Author's response to reviews

Title: Internet trials: Participant experiences and perspectives

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Author's response to reviews: see over
Reviewer 1:

Major compulsory revisions

Comment 1: The nature of the questions included in the survey needs to be clarified, and the means by which the ‘trade-offs’ were identified specified.

The authors state that six trade-offs were identified in participant responses -these are discussed in detail and are the primary contribution of the article to the literature. However it is currently unclear how these were extracted from participant responses (what were the open-ended questions that elicited these responses?), and how these relate to listed advantages and disadvantages. For instance, were these six trade-offs generated by the researchers based on lists of answers to questions about advantages and disadvantages separately (essentially interpretations of participant responses), were the trade-offs specifically listed by participants as such originally (i.e., did a given participant have to provide both advantage and disadvantage), or were they defined by the researchers in the survey and participants merely responded to advantages/disadvantages of each (so the six themes had been pre-generated)? Each of these options engender very different interpretations by the reader and thus this need to be clarified. Although there are some references to the survey that in part address this, it needs to be specified directly to avoid confusion and assist interpretation.)

Reply: We asked participants 2 open-ended questions:

“1. As a participant in medical research (having participated in the stretching trial) - what do you see are the advantages for you, when participating in medical research on the internet compared to participating in conventional research (research conducted in person, over the phone or in written surveys)

2. What do you see are the disadvantages for you, when participating in medical research on the internet compared to participating in conventional research (research conducted in person, over the phone or in written surveys)”

Content analysis was then carried out on these responses producing 106 codes, and creating the list as seen in Appendix 1 (now table 4) This list of advantages and disadvantages was then grouped into the 6 main categories. Neither the codes, nor the 6 categories, were pre-determined: we generated them inductively from the participants responses.

The survey questions have now been included as an appendix (Appendix 1), and the analysis section has been expanded to include more details of how the advantages and disadvantages were analysed (as noted below):

Content analysis was used to analyze open-ended responses.[10] A list of 106 codes were developed from the open ended responses about advantages and disadvantages of participation. After finalization, the complete list was then re-applied consistently to all of the data. This allowed us to determine which were the more or less frequently occurring
codes. The codes were then grouped into 6 main categories. Each of the 6 categories had a ‘positive’ and ‘negative’ dimension. That is, that most advantages of participation had a ‘mirror’ disadvantage of participation: advantages and disadvantages could be conceptualized in pairs. These pairs, or trade-offs, will be presented and discussed below.

Comment 2: Appendix 1 – the ‘star’ system used is not appropriate. Use of frequency and percentage data is an appropriate way to summarise the kind of data reported here. It seems as though this data is actually more important than that provided in the earlier tables in terms of contribution to the literature. It needs to be provided in the text and in a more accurate, professional format. This would go some way towards addressing the problems raised in point (1) through clarifying the nature and content of participant responses.

Reply: This table presents the codes that we developed from participants’ open-ended responses, not their agreement or disagreement with items on a list. For this reason we would prefer not to provide specific percentages for each item: the fact that a participant did not mention an issue does not mean that they may not agree with it if given the opportunity.

However, we are happy to provide a general sense of the frequency of response, and it is important that this table is easy to read. We would be grateful for any advice about how you think it would be best presented. We have removed the star system as suggested and have substituted a new system of coding to give a sense of the frequency of response using a scale of A-C where A=most frequently reported and C=least frequently reported. However we are willing to make any changes that you think would further improve the readability of the table.

Minor Essential revision

Comment 1: It is important to note why RCTs are advantages compared to other methods when discussing their increased use.

Reply: The first paragraph of the introduction has been expanded to briefly address this issue.

Since the 1950s, randomised controlled trials (RCTs) have been used to test the effects of health interventions.[1] RCTs have become the accepted gold standard for evaluating interventions and their now well accepted key principles ensure a minimization of bias which is more frequently observed in other types of studies.[2] A recent development in clinical trial methods has been the emergence of Internet-based RCTs. In Internet-based trials, the Internet is used for recruitment of trial participants, delivery of the health intervention, and/or data collection.[3-5]
Comment 2: The authors note there are major differences (more a spectrum) in terms of use of the internet within RCTs, whether just for recruitment, recruitment and data collection, presentation etc. Should specify how this study pertains to the different types of trials.

Reply: The participants in this study are reporting upon their experiences of a fully online trial. They had no personal contact with investigators, and all aspects of the trial were conducted over the Internet. The following has been added into the discussion:

Participants were reporting upon their experiences of participating in a fully online trial. As such, the results may not apply to other trials which use the Internet for only part of the trial. Although the results from respective elements of conducting a trial online may apply to partially online trials, the participants overall experiences may differ.

Comment 3. Many of the ‘negative’ comments regarding the trial seem to similarly apply to non-internet-based trials (e.g., problems with subjective reporting methodologies). This should be discussed.

The following has been added to the discussion:

Some of the issues that participants noted with data collection (for example self report and subjective reporting) are not limited to data collection via the Internet, and apply to all modes of trial conduct. In the case of Internet-based trials, self report is unavoidable, and subjecting reporting is likely to occur in almost all instances. However, researchers conducting trials using other, more conventional modes can design their trials to avoid these problems if desired.

Comment 4. The authors should expand further on the statement in the Introduction regarding ‘transferability of findings’ – this is an important point that should be discussed.

The introduction has been expanded and now reads:

Internet-based trials have several potential advantages over conventional trials. Participants from all over the world can participate in a trial managed at a single site, decreasing costs and potentially increasing the equity of access to medical research. As it is possible to recruit large, diverse samples, including participants who would otherwise be difficult to access, Internet trials may also increase transferability of findings. This is an important advantage as conventional trials commonly recruit highly selected groups of participants, thus limiting the transferability of their results and the overall relevance and value of the research.(6) Finally, participants may feel more comfortable participating anonymously in Internet-based trials, and may be more open and honest with self-completed questionnaires.(7)
Discretionary Revisions

Comment 1. Suggest dropping the ‘short survey’ from the paper as the number of participants is low, its relevance is unclear and the data is not well utilised.

Reply: This is in contrast to what Reviewer 2 notes. (comment 2).

Due to the difference in opinions between the 2 reviewers, we have left the results of the short survey as is. We are happy to make changes if the editor requires any.

Reviewer 2:

Minor Essential Revisions

Comment 1: This was quite a low response rate, it needs to be said in the discussion that this will be a highly motivated sub-sample who are already engaged and willing to participate on-line.

Reply: The discussion now reads:

Furthermore only 33.4% of those invited to participate completed the survey. These participants are likely to be highly motivated to participate in research, and have already participated in online research....... our sample does represent a proportion of the population who are interested and willing to participate in Internet-based medical research.

Comment 2: The response of the short survey are the more interesting as these are the people who were willing to participate but did not have a successful experience with the internet method. Not enough information is given about reasons for poor follow up which were related to the study (not liking the questions - more is needed on this so that questions can be developed better). How many of those who dropped out of the trial reported study problems?

Reply: As noted in reply to Reviewer 1, Discretionary comment 1, we have left this section as is.

Comment 3: The 'fudging' aspects reported here are very interesting and are what make this paper most useful to others doing internet trials. I feel more depth should be given to reasons people don't report the truth on an internet trial. If 56% were not consistent, what does this mean?

Reply: Little information was obtained regarding why people don’t report the truth. What we were able to determine is that the reason they fail to tell the truth is the desire to report the ‘desirable’ answers. All the information we have regarding this issue is described on page 10-11. This issue is an area for further investigation. The following has been added to the discussion:
We also recommend further investigation into the relationship between the mode in which trials are conducted and the truthfulness of disclosure. An exploration into the reasons why people are more or less likely to report truthfully when participating in Internet-based trials, and the implications this has upon the trial results is warranted.

Consistency is referring to reporting levels of soreness consistently from one week to the next. As we have now included the survey questions as an appendix, this should be self explanatory.

Discretionary Revisions
Comment 1: The survey was carried out using the internet, this mean people who participated in the trial but didn't like the internet method will be less likely to engage in the survey too. I would suggest putting in the recommendations that future surveys should be multimedia (postal, phone and internet) to capture the views of people who tried the internet and were put off (which might have been 2/3 of the people in the trial for all we know).

Reply: We agree with the reviewer, however in our case, the only contact details we had for these participants were email addresses.

The following has been added to the discussion:

This survey was only conducted via the Internet. Alternative forms of contact was not possible as no personal contact details (other than email addresses) were collected during the RCT. Participants who may have had a negative experience using the Internet for research may have been less inclined to participate in our survey. Future surveys may benefit from using various modes of data collection (eg. postal, phone and internet).

Editors Comments

Editor Comment 1: This involves the six trade-offs identified in the participant responses. As articulated in review, the authors need to be more explicit in how these were extracted and how they relate to the listed advantages/disadvantages.

Reply: This has been addressed – see Reviewer 1; Major essential revisions Comment 1

Comment 2: the authors consider implications for multimedia or mixed mode alternatives.

Reply: This has been addressed - see Reviewer 2, Discretionary revisions Comment 1.
Comment 3: I would also recommend that the authors consider revising use of the ?star? system, as this makes comparison somewhat cumbersome.

Reply: This has been addressed – see Reviewer 1: Major essential revisions Comment 2.

Comment 4: I would also recommend that they consider more fully incorporating the findings presented in Appendix 1 into the body of the paper.

Reply: We have now moved this appendix in to the main document as a table. The findings presented in this table are described on pages 11-15. We felt that the text adequately described the main features of the results.

We have expanded upon this part of our study in the methods section, the results section, and in the discussion. The additional information is noted below:

Methods: Also noted in reply to Reviewer 1 Major revision comment 1

Content analysis was used to analyze open-ended responses.[10] A list of 106 codes were developed from the open ended responses about advantages and disadvantages of participation. After finalization, the complete list was then re-applied consistently to all of the data. This allowed us to determine which were the more or less frequently occurring codes. The codes were then grouped into 6 main categories. Each of the 6 categories had a ‘positive’ and ‘negative’ dimension. That is, most advantages of participation had a ‘mirror’ disadvantage of participation: advantages and disadvantages could be conceptualized in pairs. These pairs, or trade-offs, will be presented and discussed below.

Results:

As discussed in the methods section, the advantages and disadvantages of participation were captured in 106 codes. We were able to group these codes into 6 overarching categories. The codes and categories are presented in Table 4. After grouping the codes into categories we developed an original, interpretive finding: advantages and disadvantages could be conceptualized in pairs. Each of our six categories was a quality or characteristic of internet trials; each had a positive and negative dimension. The six categories were:

1. **Flexibility, convenience, connectedness and understanding for participants**
2. **Degree of burden and ease of use for participants**
3. **Security, Privacy and Confidentiality**
4. **Researcher experience, as perceived by the participants**
5. **Technical aspects of the research technology**
6. **Information quality**
Because each of these six categories had a positive (advantageous) and negative (disadvantageous) dimension, we concluded that the advantages and disadvantages of internet trials could be conceived of as trade-offs. Each advantage of internet research has a ‘mirror’ or ‘twin’ disadvantage. We note that this is our interpretive analysis across all of the data: while some individuals discussed both negative and the positive dimensions of a given category, others might emphasise one or the other.

Discussion: summary of results.

Our central, interpretive and most original finding in this study was that elements of participating in Internet-based trials have both positive and negative dimensions. Most of the advantages of participation had a ‘mirror’ disadvantage of participation and could be conceptualized in pairs, or as trade-offs.

Discussion: Area for further research

We suggest future research testing our categories which were created to classify the advantages and disadvantages reported by the participants, and their positive and negative dimensions, in order to determine prevalence of agreement, as well as the preferences and prevalence in different population groups.

Comment 5: inclusion of text on the relative advantages of RCTs;

Reply: this has been addressed – see reviewer 1 Minor Essential revision Comment 1

Comment 6: embellishing on text exploring major differences in terms of using the internet;

Reply: I think this has been addressed by the reply to Reviewer 1, Minor essential revision comment 2. If this is not the case, could the editor please expand upon this comment.

Comment 7: exploring reasons/implications for people not reporting the truth on internet trials;

Reply: Our exploration into reporting the truth in Internet trials was minor. We have added an “areas for further research”, in which the following is noted:

We also recommend further investigation into the relationship between the mode in which trials are conducted and the truthfulness of disclosure. An exploration into the reasons why people are more or less likely to report truthfully when participating in Internet-based trials, and the implications this has upon the trial results is warranted.
Comment 8: briefly discussing applicability of findings to non-internet-based trials.

The purpose of the study was to explore participants’ experiences in relation to Internet based trials. As such, we are concerned that extrapolating our findings to make inferences about non-internet-based trials might be over-interpreting the results. We have noted in the discussion (on page 20) that the results may not be applicable to partly online trials, and it would be even more tenuous to apply them to entirely non-internet based trials. It would also considerably expand the scope of the paper and will be difficult to do properly without considerably expanding the text. In view of these issues, we would prefer not to discuss the applicability of the finding to non-internet based trials.