Reviewer’s report

Title: Extending access to a web-based mental health intervention: who wants more, what happens to use over time, and is it helpful? Results of a concealed, randomized controlled extension study

Version: 0 Date: 27 Aug 2018

Reviewer: Filip Drozd

Reviewer's report:

General comments

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This study examines the benefits of adding extended access to a web-based intervention among a sub-group of participants that have already participated in a main trial, as compared to a sub-group of participants that had their access discontinued. Overall, the use of the intervention was very low in the extended trial, as measured by the number of logins, and this did not seem to have any additional effect on recovery and several secondary measures.

There are several great concerns about this study, some of which are beyond the point of no return. First, this study is not designed to provide clear answers to your research questions. Second, despite that the extension of the main trial seemed planned in advance, it was clearly not sufficiently powered. Third, the analytical approaches, including a lack of retention/missing data analyses and the use of repeated-measures ANOVA, are problematic. Finally, the simple measure of use as number of logins and lack of any measures of use of intervention materials in participants daily lives, leaves major unanswered questions in this study.

No matter how painful it is to condemn the study at this point in your research, with all the effort you have put into this extension, it simply does not hold up against necessary standards for good and publishable research quality.

Specific comments

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INTRODUCTION

1. Is the Big White Wall owned and distributed by an insurance company? Please specify.
2. What does this paper contribute to beyond the submitted paper under review? See page 5, lines 5-7. I do not quite understand the difference between these papers as it sounds as if you have already examined the research question herein, in the paper under review.

METHODS

3. I do not believe this study is set-up to properly answer your study questions. It would be more appropriate to compare two groups, of which one received an intervention as-is and a second that received an extended version of the intervention, against each other. I do not know what to make of these results. As a minimum, you need to thoroughly examine who were those that opted in and used the intervention for the extended period? But even then, I am not convinced these results will really tell us anything about your research question with the current study design.

4. P6, line 1: Describe what is meant by treatment setting in the stratification?

5. For some reason, I have a hard time grasping the study population. What were their problems/mental health issues? Why were they seeking help from outpatient mental health programs? I also notice that most were female according to Table 1? Were these recruited at a women's hospital or clinics were females are typically overrepresented? Please explicate.

6. P7: Please provide information about the professional content of the BWW intervention, who performed the moderation, and extent of moderation.

7. In the section on Statistical Analysis, it is a bit unclear if RAS-r scores and the secondary measures were compared across all timepoints (three timepoints) or from the main trial's study ending to 3 months added access (two timepoints)?

8. There is no consensus on the best ways of measuring use of internet interventions and this is an extremely complicated issue. For these reasons, it is recommended that usage is examined by several different measures, while you investigated engagement/adherence with the intervention only as number of logins. Personally, I would also like to see intervention use possibly conceptualized as a latent construct to integrate several measures of use. However, number of logins represents a very narrow and restricted snapshot of participants' intervention use which does not really tell us much. See this in relation to comment 15 below.

9. A problem is the choice of using repeated measures ANOVA (RM-ANOVA) to analyze the data. McCulloch (2005) has written a nice piece of paper that explains why and that it may only be used when all assumptions for the RM-ANOVA have been met (to a highly exact
degree), which occurs in very rare cases. After McCulloch's seminal paper, statisticians and researchers have even gone as far as recommending NOT to use RM-ANOVA, but rather linear mixed models. In this study, you may have used a student's t-test or preferably ANCOVA in randomized experiments to correct for baseline values. By the way, and this is entirely sub-ordinate to my main point about RM-ANOVA and its use, I do not understand the argument that because of a lot of missing data at study end-point, you decided to use RM-ANOVA. How is this an argument for using RM-ANOVA?


RESULTS

10. What was the effect in the original trial and who were the participants that opted in for the extension trial (less than 25% of the original study cohort)? This needs to be thoroughly examined and reported. I noticed that those who opted in also used the program far more than those who declined to continue their participation (p. 9). In which case, assessing the use of what participants learned and received of materials in their daily lives, is crucial to understanding the main results in this study (see comment related to the Discussion below too).

11. Furthermore, if participants who opted in, were some of those that also improved in the main trial, what does this extension study add beyond what would be expected? I mean, why would these participants continue to use the intervention? Why would they take advantage of the extended access, if their problems were solved or they already (felt they) had the necessary materials and know-how to continue with self-directed activities without logging in to BWW?

12. You should also present the baseline scores for the outcome measures in the extension trial in Table 1. These should be contrasted somehow against baseline scores in the main trial/the effects of the BWW in the main trial. The latter is related to comments 10 and 11 above.

13. Please provide the exact numbers and percentages for gender in the discontinued intervention group.

14. A missing data analysis would be required with the amount of missing data in this study, regardless of the chosen approach for main analysis. Who were the participants that dropped out at study end-point? Alternatively, which participants remained in the study?
DISCUSSION

15. A clear study limitation is that these participants received the BWW intervention prior to this extension trial. This means that they may have downloaded materials, kept notes, continued practicing exercises, etc. during this extension period, and may not necessarily have had the need to log on. Thus, a lack of any measures of uses and applications of materials and the things participants learned during the main trial in their daily lives, is such a major limitation in the study that it affects its' quality and questions the validity and reliability of the findings. A relevant point here is that the BWW's function might have been that of perceived available support (you are onto this at page 13), that is always comforting and reassuring, and thus can be a relief for some, and even cause a (small) symptom reduction. This may have reduced needs to log in and, consequently, affected the study results and conclusions. All the while participants may still have used materials, tasks, and exercises in their daily lives.

16. Address clearly the fact that most participants in this study were females, as a study limitation.

17. It is a shame that the study probably was underpowered, given that it seems the extension trial was planned in advance, and that substantial missingness contributed further to underpowering the study. Although you do mention this as a study limitation - unfortunately - there is nothing to be done about this now. Also, performing post-hoc power analyses is futile as power is the probability of rejecting the null-hypothesis in a future study. The power, after having conducted the study, is simply either 1 (if the null-hypothesis was rejected) or 0. Post-hoc power analyses are therefore fundamentally flawed.

FIGURES & TABLES.

18. I think Figure 2 is not as informative as it would be if you plotted the number of participants (Y-axis) against the number of logins (X-axis) to provide information on how many participants that did not log in at all, logged in once, twice, etc.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes
Are the conclusions drawn adequately supported by the data shown?  
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?  
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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