Author's response to reviews

Title: A pragmatic pilot randomized trial to investigate the effectiveness of BehaviouRal ActiVation group therapy in reducing dEpressive symptoms and improving quality of life in patients with depression: The BRAVE pilot trial protocol

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Author's response to reviews: see over
Dear Dr. Lancaster,

July 30, 2015

We would like to thank you and the reviewers for taking the time to carefully review our manuscript entitled “A pragmatic pilot randomized trial to investigate the effectiveness of Behavioural Activation group therapy in reducing depressive symptoms and improving quality of life in patients with depression: The BRAVE pilot trial protocol” (MS:1553760329157748). We have made thorough revisions to the manuscript in accordance with the constructive feedback provided during the peer review process. We feel the manuscript in its revised form will be of high interest for the journal readers. We detail below our response to the reviewers’ comments:

**Reviewer 1 Comment 1 (page 6 paragraph 2):** Which professionals offer this intervention what training and skills do they have to do this?

**Author Response to Reviewer 1 Comment 1:** A multidisciplinary team of clinicians that include psychiatrists, occupational therapists, recreational therapists, and clinical psychologists specializing in mood disorders provide services to patients in this tertiary care setting based in a psychiatric hospital outpatient services. The clinicians providing the behavioral activation program for the planned trial include: psychiatrist, occupational therapist, social workers and recreational therapist all are trained in behavioral and psychotherapies. In addition the planned *Out of the Blues Program* clinicians were also specifically trained in behavioral activation and attended a behavioral activation workshop prior to the design of this protocol. This description is now included on page 6 paragraph 2 of the manuscript.

**Reviewer 1 Comment 2 (page 8 paragraph 1):** Check hyphen

**Author Response to Reviewer 1 Comment 2:** On page 9 paragraph 1 we have replaced the former sentence, “The BA intervention will be delivered in a group of 6-12 participants as an add on therapy to usual care,” to “The BA intervention will be delivered in a group of 6-12 participants as an adjunct therapy to usual care.” We thank the reviewer for highlighting this error.

**Reviewer 1 Comment 3:** consider positioning/describing nurse as researcher - with skills to collect data

**Author Response to Reviewer 1 Comment 3:** We have revised our description of the study nurse, please refer to page 10 paragraph 1, it now reads “Following this, a nurse
with specialized training in research (education in data collection) who is not trained in behavioral activation will be present at the group time to collect study related instruments and check the suicide risk question on the mood scales to ensure participants safety and clinical care.”

**Reviewer 1 Comment 4:** - clarify the purpose of this activity - communication activities need careful analysis - in a research process - please bear this in your study

**Author Response to Reviewer 1 Comment 4:** We thank the reviewer for highlighting the areas requiring further clarification, especially with regards to the description of our intervention and controls. This support group is intended to simulate the intervention group format to minimize risk of a biased estimate of BA effectiveness by reducing the potential placebo effect which may result from frequent clinic visits and having additional attention beyond usual care. We understand that communication activities require careful analysis, however the purpose of including the support group was intended to provide more realistic estimates of how BA would fare when compared to usual care. We do not intend to perform analysis of communication activities during these support sessions. We have revised the manuscript to ensure this is clear when describing the purpose of the active control arm.

**Reviewer 1 Comment 5:** Please describe the parameters of engagement (located on pdf provided to us on page 10 paragraph 2).

**Author Response to Reviewer 1 Comment 5:** Engagement will be evaluated at during the qualitative stage using open-ended questions aimed at determining patient satisfaction with the current treatment design. Engagement will also be evaluated during the BA program using assessment of attendance and involvement in group therapy. In addition, the qualitative study aspect aims to collect data relating to participants’ experience in the program, as well as their perceptions of improvements in mood and functioning. This qualitative data will provide feedback to shape the main trial protocol. This has been clarified on page 11 (paragraph 1) of the manuscript.

**Reviewer 1 Comment 6:** - i suggest that you include a brief overview of these issues in your introduction (referring to Thabane et. al description of pilot study aims).

**Author Response to Reviewer 1 Comment 6:** We have revised the manuscript to emphasize the aims of pilot studies in the study introduction. Please refer to page 4 (paragraph 2) of the manuscript.

**Reviewer 1 Comment 7:** - introduce these aspects and the role of feasibility studies - will enhance your framing of study

**Author Response to Reviewer 1 Comment 7:** Please refer to previous response (author response to reviewer 1 comment 6).

**Reviewer 1 Comment 8:** what parameters will you use to decide if it is patient centered

**Author Response to Reviewer 1 Comment 8:** The interviews throughout the study
period provide opportunity to establish whether patients feel their needs are being met, and whether they feel the program is responsive to such needs. Participants will be asked whether they feel the program is tailored toward their needs, and what changes should be made to address such needs. Answers to these questions will allow us to ensure the program is patient-centered. The description is included now on page 18 (paragraph 1).

**Reviewer 1 Comment 9:** I suggest that you give the issue of excluding English language speakers further thought. While I fully appreciate your dilemma - and that you have chosen to do this study as an "ideal" - it still creates more marginalisation of populations who do not speak the dominant language in which services are provided - these populations are at greatest risk in a health care system.

I therefore suggest that you give serious consideration to this criteria and consider other ways in which the intervention can be managed - you may want to consider using a subgroup approach - at this point of the study.

*I realise that you are faced with a very difficult decision - but further thought on this matter will be appreciated*

**Author Response to Reviewer 1 Comment 9:** We in no way neglect the reviewers important point that this intervention needs to be scalable to the larger network of patients suffering with MDD, especially more marginalized populations. However, this type of assessment should be considered during the full-phase randomized trial, the purpose of the pilot trial is to assess feasibility under optimal conditions. We think it would be premature to move forward to assess the use of translators at this stage, it would also require additional resources to include a reasonable number of non-English speaking participants in a subgroup of the intervention (in efforts to assess translator feasibility) if we are to find the intervention doesn’t work under less demanding constraints. We will consider this suggestion during the full-phase trial by first assessing how many patients are being referred to our services and what are their preferred languages. In addition, inclusion of a translator may impact the entire arm of patients (since the BA therapy proposed in this trial includes group work) as such the full trial would require an additional arm with the “subgroup” of patients requiring language assistance since the inclusion of the translator could contaminate the findings. Ultimately our goal is to first establish efficacy; by which we demonstrate an interventions’ effectiveness under optimal conditions. Use of a translator to enhance generalizability of findings should be considered during phase-4 trials or once this intervention is assessed in an implementation trial. We are currently not at this stage.

**Reviewer 1 Comment 10:** would you consider gathering information from the close associates of participants - family members /carers

**Author Response to Reviewer 1 Comment 10:** We will not be gathering information from close associates of participants since the information collected from participants for this trial requires answers pertaining directly to the experience of the intervention.

**Reviewer 1 Comment 11:** Patients with depressive conditions may have communication
challenges- consider how you might mediate these challenges

**Author Response to Reviewer 1 Comment 11:** Depression is known to have an impact on memory, attention and concentration. At the baseline assessment of the potential participants, a clinician will be meeting each patient individually and have a clinical interview that includes a confirmation of diagnosis of depression and screening for other mental and physical health problems. If the patient or the clinician indicated that there are difficulties with cognitive function, the patient will be asked about whether they would like to participate in the study and given full details of the requirement in the study and also if there are specific supportive measures that they would like the team to help out with. For examples some patients may require a reminder call the day before their next session or a written plan from the clinician to document what they need to do for homework.

**Reviewer 1 Comment 12:** *I suggest that you reconsider using the term grounded theory - you may want to describe as a thematic analysis - given that grounded theorising is a much more intensive and structured process than you have described.*

**Author Response to Reviewer 1 Comment 12:** We thank the reviewer for their suggestion, however we have followed the methodology for grounded theory described in the literature. We have designed our qualitative study based on two previous guides (Charmaz K: Constructing grounded theory: A practical guide through qualitative analysis: Pine Forge Press; 2006, Charmaz K: Constructionism and the grounded theory method. In: *Handbook of constructionist research*. edn. Edited by Holstein JA, Gubrium JF. New York: Guilford Press; 2008: 822). We are hesitant to revise our classification of qualitative methodology, since we have maintained strict adherence to these guides.

We thank the reviewer and editor for their constructive evaluation. We hope we have clarified any of the issues brought forward.

Best regards,