Author's response to reviews

Title: The use of Mindfulness Based Cognitive Therapy for improving quality of life for inflammatory bowel disease patients: A protocol for pilot randomised controlled trial with embedded process evaluation

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Version: 2 Date: 26 November 2013

Author's response to reviews: see over
26/11/2013

Dear Editors and Reviewers,

The use of Mindfulness Based Cognitive Therapy for improving quality of life for inflammatory bowel disease patients: study protocol for a pilot randomised controlled trial with embedded process evaluation.

MS: 1196623958109902

Thank you for your e-mail regarding our manuscript. We thank the editor and the reviewer for their comments.

We have read these and responded in detail below. We have also altered the manuscript accordingly and believe that it is improved. We hope that the paper can be reconsidered and is now suitable for publication.

All authors have seen and agreed the changes.

Yours sincerely

Mariyana Schoultz (on behalf of the co-authors)
Editorial requests:

1) Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ?___________: study protocol for a pilot randomized controlled trial.? 

1. The title has been accordingly changed on page 1 and 2 into the following: The use of Mindfulness Based Cognitive Therapy for improving quality of life for inflammatory bowel disease patients: study protocol for a pilot randomised controlled trial with embedded process evaluation.

2) Please mention each author individually in your Authors? Contributions section. We suggest the following kind of format (please use initials to refer to each author’s contribution): ?AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.? 

2. The contribution section on page 12 has been changed as advised and now states: All authors have contributed to the design of the study and the preparation of the draft manuscript. MS under direct supervision of AJMW, as chief investigator and grant holder, co-conceived the study, drafted the study protocol and study materials, applied for ethics and NHS R&D approvals, and drafted the manuscript; AJMW co-conceived the study and participated in design of the study and study materials, statistical planning and revision of the manuscript. GH contributed to the design of the study, particularly with the conceptualisation of the theory for the process evaluation. IA provided the statistical analysis plan and commented on the draft manuscript. All authors read, commented on and approved the final manuscript.

3) Please include a figure title and legend section after the reference list. The figures should not be included in the main body of the manuscript.

3. Figure title and legend section has been added on page 16 as advised: 
Figure 1. Agenda of activities for session 1
Figure 2. Example schedule for a day of mindful practice
Figure 3. Consort diagram describing flow of patients through study
Figure 4. List of topic guides.
Reviewer's report

I have read through the manuscript, and have a reservation to accept this protocol. The reasons are as follows:

1. The design of this study are not optimal, because:
   1) IBD including UC and CD, it is not ideal to include both in one study;

   1) Thank you for your comment. While the trial design when testing a new compound or a biologic agent should take into account the potential effect on a specific subset of patients (and thus separate CD from UC in the case of IBD), when exploring a treatment that is not disease-specific, such as the psychological intervention in this trial, what matters most is the symptoms that participants have (Sands, 2005). The symptoms that UC and CD patients often experience are similar and are described in the background section. Confirming this, there are a number of published studies that have included UC and CD patients together in their design when investigating the effects of a non-pharmacological intervention (Maunder, 2001; Kennedy 2004; Diaz 2007; Jaghult 2007; Oxelmark 2007, Larsson 2009;). This has now been made more explicit in the manuscript on page 5.

   2) IBD can be defined as acute stage and chronic stage, it is not ideal to mix both in one study, and the design is totally different.

   2) I totally agree with the reviewer and the exclusion criteria for this study support that. In addition, to make the above point more explicit, the text on page 6 and 7 (point 9 and 6) has been altered.

   3) The primary outcome is Qol, it is not ideal to put diseases index as a second outcome;

   3) While disease activity is an important outcome, the main focus and aim of this study is to explore the potential use of MBCT program in improving quality of life. Quality of life has been used as a primary outcome measure in several other studies (Kennedy 2004; Wells 2006; Jaghult 2007). This has been made more explicit at the last paragraph on page 8.

   4) How many UC or CD will be included in the study?

   4) This is a pilot study where one of the objectives is to determine how many UC and CD patients are likely to be recruited and also whether it is feasible and clinically meaningful to bring both of these patient groups together.
   The sample size is n=40 for UC+CD (page 10, paragraph 5). It is difficult to predict how many of each will be included while recruitment is still on-going. However, the randomisation process in this study is ensuring similarity between both groups and that both arms have matching numbers of UC and CD patients. This has been made explicit on page 7 paragraph 5, under the randomisation heading.

2. Team of the study. It will be much better to have a GI specialist in the team, as CO-I or Co-PI.

2. Thank you for your comment. I totally agree with the reviewer and we do have a GI specialist in the team. This information has been made more explicit now in the title page and page 12 (authors contribution section).