Reviewer's report

Title:Counselling versus low-intensity cognitive behavioural therapy for persistent sub-threshold and mild depression (CLICD): A pilot/feasibility randomised controlled trial

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Reviewer:Derek Richards

Reviewer's report:

The authors present results from a pilot feasibility RCT for mild and subthreshold depression using two different interventions, namely face-to-face counselling and low-intensity face-to-face cognitive behavioural therapy. The study is very welcome and very interesting as it is an important area of investigation due to the fact that first, little enough is known of the potential of psychological interventions for people with subthreshold symptoms, second, there is a significant potential for interventions to be population based preventative interventions, and third, the utility and potential flexibility of low-intensity interventions have yet to be fully realised. There are some points that require the authors attention before being published.

BACKGROUND:

The background literature and presentation are generally clear and concise, a couple of points:

a. In the last sentence of the first paragraph there are a number of central concepts named, perhaps taken as given, it might be useful to consider these for the audience and reader; especially persistent – how might that be defined and referenced; the question of amount of time again how might that be defined and referenced; similarly active monitoring and low-intensity interventions; although the latter is defined and referenced in paragraph 2.

b. The reference used (8) is 14 years old, is there any more recent supportive data?

c. In the fourth paragraph the authors mention that the two approaches are recommended, are you referring to National Institute for Health and Clinical Excellence (NICE) recommendations? Can you clarify this in the text?

METHOD:

a. It might be useful to explain more fully the importance of timing, as it is relative to mention short-term. It seems to me in the context of the study that

a. 3 months = outcome from intervention – depressive symptoms (+ or -)

b. 6 months = depression diagnosis or not (moved to remission/ recovery or not)

b. Reference [19] under the heading recruitment, line 2, referring to the
recruitment methods developed for the study, is missing
c. The inclusion/exclusion criteria could be integrated into the text opposed to having it as a figure/table
d. How was the eligibility of ‘capable of taking part in the research procedures’ assessed?
e. Small point: in the list of inclusion/exclusion only use punctuation at end of list only
f. Screening took place with the GP. Were GPs trained in screening for depressive symptoms? To assess eligibility for inclusion into the trial as outlined? At this point the author(s) report n=29 were excluded; what were the reasons for exclusion at this point? Could they be included into the flow under the category – excluded by GP?
g. Similarly, what were the reasons for declined at baseline visit?
h. In flow diagram, reasons for exclusion at baseline visit n=22, but number of reasons adds to n=24: is this because of multi-reasons for some participants?
i. The intervention for face-to-face is described adequately. The intervention for bibliotherapy is described, but raises a complication: was there a third intervention, an online intervention. Did participants in one arm receive two low-intensity interventions? Or a blended bibliotherapy/telephone/online low-intensity intervention? The authors need to clarify the interventions under investigation, and the place of any confounding low-intensity intervention?
j. The type of support used in the different interventions is described and very different. Has this point been considered fully in the article and especially the discussion of the results?
k. In the section on outcome measures please specify at what point the economic data was collected, e.g. CSRI, EQ5D5L?
l. You might mention what % was the composed random sample of participant therapist/supporters were included in the adherence checks for both measures?
m. Also I have questions over the use of these adherence measures to assess the adherence of: “guidance delivered by trained support staff,” not their ability to be supporters but the ability of the measures to accurately assess what their trained guidance was? Is it appropriate to rate them again a therapy manual, the one designed for the study?

RESULTS

a. The results are clearly reported.
b. While the n=50 was not reached a n=36 is acceptable for this type of study
c. There was
d. Good research retention at 6-months, was any particular protocol employed/incentives used?

DISCUSSION
a. The first paragraph talks about the findings here might be the first steps in contributing to a full-scale comparative trial. I would temper this with some consideration of the points raised earlier in terms of:
   a. The different types of supporters
   b. Clarification about the use of 1 or 2 low-intensity interventions
   b. It would seem that the cost of recruitment is prohibitive and that a different strategy (ies) would need to be explored to reduce costs and increase participation?
   c. The findings show:
      a. PCC delivered by trained clinicians achieves positive outcomes and low-intensity interventions delivered by non-clinical supporters achieves positive outcomes; outcomes from both methods of delivering and different support models work (equally) well.
      d. Nothing is mentioned of the impact of ‘the problem with adherence that was identified in the PCC arm.’

Overall a good study and very welcome study.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

none