Author's response to reviews

Title: Tea, talk and technology: patient and public involvement to improve connected health 'wearables' research in dementia.

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Author’s response to reviews:

Thank you to all reviewers for taking the time to provide constructive comments on our paper.

Reviewer #1

1. It is not clear where the focus of the paper lays i.e. is it a about patient and public involvement or choosing the best device for your research study?

Response: It is about both of these things - our paper is about using patient and public involvement in order to shape a new platform for research (which included choosing devices for future studies). In order to reflect on how well we did the former, we needed to convey the content of discussions about the latter.

We believe our methods and findings will be of most interest to the involvement and engagement community, although those specifically interested in wearable devices or dementia research may also find our paper of interest. We have approached RI&E because the focus is on involvement rather than research and several papers have adopted similar structure and styles to our own.

The changes made throughout this paper, particularly the reworked discussion, should hopefully make the focus and contribution of this paper clearer.
2. The results are thin, the tables could be more descriptive, and the PPI feedback of the devices needs more depth.

Response: The results section is currently over 2,000 words, excluding Table 3 which we regard as one of the main contributions of this paper. We also note that Reviewer 4 was satisfied with the content of the tables: “The tables in the paper are well presented and add value to the text. In particular, table 3 provides a helpful summary of feedback and recommendations.”

We feel extension of this section would make the paper overly long, without adding insights that are not already reflected in the current text and tables.

3. You mention that involving people living with dementia is challenging but you do not go on to say why - this would help other researchers conducting similar investigations.

Response: The following text has been added to the introduction:

“Involving people with dementia or cognitive impairments in influencing future research is not without challenges; for example, in addition to memory problems, people with dementia may experience difficulties with visual perception and understanding complex information. Therefore to support people to be involved, adequate attention needs to be paid to choosing easily accessible venues for activities, providing straightforward written and verbal information and considering the pace and structure of activities.”

4. Why did you not give the same devices to each group? This would allow for a better comparison.

Response: This was not a research study and therefore we felt that applying pressure to allocate devices in a systematic sense (e.g. at random), rather than allowing people to self-select, was not appropriate.

Please also see our response to points 10 and 16.

5. The title is eye catching but then you include people as young as 50 in the workshops, so it doesn't really support the title, this needs some explanation

Response: Thank you for drawing our attention to this. We therefore propose a new title

Tea, talk and technology: patient and public involvement to shape connected health ‘wearables’ research in dementia.

Reviewer #2:

6. Although lengthy and occasionally repetitive (I felt that I didn't learn anything new in the discussion that wasn't already in the results)
Response: Both Reviewer 2 and 3 commented on the discussion, therefore we have substantially reworked the discussion to shorten it, reduce repetition and focus more on the impacts of involvement.

7. In presenting the background evidence of patient and public involvement (and participation) in dementia research, as well as the sentence on p21 about calls for people affected by dementia to have more opportunities to participate in and influence research I was surprised that the authors did not reference the Join Dementia Research initiative (increasing participation) nor the Alzheimer’s Society’s Research Network (formerly QRD) which for over 17 years has involved people affected by dementia across the whole of the research process, particularly in setting research priorities, funding decisions and supporting the delivery of research.

Response: Thank you for these useful reference suggestions, which have now been included.

8. The justification of people to involve in the workshops seems sound, although given that many people with dementia are likely to have co-morbidities or health conditions which could affect their participation in research of this kind, it might have been wise to have made more effort to recruit people with dementia with more complex needs. This could perhaps have been achieved through extending the recruitment to other groups. This could be reflected in the discussion section where multiple long-term health conditions are mentioned as a recommendation for future involvement. I also wonder what steps the researchers took in addressing the lack of recruitment of people with MCI- e.g. did they approach memory assessment services?

Response: Due to strict time limitations (purchasing for the device pool had to be completed within the financial year), we approached colleagues conducting a research study related to MCI but did not have time to approach memory assessment services. This is a fair comment and a useful suggestion for others. We have extended this paragraph in the discussion:

“Furthermore, we also sought help from colleagues working on a study related to MCI to help advertise our involvement opportunities. Nonetheless, these strategies did not overcome this problem. In future, researchers could consider working alongside healthcare professionals and associated services (e.g. memory assessment services) in order to identify people with MCI and others who could be involved in shaping research, such as those with multiple long-term health conditions.”

9. On page 17 there is a very helpful description of the support that people with dementia and their carers will need in relation to the set up of devices and having access to smartphones/tablets. It would be useful to acknowledge the impact on the costs of future studies to provide this.

Response: We have added the following sentence to the discussion section:

“Whilst it is true that this may increase the financial costs of such research, relying purely on information and support provided by device manufacturers may be a risky alternative.”
Reviewer #3

10. The background is written clearly, but I am not sure that it completely fits with the aims of the paper. The aim of the authors is to involve members of the public in discussions to inform the development of the device pool, platform, and written guidance on support within Dementia Platforms UK, but the numbers of people involved, particularly those with dementia or MCI make confident conclusions more difficult to reach. Had the aim been to conduct a feasibility study to understand effective engagement the rationale would be clearer.

Response: The reviewer has correctly identified the aims of this paper. We would like to emphasise that this paper reports on public involvement, which is distinct from recruiting people as participants in a research study. We did aim to talk to people from a range of backgrounds and with different personal experiences; however, there was no attempt to secure ‘representativeness’ or avoid ‘sampling bias’ as one might with a research study.

We do recognise that there is a debate about ‘representativeness’ in public involvement (see for example http://www.healthtalk.org/peoples-experiences/medical-research/patient-public-involvement-researchers/representativeness-and-diversity-people-who-get-involved). In our view, public involvement is about using personal experience to make sense of, influence and shape research. Whilst we agree it is of importance to involve a diverse range of people with relevant experience, the actual numbers of people involved is far less important.

Nonetheless, we do acknowledge that we found it difficult to engage people with mild cognitive impairments. We have extended this section in the discussion.

11. I'm unclear whether the focus here is PPI or technology and if both, whether the balance is right. The study itself seems to focus on a discussion of the methods for involving people affected by dementia in testing the feasibility of technology, but does not show the impact of that involvement on the outcomes.

Response: In the short term, we regard the ‘outcomes’ of public involvement in this study as the recommendations for the development of the platform and the conduct of future research, including decisions about the procurement of relevant devices. These decisions are systematically described in the text of the results section. Table 3 also summarises the main feedback points from those whom we involved and the recommendations which were made as a result. We have endeavoured to make the nature of this impact clearer by:

(a) adding a key, which shows which of these recommendations were implemented;

(b) adding further text to the discussion regarding how recommendations influenced purchasing decisions:

“In line with the recommendations produced as a result of our involvement activities, the devices we ultimately purchased were low-maintenance, robust and discreet. These deceptively simple requirements meant that we favoured waterproof devices with longer battery life over other,
ostensibly more popular, devices that were currently available on the market. We also purchased a greater range of accessories than we originally anticipated, in a bid to increase wearability.”

(c) and; revising the final line of the methods section as follows:

“The lead author (LH) was then invited to subsequent meetings regarding purchasing decisions to provide input into decision-making in line with the recommendations and to record which recommendations were subsequently implemented.”

There may be wider impacts of these recommendations on studies that use the platform in future and/or follow these recommendations (e.g. enhanced recruitment and retention of study participants). However, we are unable to comment on such impacts until those studies are actually underway and generating data, which could be some time.

Please also see our response to point 1.

12. I would welcome more information regarding safeguarding and how participants were prepared for the activities. I.e. the information they were given beforehand. It would be interesting to see the recruitment posters, or see more discussion around the recruitment strategy.

Response: Whilst we did not formally ‘recruit participants’, as would be the case in a research study, we did advertise events and therefore propose that these posters are included as supplementary online materials (at the discretion of the Editor).

13. The discussion is very detailed, in terms of the themes that they have identified. However, am not sure how novel the findings are - there are references missing regarding the benefits of involvement, attitudes to technology and challenges of home testing. A clearer case for what is added to the discussion could be made.

Response: We have made changes to the discussion to shorten it, reduce repetition and focused more on the impacts of involvement. Additional references to key sources have been added (also see point 8).

14. This might be helped by providing a clearer sense of how many people with dementia, carers and people without dementia were involved.

This information is provided in Table 2. To engage people who were living with dementia and were aged under 65 years, we visited a drop in support group meeting. This featured several activities going on simultaneously in a large, open space accommodating people living with dementia, care workers and carers. In this causal environment, it was difficult to keep track of exactly who was participating or merely watching and who they were. Therefore, for this activity we had to approximate numbers of those involved. The following footnote has been added to Table 2 to make this clearer:

“This was a drop in activity, which took place within an open space. Therefore, we can only provide approximations for the numbers and types of people who participated.”
15. Any limitations to the approach taken should be addressed, particular the impact that the low numbers of people they recruited have on their findings. How far might different numbers of people in each group affect how much comments can be compared.

Response: Please see our response to point 10 re: sampling and numbers.

16. The decision to allow participants to self-select for home testing makes sense, but there does need to be some acknowledgment of the potential bias this creates. How representative is this sample of people affected by dementia? Considering the differences between those who were digitally excluded and those included would be of interest and impact results.

Response: Please see our response to point 10 re: sampling and numbers.

17. In my view, a more detailed explanation should be given of the decision not to seek ethics approval, including any guidance the authors received. The INVOLVE/NRES guidance does say that involvement activities do not require approval as they just ask people to give examples from their experience. It is not clear that this is what happened in practice… More detail on guidance that states ethical approval was not needed for this work and detail of the interpretation of guidelines would be valuable for future studies.

Response: We took guidance from the INVOLVE/NRES document titled ‘Public involvement in research and research ethics committee review’ (dated March 2016). Although arguably of interest, it is not the focus of this paper to provide an extended discussion of the differences between involvement and research.

In summary, we have made these changes to the paper:
- We have added the INVOLVE document as a reference.
- We have added a statement that we sought advice from our University’s research ethics committee before embarking on our activities and they agreed research ethics approval was not necessary.
- We have added a new section in the methods explaining the procedures for home testing, which make clear that the purpose was distinct from research.
- We have extended the section discussing the ethics and logistics of involvement in the discussion.

In addition, for clarity, we will outline what the INVOLVE document says and explain our own rationale; however, given the readership of this journal, we do not think that this level of detail should be included in the paper.

The INVOLVE document states:
“You do not need to apply for ethical approval to involve the public in the planning or the design stage of research, for example helping to develop a protocol, questionnaire or information sheet, being a member of a research advisory group, or preparing an application for funding or ethical review, even when those people are approached for this role via the NHS.” It goes on to state: “When you submit an application for ethical review for your research, you should fully describe how the public have contributed to the planning and design of the proposed research and will continue to do so in its conduct and management. In reviewing an application, the REC will need to address any ethical issues which may arise from how the public will be involved in conducting and managing the research.”

The purpose of this project was to involve people in designing a platform that would host future research. The people were advising on how this research would be designed and conducted (including which devices we might use), not participating in it themselves. The research to be completed is in the future and will be hosted by the platform. Our intention is that researchers that use the platform in future will be able to cite our activities as evidence of public involvement in when they apply for ethical approval for their own research projects. Therefore we believe these activities constitute involvement, not research, and have value in their own right.

Had this been a research or feasibility study, we would have followed several procedures that were deemed unnecessary for this PPI project. For instance, we may have, but did not:

- Sample particular individuals based on predefined eligibility and exclusion criteria (inc. clinical diagnoses and the exclusion of particular co-morbidities);
- Recorded demographic and clinical information (DOB, diagnoses, history from medical records);
- Conduct formal, audio-recorded focus groups and/or interviews to be analysed using qualitative analysis techniques.
- Randomly assign devices to individuals.
- Exclude individuals who did not want to borrow a device.
- Collect, store and analyse the data generated by devices tested.

18. People were invited to test devices at home, and the language used in reporting this, makes this sound more like a feasibility study.

Response: Users were invited to borrow a device to give them the opportunity to develop familiarity and experience with devices. This enabled them to better comment on research scenarios that included use of such devices and make recommendations about future research design and the features of devices to be used as part of these, based on their personal insight.
Had this been our purpose, testing device preferences as part of a feasibility study or other research project would have been set up very differently (see previous point re: feasibility study design).

We have now added a new section in the methods explaining the procedures for home testing, which make clear that the purpose was distinct from research.

19. A section explaining the steps they took to make sure that ethical issues e.g. around data security were managed and explained to people taking part should be included. This is discussed as a discussion point within the workshops, but is not addressed for the study itself.

We have added a new section in the methods explaining the procedures for home testing, including ethical aspects. The discussion has also been extended to include consideration of ethical, as well as logistical, issues associated with involvement.

20. Some of the tables and figures are missing from the main text - it would be helpful to see them within the discussion, rather than in an appendix.

Response: Due to the submission guidelines of this particular journal, we had to submit figures and tables over a page separately, rather than being embedding these in the main text.

21. It was a little surprising that issues of dexterity were not apparent in the feedback, but perhaps this is covered under the device wearability theme.

Response: This came out more strongly in relation to accessing feedback on the device the wearable was paired with (i.e. the smartphone or tablet) and so we have amended the following sentence:

“This appeared to be partly down to the complexities of various interfaces, limitations in manual dexterity as well as screen size.”