Reviewer’s report

Title: Effectiveness of Balancing Everyday Life (BEL) versus standard occupational therapy for activity engagement and functioning among people with mental illness - a cluster RCT study

Version: 0 Date: 23 Mar 2017

Reviewer: Daniel Bressington

Reviewer's report:

Thank you for submitting your work to BMC Psychiatry. The topic is an important clinical issue and the paper is generally well-written.

I have some feedback and comments for your consideration. The main observation is that the manuscript is missing some important information required for reporting a cluster RCT. The authors should revise the paper to ensure that it adheres to the CONSORT guidelines (including providing a CONSORT study flow diagram). In addition, the potential effects of cluster randomisation do not seem to be considered in the analyses or sample size calculation- which could seriously distort the study results.

More specific comments are as follows:

Title:
Should this be a cluster RCT?

Abstract

Currently the "background" section contains information about the study aims and measured outcomes, but not much relating to the clinical problem that is being addressed. I think this section would benefit from some information about the need to improve quality of life in order to promote recovery from SMI (i.e. to place the study in context).

The "results" section of the abstract might be clearer if it focused on the study's primary outcomes. It would also be improved if the p-values of the results were included.

The "conclusion" section mentions "doing", but in order to understand this the reader is required to read the full paper. It would be helpful to specify what this refers to. This section also mentions "shortening the time it took for participants to recover" - as the study measures well-being and functioning I think it is not appropriate to assert that the intervention hastens recovery. Recovery as a concept/outcome is not specifically measured.
The keywords do not seem to relate closely to the study: "recovery" is used, but as mentioned only a few aspects of recovery are measured. Similarly, "everyday life" seems vague and "peer support" does not seem to be a major part of the study. It would be advisable for the authors to identify relevant MeSH terms for these keywords to ensure that the study can easily be identified through searches.

Introduction

The text in lines 10-18 requires references to support the assertions.

The description in lines 33-56 should be reduced (this contains information that could be in the "intervention" section of the methods). Similarly, this text also requires references to support it.

Page 5, line 17: "persevering" could be replaced by "enduring" as this is a more universally recognized term.

Methods

As mentioned, this section should be restructured (using appropriate subheadings) and revised to adhere to CONSORT guidelines for RCTs. For example, there is no information about blinding of outcome assessors and no details about specific methods of randomization/who was responsible for randomization.

The text relating to recruitment, movement of participants through the study and demographic characteristics (page 6, line 50 to page 7 line 30) would be better placed in the results section (a CONSORT diagram is also required). Also, how many potential participants refused to take part? What were the reasons for this? Were their demographic/clinical characteristics different from those who agreed to take part?

The inclusion and exclusion criteria should be more clearly stated - currently, it is mentioned that these were assessed by the "gatekeeper", but how were these assessed? (for example, what was used to measure "motivation for lifestyle change" and how did they ascertain that substance abuse was not the main diagnosis?).

Selection of participants: it is currently mentioned that the "gatekeeper" chose participants meeting the inclusion criteria, i.e. that they were not randomly selected. This is likely to have introduced bias and this limitation should be mentioned in the "methodological limitations" section at the end of the paper.

The description of the intervention should be clear enough to enable other researchers to faithfully replicate the intervention in subsequent studies. Please re-write this with reference to
the TIDieR guidelines/checklist. A table outlining the interventions stages might be useful to improve clarity.

It is mentioned that the "the BEL programme is led by one or two OTs". why was this? Could this inconsistency result in a lack of fidelity to the treatment protocol?

Instruments: the psychometric properties of Swedish language versions of the instruments are mentioned for some (i.e., the MANSA), but not all instruments. Which languages were the other instruments? If they are not Swedish versions how was the translation and validation of these carried out? Similarly, terms such as "good", "satisfactory" and "adequate" are used to describe various aspects of psychometric properties the measures, these are too vague and should be quantified (i.e. by providing the Cronbach's Alphas etc.)

Data analysis:

How were missing data dealt with? Was intention-to-treat analysis used? If not, why not? And how might per-protocol analysis (if used) have biased the results?

Cluster randomization was conducted, but the potential clustering effects (i.e. intra-class correlations) are not mentioned or considered in either the analyses or sample size calculation. Please provide a good justification for this, or consider reanalyzing the data.

The non-significant p-values would be useful to report in the tables.

Discussion:

This engages well with current empirical evidence. But, the statement on page 16 (line 12) "spontaneous remission….." should be clarified.

Methodological limitations:

This requires further development/information - particularly potential bias (as may be appropriate) arising from: blinding, randomization, sampling, analysis strategy etc.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No
Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Unable to assess

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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Acceptable

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