Reviewer’s report

Title: The clinical and cost-effectiveness of an ultra-brief intervention for common mental health syndromes in primary care: study protocol for a cluster randomised controlled trial

Version: 2
Date: 22 September 2014

Reviewer: Simon Coulton

Reviewer’s report:

I read the manuscript with great interest but found it difficult in some respects to review and comment on the methodological quality of a study protocol of a study that is already recruiting. I think the authors need to be specific in the introduction and the abstract that this study is already recruiting. I had a number of comments that may improve elements of the clarity of reporting and have listed them below for consideration by the authors, all of them would be considered compulsory major revision.

1. I found the introduction a little rambling at times and lacked a real sense of the question being addressed and the reasons why it needed addressing. I failed to understand why the intervention was an ultra brief intervention, it is far more intensive than most brief interventions and appears more intensive than the treatment as usual condition. Is the intervention specifically designed for the Maori population, or designed to ensure inclusion of this population? Some of the figures quoted appeared contradictory, I couldn’t assimilate the male/ female and Maori/non-Maori proportions stated in the introduction. I think this section would benefit from more focus and addressing the need for the trial.

2. Hypotheses should be stated as null hypotheses, as stated they are not testable using the study design. Hypothesis one has two outcomes, clinical and economic and is unclear on what basis these outcomes will be assessed. It also appears to replicate hypothesis 3. Hypothesis two has similar problems with two outcomes, distress and functioning and two end-points, 8 and 12 weeks. Hypotheses need to be very specific and testable so as a reader of the protocol I can see what you are aiming to test and as a reader of your completed study I can see whether you have met those ends.

3. On the inclusion criteria participants have to score 35 or less on the Kesler-10, is there a lower threshold? There are no stated inclusion/ exclusion criteria stated for practices and this is important for a cluster trial.

4. In the recruitment section the tense changes and this should be addressed. Randomisation was stratified by number of GP’s in the practices, can the exact stratum be stated. 59 of the 63 consenting took part in a two-hour training session prior to randomization, what was covered in this session, is it the case that all GP’s were trained in the intervention prior to being randomized? In the second paragraph there is a spelling mistake ‘to hour’ instead of ‘two hour’.
5. It is not clear whether the UBI augments treatment as usual, this needs to be clarified.

6. The primary outcome measures are Kessler-10 and HADS, you cannot have two primary outcome measures, you need to state which outcome will be assessed as a measure of effectiveness. In addition some evidence of the responsiveness of Kessler would be useful, I have only come across it as a case finding tool, not as a measure of intervention effectiveness.

7. The cost-effectiveness outcome measures appear very narrow and as stated are unlikely to capture all pertinent costs. Will these be measure retrospectively at baseline, how will unit costs be derived, I failed to understand what ‘WSAS and EQ-5D will be used to provide additional outcome measures for comparison with K10 shifts’ actually means, this in addition to no detail of how the economics will be analysed highlights this as a very weak area of this protocol and this needs to be addressed.

8. The sample size calculation allows for no-loss to follow-up at 6 months, as the outcome is participant completed is this realistic?

9. The analysis looks at improvements in scores, what if some patients deteriorate? As you have an element of stratification in this study it should be taken into account in the analysis. GP’s within clusters will also need to be explored as an additional level in any multi-level model. It is assumed that the study will be reported in accordance with the Consort for cluster trials and needs stating. No detail of secondary analysis is stated, how will secondary outcomes be analysed and adherence be incorporated into the analysis?

Addressing these comments should significantly enhance the quality of the paper and the value of the protocol.

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests