Reviewer’s report

Title: The PREMIUM randomised controlled trials of the effectiveness and cost-effectiveness of lay counsellor-delivered psychological treatments for harmful and dependent drinking and moderate to severe depression in primary care in India

Version: 1 Date: 13 February 2014

Reviewer: Tara Donker

Reviewer’s report:

General comments:

This paper describes the design of the PREMIUM project, in which two RCTs aimed to evaluate the effectiveness and cost-effectiveness of two psychological treatments (Healthy Activity Program [HAP] and Counseling for Alcohol Problems [CAP]) for depression and alcohol use disorders in India. While evidence-based treatments for depression exist, a substantial amount of patients do not receive treatment. This is especially true for low and middle income countries. Therefore, efforts to improve scalability/dissemination of evidence-based treatments, as intended by the PREMIUM program, are very important. The manuscript is well-organized and provides a detailed account of the rationale and methodology of the study. However, part of the hypothesis has not been described and a few methodological details are not provided.

Minor Essential Revisions

Abstract
1. Please rephrase the first sentence of the Methods/Design (“parallel group, randomized… Goa, India”) into a readable sentence.

Background:
2. Objectives and hypothesis: The authors refer to Table 1 for the summary of secondary hypothesis. However, this is just an overview of the included measures, no direction of an association is provided. Since hypotheses are central to a study, please describe the hypotheses in this section. Also, please provide the hypothesis regarding the cost-effectiveness of the programs.

3. Please add evidence about cost-effectiveness studies of lay-counselors led PTs to the background.

4. Rephrase sentence “Although the evidence in support of brief interventions…with addictions treatment services can be enhanced” on page 6 into two sentences, as it is currently difficult to read.

Methods:
5. I suggest to change the following headings: ‘participants’ and ‘informed
consent’ to a combined “participants and procedure”, because the informed consent section is a description of the recruitment procedure and this needs to be addressed earlier in the method section.

6. Inclusion criteria: participants will be included if they screen positive on the PHQ and/or AUDIT (plus their cut-offs) and if they provide informed consent. This information needs to be added to this section.

7. Please state whether the PTs are offered individually or in group-format, the method of delivery (e.g. face-to-face) and where treatment takes place (e.g. in the mental health clinic) to allow for replication. Also provide a rationale of the flexibility of treatment duration (between 1-4 sessions in CAP, up to 8 sessions over 3 flexible phases for HAP).

8. Are there protocols of the PTS developed for this study available? If so, please add those references to the manuscript or, if so, state that these protocols are available by the author upon request in case investigators may wish to replicate the study.

Discussion

9. An accompanying discussion of why the trial was designed the way it was, is encouraged.

10. please add possible limitations to the discussion section.

Discretionary Revisions

Abstract

11. In the method/design section, please rephrase “Those who consent will be …respective psychological treatment” to ‘those who consent will be allocated in a 1:1 ratio to receive either the respective psychological treatment plus enhanced usual care or enhanced usual care only’ in order to describe the experimental condition prior to the control condition.

Background

12. “Identifying effective PTs delivered by non-specialists….priority setting exercise”: In order to stress out the clinical/societal relevance of the project, please add the reason for prioritizing these PTs (e.g. cost-effective while maintaining effectiveness, increased scalability).

13. In summarizing relevant studies examining the benefits for previous interventions led by lay counselors, are there any harms known for each intervention examined? If so please add.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I declare that I have no competing interests