Reviewer's report

Title: Delivering internet-based exposure treatment for irritable bowel syndrome in a clinical setting: a randomized controlled trial.

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Reviewer: Rona Moss-Morris

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Review for BMC Gastroenterology

Delivering internet-based exposure treatment for irritable bowel syndrome in a clinical setting: a randomized controlled trial.

This follow-up trial of an internet-based treatment for IBS adds to an increasing body of work suggesting that brief psychotherapy interventions are an effective treatment for at least some people with IBS.

There are some key issues with the reporting of this trial and the data analysis which need to be revised. Most of these would fit under minor essential reasons, except for the issues raised about the analysis under point 3 which are major issues for revision.

1. The title of the paper should include that it a feasibility RCT. It is not presented as a definitive trial.

2. The copy I downloaded from your site did not include an abstract. I am not sure if this is an error on the site but clearly it is difficult to provide a complete review without evaluating the summary of the paper.

3. The authors state that the trial is presented according to CONSORT guidelines but they deviate from this in a number of respects:

   • The question posed at the need of the introduction should be broken down so that it relates first to the primary outcome and then to the secondary outcomes. The time point for the assessment should also be included i.e. that differences are expected at the end of treatment and that changes in the intervention group will be maintained at 12 months follow-up.

   • The flow chart does not correspond to a CONSORT diagram. It should include assessment periods (including baseline), n’s for each assessment period, reasons for drop out at each time point, and the number of participants analysed. The outside arrow for the treatment group pointing to the final assessment box does not make sense.

   • The allocation concealment for the randomisation process is not clearly described.
The statistical analysis section states that data are analysed by intention-to-treat, yet the effect sizes in the tables are presented as completers and only completers are included in the follow-up analysis. This is not correct and must be sorted before publication. All people randomised should be included in the analysis of the data and the data displayed should relate to these analyses.

4. The power analysis is very sketchy and requires more detail. What study was the effect size it based on and was it 60 people per group? Was the effect size for end of treatment or follow-up?

5. A one month wash-out period is alluded to on p. 5 but it is not clear what drugs this wash-out includes. There is also no data presented as to change of treatment during the treatment and follow-up periods and whether patients started new drug or psychology therapies during this time. This is crucial and these data should be included in a sensitivity analysis or the lack of data in this area needs to be discussed as a limitation.

6. The last paragraph on p. 5 is also confusing. Perhaps the word ‘inclusion’ in the first sentence should be ‘recruitment’?

7. The quote on p.7 (reference 21) needs to have a page number.

8. Details of the psychiatric assessment referred to under data collection (p.10) should be provided i.e. what was this for, what did it include and who conducted it? It should also be explained under procedure or screening.

9. There are no data on how many sessions were completed by the ICBT group and how long patients took to complete sessions? Adherence data to the programme is important and we need to know how many people dropped out of the treatment. Even patients who complete follow-up questionnaires do not necessarily complete treatment.

10. The discussion needs to be altered in accordance with a proper intention-to-treat analysis.

11. On p.16 – the authors raise the issue of predictors of treatment efficacy and who should treatment be offered to. In the penultimate sentence they refer to mediation in this regard but in fact they are referring to moderation. Analysis to work out who responds to treatment best looks at interactions and moderator effects. Mediators look at mechanisms of an intervention and process variables. Indeed, the authors could look at moderators or predictors of treatment outcome in their own data and this would strengthen their findings.

12. Finally, as a discretionary point for revision the authors argue in the discussion that psychological therapy may be best targeted to patients who are suited to it. However, this depends on the model of therapy. For instance, if the therapy is focusing on underlying psychopathology, or as in this case of this study anxiety, then this supposition may well be true. However, if the intervention is based on maintaining cognitions and behaviours and a more self-management
approach, it could be argued that this is applicable for all IBS patients.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests