Author’s response to reviews

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

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Editor Comments:

Thank you for submitting your revised manuscript. Each of the reviewers has acknowledged that the manuscript is now improved following your revisions. However, all three reviewers feel that the rationale (and evidence base) for incorporating mindfulness into CBT, while strengthened, nonetheless needs further attention and two of the reviewers are requesting additional information about the training of the staff who administered the intervention. Thus, I would encourage you to respond to each of the reviewer comments, but with a particular emphasis in each of these concerns. BMC Psychiatry operates a policy of open peer review, which means that you will be able to see the names of the reviewers who provided the reports via the
online peer review system. We encourage you to also view the reports there, via the action links on the left-hand side of the page, to see the names of the reviewers.

Reviewer reports:

Alice Tickell (Reviewer 1): Dear Authors: Thank you for the opportunity to read your revised manuscript. The changes you have made since the last submission, in relation to the comments made by me and my fellow reviewers, have greatly improved the paper. The Introduction is much clearer, and you have explained the background and rationale for the present study. I am pleased to see that the Discussion now includes a much more balanced interpretation of your findings. I understand that you do not have any additional data to benchmark the outcomes against and you have included this in the Limitations. I noticed a few typos that need correcting (e.g. in the References), so I would recommend a final proof-read of the paper to resolve these.

– Corrected minor errors in reference section and proof-read final manuscript before re-submitting

Also, in the Introduction you state: "Evidence suggests that mindfulness-based interventions are effective in treating anxiety and depression (22) and perform comparably to CBT (23), but limited work has looked at mindfulness within the context of CBT." This is not strictly true if you consider there has been extensive work to develop and evaluate Mindfulness-based Cognitive Therapy (MBCT), which is a programme that teaches a combination of mindfulness and CBT skills. You may want to mention this, or just rephrase slightly to make it clearer what you mean.

– This has been made clearer. We now explicitly acknowledge the evidence base around mindfulness based interventions (MBCT + MBSR) in treating anxiety and depression, followed by posited mechanisms for how they may work, and then we identify what may be missing in the literature. We appreciate that it was inaccurate to state that there was limited work looking at mindfulness and CBT, and thus this statement has been removed. The paragraph is now as follows (Background section, Pages 5-6): Mindfulness is the process of being nonjudgmentally aware of the present moment, including one’s thoughts, sensations and environment, while encouraging inquisitiveness, open observation, and acceptance (21,22). Evidence suggests mindfulness-based interventions, such as mindfulness-based cognitive therapy (MBCT) and mindfulness-based stress reduction (MBSR), are effective in treating anxiety and depression (22,23). Mindfulness, as it is taught in these interventions and in the CBTm classes, is intended to reduce identification with thoughts and feelings by cultivating an awareness of the impermanence (arising, passing and changing) of these mind productions. There is accumulating evidence that mindfulness meditation, with the goal of calm attentiveness and acceptance, down-
regulates mental activity within the default mode network (DMN). DMN activation is associated with mind wandering, negative affect and rumination as experienced by those with anxiety or depression (24). Other work shows that mindfulness may improve cognitive flexibility, working memory capacity, goal directed behaviour, and emotional regulation, as one’s attention and cognitive resources are shifted away from dysfunctional thoughts and emotions (25). Moreover, these complex functions may be modulated by neural networks, whose resources can be constrained by negative emotions and mind wandering; meditation allows for a more flexible allocation of these limited resources, such that they may be available for other, more salutary, cortical functions (24).

To our knowledge, there is no research on brief, low intensity, large group CBT interventions which incorporate mindfulness in the literature. Thus, the current study sought to evaluate the 4-session CBTm class intervention in a Canadian population.

Shian-Ling Keng (Reviewer 2): Thank you for extending the opportunity to review a revised version of manuscript. While the authors have addressed the majority of my comments in their revision, I thought the response regarding the rationale to incorporate mindfulness into CBT (and other relevant evidence with regards to interventions that already incorporated mindfulness and CBT (e.g., MBCT)) could be more in-depth. For example, the revision seems to have missed out (or does not sufficiently acknowledge) quite a bit of literature that exists in support of the effects of MBCT in treating depression and other disorders (e.g., for one of the many reviews on the efficacy of MBCT, see Piet & Hougaard, 2011). Therefore I question the accuracy of the statement "but limited work has looked at mindfulness within the context of CBT (24,25)").

− We acknowledge that is was inaccurate to state that there was limited work looking at mindfulness and CBT – this statement has now been removed. We now explicitly mention that there is evidence for mindfulness based interventions (MBCT + MBSR) in treating anxiety and depression. We cite one meta-analysis of 39 studies which found that mindfulness-based interventions are moderately effective in treating anxiety and depression symptoms (Hofmann et al., 2010). We also cite a recent review which investigated how mindfulness practices have advanced cognitive and behavioural treatments for depression and anxiety (Hofmann et al., 2017). The paragraph is now as follows (Background section, Pages 5-6): Mindfulness is the process of being nonjudgmentally aware of the present moment, including one’s thoughts, sensations and environment, while encouraging inquisitiveness, open observation, and acceptance (21,22). Evidence suggests mindfulness-based interventions, such as mindfulness-based cognitive therapy (MBCT) and mindfulness-based stress reduction (MBSR), are effective in treating anxiety and depression (22,23). Mindfulness, as it is taught in these interventions and in the CBTm classes, is intended to reduce identification with thoughts and feelings by cultivating an awareness of the impermanence (arising, passing and changing) of these mind productions. There is accumulating evidence that mindfulness meditation, with the goal of calm
attentiveness and acceptance, down-regulates mental activity within the default mode network (DMN). DMN activation is associated with mind wandering, negative affect and rumination as experienced by those with anxiety or depression (24). Other work shows that mindfulness may improve cognitive flexibility, working memory capacity, goal directed behaviour, and emotional regulation, as one’s attention and cognitive resources are shifted away from dysfunctional thoughts and emotions (25). Moreover, these complex functions may be modulated by neural networks, whose resources can be constrained by negative emotions and mind wandering; meditation allows for a more flexible allocation of these limited resources, such that they may be available for other, more salutary, cortical functions (24).

To our knowledge, there is no research on brief, low intensity, large group CBT interventions which incorporate mindfulness in the literature. Thus, the current study sought to evaluate the 4-session CBTm class intervention in a Canadian population.

Further, I find the authors' response to Reviewer's query regarding the mindfulness qualification of the therapists who delivered the intervention (i.e., "Sessions were led by two staff psychiatrists who received training in CBT and mindfulness") to be unsatisfactory. More information about the type and extent of mindfulness and CBT training received by the therapists would enable a better evaluation of the efficacy and quality of the intervention as a whole.

I have contacted both facilitators and have detailed information about their training, which is now included in the manuscript (Methods section, Page 7): Sessions were and were led and facilitated by two staff psychiatrists. One facilitator received certification from the Academy of Cognitive Therapy in 2004 and received the Beck Scholar Award in 2013. The other facilitator completed a 5-day in-person training course on Core Concepts in CBT at the Beck Institute in 2009, as well as 8 hours of online training on Integrating CBT and Mindfulness through the Beck Institute's online training program. Neither facilitator received specific training in MBSR or MBCT.

Lena Wimmer (Reviewer 3): The manuscript, which is now entitled "An Evaluation of Large Group Cognitive Behaviour Therapy with Mindfulness (CBTm) Classes", has clearly benefitted from the revision, as it is now more accurate and balanced. However, the authors should still address a few issues to increase transparency of reporting: Background: - p. 5. l. 48ff.: "It is thought one is better able to regulate their emotions and thoughts after entering a relaxed and attentive state with mindfulness, thus making it easier to apply CBT skills": To the best of my knowledge, this is only one rationale for incorporating mindfulness into CBT, and it is inconsistent with the finding that mindfulness-based interventions that do not involve CBT, such as MBSR, have been found to be effective in treating anxiety and depression. This means that
mindfulness is based on (a) specific mechanism(s) for reducing symptoms of anxiety and depression that go(es) beyond preparing clients for CBT. Please provide at least one further rationale why one should link CBT with mindfulness.

− We agree that this rationale for incorporating mindfulness into CBT is inconsistent with the finding that mindfulness based interventions, such as MBSR, are effective in treating anxiety and depression. We also agree that mindfulness is likely based on several (potentially overlapping) mechanisms to reduce symptoms of anxiety and depression. We now offer a more balanced explanation of mechanisms that may govern how mindfulness improves anxiety and depression symptoms, and they are not intended to be in juxtaposition to either MBSR or MBCT, our CBTm intervention builds off that previous work. What makes our intervention unique is that it is the first to incorporate mindfulness with large group CBT, and in a Canadian population at that. The paragraph is now as follows (Background section, Page 5-6): Mindfulness is the process of being nonjudgmentally aware of the present moment, including one’s thoughts, sensations and environment, while encouraging inquisitiveness, open observation, and acceptance (21,22). Evidence suggests mindfulness-based interventions, such as mindfulness-based cognitive therapy (MBCT) and mindfulness-based stress reduction (MBSR), are effective in treating anxiety and depression (22,23). Mindfulness, as it is taught in these interventions and in the CBTm classes, is intended to reduce identification with thoughts and feelings by cultivating an awareness of the impermanence (arising, passing and changing) of these mind productions. There is accumulating evidence that mindfulness meditation, with the goal of calm attentiveness and acceptance, down-regulates mental activity within the default mode network (DMN). DMN activation is associated with mind wandering, negative affect and rumination as experienced by those with anxiety or depression (24). Other work shows that mindfulness may improve cognitive flexibility, working memory capacity, goal directed behaviour, and emotional regulation, as one’s attention and cognitive resources are shifted away from dysfunctional thoughts and emotions (25). Moreover, these complex functions may be modulated by neural networks, whose resources can be constrained by negative emotions and mind wandering; meditation allows for a more flexible allocation of these limited resources, such that they may be available for other, more salutary, cortical functions (24).

To our knowledge, there is no research on brief, low intensity, large group CBT interventions which incorporate mindfulness in the literature. Thus, the current study sought to evaluate the 4-session CBTm class intervention in a Canadian population.

− The main rationale for developing the CBTm classes was highlighted in the previous paragraph (Background section, Page 5): Early research on large-group CBT suggests it may improve clients’ anxiety symptoms more effectively than clients on wait-list (20) or even small-group therapy (21). These initial findings are corroborated by recent UK studies demonstrating large-group interventions are efficient, well tolerated, and effective in treating symptoms of anxiety and depression (22-24). Large-group CBT was introduced at a tertiary care clinic in Winnipeg, Canada in 2014 to manage the problem of persistently long wait times. These
transdiagnostic 2-session CBT classes were rated useful by clients, led to modest improvements in anxiety symptoms, and reduced wait-times from approximately one year to three months (20). Given these promising findings and client feedback, the CBT classes were expanded to 4 sessions and introduced mindfulness within the core content. These 4 session transdiagnostic Cognitive Behaviour Therapy with Mindfulness (CBTm) classes were independently developed and administered at the clinic to introduce clients to CBT principles, basic mindfulness strategies, and to provide various self-help resources at a time where they otherwise may not have had access to therapy.

Methods: - p. 8 l. 18f.: You now report that "Sessions were led by two staff psychiatrists who received training in CBT and mindfulness": To assess the quality of instruction it would be good to get more information about the psychiatrists' training: What was the level of experience with mindfulness? Were they certified MBSR or MBCT teachers, etc.?

- I have contacted both facilitators and have detailed information about their training, which is now included in the manuscript (Methods section, Page 7): Sessions were and were led and facilitated by two staff psychiatrists. One facilitator received certification from the Academy of Cognitive Therapy in 2004 and received the Beck Scholar Award in 2013. The other facilitator completed a 5-day in-person training course on Core Concepts in CBT at the Beck Institute in 2009, as well as 8 hours of online training on Integrating CBT and Mindfulness through the Beck Institute's online training program. Neither facilitator received specific training in MBSR or MBCT form

- p. 9 l. 26f.: "They could also seek out recorded instructions for the other meditations but no specific direction was given for this": There are two ways in which I find this approach to be problematic. First, if clients used exercises at their own discretion, this complicates assessment of treatment adherence, because it is eventually not clear what exactly clients were practising. Second, leaving the choice of meditations to clients' discretion carries the risk of adverse effects. There are guided meditations of uncertain quality freely available online, and it cannot be assumed that clients were able to judge the quality without further instruction. This is compounded by recent warnings about potential adverse effects of meditation even when correctly applied, e.g. Lindahl, J. R., Fisher, N. E., Cooper, D. J., Rosen, R. K., & Britton, W. B. (2017). The varieties of contemplative experience: A mixed-methods study of meditation-related challenges in Western Buddhists. PloS one, 12(5), e0176239. Van Dam, N. T., van Vugt, M. K., Vago, D. R., Schmalzl, L., Saron, C. D., Olendzki, A., ... & Fox, K. C. (2018). Mind the hype: a critical evaluation and prescriptive agenda for research on mindfulness and meditation. Perspectives on Psychological Science, 13(1), 36-61. This should be acknowledged in the limitation section of the discussion.
Thank you for identifying this limitation. We have included the following in the limitations section of the discussion (Page 19): Another notable limitation is we allowed clients to access meditations at their own discretion – this complicates assessment of treatment adherence and carries the risk of adverse effects as there are meditations of uncertain quality available online. Moving forward it may be helpful to encourage clients to limit their use to a few high quality meditations, which we provide as resources. Restriction of the classes to one tertiary care clinic is also a limitation – local work is being done to expand the availability of CBTm classes across multiple sites and different settings (such as primary care) in Manitoba, Canada. Future research will stem from this initiative, offering a clearer picture of the effectiveness of large-group CBT in this region.

- p. 13 l. 24-32 "the effect of the gap between baseline and the first attended class (a binary dummy variable that is coded 1 after the gap has occurred), and the effect of the gap between the last attended class and follow-up (a binary dummy variable that is coded 1 starting with follow-up)" I do not understand why the "gaps" were treated as dummy variables - did not each participant experience "gaps" between baseline/first class and between last attended class/follow-up? If so, both gap variables would have to be coded 1 for each participant, and as a result would not carry information. Please correct me if I see this incorrectly. - p. 13 l. 33 f. "These same variables were used as random effects in the model as these effects are likely to vary between individuals": To my knowledge, in a mixed model one and the same variable is to be treated as either fixed or random but not both.

The model was a within-subject model, meaning each subject had multiple observations with time-varying variables. The gap variables both start as 0's in the earliest observations and then switch to 1's once they pass the two assessment gaps. Imagine that you have an individual from the study and their measurements over time. If they have 5 visits, then you have 5 measurements and 5 observations in the data. The first observation is from their baseline screening. It contains their scores from baselines and all the gap variables are 0, because at baseline they have not experienced any gaps. The second observation is from their first CBTm class and contains the scores measured then, but now the screening gap variable is coded as 1 because they have experienced the gap. The next gap happens at first group session - that dummy variable is changed from 0 to 1 for that session. Once a variable has been switched to a 1 then it also remains coded as a 1 for all later observations. So if you typed the data out it would look something like this:

<table>
<thead>
<tr>
<th></th>
<th>gap 1</th>
<th>gap 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>first</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>second</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
third visit        1    0
fourth visit       1    1
fifth visit        1    1

- In the model, each individual can have up to 5 observations and these observations can have different values for each variable, including for the two gap variables.

- This is also why there are fixed effects and random effects in the model, because the random effects are not for the variables themselves, but rather to control for random effects in the individuals. It’s the individuals that are random in the model and not the treatment effects we are interested in. It helps to imagine graphing scores for individuals over time. Some people start higher or lower so the baseline score is random across individuals. Some people improve more or less than others and some may actually get worse - so the slopes you observe over time, which vary across people, are random. The model examines whether the difference across individuals are larger than we would expect based on pure randomness. If they are larger, then that indicates that the effects we are examining vary across individuals (e.g., the treatment is more effective for some and less effective for others).

- We clarified this in the methods by replacing the statement “These same variables were used as random effects in the model as these effects are likely to vary between individuals” with “The random effects examine the difference between individuals with respect to their baseline score and the changes over time” (Methods section, Page 12).

- Also added the following statement in the Results section, Page 14: There was significant variation in effect across individuals based on the regression model

- Regarding my comment on the original submission: 'The order in which the steps of the analytical approach is presented does not match the order that is given in abstract, introduction, and results. For instance, the results section reports acceptability before changes in anxiety and depressive symptoms, in the analytic strategy section the order is reversed. I think the article would be easier to read if the order was kept the same throughout.' I am sorry for having caused confusion here. The comment referred to the following: In the analytical strategy section, the last paragraph (p.14, l. 11-15), after describing how changes in clinical symptoms were tested, describes how baseline predictors of class completion were assessed. In contrast, the results section reports baseline predictors of class completion before changes in clinical symptoms are reported. This means that the general flow of each section is not, but should be Acceptability --> Anxiety and Depressive symptoms.
Thank you for clarifying. This paragraph has now been moved to the beginning of the analytic strategy section.