Author’s response to reviews

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

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Author’s response to reviews:

Editor Comments:

All three reviewers have provided considered, detailed feedback on your submitted manuscript. Despite finding the research question of significant interest, they share several concerns about the manuscript which prevent its acceptability in its current form. There are concerns about the
statistical method chosen to analyse the data, the choice and rationale of number of logins as the sole usage characteristic, and the interpretation of the study's results. If you are willing to undertake the major revisions recommended, I would be pleased to reconsider your paper.

Response: We thank the reviewers for their detailed feedback and the opportunity to revise and resubmit our manuscript. We are glad that the reviewers and yourself found the topic of the manuscript of interest. We have carefully considered the reviewers comments, made substantial modifications and submit a fully revised paper for consideration. We have undertaken major revisions and have opted to reframe this manuscript slightly to better communicate the study objectives and research questions. Although the study was planned a priori as an extended trial with randomization within a larger RCT, this study actually had several questions. The first questions addressed by the study were those of who wants additional intervention access and what they do with that access when they have it. We had no idea a priori how many participants would opt into this extension study and answering that was one of our main objectives to inform payor and implementers about use of this and similar interventions. We did include the randomized component to answer a question about what happens when you continue or discontinue access amongst a group of interested participants. The fact that we were underpowered to answer this question was a result of the overall low interest in continuing the intervention. However, we still report the results of the extension RCT to provide some data regarding the effects of continued vs discontinued use. These questions were driven by the available literature suggesting sustained utilization of similar interventions is low, and our desire to inform payors and implementers about use and benefit of the intervention.

We have tried to address all reviewer comments and have revised the paper extensively, adding new content to further characterize the interested participants from those that did not want to continue, and intervention component usage data throughout the study. Some of the reviewer comments regarding our statistical analyses led to adjustments in the methods used and further explanation of these methods in the manuscript.

We thank you for considering our revised manuscript for publication in BMC psychiatry and look forward to your response.
Reviewer reports:

Saskia M Kelders (Reviewer 1): The idea behind this paper is interesting: can we enhance the effectiveness of an intervention by giving participants more time to access it? However, currently, the paper does not provide enough insight in this question. I have a couple of comments that may enhance the value of this manuscript.

Response: Thanks for the feedback which has allowed us to better refine our study aims and questions and re-frame the manuscript around them. We really had 3 research questions in this study: 1) what proportion of intervention users after 3 months will be interested in extended access to the same intervention for another 3 months, 2) what does usage consist of the second 3 months and how does it compare to usage in the first 3 months? 3) Do those interested participants get additional benefit from extended access compared to a group who has their access discontinued? These have been specifically stated in the Study Design section on page 6.

Based on additional feedback from reviewers we have added to question #1: what proportion of intervention users after 3 months will be interested in extended access to the same intervention for another 3 months and how do they compare with users who were not interested?

Major comments:

1. The paper states that it is about engagement, but engagement is often seen as more than only usage (a behavioral aspect) and includes also affectional and cognitive factors. In this case, 'usage' would be a more fitting term, as it is only about whether and how many times participants log into the system.

Response: Based on your suggestion, we have revised to the term usage which we agree is more representative of what this study examines. We did collect data on all components and have added this to characterize use of the specific intervention components before and during the extension. See Table 3.

2. In the introduction, it is hard to follow the reasoning behind why extended time to access an intervention could enhance effectiveness. The second paragraph strings observations from other studies together, but I don't see the argumentation for your premise. If fit between a user and the system improves engagement (or usage), then why would a longer period of time to access a system be beneficial?

Response: See response above re: the research questions. By reframing the introduction around the research questions, we think that the reader will better make the links between the literature
cited and the study. A primary rationale for this project was the fact that this intervention, like many others, is offered by the developer as a 6-month subscription. In our case, our decision makers were considering making the intervention publicly fundable so a big question for them related to cost and value for money. From many other studies, we knew sustained usage (or engagement) of similar interventions is low, so we studied a briefer subscription (3 months) and embedded this extension study to determine if the 6-month subscription had any utility. We have added an explanation of this rationale in the Study Design section – page 6, lines 1-12.

3. It is stated a few times that it is hard to define an optimal dose or intended usage for this kind of intervention. But just because it's hard, doesn't mean that you don't have to try to give some more information. E.g. why was the 3 month period for the initial study chosen? And why another 3 months as extension? And: there were self-directed modular activities within the intervention. Was there an intended usage for that? What do you expect a 'typical' user to do within the platform? Or are there different ways that the system can be used? This information is needed to make sense of any of the usage data that you mention.

Response: See above response as well. Six months is the default subscription offered by the developers. We chose 3 months as a period of time that represents 50% of the default subscription length, is adequate time to allow account activation and use, and corresponds with the period of many manualized psychotherapies. The intervention itself has been described by the developers (see Harding C, Chung H. Behavioral health support and online peer communities: international experiences. Mhealth. 2016;2:43). We really had no idea how it would be used by our participants, or how it should be used, and as such we can’t speculate to define an intended usage. It is a multi-component intervention that is largely self-directed with some system guidance based on prompts. Individual users may interact with the system in completely different ways and achieve equal benefits. For example, a user may exclusively use the anonymous peer support component, while another user may only access guided courses. We have added more discussion of the intervention components under the Intervention description in the methods section on page 8.

4. Overall, the paper provides little data. In essence not much more that the follow up data of an RCT when often this follow up data (when participants would not have been given the option to access the system) would be reported in the main paper on the RCT. I do very much like the idea of exploring the question to whether prolonged access can have benefits and the way the study attempts to do so, but in this case, I think there is just not a lot of data to provide insight in this question. It would really strengthen the paper if more usage data can be included. What did the people do who accessed the system? What features did they
use? Was it more social or more the self-directed modules? And was this different than during the initial period?

Response: Thanks for this feedback. We had initially planned to include the extension with the main trial manuscript but opted to separate them because this extension study actually answers multiple distinct questions that we have tried to more clearly articulate in this revision. We have added results in relation to the 3 specific research questions now stated. These additional results include: 1) a comparison of those participants who were interested in extended access vs those who weren’t (Table 1) and 2) additional details of usage in the first and second 3 months (Table 3). Of note, usage was so low in the second 3 months, that comparisons of usage are minimally meaningful.

5. The intervention itself needs some more explanation. E.g. What is it exactly that these Wall Guides do? On what topics are the guided support courses? How long do they take? And how are they guided? Do users decide for themselves what to do with the system, or are they helped in any way? What were these creative bricks?

Response: As per response to your #3 comment, we have added some additional description of the components. The intervention is also described in Harding C, Chung H. Behavioral health support and online peer communities: international experiences. Mhealth. 2016;2:43. The Wall Guides are trained mental health professionals under the supervision of a psychiatrist or clinical psychologist, who work 24/7 to monitor content on the discussion forum and will intervene with their own posts if needed. They also respond to posts if no response has occurred from the peer community. The guided support courses cover a range of mental health and well-being topics – some examples have been added to the text on page 8. They run on a recurring basis and vary in length with all consisting of multiple sessions.

6. The discussion lacks depth. There are some interesting remarks, but it is not truly discussed what the findings mean. Specifically:

a. P11: 'the study yields important information about the commonly observed problem of limited engagement': what important information is that? What have we learned?

Response: We have made revisions to the discussion to align with the revisions to our manuscript frame and the specific research questions. We hope this addresses this comment.
b. The subgroup that enrolled in this extension study, was already more active than other participants. But even these did not use the system much in the second three months. Why is that? What does that say about his intervention? And about interventions in general?

Response: This is one of the main findings of this study. These interventions do not achieve high uptake and sustained use over time is low. The conclusions we draw from that is that either: use will be sporadic for most and therefore availability of the intervention needs to reflect that; OR that most individuals do not find the intervention helpful but some really do, so shorter trials of use may be appealing to payors to allow patients to self-select for ongoing access. We have revised the discussion to clarify these implications.

c. You don't find increased effectiveness in this study. Does this mean that prolonged access is not helpful, is it because of the lacking use, or does this mean something else?

Response: In reframing this manuscript, we identify this as the third study question. Ultimately, we can’t make definitive conclusions about continued access because we ended up with so few people interested in continued access, and use in the extended period was extremely low. However, there were some users who continued to be high persistent users of this intervention. The implications go back to the response above and the opportunities to offer the interventions in ways that fit with use patterns, and to better integrate along a spectrum of available services since these interventions alone will not be effective at the population level. This was our main objective which we have now stated more transparently in the introduction on page 5, line 14. “The objective of this study was to assist clinicians and policymakers in determining the optimal timing of access to the intervention that would inform both payment models for the technology and implementation approaches for wider scale adoption of this or similar interventions.”

d. The idea that people might want to have the intervention accessible just-in-case is very interesting. Is there any literature, even in other areas, that could support this idea? How would you go about studying this in more detail? What does it mean for other interventions?

Response: This study included a parallel qualitative evaluation which does provide some insights into this finding although it was not a specific line of inquiry in our qualitative interviews. In a study of electronic medical record patient users (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4376207/) authors describe 8 distinct user clusters characterized by different frequency of use as well as different content accessed. The clusters with the most users were labelled “Dabblers” and “Infrequent Intense Users.” There were other clusters who only appeared to use at certain times – to prepare for appointments or review laboratory results. This finding is similar in that users will maintain access to the portal to be able to take advantage of it in times of need. We cited this in our original discussion but have
added additional details to support our comments re: the “Just in case” interest in access on page 18.

e. Is extending the access duration only interesting for an intervention such as this where the dose is hard to define and participants are really free in what they can do, instead of more strict, modular interventions? Or could prolonged access also be an interesting idea for those interventions?

Response: We’re not sure we can comment on this. For this type of multi-component, peer support intervention, extended access has many potential benefits, particularly when individuals may be using it sporadically for situations of distress or crisis. The length of some studies examining modular interventions have offered reasonable periods for use. We don’t know the literature on the benefit of spreading a course of Cognitive Behavioural Therapy, for example, over many months without introducing additional material. For individuals who need more time to consolidate skills, longer access could be beneficial particularly when therapy is guided, or they may want to repeat aspects of the module. It is beyond the scope of this study to be able to provide recommendations on this.

Minor comments:

7. Statistical analyses: isn't mixed modeling better to handle a lot of missing data? In my understanding, RM Anova employs listwise deletion, which is not what is described in the results section.

Response: Based on reviewer feedback we have modified our analysis to a linear mixed model analysis and add an analysis for missing data. See Statistical Analysis for description on pages 10 and 11. Results did not differ.

8. Table 1: Why are the numbers suppressed for gender within 'discontinue treatment'?

Response: This is common practice in some areas of our institution for small cell counts (<5). We have removed the suppression in the tables.

9. Table 1: Why is retirement placed in the category with 'actively looking for work' and not with 'not looking for work'? They seem to fit better in the latter category.
Response: The not looking for work group largely represents individuals on social assistance for health-related disability. For simplicity, we have just lumped all non-working individuals together into a single category. See Tables 1 and 2.

Filip Drozd (Reviewer 2): General comments

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.

Response: Thanks for your comments. We have made our best attempt to improve the manuscript to better reflect the aims of the study and hope that this makes the findings more useful to the reader. We are not aware of any study to offer extended access to such an intervention within an RCT and as such we feel this is a novel contribution. Although the study was planned in advance, we could not predict what proportion of main trial participants would opt in to continue in the study (study question #1 below), and so our recruitment was not specifically planned around this extension trial. We had expected that with 542 initial trial participants, we would retain a decent proportion but this was not the case, and a main finding of this extension study. We have reframed the paper in response to the reviewer comments to make explicit 3 distinct research questions on page 6:
1) What proportion of intervention users after 3 months were interested in extended access to the same intervention for another 3 months, and how do they compare with users who were not interested?

2) Among users with extended access, what does usage look like in the second 3 months of access and how does it compare to usage in the first 3 months?

3) Among those interested in extending access to the intervention, is there benefit of extended access compared to a group who has their access discontinued?

Based on reviewer feedback we have revised our analysis and now report results using a linear mixed effects model. You will see that the results are unchanged.

We have added some discussion about use of the material in the daily lives of participants in the limitations section. See additional responses below.

Specific comments

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INTRODUCTION

1. Is the Big White Wall owned and distributed by an insurance company? Please specify.

Response: No, it is owned and operated in the UK by a private developer. Our research group evaluated the Big White Wall, sponsored by the Ontario Telemedicine Network and Canada Health Infoway – government funded organizations – as part of an initiative to determine if the province of Ontario should adopt it under the provincial health care budget for mass distribution. The BWW developer was not involved in the study or writing of the manuscript in any way.

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.

Response: The main trial paper under review examines use and benefit from 3 months of access to the intervention in an RCT compared to a delayed access control group. By explicitly outlining the 3 research questions for this extension study (see response above) we hope this
provides sufficient clarification re: the differences. We have actually removed references to the main trial outcomes because a) it is still under review for publication elsewhere, and b) we want the extension study to stand alone.

METHODS

2. 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.

Response: Thanks for this comment. We considered the study design you describe. But our objective was in part to determine how long we should offer the intervention, if our province were to adopt it. We have added more details to the background to be more transparent about the objective, with the following concluding sentence on page 5, line 14:

“The objective of this study was to assist clinicians and policymakers in determining the optimal timing of access to the intervention that would inform both payment models for the technology and implementation approaches for wider scale adoption of this or similar interventions.”

The default intervention subscription is 6 months but we anticipated low use based on existing literature. So we wanted to offer it for half that time, 3 months, and concealed the option to extend use to see how many users would still be active after 3 months and what proportion would be interested in extended use. We have clarified our research questions and the discussion has been revised to reflect those questions. We have added a comparison between those who opted in vs out for continued access (Table 1) which we agree was a missing piece of the original manuscript.

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

Response: Apologies, an explanation of this was missing from the text. This has been added to Study Design on page 7, line 4. We recruited individuals from 3 sites which we have added to Tables 1 and 2 to illustrate where the extension trial participants came from. Randomization in the extension trial was stratified by site.
4. 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.

Response: The study population is very heterogeneous but also not fully described in this paper. It is described in more detail in the main trial and the trial protocol which are cited. We have added a little more detail in the Study Recruitment section (page 7) to help the reader have a better sense of the population. One of the recruitment sites served primarily females (~75%) which partly explains the high proportion of females, but that was the lowest volume site and the other general sites also had a higher representation of females. In part this is due to the settings recruited from including mood/anxiety clinics and trauma therapy programs which tend to serve proportionally higher volumes of female patients.

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

Response: Additional details about the BWW have been added to the text in the Intervention description in Methods on page 8.

6. 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)?

Response: For the analysis reported in this paper, we compared scores at 2 time points – baseline for the extension (i.e. 3 months after initial access to the BWW) and then again at the extension trial endpoint 3-months later (i.e. 6 months after initial access to the BWW). The first timepoint was not included because all participants had access to the BWW for the first 3 months and were re-randomized upon entrance into the extension trial, thus balancing the groups at that time point.

7. 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.
Response: We did examine several utilization variables. We used number of logins as our main “usage” variable since it is the most commonly used measure. We list the components assessed in BWW utilization data on page 9, line 1. There are so many components on the BWW it is challenging to create some meaningful construct for overall use. We have added more use information including component use in the first and second 3 months among extended users to showcase what use looked like in each time period. As mentioned in the text, use in the second 3 months was extremely low across all components. See new Table 3.

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?

McCulloch, C. E. (2005). Repeated measures ANOVA, R.I.P.? Chance, 18(3), 29-33. https://na01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1080%2F09332480.2005.10722732&data=02%7C01%7Cjennifer.hensel%40wchospital.ca%7C0868b de8b0324c3a2e9008d60ca3be57%7C26033a94b4704c0bae8b58ee1d2eeaa24%7C0%7C0%7C63 6710294794167099&sdata=KDOBYZ2Oxkv8wviYvQHt%2B6p3HR18qX050GPDCozdG %2FU%3D&reserved=0

Response: We have repeated our analyses using a linear mixed effects model. You will see that the results are unchanged.

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).
Response: We have added Table 1 which compares those users who opted in vs opted out to the extension study and continued access to the intervention. In re-analyzing our data and including all those who provided a response regardless of whether they were randomized or not, we found no differences in first 3 month use. You make a good point about the adoption of learned material into the daily lives of users which we can’t determine from this quantitative study. We conducted a qualitative study in parallel that provides some insights into this although that was not a specific line of inquiry in our qualitative study either. We don’t see this as a negative through, and feel it may be a potential explanation for our findings, or at least supports some of them. We suggest that short use of the intervention may be sufficient for most users either because they find it helpful and don’t need it anymore, or they don’t find it helpful. Either way, as we consider implementation and adoption strategies, this is useful information for clinicians and payors. In reframing the manuscript, we have highlighted our study objectives and the discussion has been revised to acknowledge these limitations and better emphasize the implications of the findings. Your suggestion would be an interesting area for further study. We include a limitation to this regard on page 19, line 1-3:

“Additionally, we don’t have any way to know if low interest or decreased use over time reflected a successful use of the materials during the initial exposure period or lack of perceived benefit from the application.”

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?

Response: See previous response. We think you are right. We were looking at change in symptoms over time to see if there was any difference between groups which might suggest that the initial 3 months is good enough and longer subscriptions aren’t needed. Instead we found that most people didn’t even use the intervention in the second access period suggesting that use isn’t predictable and some need a little bit, some need consistent use, some need intermittent use, and some just want to know they can use if they need it. See response to Reviewer #1, and updated discussion.

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.
Response: Baseline scores for the extension participants are included in Table 2 (previously Table 1). We have added baseline scores (at time of re-randomization) for those who opted in and out of the extension study to Table 1 (new table). We do not include a comparison with the main study participants because a) we were missing extensive data for most of those participants at the 3-month mark (or baseline for the extension) making most comparisons uninformative, and b) we feel the extension study can stand alone to answer the specific research questions we have now explicitly stated in the Study Design.

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

Response: This is convention in some areas of our institution – to suppress cell counts <5. We have added actual counts.

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?

Response: We have added a missing data analysis. See Statistical analysis on page 11 for explanation.

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.
Response: Completely agree. We hope that the revisions to the manuscript address these concerns. We have also added this explicitly as a limitation that could impact utilization in the second 3 months.

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

Response: We have added this, given that one of the recruitment sites does primarily serve females; however, we also note that mood/anxiety disorders (the majority of our population) affect females at a higher proportion so this limitation may not be that significant. See page 19, line 3.

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.

Response: Our reframing makes this analysis our third objective. We acknowledge the lack of power as a limitation that can’t be addressed.

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.

Response: There was so much variability in the number of logins that this plot would show the majority of users having 0 logins, then perhaps 1 or 2 users with the same number of logins, every other X bar would have a count of 0. Our objective was to compare use in the first and second 3 months so we have added a new Table (Table 3) with this data and removed Figure 2.
Kristina Fuhr (Reviewer 3): This study investigates the effect and engagement of participants with a web-based mental health intervention after the first three months of use of the intervention within an RCT (the experimental group). Participants of the main study were asked at the three-months-assessment if they were interested in another three months access to the intervention and if so were randomized to either receiving the three months additional access or not. After another three months in the present study, the number of logins, and primary and secondary outcomes were assessed again.

The study addresses a very interesting point since adherence in internet interventions is known to be very limited and small, so the question remains who is willing to participate and engage in a specific time frame and why.

However, since the main study results are not published yet, the information about the outcome of the RCT is very raw and it remains unclear what the author's mean by "there was some benefit of access to the intervention". I would recommend to either wait until results are finally published or to clarify the results.

When comparing active intervention to a wait-list control, effect sizes are mostly over-estimated, ....

My two main concerns are that the main results are unclear and also not published yet.

Response: The main trial is still under review (since April). We hope to have a decision soon but unfortunately, do not have it yet. If this paper is accepted for publication in BMC psychiatry, we would be happy to provide the editors with updates on the main trial paper once available. For the time being we have removed references to the results of the main trial and have reframed this manuscript such that we think it can stand alone.

The other point is that in the discussion the authors' focus mainly on some subgroup results, that were only mentioned in the chapter BWW Utilization, but no analyses were made also because of small sample sizes (that is also mentioned in the limitations section). I would rather be careful with the interpretation of the usage pattern of only seven (!) participants but focus more on interpretation of the results concerning number of logins and other outcomes. The authors’ found that there were no differences in the outcomes between the groups after another three months. However, the number of logins was extremely small. What conclusions can be drawn?

Response: In response to all reviewer comments, we have modified the manuscript and reframed to have 3 distinct questions addressed by this study. The results and discussion sections
follow the same outline. See responses to reviewers 1 and 2 above. The 3 questions now on Page 6 are:

2) What proportion of intervention users after 3 months were interested in extended access to the same intervention for another 3 months, and how do they compare with users who were not interested?

3) Among users with extended access, what does usage look like in the second 3 months of access and how does it compare to usage in the first 3 months?

4) Among those interested in extending access to the intervention, is there benefit of extended access compared to a group who has their access discontinued?

I have also some minor comments regarding the manuscript.

Introduction

- On p. 4, line 2, the authors' introduce the concept of "Mental Health Issues", all written in capital letters. Is this a common concept? However, on p. 5, line 2, the concept is repeated again, but this time without capital letters.

Response: Thanks for catching that. No that is not a common concept and must have been a remnant of previous drafts and editing that got missed prior to submission. It has been corrected to “Mental health problems…”

- When you report about adherence measures and problems with the engagement of users (p. 4, lines 9-20) you could also cite the literature more elaborately. For example, the problem that in every internet intervention, different measures of adherence were reported, and also definition of logins required for being "per protocol", is mostly not reported, or differs among studies (see for example Donkin et al., 2011, doi: 10.2196/jmir.1772).

Response: This reference was cited in our original manuscript. We have made some revisions to the introduction based on your and other reviewer feedback to better set up the study rationale.

- The authors' state that "overall fit between user and the platform components... are likely important factors for ongoing engagement." (p. 4, lines 17-18). Here, the authors' could also insert some reference(s) that supports this statement. Also in the next sentence, it would be interesting to name some examples for implications for payors based on low engagement of users.
Response: Thanks for this suggestion. The payor perspective was a primary driving perspective for this study that were could have been more transparent about. We have added the following statement to the Introduction on page 5:

“The objective of this study was to assist clinicians and policymakers in determining the optimal timing of access to the intervention that would inform both payment models for the technology and implementation approaches for wider scale adoption of this or similar interventions.”

We have also added a theoretical example of how low engagement impacts payors on page 4, line 22.

“Moreover, many web-based platforms work on a license- or subscription-based payment model, so low engagement by users has implications for payors, such as public or private insurers, that purchase these programs. For example, an expensive intervention, assuming it is beneficial, that garners few engaged users will not yield a high value for money and will necessitate significant investment in user acquisition, relative to a less expensive intervention that appeals to a large audience of users.”

Methods

- The authors’ cite their own trial protocol. In my opinion I would rather insert a reference here instead of using a link to a web page

Response: This is the trial reference URL – it is published open access in BMC Psychiatry. We removed the webpage and just include the reference.

- In the statistical analysis section, authors’ decide to use repeated measures ANOVA cause of "high degrees of missing data at study end" (p. 9, lines 6-8). However, this ANOVA eliminates all cases with missing data so I don't really understand why this was a better choice. Or did the authors' use some kind of method for replacement of missing data?

Response: See comments above to the other reviewers who raised this issue as well. Based on the feedback we have re-run our analyses using linear mixed effects models. Results are unchanged. We also did a missing data analysis.

Results

- When reporting the primary and secondary outcomes on p. 11, lines 4ff., the authors' should make clear that all statistical data that is referred to are reported (also for the secondary
outcomes, even if reported in a table). I would also report main effects of the ANOVAs, if available.

Response: We have added all results to the text on page 15.

Discussion

- The authors' could also discuss advantages and disadvantages of using the number of logins as only measure for adherence.

Response: We actually examined several measures of use (see page 9, line 1 for list). We comment on number of logins when comparing the groups because it is most commonly used. We have included additional data on all component usage by the extended users during the first and second 3 months in Table 3.

- In the limitations section, authors' report about "imbalances in baseline variables between groups that was likely due to chanc. We did re-run the analyses...e" (p. 13, lines 19-21). First, I dont find in the results section any of these imbalances mentioned. This result should not be reported the first time in the discussion, but before. Even if they are reported in table 1 (without statistical data), but should also be mentioned in the main text. Second, why are some significant (but not so easy to explain) results due to change and others (for example the engagement of 7 users) are emphasized even if there was not enough power?

Response: We have eliminated this statement based on our updated analyses. We have also reviewed the results section in detail to emphasize findings that follow our research questions. We still report the sustained utilization among the 7 users because this is relevant to Question #2 and understanding use patterns over time.

- On p. 12, lines 3 ff., it is discussed that the sample of the study is represented by "more treatment-refractory and severely symptomatic individuals..." Where does this information come from? If from the trial protocol, then the original reference could be cited here again.

Response: Our study population consists of individuals seeking specialized mental health treatment services at a range of hospital-affiliated programs. We have added more details about these programs to the methods – recruitment section based on other reviewer feedback (page 7). As such, this is not the type of population you would recruit from primary care or the community. We have referenced our protocol which details the study population further.