Author’s response to reviews

Title: Ethical issues and practical barriers in internet-based suicide prevention research: A review and investigator survey.

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Author’s response to reviews:

Dear Editors,

Thank you for providing to us the feedback from reviewers regarding this manuscript. Please find our response to each of the comments below.

Kind regards,

Eleanor Bailey
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EDITOR COMMENTS

1. Please change the Introduction heading to Background.

This has been done

2. Please clarify whether the survey used in your study was developed for this study or has previously been published elsewhere. If the survey has been published elsewhere please provide a reference to it in your manuscript, if the survey was developed for this study please upload an English language version as a supplementary file.

The survey was developed for this study. This has now been specified in section 2.2.2, and the supplementary file has been added and referred to.

3. Please specify in the Ethics approval and consent to participate section whether the consent was written or verbal. If verbal, please state the reason and whether the ethics committee approved this procedure.

This has been clarified

4. We note that you have not included a ‘Consent for publication’ section in the Declarations. Consent for publication refers to consent for the publication of identifying images or other personal or clinical details of participants that compromise anonymity. Seeing as this is not applicable to your manuscript please state “Not Applicable” in this section.

This has been added

REVIEWER 1 COMMENTS

1. Page 3, line 4: delete "future"

This has been changed

2. Page 3, line 6: I suggest replacing "suicide-related behaviour" with suicidal behaviour to be consistent throughout the paper.

This has been changed

Apologies for this oversight; this study is now cited appropriately throughout the text.

4. Page 4, lines 2-3: The text mentions several potential advantages of internet-based research but is silent about potential disadvantages such as selective (non-representative) samples and high drop-out rates.

We believe the section of text you are referring to is related to internet-based interventions themselves, rather than internet-based research. We do not think it is appropriate to also discuss the advantages/disadvantages of internet-based research here as well, as it starts to overlap with the purpose of the study.

5. Page 5: include a definition of an "integrative review".

Rather than define this, we have decided to remove it from the title as we do not believe it is necessary. It is not mentioned at any other point in the manuscript (EDITOR - please note title change).

6. Page 5, line 14: Could authors give an example of such a "key" conference?

Examples of each type of conference (suicide prevention and internet-based therapy) have now been provided.

7. Page 5, lines 11-14: Were there any limitations to the searches, such as year of publication (or year of conference), location or language?

This has been clarified on page 6 (lines 2-3); “Medline, PsycINFO and Embase were searched in February 2018 using the following keywords…; results were limited to peer-reviewed records published from the year 2000 onwards and available in English.”

8. Page 5, lines 16-17: What type of studies were included? All? Quantitative, qualitative, mixed methods? Studies with and/or without control group?

No restriction was placed on study design; this has now been stated in the text (see our response to comment 8 below).

9. What were the exclusion criteria?

We have now added these to the methods section on page 6 (lines 9-11); “Exclusion criteria were: 1) not an experimental study; 2) participants not recruited based on suicidality; 3) intervention not at least partially internet-based; 4) intervention not targeting suicidal ideation or behaviour. No restriction was placed on study design.”

10. What was the strategy regarding studies with blended interventions (interventions with an online and offline component)?
We have addressed this question by adding the exclusion criteria, as requested in comment 9 above (i.e., interventions with combined online and offline components were acceptable). Please let us know if you would like us to clarify this further in the text.

11. Page 6, lines 3-4: The survey aimed to recruit multiple respondents per study. Were the replies of multiple respondents grouped per study? If not, this method could have introduced a serious bias to the data.

We acknowledge this possibility and believe we had adequately addressed it in the limitations section, where we stated “Secondly, respondents were not required to name the specific projects they were referring to; it is therefore possible that multiple respondents provided data based on the same projects.” We hope this is satisfactory for the reviewer.

12. Page 6, line 22: I suggest replacing "to identify codes" with to allocate codes, or to code the data. The current phrase suggests that authors have found the codes in the data, while they were provided / labelled by the researchers.

This has now been amended.

13. Page 7, line 7, lines 14-22, lines 23-line 7(page8), page 8(lines7-10): Include the references of the studies in the text.

References have now been added.

14. Page 8, line 13: earlier it was said that respondents were encouraged to report their co-authors to the researchers so that they could be invited as well. Were these researchers included in the 30 "individual researchers"?

No respondents reported co-authors; this has now been stated in the text (page 9, lines 9-10).

15. Page 13, lines 6-7: This seems to be a repetition of the previous lines. Consider deleting.

We have attempted to reduce repetition in this section, see page 14 (lines 5-7): “Delays or additional costs to the study, and additional burden on research staff, were reported by individual respondents as other negative impacts of addressing the ethical and practical issues.”

16. Page 16, line 22; page 17, line 3; and page 18, line 8: I am unsure what you mean with "consumers with lived experience of suicidal behaviour". It might be more clear to say research participants.

We believe the term “consumers” is more accurate here, as people with lived experience of suicidal behaviour may be consulted in the design of interventions or research procedures without necessarily being “research participants”.
17. Page 17, lines 15-17: It could also be that people with negative experiences want to participate to vent their frustration, while those with positive experiences feel no need to participate.

Thank you for this suggestion, the following statement has been added on page 18 (lines 22-24): “It cannot be ruled out that suicide researchers with more negative experiences of online interventions, such as those who had encountered serious adverse events, chose not to participate. Alternatively, it is possible that researchers with positive experiences felt no need to participate whereas those with negative experiences participated to vent their frustration.”

18. Table 1 - The references of the studies must be included in the text and in the list of references.

This has been done.

REVIEWER 2

1. In the opening paragraph, rates per 100,000 pop are generally more meaningful than the relatively random suicide statistics cited here.

We have added the global crude suicide rate to the opening sentence (page 3, lines 2-3): “Suicide accounts for close to one million deaths worldwide annually, with a crude global rate of 10.6 suicide deaths per 100,000 population.”

2. On p. 4 (lines 2-7) the ethical challenges associated with internet mental health service delivery have been well studied and many jurisdictions have developed specific ethics guidance for such online service delivery. Although such guidance is primarily clinical service orientated, rather than for internet research, it is relevant and none of this work is cited here. Also relevant to p. 16 lines 1-2.

The introduction has now been expanded to briefly address the ethical challenges associated with delivering telehealth or e-health services to clients who are at high risk for suicide. We have also reinforced that it is the reduced contact with a mental health professional characteristic of internet-based interventions (compared to telehealth or ehealth services) that we anticipate leads to particular ethical/practical challenges. Specifically, refer to page 4:

“Over the past decade, use of the internet to treat mental health problems, including suicidal ideation and behaviour, has become increasingly common (19, 20). The internet offers many advantages over traditional face-to-face therapy, including wide reach, cost-effectiveness, accessibility and ability to combat stigma-related issues (21-23), with social-media-based interventions also having the potential to reduce isolation and increase belongingness (24, 25). Internet-based interventions, including smartphone applications, may also have the unique ability to enable real-time monitoring and detection of suicide risk (26). Despite this, the limited face-to-face contact and protracted availability afforded by the internet means that internet-based interventions are impacted by a range of ethical and practical challenges. The ethical and practical challenges associated with online mental health service delivery to individuals at high
risk of suicide have been well studied (27, 28), and management of suicide risk has been embedded into standard ethical codes and guidelines for health practitioners and services (29, 30). Static, self-directed interventions designed to prevent suicide are increasingly being developed and evaluated, but the relative lack of therapist involvement likely give rise to particular ethical and practical issues.”

3. The literature review and discussion would benefit from a more recent Andriessen et al paper (2019) DOI: 10.1177/1556264619859734

This has now been cited throughout the text.

4. There is no "Aims" section between the literature review and the Method section, although Aims are mentioned in the final parag of the Intro. (Editor to decide).

We do not believe a separate “aims” heading is necessary given our aims are clearly stated at the end of the introduction, but will happily be guided by the editor on this.

5. It is not clear whether Phase 1 of the study (document review) informed the design of the survey in phase 2. Ideally, this should have been the case…

Because the survey was designed at the outset prior to ethics approval, it was not directly informed by the phase one results. However, many of the authors are experienced researchers in this area and therefore had a good understanding of the types of studies that would likely be identified via the literature search; this was considered in the design of the survey.

6. The wording of parag 2 p. 6 lines 8-9 implies bias by the researchers in assuming that ethics review would necessarily impose "barriers" rather than helpful assistance to researchers in this area. Such bias is absent in related statements of purpose (p. 4 lines 22-24).

Thank you for this comment. We have changed the word “barriers” to “issues”, as this more accurately reflects the survey content. Survey questions on the impact of actions taken to address these issues allowed respondents to also provide information about positive and helpful aspects of such processes.

7. Section 3.2.2 would benefit from specification of some of the elicited differences between face-to-face and online interventional and prevention research. Note also that, in general, prevention research in general is a specific subset of interventional research.

Respondents elaborated on the differences between face-to-face and online research using an open-ended text box; these were therefore analysed qualitatively and are discussed in section 3.2.3. This has been specified in the text in section 3.2.2 (page 10, lines 1-2): “All agreed that there were differences in the ethical and practical issues encountered between online and offline intervention research; these differences were expanded on using free-text responses and are included in the qualitative analysis.”
We are also aware that prevention research is a subset of interventional research, but are unsure if the reviewer is referring to any particular misuse of these terms in the manuscript. We have therefore not amended the manuscript in response to this comment.

8. Some of the survey results reported in section 3 could be argued to be non-specific to online suicide prevention research and common to many forms of health-related research - e.g. concerns about adequate understanding of the risks, provision of false or understated clinical information, biased sampling because of exclusion criteria etc. These generic research ethics concerns could be referenced and mentioned as such.

Thank you for this suggestion. We had aimed to address this in the original discussion, but have added some wording in the first paragraph (page 15 line 24 – page 16 line 4) to further emphasise this:

“Results indicate that trials of internet-based interventions for suicidality are characterised by many of the same challenges associated with suicide prevention research, and indeed human research more generally. These include: concerns about potential harm to participants; risk management; recruitment difficulties, particularly where third party referrers are used; conflicting views of ethics committee members and researchers; and the impact of inclusion and exclusion criteria on sample generalisability.”

We also amended this sentence on page 16 (lines 25-26): “Difficulties obtaining target sample sizes, with consequent reductions in power to detect effects, was a common experience for survey respondents and is consistent with the literature regarding challenges in suicide prevention research, and health research more generally.”

We would also like to emphasise that the aim of the study was to describe the ethical and practical barriers associated with this research area, as perceived by researchers, regardless of whether or not these were particularly unique. Although we anticipated, and indeed found, that there were some unique issues, we do not believe we claim in the manuscript that every issue identified was unique to this area. We have however toned down the language throughout to ensure the manuscript is not interpreted in this way.

9. The finding related to conflict between researchers and RECs again contains some points that could be argued to be generic (p. 10 lines 4-9) and not unique to this type of inline prevention research. This warrants comment by the authors. The same applied to findings reported on p. 12 lines 13-17.

Please see our response to comment 8 above and refer to amendments made on page 15 line 24 – page 16 line 4.

10. It is not specified whether the exclusion criteria specified on p. 12 lines 17-18) were determined by the researchers themselves or by their RECs. It should be mentioned, here or in related discussion of this finding, that in general almost all studies have inclusion and exclusion criteria - this is not unique to online suicide prevention research - and such criteria impact on generalisability.
The nature of the collected data precludes us from being able to make any definitive statement about whether the exclusion criteria were determined by the researchers themselves or their HRECs; as such we have not amended the manuscript in response to this comment. We believe it is likely, however, based on the rest of the results, that exclusion criteria based on suicide risk were either requested by the HREC or established in anticipation of HREC requirements.

We agree with the reviewer that the impact of inclusion/exclusion criteria on generalisability is not unique to this research area, and that many studies exclude participants on the basis of suicide risk. The point we are trying to make, however, is that excluding participants based on high risk for suicide in the evaluation of interventions designed for suicidal populations significantly limits generalisability.

To address the reviewer’s concerns, we have amended page 15 line 24 – page 16 line 4 in the discussion to acknowledge that the limited generalisability imposed by inclusion/exclusion criteria is not unique to this research area specifically (also amended in response to comments 8 & 9 above): “Results indicate that trials of internet-based interventions for suicidality are characterised by many of the same challenges associated with suicide prevention research, and indeed human research more generally. These include: concerns about potential harm to participants; risk management; recruitment difficulties, particularly where third party referrers are used; different standards of ethics committees and researchers; and the impact of inclusion and exclusion criteria on sample generalisability.”

11. Similarly, issues regarding measuring experimental treatment effects in relation to standard of care (p. 13 lines 1- 7) (where placebo would be unethical) are generic to all intervention research, including clinical trials. This should be mentioned in the related discussion to provide perspective, as these issues enjoy considerable and ongoing debate in the current research ethics literature, in relation to research costs, impact on sample size, efficacy measurements etc.

Thank you for this suggestion. We have contextualised this finding against the broader literature on page 16 (lines 14-17), as follows:

“The interventional effect of the comparison group is a common methodological limitation of clinical trials with high risk populations, where true control conditions are not viable due to the ethical implications associated with withholding treatment.”

12. The mentions of well-being of research assistants (p 14 line 17) is underdeveloped and is only expanded upon briefly later in the paper (p. 17 line 1).

We appreciate the request for further information here, however, we have reported all available data on this in the results section. As we recognise this is underdeveloped, we recommended this be expanded on in future research. In the absence of any more data we are unable to expand on these results further.
13. The Discussion section seems to start with comments on phase 2 while comments on phase 1 only seem to appear on p. 16 line 17. Consider sequencing more consistently.

Thank you for this suggestion. Originally the discussion was written as the reviewer has suggested, but after several iterations we decided that the findings of the study were better synthesised and reported with the discussion structured as it is currently. The current structure describes what we believe to be the most important findings first, rather than what was found chronologically, and helped to reduce repetition.

14. The closing section of the discussion makes much of the fact that most of their researchers/respondents reported 'problems obtaining ethics approval' must also be compared with the literature on common (or local) outcomes of ethics review in general - this reviewer is not persuaded that these are in any way unique to internet-based research proposals. It is the business of RECs to raise careful questions - are these necessarily 'problems' or could they also be useful research enablers or support referred to by 20% of your sample? Instead, what is missing and what could be proposed in section 4.1 for future research is a closer study of how REC comments on internet based suicide research proposals differ qualitatively from comments on other types of prevention or intervention protocols. Stating that respondents "experienced problems" (p. 16 line 6-7) is very vague and suggests an underlying anti-REC bias alluded to elsewhere. This point also suggests that some of the findings of the study are not 'unique' (p. 18 line 1) to this specific type of study, but are common to this and other research topics and designs.

We have added the following sentence to the limitations, page 16 (lines 4-8): “Finally, it is acknowledged that several of the ethical and practical challenges described in this study are not unique to internet-based suicide prevention research, and often characterise intervention research more broadly. Future research could expand on the differences between research ethics committee feedback across different study designs and disciplines, for example through comparative qualitative analysis.” Also see our response to comment 8.

Regarding the comments about anti-REC bias, we think this is an important point and would like to try and reassure the reviewer by emphasising: 1) that one of our findings related to the positive impact of HREC requirements on studies; 2) that we have emphasised the importance of a collaborative relationship between HRECs and researchers; 3) we acknowledged and normalised the response of ethics committees in paragraph 3 of the discussion, “Considering the shortage of available evidence, together with the reality that people at elevated risk of suicide may be particularly vulnerable, it is unsurprising that research ethics committees, who are mandated to weigh the benefits of research participation against possible risks, are concerned about the potential for harm.”

We do agree that the term “problems” carries negative connotations, but unfortunately this was the wording used in the survey; we therefore do not feel we can use a different term without misrepresenting the data. However, we note that the same wording has been used in other similar published studies (e.g., Andriessen et al 2019a; Andriessen et al 2019b)

References:


15. The paper should refer to 'research ethics committees' or RECs throughout, rather than "ethics committees" as there are many forms of ethics committee that are not research ethics committees.

This has now been amended.

16. "Ethical approval" (p. 8 line 22) should be 'ethics approval.'

This has been amended.

17. The statement (p. 3 line 25) that the field has a "lack of evidence" regarding effective interventions may be overstated and could be replaced with 'relatively little empirical evidence regarding…'

This has been amended as suggested.

18. Some useful generic comments on ethical issues in online/social media based research may be relevant and found at https://doi.org/10.1177/1556264619901215

For the most part this editorial focusses on issues related to social media data, so we have not cited it as it is beyond the scope of the manuscript. However, we found it interesting and thank the reviewer for the recommendation.

19. Insert a comma after "were identified" (p. 10 line 23) otherwise it reads as if only 3 themes were found.

This has been done.

20. The general recommendation that there be better bilateral pre-submission conversations between researchers and RECs has been made in general and for mental health professionals has been made before and could be referenced (e.g. DOI: 10.1177/0081246316654348)

This has now been referenced on page 16 (lines 23-25), as follows: “Consistent with recommendations for clinical research more generally (57), respondents emphasised the importance of collaboration and open dialogue with ethics committees… “

Citations have been added.