Author’s response to reviews

Title: DIAMOND (DIgital Alcohol Management ON Demand): a mixed methods feasibility RCT and embedded process evaluation of a digital health intervention to reduce hazardous and harmful alcohol use

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Author’s response to reviews:

We thank all the Reviewers for their helpful feedback. We have responded to each comment below.

Editor:

Comment: Please refer to the CONSORT extension to pilot trials when revising the manuscript (Eldridge et al PFS 2016) and ensure primary outcomes are feasibility outcomes and secondary outcomes include any patient centred data collected, and all limitations are discussed.

Response: We have amended our results section and Figure 1 to follow the CONSORT extension as suggested. Please see pages 16, 19 and figure 1.

Reviewer 1:

Comment: The current manuscript presents the findings of a feasibility trial and process evaluation of an online treatment for alcohol use reduction. I credit the authors with their efforts
in this important area. I think the paper holds some merit by way of informing the authors subsequent rethink of an RCT. However, on this basis alone I do not feel the manuscript has adequate merit or contributes to the furthering of knowledge in this area in any real way.

Response: We thank Reviewer 1 for his comments and address specific remarks below.

Comment: Unfortunately for the authors study recruitment and attrition, and seemingly a number of project delays lead to a failure to have adequate data to analyse and consequently this reviewer does not feel there is much to gleaned from manuscript for a wider audience.

Response: We disagree that the delays reduced the volume of data, as we would have had at most three patient interviews. However, it is still regrettable that these three people were not available.

Comment: The authors primary conclusion was that it was not feasible to conduct such a trial on a larger scale. As such the primary outcome results are absent but even much of the process evaluation has methodological flaws e.g. sample size and the nature of the sample themselves.

Response: We conducted a feasibility study and as such our primary outcomes were recruitment, retention, and collection of secondary data to inform a Phase 3 trial. We have made this clearer in the revised draft. Please see 10, 16, 19, Figure 1 and the outcomes Table 1, suggested by Reviewer 2.

Comment: Furthermore, this "thematic" analysis does not truly cover themes at all, but rather a short list of difficulties faced. And with such numbers it is difficult to believe that strong themes could truly emerge.

Response: We agree with Reviewer 1’s comments about the small numbers making strong themes difficult to justify. We have amended the abstract and pages 19-20 to reflect this.

Comment: Finally, there are a number of structural issues with the paper, although minor, add to its overall frailty. This includes the listing of outcomes without adequate structure (e.g. what are primary?, what are the measures used to assess these outcomes?), how are the exclusion criteria confirmed (e.g. severe illness?).

Response: We have amended our outcomes as discussed above and provided a clearer CONSORT diagram. We agree that the exclusion criteria ‘severe mental or physical health problem’ were not clearly defined and have amended this to ‘having a serious mental health
conditions such as schizophrenia or bipolar disorder; having a serious physical health problem (e.g. liver disease, cardiovascular disease, cancer)’, pages 12-13.

Comment: Additionally, I feel the methodology could benefit from a more clear flow diagram indicating where the process evaluation recruited and dropped off from (e.g. page15).
Response: We agree and have added a clearer CONSORT flow diagram (Figure 1).

Comment: There are also present a number of grammatical errors, largely around the placement of references (e.g. line 132,343,366) and some areas might benefit from more academic style writing (e.g. paragraph at line 169).
Response: We have amended these grammatical errors and the paragraph (now starting line 179).

Reviewer 2:

Comment: Thank you for giving me the opportunity to review the paper. I am sure you know that as a reviewer it is always nice to receive a high-quality well-written paper to review. I enjoyed the narrative flow of the paper, 1) you set up a well thought out study, 2) you administer it, 3) for unforeseen reasons it fails to recruit, 4) you reflect extensively on this failure thereby providing lessons for other researchers. Nevertheless, I have quite a few comments and suggestions of how I feel your paper might be improved.
Response: We thank Reviewer 2 for his positive remarks about the paper and address the specific comments below.

Comment: L319-355: Please could you tell the readers what measures were actually collected, the lengths of the measures (i.e. number of items) and when? A diagram might be a good way to get this across clearly and would act as a clarification to the text. If would also be good for readers to be able to ascertain an impression of the amount of time participation takes for both the participants and the people collecting the data. This might feed into the reasons for the failure to recruit.
Response: These measures have been put into a table, as the Reviewer’s suggested, and are clearer. The table will go on page 17 under the secondary outcome measures.
Comment: L562: I think that one real strength in this paper is in its lessons for other researchers conducting feasibility trials, generalisable beyond the specific context. I think you might want to consider writing your conclusion in the light of this. In other words, one main reason why this paper is interesting is because it may help other researchers designing studies in the future who may face similar problems, outside the context of alcohol use studies. If you could finish this paper off by writing in more general terms about the lessons you learned I think that this would really widen scope of the paper. You could also, perhaps, think about “upselling” these more general "lessons" in the abstract and introduction.

Response: Thank you, we have added the Reviewer’s suggestions to the abstract and the first paragraph of the conclusion section.

Comment: L563 & L569-570: Can you really claim that randomisation, retention and data collection methods were thoroughly tested, given the recruitment was so low? I am not sure that you can. For example, the small sample may mean that you were unable to see fundamental problems with the data collection instruments. I think you have to 1) convince me that I am wrong, or 2) accept that the small sample size meant that you could not really assess these factors fully. I do not think that situation 2 weakens your paper in any way.

Response: We agree with the Reviewer’s comment and have amended the paper to reflect option 2, please see the final paragraph of the abstract and we have added the Reviewer’s suggested line to lines 596-7. We have also amended the sentence from line 617 to say ‘This feasibility study struggled to recruit participants and so was not able to fully test recruitment, randomisation, retention and data collection methods’.

Comment: Abstract: 579 + 548 = 1127. Where does 1189 come from? Oh, I see, the consort diagram. It might be worth clarifying those who are missing at this point in the text, somehow.

Response: We have amended the abstract text to clarify these figures.

Comment: Abstract: You might think about incorporating the information which is in bullet point format at the end of the results into the main body of the text. It seems unnecessary to put it as bullet points in the abstract.

Response: This has been done.
Comment: L166-167: I do not quite understand what you mean by "assessment only or information only". Please could you make this a little clearer?

Response: These are websites where a user’s alcohol intake is recorded and feedback given on their level of intake; or websites which just give generic information about alcohol-related harms. This has been made clearer in lines 168-171.

Comment: L171: please could you very briefly reiterate the reasons people do not access treatment, it would just make the paper a bit easier to read.

Response: Yes, this has been added to lines 180-183.

Comment: L192: Recruitment is very likely possible and was possible in the study, it was just not anywhere near the numbers required for an RCT. Should you be asking something more like "To estimate recruitment rates to a full RCT"? So, ask a "to what extent" question rather than a "yes/no" question.

Response: We agree with the Reviewer and have amended this aim accordingly.

Comment: L196: This aim is a bit vague. Please can you specify what kinds of problems?

Response: This aim has been amended to ‘To understand the reasons for any difficulties in recruitment and retention to the trial, and with data collection or use of the DHI.’

Comment: L218: I'm not sure what this "overall research question" is. Please could you clarify?

Response: This paragraph has been re-written, starting line 235: In addition to PPI input, we also had significant and meaningful input from other stakeholders, including commissioners, who we approached to determine whether CDAS would be an appropriate place to recruit. Their commissioning specifications included services for hazardous and harmful drinkers so they were certain that recruitment would be possible from these sites. The alcohol commissioners, along with alcohol service providers, helped to refine the trial procedures including inclusion / exclusion criteria, recruitment and follow-up.

Comment: L347: please could you expand on where this figure of 2000 comes from? Is it not the case that one of the purposes of this study is to estimate the SS for a full trial? If this is the
case where does the 2000 come from? Note: I'm not trying to trick you here, sample sizes like these are very difficult to estimate analytically and often it comes down to a judgement. The same size of 100 in each arm seems fine in my judgement, I just wondered if you could add in a bit more justification for these numbers, possibly a citation from somewhere.

Response: We agree with the Reviewer and have given more justification for the sample size for the feasibility study with references and removed the mention of sample size for a potential fully-powered RCT as we agree this is confusing.

Comment: L348: Please could you expand on where the 10% of the full sample size comes from?

Response: As described above.

Comment: L351: I am guessing this is a self-reported measure of alcohol consumption. Please could you make this clear and also add details about how exactly it was collected. So, was it collected face to face, over the phone, by filling in details on a website? Did the method of collection differ between the treatment and control (TAU) group? If so might this impact the validity of the measure? If not, you need to state that the measure was collected in the same way.

Response: Yes all outcomes are self-report and collected online for both arms. We have added this information to the Table of outcome measures on page 17. Hopefully this is now clear.

Comment: L506: "and one participant visited the website 159 times, on four separate days." This is highly unlikely. Alarm bells are ringing that there is something wrong with the way visits were measured. Please could you expand on this as it relates to the feasibility of the data collection? I think this figure needs explaining away somehow.

Response: Thank you, we have clarified this in the text: one participant accessed 159 pages over four days, so they may have only looked through rapidly without taking in the information.

Comment: L563: Can you really claim that randomisation, retention and data collection methods were tested, given the recruitment was so low? I am not sure that you can.
Response: We agree with the reviewer and have amended this sentence to say ‘This feasibility study struggled to recruit participants and so was not able to fully test recruitment, randomisation, retention and data collection methods’.

Typos, Language and Grammar

Comment: Abstract: "attending participating", maybe say "attending the participating". It is difficult to parse as it is.
Response: This has been changed to “attending four”.

Comment: Abstract: "everyday" not "every day".
Response: This has been changed.

Comment: L132: You are missing a fullstop.
Response: This has been added.

Comment: L149: Who does "they" refer to? (both times)
Response: “They” refers to digital health interventions (DHI). We have changed the sentence to make this clear.

Comment: L164: You need to add "an" before the word effective.
Response: This has been added.

Comment: L171: "Don't", replace with "do not"
Response: This has been done.

Comment: L195: "the sample size calculation"
Response: This change has been made.
Comment: L195: remove the full stop.
Response: This change has been made.

Comment: L205: please make this line into a sentence, or make it a heading.
Response: This has been made into a sentence.

Comment: L213: "one of the representatives" please add the word patient here.
Response: This has been done.

Comment: L323-324: This sentence is clunky. Perhaps something like: "When clients declined to take part and offered a reason, alcohol counsellors recorded this reasons and included it in the recruitment log".
Response: This has been changed as suggested.

Comment: L328: "follow up measure" something wrong here. Add plural to "measure"?
Response: Yes it is plural and has been changed.

Comment: L329: "with a £10 shopping voucher being offered for completion …".
Response: This has been changed.

Comment: L464: Please indent this quotation.
Response: This has been done.

Comment: L557: "the main weakness of the qualitative study…", replace "for" with "of".
Response: This has been done.
Reviewer 3:

Comment: The investigative team employed rigorous methodological principals in designing this study. The writing style is clear, the topic is of noteworthy importance. I was very enthusiastic to read and review this study. However, the challenges experienced with recruitment of participants is extraordinary. Out of 1253 screened only 10 participants were recruited and of these 3 were lost to follow-up. Thus the main conclusion is that this was not the appropriate setting to pilot the intervention and RCT. The most important data came from the interviews.

Response: We thank Reviewer 3 for her positive remarks about the rigor and writing style. We agree with the specific comments and criticisms and address these below.

Comment: However, it is surprising that some of these barriers were not identified prior to expending so much time and resources. The authors note that the study was informed by clinician, but they did not seem to provide accurate information or helpful guidance. Before embarking on a study of this size, I wonder what if any efforts were made to examine clinic records to get a better sense of the profile of patients to see the proportion of dependent drinkers and identify alternative settings earlier on in the study.

Response: We did have PPI and clinical / commissioners involvement, as previously mentioned. The commissioners had commissioned a service for harmful and hazardous drinkers as well as dependent drinkers, so it was reasonable to expect a higher proportion of clients would be eligible to take part in our study than was actually the case, and we make this point. However, we accept that their views (which informed their input) may not have been entirely accurate. We feel that this misunderstanding of the commissioners as to what services they are actually commissioning is an important finding and have put this in the conclusion. We have also now added the suggestion of reviewing clinic records to the limitations section.

Comment: In addition, is not clear what role, if any, members of the target population of drinkers, were used in planning this study. The lack of interviews with patient participants is a significant limitation of this pilot/feasibility study. It is critical to include the patient perspective in planning any type of intervention study and is even more important in this context where recruitment and retention is a significant issue.

Response: As we mention in the PPI section, we sought the perspective of people who had used the CDAS services in planning the study, and three patient representatives volunteered to participate in the trial management group, review the protocol and help to revise it. They also
tested the trial materials and the digital intervention. They all felt the trial was important and feasible.