences in both directions with a 5.75 point reduction up to a 11.75 point increase on a 39 point scale, (higher scores equate to better function). The impact of missing data is unclear as data are not yet published for one study (Sledge et al., 2011) and there was insufficient data available from Kaufmann 1995 (Kaufmann et al., 1995).
Social relations	1 (45) (Craig et al., 2004)	1 (89) (Sledge et al., 2011)	Significant Others Scale (SOS)(Craig et al., 2004)	MD -0.10 (-0.53, 0.33)	One study with a moderate risk of bias showed there was no overall significant difference in client rated social relations. The range of values for which we can be reasonably sure that the true effect actually lies between is a 0.53 point reduction up to a 0.33 point increase, on a 7 point scale (higher scores equate to better social relations). The impact of missing data is unclear as data are not yet published (Sledge et al., 2011)
Mental Health Symptoms	-	1 (90) (Kaufmann et al., 1995)	Symptom Check List (SCL)-90; Brief Psychiatric Rating Scale (BPRS) (Kaufmann et al., 1995)	NE	There was insufficient data available from Kaufmann 1995 to calculate an estimate of effect and 95% CI (Kaufmann et al., 1995).
Satisfaction with service	2 (125) (Craig et al., 2004; O'Donnell et al., 1999)	1 (89) (Sledge et al., 2011)	Service Satisfaction Scale (VSSS) (Craig et al., 2004); Client Satisfaction Questionnaire (CSQ) (O'Donnell et al., 1999)	SMD 0.76 (-0.59, 2.10)	Two studies with a moderate to high risk of bias showed there was no overall significant difference in client rated satisfaction for clients managed by consumer-providers compared to professional staff, The range of values for which we can be reasonably sure that the true effect actually lies between is 6.49 points fewer to 23.1 more on the VSSS a 54 point scale (higher score equate to greater satisfaction). The impact of missing data is unclear as data are not yet published (Sledge et al., 2011).
Attrition	3 (218) (Craig et al., 2004; O'Donnell et al., 1999; Sledge et al., 2011)	3 (199) (Gordon et al., 1979; Kaufmann et al., 1995; Rogers et al., 2007)	Number of dropouts	RR 1.29 (0.72, 2.31)	Based on data from three out of six studies, there was an absolute risk reduction of losing 5 more people out of 100 through dropping out in the group with consumer-provider involvement. The range of values for which we can be reasonably sure that the true effect actually lies between is 4 less people and up to 20 more people than those lost in groups treated without consumer-provider involvement. The impact of missing data on comparative attrition rate is unclear, as we were unable to determine whether losses were balanced across treatment groups in two studies (Gordon et al., 1979; Rogers et al., 2007), and Kaufmann 1995 was stopped early due to low rates of participation in the intervention group (Kaufmann et al., 1995).

CI= confidence interval; NE = not estimable; MD= mean difference; SMD= standardised mean difference; RR = relative risk

FIGURES

Figure 1 Risk of bias summary for included studies

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias): Self-reported outcomes	Blinding (performance bias and detection bias): All other outcomes	Incomplete outcome data (attrition bias): up to 6 months	Incomplete outcome data (attrition bias): post 6 months	Selective reporting (reporting bias)	Groups comparable at baseline?	No contamination between treatment groups?
Bright 1999	?	?	+	+	+		+	+	+
Clarke 2000	?	?	+	+	?	?	+	+	+
Craig 2004	+	+	+	+		+	+	+	+
Gordon 1979	?	?		?		?	?	?	?
Kaufmann 1995	?	?	+	?	+		+	+	+
O'Donnell 1999	?	?	+	?	?	+	+	+	?
Rivera 2007	?	?	?	+	+	+	+	+	?
Rogers 2007	+	?	+	?	?	?	+	?	+
Sells 2006	?	?	+	+	+	+	+	?	?
Sledge 2011	+	+	?	+	?	+	?	+	?
Solomon 1995	?	?	+	?	+	+	+	+	+

Green indicates items with low risk of bias, red indicates high risk of bias, yellow indicates items where the risk of bias is unclear due to insufficient information, and blank squares indicate items that are not applicable within individual studies.

Figure 2. Flow diagram of selection of studies for inclusion in the systematic review

^aincludes duplicate citations

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Pitt, VJ;Lowe, D;Pictor, M;Hetrick, S;Ryan, R;Berends, L;Hill, S

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