Reviewer’s report

Title: An Evaluation of Large Group Cognitive Behaviour Therapy with Mindfulness (CBTm) Classes

Version: 0 Date: 20 Dec 2018

Reviewer: Alice Tickell

Reviewer's report:

Thank you for the opportunity to review your manuscript, titled 'An Evaluation of Large-Group Cognitive Behaviour Therapy with Mindfulness (CBTm) Classes for Mood and Anxiety Disorders'. Overall, the paper has many strengths such as its large sample size and high external validity. I have a few comments that I hope you can address to clarify the study rationale and the conclusions drawn from the data. I have also made some suggestions for additional measures you could include to strengthen the paper.

Introduction:

(1) CBTm is a new and independently-developed intervention that readers may not be familiar with. Some more background information on the CBTm programme would be welcome. For instance, you mention that previous work from your group has used a 2-session CBT class for people with anxiety disorders, but now you are expanding by using a new 4-session CBTm class for people with anxiety and/or mood disorders, but the logic of this progression was not explained.

I suggest you state more explicitly:

* What was the decision behind developing a new intervention? I.e. why did you not use an existing programme (e.g. Stress Control)? What does the development of CBTm add to the field? What was the rationale for including mindfulness?

* Precisely what clinical population was it was developed for? The inclusion criteria for your study was the presence of a mental health diagnosis - is this a transdiagnostic intervention? Or is it, as your title suggests, specifically for people with mood/anxiety disorders?

* What was the target of treatment (the mechanism)?

* What are the expected outcomes?

* You mention that it is part of a stepped care model: What are all the steps?
Providing this information will give a clearer rationale for your hypotheses. E.g. If the treatment explicitly targets the cognitions that maintain mood/anxiety disorders, then one would expect a reduction in anxiety/depression symptoms… If the purpose is just to facilitate and maintain interest in pursuing CBT, then perhaps one would not expect an effect on symptoms, and the main outcome would be acceptability/engagement.

(2) Linked to the first point, please state clearly the aims of your study, and what your primary/secondary outcomes are. Currently, in the Introduction you state that you have two primary outcomes (acceptability and retention rates, and clients' change in anxiety and depression symptoms), but in the Abstract you state that changes in anxiety and depression symptoms are a secondary outcome. Therefore, it is not clear which outcomes are primary and which are secondary.

(3) In the final paragraph, the rationale for the current study is outlined as to address three gaps in the extant literature. To make your study rationale stronger, instead, state the reason why your study needs to be done, i.e. how it furthers the field, instead of how it fills a gap. Sometimes gaps exist for a reason!

(4) When presenting your own hypotheses, use the past tense, e.g. 'We sought to expand these findings… Based on our previous work, we hypothesised…'

Methods:

(1) Please could you clarify certain aspects of the intervention:

* What was the level of interaction with fellow attendees/facilitators?

* How much homework was allocated each week?

* You mention that there was an average of 30-40 clients per session. Does this include the family/friends who accompanied clients? What was the average overall group size?

(2) Could you benchmark the outcomes from this intervention against other interventions in the stepped care model at this service, e.g. the small group CBT? It would strengthen the manuscript if there was some comparison data.

(3) The PHQ-9 and GAD-7 have clinical cut-offs and criteria to evaluate whether reliable improvements/deteriorations occurred (Evans, Margison, and Barkham, 1998). Using these to report the rate of recovery, reliable improvement/deterioration, and reliable recovery would provide some additional information about the clinical significance of symptom change.
In your multi-level model, could you take into account the class groupings? Evidence suggests that differences between groups can account for a small proportion of the variance in post-treatment outcomes (Delgadillo et al., 2016).

Results:

(1) In the sections on Anxiety Symptoms and Depressive Symptoms, include whether the symptom changes are clinically significant or not according to McMillan et al.'s (2010) criteria.

Discussion:

(1) As mentioned above, move the information about McMillan et al. (2010)'s criteria to the Results section. This is an indicator that you calculated, so it is better placed there.

(2) On line 28, you state: 'It is important to highlight that we expected dropout…' If this was a hypothesis/expectation, then move it to the Introduction section. Placed in the Discussion, it seems like a post-hoc explanation for your result. Here it is enough to state that your rate of drop-out is consistent with other similar large-group interventions found in the extant literature.

(3) On line 33, you state: 'We anticipated some clients would achieve symptom improvement or remission at earlier stages and not require the 'complete' 4-session intervention'. Do you have any evidence that people who dropped out achieved symptom improvement or remission to back up this claim? If you do not have the evidence to back this up, then remove this sentence. On the contrary, your results suggested that it was participants with more severe depression symptoms at baseline who dropped out.

(4) The effect sizes in your study are below efficacy benchmarks for guided self-help interventions and are found to be not clinically significant according to the McMillan's criteria that you use. However, I am not sure the subsequent conclusions you draw from this result are adequately supported:

* Your interpretation of the lower effect sizes compared to benchmarks/extant literature is: 'In regards to length, four 90 minute sessions is brief when compared to formal CBT programs and the extant literature on large-group CBT discussed above.' (line 48). However, CBTm might actually be similar in length or longer than the intervention used by Horrell et al. (2014) if you take into account homework time. As mentioned above, it would be helpful to know how much homework was allocated.

* Another possible interpretation that you do not mention is that the lower effect sizes may reflect that CBTm is less effective than the interventions tested in the extant literature.
Another possible interpretation is that studies in the extant literature have limited their sample to those with an anxiety disorder or mood disorder, whereas your sample included those with any mental health diagnosis (10% did not have a primary diagnosis of anxiety/mood disorder).

You mention that local work is being done to expand the availability of CBTm classes across multiple sites and different settings. This conclusion seems premature, considering your study suggests that there may not be strong evidence for its effectiveness/clinical impact. I would question whether more work needs to be done first to test CBTm in controlled trials, before disseminating extensively. It is possible that there are more effective alternatives. Refer to Onken, Carroll, Shoham, Cuthbert & Riddle (2014) for a model of intervention development.

(5) In relation to your finding that people with greater depression severity and low education were more likely to drop out: it would be interesting if this were discussed in relation to the format. You could speculate what it is about the large-group format that makes it less accessible to these groups: E.g. the focus on independent study/lecture format may be more challenging for those with a lower education; there may be motivational challenges for those with more severe depression symptoms. You could draw out the implications more fully here. What kinds of interventions might be more suitable for these groups?

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

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

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

No

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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