Reviewer’s report

Title: Randomised trials relevant to mental health conducted in low and middle-income countries: survey of studies published in 1991, 1995 and 2000 and assessment of their relevance

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Reviewer: Nancy Wilczynski

Reviewer’s report:

General

This manuscript describes the protocol for a study designed to survey reports of trials relevant to mental health with participants from low- and middle-income countries. The aim of the study is to describe in detail the quality, content, accessibility and relevance of identified trials. The rationale for conducting the study overall is adequately described in the Background section of the manuscript. The Methods section details a previously conducted search for trials that was performed as part of the main Practihc project and provides a description of work that is to be undertaken. It appears that the stated aims of the study will be adequately addressed using this protocol. Although there is sufficient detail to allow for replication of the work in some areas, sufficient detail appears to be somewhat lacking in other areas and therefore requires clarification. These areas are outlined below.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

One of the key components to this study is the sample of trials to be surveyed. The authors indicate that they will use the database constructed for the main Practihc project. In describing the methods for the Practihc search which has already been conducted (pg. 4-5 of the manuscript) the following areas require clarification:
1) provide the rationale for targeting the publishing years 1991, 1995, and 2000;
2) provide the rationale for searching the databases summarized in Appendix 2;
3) define â€œlower income countriesâ€ and indicate how this definition fits into the four income ranges noted in Appendix 1;
4) provide additional details on the method for determining the eligibility of articles for the Practihc project, that is, was the eligibility assessment done in duplicate and how were disagreements resolved; and
5) provide the definitions that were used for classifying reports as â€œrandomised trialsâ€ and â€œpossible randomised trialsâ€

Although Appendix 2 is a welcome addition to the manuscript and outlines an extensive literature search some essential details appear to be missing. For example, the rationale for searching these specific databases (as noted above) and the rationale for use of the various search strategies are not provided. Additionally, some data appear to be missing (e.g., data for unique references, CCT/RCT and target years for Pascal [French language database]) while other data appears to be questionable (â€œ?â€ as denoted by the authors).

When describing the methods for the project the authors are currently undertaking (commencing on pg. 5 of the manuscript) the following areas require clarification:
1) provide definitions for randomised trial, quasi-randomised trial, controlled clinical trial, historical controls, concurrent controls, and case control studies;
2) provide a definition for â€œmental health problemsâ€ â€œ the authors state that â€œMental health problems could include any psychiatric or psychological problem or disorderâ€ (pg. 5) â€œ are they using DSM-IV (or some other source) for defining the list of disorders;
3) describe how the list of the terms in Appendix 3 was derived â€œ the authors indicate that these terms are â€œMeSH headings within Mental Healthâ€ (pg. 5) but how was the list derived (is the list intended to be comprehensive?);
4) will the reference lists of identified studies also be reviewed to identify additional trials;
5) what will be done if the review of the random 10% sample of all citations from the Practihc search shows that mental health trials have been missed;
6) provide details of the systematic search of thesis and other grey literature that will take place in Colombia
7) provide a definition for those at risk of developing schizophrenia;
8) indicate whether the register of trials maintained by the Cochrane Schizophrenia Group contain reports that are a representative sample of all trials conducted in high income countries;
9) provide additional details regarding the data extraction for this study, that is, will the abstract or full-text of the article be used; will a training period be undertaken for the data extractors; how were the data extraction forms derived; how will data points be operationalized (e.g., what definition is being used for single blind and double blind; what constituents allocation concealment - is it enough to just have the drugs prepared in pharmacy or to have sealed numbered envelopes [or should the enveloped be sealed, consecutively numbered, and opaque] or in Appendix 4 under allocation concealment are the authors coding the content of the articles based on a scoring system?);
10) when testing for reliability of data extraction, what level of discordance will lead to further duplicate extraction (pg. 7);
11) indicate how the mean quality score is calculated is this only based on grading of allocation concealment?; and
12) when comparing high- and low-income studies for trials in schizophrenia will any statistical analyses be undertaken?

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Appendix 1 The following items should be defined: GNI, FY02, and Atlas methodology. Additionally, because GNI per capita is not defined the significance of the income ranges is lost. Some notation should be made for the four countries appearing in the final 4 rows of the table.

In the methods section of the manuscript the authors state that The list of countries was obtained from the World Bank for each of the three years (see Appendix 1). However, in Appendix 1 it is not clear whether the countries listed maintained the same income level across the 3 time periods.

Discretionary Revisions (which the author can choose to ignore)

Abstract Aim The first occurrence of middle income countries should be hyphenated. The authors should be consistent in hyphenating this phrase and the phrase high income countries throughout the manuscript.

Abstract Background The wording of second sentence is somewhat awkward. Perhaps the word and should be deleted: Despite this, relatively little is known about the quality and content of clinical research undertaken in these countries, or the relevance of the interventions evaluated, AND specifically that of randomized trials.

Abstract Discussion The first sentence could be revised slightly with the deletion of two occurrences of : Trials and systematic reviews of trials are the gold standard of evaluation of care and increasingly provide the basis for recommendations to clinicians, TO providers of care and TO policy makers.

When describing the methods of the Practihc search all the databases that were searched should be described at an early point in the manuscript as the reader is initially left with the impression that only the Cochrane Library's CENTRAL database was searched (pg. 4). It is indicated further along in the Methods section (pg. 5) that several other databases were searched to assess the completeness of CENTRAL.

Background 5th paragraph The second sentence should read: The number of trials relevant to The number of trials relevant to

Methods 2nd paragraph should be deleted from the second sentence.

Methods 2nd paragraph - http://www.cochrane.co.uk/meerkat/meerkat.htm creates an error in internet explorer object not found

Search strategy with the Practihc database should be MeSH (pg. 5).
Why does the phrase “logical-or” appear as the final line of Appendix 3?

The meaning of the latter part of the following sentence is unclear: “Reports in Chinese, Portuguese and Polish for which data has been extracted for the Practihc project will be checked for potentially eligible studies using the extracted data for “problems being addressed” and “outcomes”. (pg. 5-6).

The meaning of the asterisks (*) in Appendix 4 is not clear.

A period is missing from the following sentence on pg. 7: “This will be carried out by entering the citation into PubMed and seeing if it is indexed”

Reference 9 “the full name of the journal is used rather than the abbreviation.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests.