Title: Exploring reasons for non-participation and withdrawal from a randomised controlled trial of telehealth and telecare in England: a qualitative study

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Author’s response to reviews: see over
Dear Professor Wootton,

Many thanks for providing us with an opportunity to revise and resubmit this paper in response to the comments from peer review. The comments have been most helpful, and we are grateful to both reviewers for their careful assessments and useful insights on the paper. We feel that addressing the comments has greatly improved the paper.

In addition to the reviewers comments you asked us to remove the box or re-format it as a table. We have deleted the box and incorporated a summary of the interventions referred to within the text (see bottom of page 6 and top of page 7).

We have included the remaining table within the main document and following the references as requested.

We hope you will agree that we have improved the manuscript in keeping with the requirements and suggestions of the reviewers. Please see the remainder of the document below which addresses each point in turn, and details the location of changes in the manuscript.

Yours sincerely,

Caroline Sanders

Reviewer 1

Major Revisions

1. It is pointed out that 36.7% of 9214 subjects did not enter the trial. Have those subjects been described (at least in regards to their basic demographics) elsewhere? This should be addressed.

Response:
In its entirety the WSD Evaluation comprises multiple (nested) study designs and cohorts, of which the current qualitative study is just one part. The overarching study design is a pragmatic cluster randomised controlled trial (RCT) of telecare (N = 2,600) and a parallel cluster RCT of telehealth (N = 3,230). Other studies that form part of the overall WSD Evaluation are essentially nested within these two cluster RCTs, although some qualitative studies include participants who were never formally part of the cluster RCTs (e.g. trial refusers as in the current qualitative study). Nevertheless, given this structure it is appropriate that the evaluation was implemented in such a manner to allow compliance with the CONSORT reporting guidelines for cluster RCTs. These guidelines clearly state
the type of descriptive information required for clusters and individuals at each stage of participant flow through the trial. In the Enrolment phase of a cluster RCT (which is concerned with recruitment into the trial) only information on clusters is required (i.e. Number of clusters assessed for eligibility; Number of clusters excluded; Breakdown of reasons for exclusions; Number of clusters randomised). Information on individuals (from the randomised clusters) who were invited to participate but who refused is not required under CONSORT guidelines and therefore, given the substantial administrative burden that collecting this additional information on non-participants would have placed on the WSD recruiters, demographic information was not systematically collected on trial refusers. Baseline data on trial participants is reported elsewhere (Steventon et al, in press) and shows very close correspondence between trial arms for all variables examined. Our approach to the collection and reporting of demographic descriptors is in line with the relevant reporting guidelines and comparable to recent published pragmatic trials.

The reviewer's concerns about the representativeness of participants in the trial are understandable but arguably misplaced. A pragmatic (cluster) RCT seeks to achieve appropriate statistical power, with an essentially unselected sample of participants, professionals and clusters that reflects the heterogeneity encountered in real world practice. It is recognised that no pragmatic trial can achieve true representativeness but heterogeneity (of participants, professionals and clusters) and random allocation (of clusters and/or individuals) allows for the best estimates of the effectiveness of the intervention. The issue of whether trial refusers were similar or dissimilar to the trial participants is therefore less relevant than the issue of whether heterogeneity was achieved and randomisation was implemented appropriately. These issues are treated more fully in the quantitative papers (Steventon et al, in press; Cartwright et al, under review) and we feel that in-depth discussion of such matters in the current paper is likely confuse and distract rather than enlighten.


2. In addition, was any subject offered participation in an interview and refused it?

Response:

Out of the people who did not enter the trial after receiving a home visit to explain the trial, 61 people were contacted by telephone after being sent an information sheet and invitation letter to take part in a one-off interview in order to explore their current management of health or social care problems and their reasons for not taking part in the trial. All of these people had agreed to receive information about the qualitative study and to be contacted by the evaluation team. 42 out of the 61 declined to take part in an interview when telephoned. However, most people volunteered information on their reasons for declining to take part in the trial which are summarised in the box below, and this information has now been included in the revised paper (bottom page 8).

<table>
<thead>
<tr>
<th>Reason for non-participation offered by those who declined to be interviewed for the qualitative study</th>
<th>Number of people giving reason for non-participation in the trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too ill or incapacitated</td>
<td>8</td>
</tr>
<tr>
<td>Did not understand the intervention and why they were being offered to join the trial</td>
<td>8</td>
</tr>
<tr>
<td>Reason</td>
<td>Count</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Did not think they needed TH or TC and/or did not want it</td>
<td>11</td>
</tr>
<tr>
<td>Thought the trial would be too disruptive</td>
<td>3</td>
</tr>
<tr>
<td>Personal reasons (going away, death of family member, work commitments)</td>
<td>6</td>
</tr>
</tbody>
</table>

Whilst we have these specific figures on the volume of people invited, we do not have any detailed demographic data on them, other than names and addresses, and the arm of the trial they were to be included in. This relates to the flow of consent for data sharing because potential participants for the trial were initially contacted to ask permission for their contact details to be shared with the evaluation team. Once this permission had been obtained further details were then to be collected from them as part of the trial. This was important to ensure that data was managed according to the process agreed with the ethics committee and adequately protected prior to formal consent for the trial. All of this process of managing and sharing data was outlined fully in the application to the ethics committee as part of the process of gaining ethical approval for the study.

3. The investigators state that they aimed for maximum variety in ethnicity in their sample, but ethnicity is not described in Table 1.

Response:

Ethnicity was one of the factors we considered in attempting to achieve an appropriate and varied sample. We also mentioned other variables which as the reviewer pointed out were included in table 1; including gender and age. The latter were received from the recruitment sites and are much easier to define in a table form. As a result we were able to ensure we achieved a reasonable balance of men and women as well as a varied sample regarding age. Data on ethnicity was not available prior to recruitment in the trial and it was collected later from participants themselves as part of the survey questionnaire. In some cases we were able to gain qualitative information when we arranged the interview as some participants talked about their background in terms of where they came from, and some stated that they had problems with English language because they had emigrated from a specified country. We did not ask them to define their ethnicity in the interview and we did not want to impose ethnicity categories based on our assumptions. We considered ethnicity in qualitative terms whilst conducting the research. For example, because the majority of interviews were conducted in an area of East London well known for comprising an ethnically diverse population, we would have found it to be unusual if the sample was made up of white people only who spoke only English. There were 5 members of the final sample who described their experiences of having immigrated to the UK from countries in South Asia, Africa and Eastern Europe; these participants spoke English as a second language. Consequently, we were satisfied that the overall make-up of the participant group was reflecting adequately the ethnic diversity in the general population of the sites in the trial. We have now included a symbol in table 1 to reflect this information as an indication of ethnic diversity in the sample.
4. It is unclear to this reviewer how information from Observational Visits was used: “Field notes were made of observational visits and explored thematically alongside interview data.”

Response:

We had initially restricted the paper to a very minor inclusion of examples from the observational data because we were wary that further inclusion of that material could make the paper overly long. However, based on this comments and a comment from reviewer 2, we have now included further examples from that data that now extends across the 3 themes (see pages 13, 14, 16, 19/20). We hope this adds to the themes presented and helps to build a more complete picture of our interpretation of the data.

Reviewer 2

1. In the title and throughout the article the authors refer to participation in a trial. This trial involved telehealth and telecare treatment interventions. In a sense, potential participants were asked simultaneously to enroll in a research study and in a TH/TC program. Yet, participants may have different reasons for non-participation in research studies and non-participation in TH/TC programs. The authors never make the distinction and the article would benefit tremendously if they would, given that the audience is familiar with non-participation in research and one of the keywords is “trial participation”. Refusal to enroll in, or deciding to withdraw from, a research study has been extensively studied due to its methodological implications. At the very least, the authors should acknowledge this literature in the Background section and note that they are studying non-participation and withdrawal rates which cannot be attributed to baseline refusal to participate in research. In fact, when they note the 36.7% non-participation rate on page 6, they might compare it to similar non-participation rates in chronic care interventions which do not involve TH/TC in order to suggest the magnitude of the problem when TH/TC is a component of the intervention. The concluding sentence in the Background section states, “Whilst this study is focusing on non-participation and withdrawal from the WSD trial, it was clear that participants were mostly reflecting on the potential impact of telehealth and telecare if they were to take part in the trial.” This is a key point and belongs in the Results section with an explanation how the researchers determined “it was clear.”

Response:

We agree that this is an important distinction and that was the reasoning behind our final statement in the ‘background’ section which we have now elaborated to make the distinction more explicit and to state that the issue would be illustrated via the results section and returned to in the discussion.

Whilst we had referenced the work of Donovan and colleagues regarding the wider literature on non-participation in trials, we agree that there is a much more extensive literature that could be referred to. We have now more explicitly acknowledged the literature on non-participation in drawing out the overlaps and distinctions with the current study (page 6).
2. The title includes “randomized controlled trial” but the randomized and controlled aspects of the trial have little relevance to the qualitative study described. Further, they would cause search engines to identify the article when searchers are actually looking for (quantitative) RCTs on telehealth. I suggest eliminating the phrase in the title.

Response:

Done. We have now deleted ‘randomized controlled’ from the title. Instead we have included reference to the ‘Whole System Demonstrator’ because it is also possible that people would want to search for papers reporting specifically on the WSD project.

3. The authors mention “barriers” to healthcare twice in the article, on pages 5 and 18. Given that “barriers to care” is a common phrase in the literature and that this study focuses on one of the major barriers to widespread adoption of TH/TC as a mode of healthcare delivery, I would urge the authors to use it both in the title and as an organizing framework. In fact, it could serve as a formal research question: “What are potential participants’ perceived barriers to participation in TH/TC interventions for chronic care?”

Response:

We have followed the reviewers advice and have now included ‘barriers’ within the title and the keywords.

4. In the Abstract, the authors refer to “non-uptake” but that phrase is never used in the body of the article, and the term “uptake” is used only once, in the Conclusion. They should eliminate it and refer instead to “non-participation and withdrawal” or simply “non-participation”

Response:

Done. We have deleted any use of the term ‘uptake’. We have changed to ‘non-participation’ in the abstract, and where we have referred to uptake in the discussion, we have replaced that with the term ‘adoption’ as this is a common term used in the literature on telehealth and telecare (e.g. see work of May et al).

5. On page 6, the authors should elaborate on how, “eligible patients within practices were then approached to take part.” Did their physician or nurse attempt to enroll them? In person? Given the potential relevance of the initial presentation to the patients, the authors should clarify communication-relevant information: messenger, message content, medium, timing, and location.

Response:

We agree that the paper warranted further detail regarding recruitment. We have now added this detail and cross-referenced further papers where additional detail is described (see pages 7-9 ‘participants and methods’).

6. On page 7 the authors do a good job of defending a relatively small sample size. In order to anticipate the inevitable objections of quantitative researchers, the authors should note in the sampling paragraph or in the Discussion’s
limitations paragraph that qualitative research does not aim for generalizability, but aims rather for transferability. A source citation for transferability and for the small sample size would help to support the sampling method used.

Response:

Done. See reference to Sandolowski in ‘strengths and limitations’ section (p.23).

7. On page 8, reference is made to coding for “emerging themes” but coding requires some sort of guiding question, as one could code for a wide range of perceptions, from language used to describe symptoms to the failures of the healthcare system. If the coded themes related to a question about barriers to participation (or something similar) the authors should say so.

Response:

We acknowledge that further detail regarding coding could be valuable. However, we did not code in relation to a specific question about barriers to participation. Rather, we had a set of topics that we thought might have some bearing on whether or not people would want to receive and use the interventions. Examples of these are offered on page 9. Beyond this, we were very much open to what might emerge from the data and whilst we have not professed to use a grounded theory approach, we were to some extent influenced by some of the techniques of grounded theory. So, whilst we had some provisional thoughts on things that might influence decisions to decline participation or withdraw, we were open to being surprised by the data. We have further elaborated on our approach on pages 9-10.

8. On page 8, the authors should provide a more detailed description of the analytic technique used for coding. If Atlas.ti software was used, are the authors able to provide a measure of inter-coder reliability? If not, more detail should be provided regarding what constitutes a “theme” and how the discussions resulted in combining or splitting emergent themes.

Response:

Please see comments and changes referred to in response to comment 7 above regarding the greater detail required regarding coding techniques. Additionally, whilst we did use Atlas.ti to aid in the organisation of the data, we did not use it as a means of checking inter-coder reliability. Of course, there have been running debates regarding the importance of inter-coder reliability and the ‘measurement’ of independent coding. Whilst we coded independently, and discussed the distinctions and overlaps in the approach to coding as a means of ‘refining’ the coding framework, we did not ‘measure’ this. However, we have added further information on the coding process (see pages 10-11).

9. On page 8, the description of the “observational work” deserves a separate, more detailed paragraph because observation is a different method and because the participants observed were apparently different from those interviewed. Interviewing and observation work well together in this study, but they are separate methods and led to separate, though related, results.
Response:

Please see our response to point 4 made by the first reviewer stating our inclusion of further references to and examples from the observational work.

10. In the Results section, are the three themes presented the only themes that emerged? On page 14, the article mentions, “a final strong theme” but doing so implies weaker themes also emerged and the reader is left wondering who determined strength and weakness of themes. A numerical calculation of the frequency of themes would convey to the reader that accuracy is important to qualitative research. At present, each of the three broad themes seems to have a number of variant subthemes. For instance, the technical competence theme mentioned the complexity of the modern world, the generation gap, limited English proficiency, lack of technical support, and mechanical problems. Explicitly state why those were all categorized as “requirements for technical competence and operation of equipment”? Providing detailed information about the boundaries drawn between themes indicates rigor was important to the researchers. Further, simplifying theme categories would clarify results. I’d suggest: Perceptions of Technology, Perceptions of Self, and Perceptions of Healthcare.

Response:

Please see our response to points 7 & 8 above where we have outlined changes to elaborate the coding process to offer greater detail on the approach taken and the main themes. We have left the titles for the themes unchanged as we fear this would over-simplify the meaning of what each theme captures and expresses via the processes we adopted in developing the themes.

11. In qualitative studies, the interesting narrative elements often are lost in the body of the text, and the problem is worse in medical journals because the audience is accustomed to reading data in tabular form. Consider presenting one or more tables consisting of several brief excerpts illustrating each theme.

Response:

We agree that the interesting narrative elements can indeed be lost in short journal articles. We did attempt to illustrate themes using tables in an earlier version of this paper and the consensus of the research team and independent comments indicated that this detracted from the narrative thread of the paper. Consequently, we decided to retain the current format.

12. On page 13, one participant mentions the burden placed on his wife, and later three caregivers mention the burden for patients who are too ill. In the Discussion section, the authors address the importance of caregivers in determining enrollment, but their influence perhaps merits more explicit exploration in the Results. On that subject, the caregivers’ perceptions on page 13 and 14 seem to fit better in the “disruptions” theme subsection, as they seem to indicate TH/TC could only interfere with a caregiving system that is working. I’d place it on page 15, in the paragraph beginning, “Other respondents who had quite severe problems were often already receiving specialized services.”
Response:

We appreciate this comment and realise it is possible to see overlaps across themes. However, the final section on disruption to health and social care services was more about the expectations from ‘formal’ rather than ‘informal’ and unpaid caring which is a usual part of ‘self-management’ outside of the formal health and social care sectors. We feel it sits well in its current location in the paper as it also serves to illustrate the complexities of that theme, and as we have noted, it illustrates well the ways in which such interventions can fall ‘between two stools’ where people perceive that they may be ‘too well’ or conversely, ‘too sick’.

13. Overall, the Discussion section is quite good, particularly its integration of the findings with previous research. I’d suggest mentioning explicit practice implications for each of the themes addressed. For instance, the perception of complicated technology suggests TH/TC should be targeted only to those who can use it effectively, should be simplified, or should be introduced in more understandable terms. The authors should not save all the practice implications for the Conclusion.

14. The article would benefit from a Discussion paragraph suggesting areas for future research. The study participants had very intelligent observations which researchers should attempt to prove or disprove. Three avenues of research suggest themselves. First, does TH/TC encourage dependency among (some) participants? Second, are technical issues problematic for (some) TH/TC participants? Third, does TH/TC negatively affect existing healthcare delivery systems?

Response:

We are responding to the final 2 points together as they both relate to the discussion section. We do not believe that technology should be targeted only to those who perceive they can use it effectively. Rather, we think the implication is that addressing concerns about perceived competency to use equipment can diffuse anticipation of problems that might be based on misunderstanding (p22). We also think it implies that interventions should be tailored to ensure they will fit in with individual life circumstances and approaches to self-management. We have now added this point (p21).

We have also added an additional paragraph to the discussion section outlining additional implications for future research (p23).
Additional Changes

We have made a small change to text where we previously referred to a comment made by Martin Scarfe who was Director within the Newham site (top of page 6). We have deleted this reference because the weblink to verify the quote is no longer live. Instead, we have changed the wording slightly and referred to a different source which is easily available with a live weblink.