Author’s response to reviews

Title: A pragmatic pilot randomized trial to investigate the effectiveness of Behavioral 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
Response to Editorial comments

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Manuscript ID 1553760329157748, submitted to Pilot and Feasibility Studies. 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

Dear Dr. Kathard,

Please see our point-by-point response to the editorial comments as requested. We are also including the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) upon which we based our current study reporting. The revised manuscript in track changes shows the specific item numbers of the SPIRIT guidelines.

Editorial Comments and our responses are below:

"This is an interesting study and worthy of publication. However at present the manuscript needs some more work to restructure it into a format that is easier to read, less repetitive and more concise.

A suggested structure is:

Methods
Study Objectives
Study Design
Study Setting and Ethics approval
Eligibility Criteria
Recruitment and Consent (amalgamate with text from page 22 and 28)
Trial Design Characteristics
Time line
Intervention group (amalgamate text from pages 8-10, 19-20)
Control group (amalgamate text from pages 8-10, 19-20)
Allocation/randomisation
Blinding
Outcomes
Data Collection ? quantitative data, qualitative data
Sample Size
Data Analysis ? quantitative feasibility outcomes, qualitative, quantitative secondary patient-centred outcomes (to keep in order of objectives)
Discussion incorporating monitoring, harms etc and how objectives will aid future trial design

Authors’ response

We have followed the SPIRIT guidelines in reporting this study. For clarity we have now included the SPIRIT checklist to include the page number of the manuscript corresponding to the checklist items.
Please also address the specific comments below.

1. Title ? please take out the word ?effectiveness? as this is not tested in a pilot trial ? maybe replace with ?use??

**Authors’ response**
The title reflects the main trial and in the interest of transparency we opted to keep the title for the pilot and main trials the same besides adding “pilot” to the pilot trial.

2. Abstract Background ? line 11, please expand what aspects of feasibility will be tested eg recruitment, acceptability of the intervention etc. Please delete ?effectiveness? in line 12 and replace with eg. ?to explore whether changes in patient-centred outcomes can be seen before the main trial is conducted?

**Authors’ response**
We have changed this paragraph, please see page 1 [track changes].

3. Background pages 5-9? the programme summary contains some background information but also some information that should be in the methods regarding the intervention and control group delivery some of which is again repeated in the methods. Similarly on pages 8-10 some information (literature review) is suitable for the background/introduction and some for the methods. Please condense this information and put in the appropriate places, and ensure that there is no repetition. Some may be suitable for the Discussion.

**Authors’ response**
Please see earlier comments regarding the SPIRIT guidelines, item 6.

On page 7 the hypothesis for the main study is given ? please make it clear that this is for the main study.

**Authors’ response**
This has been changed, please see page 10 [track changes]

4. The main Methods section should begin on page 10 before Study Objectives, then the heading on page 12 could be ?Study Design?. The study objectives listed on pages 11/12 should be stated once ? currently some are repeated on page 15. Please amalgamate together on pages 11/12.

**Authors’ response**
Please see SPIRIT checklist items 7 and 8

On page 12 under Study Design, 2nd sentence, before ?The qualitative study component?? please add some text about the quantitative study component.
This helps orientate the reader by putting the methods in the order of each stated objective.

**Authors' response**
Quantitative component description has been added. Please see page 13 [track changes].

5. Please add presentation of confidence intervals to the statistical analysis section (3rd sentence) as this is good practice.

**Authors' response**
This has been added.


**Authors' response**
This has been changed. Please see page 16 [track changes].

Last line ? how is opioid addiction medicine related to this study?

**Authors' response**
This sentence has been deleted.

7. Please integrate the Qualitative Study Design section as indicated above by separating the data collection and analysis sections and putting in the order of the objectives to be addressed.

**Authors' response**
This has been changed, please see revised manuscript with changes tracked for ease of identification of new changes.

8. Discussion ? there are a number of small sections at the end of the protocol. Can some of these be put into the discussion eg. monitoring, harms? Please expand a little how the pilot will help inform the main study in terms of each of the objectives listed. Also is the main study to be multi-centred?"

**Authors' response**
Please see SPIRIT guidelines items 21a-31c.
The main study will not be multisite. Our psychiatric program is a tertiary care program catering for the greater Hamilton area and receiving referrals from a 2 million catchment area. We do not expect the same facilities are available in the community settings to run the trial in multiple sites.