Author’s response to reviews

Title: Research protocol for a complex intervention to support hearing and visual function to improve the lives of people with dementia

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Author’s response to reviews:
Reviewer reports:

Reviewer #1: This study protocol for a visual and auditory intervention is very ambitious, the area of research is very interesting and could have a great impact on the well-being and functioning of those requiring assistance with implementing and maintaining visual and auditory
functioning. The inclusion of a variety of stakeholders is very beneficial to the development of the intervention.

I have some comments about the manuscript below.

1. Titles and numbering of tables are incorrect; there are two table 1s, thus table 3 is incorrectly labelled as table 2 and table 4 incorrectly labelled as table 3

2. Page 13 line 2, should say Table 3, not Table 2.

3. Please do not use 'affected participant' use an alternative like 'person with dementia' 'participant with impairment' or simply 'participant' as you refer to 'affected participant' and 'significant other' together.

Thank you very much for your careful review and for your kind comments. All of the points above have been addressed in the revised manuscript. All instances of ‘affected participant’ have been amended to read ‘person with dementia’.

4. You state that quality of life instruments are to be used. You include a measure of loneliness, as outlined in Table 3. If this is intended to measure quality of life it is not appropriate. Loneliness is one component that could affect overall quality of life in dementia, it will not give you an indication of overall quality of life. I would suggest a dementia specific quality of life instrument along with a sensory impairment quality of life instrument, if one exists.

Thank you for this point, the manuscript has been updated to include the DEMQOL, a dementia specific quality of life instrument that was previously omitted by error. This has been amended in Table 3.

5. Please indicate the severity of participants with dementia. You state you intend to include people with mild to moderate dementia in step 4. Is this the same for the other steps? Could you also give a reason why you are only including mild to moderate and not severe?
Thank you. We have indicated the severity of dementia as mild to moderate and the reasons for this have been included in the participant section on page 9-10.

6. There is no mention in text of the process for capacity assessment or the use of personal consultees. The declaration on page 25 states all participants must have capacity, I suggest mentioning this in the participants or recruitment sections on pages 9 and 10 and stating whether and how capacity is assessed.

Thank you for your advice. In addition to outlining the severity of dementia, we have also included details of how capacity will be checked in the recruitment section.

Reviewer #2: Research protocol for a complex intervention to support hearing and visual function to improve the lives of people with dementia

Summary:
This protocol outlines a four stage process in the development of a new complex intervention designed to support hearing and vision function in people living with dementia and their caregivers. The four stage process includes 1. Defining the gap in care and scoping existing evidence on the impact of sensory deficits in dementia, 2. Developing a prototype intervention, 3. Refining the prototype intervention, and 4. Field testing the intervention prior to a definitive trial. The protocol includes persons living with dementia and sensory impairments, their caregivers, expert physicians, and patient and public voice representatives, all with defined roles at each of the four steps. Feasibility objectives of the field testing stage include recruitment rate, retention, tolerability and utility of the assessment procedures, and rating participant reaction to the intervention components, frequency and duration of the therapy sessions.

General Comments:
This is a very comprehensive outline of key stages that have contributed to the development of the intervention. It is unclear which stages have already been conducted, which are ongoing and which are yet to commence. Please indicate a timeline in Figure 1 and change tense accordingly in stages where the work is already complete.
Thank you for taking the time to provide us with detailed feedback on our manuscript. In relation to the above point, we have added the length of time spent on each of the development stages to Figure 1. Whilst we appreciate the reviewer’s suggestion of changing tense for work that has now been completed, however we have decided against this as each of the steps of the development programme will have individual standalone outputs detailing the results. At the time of writing, none of the stages had commenced and the manuscript was very much conceived as a protocol paper for the development of a complex intervention. We feel that the manuscript will be made more complex and harder to comprehend should we change tense in relation to where we are in the development process.

The terms "sub-studies", "stages" and "steps" all appear to be used interchangeably. Please be consistent and use either "stages" or "steps" rather than "sub-studies".

Thank you for this point. The manuscript details a four step process, including 5 sub-studies (outlined in table 1). The references to the steps- which were previously interchangeably described as stages and steps have all been changed to steps in the revised manuscript. The title and in text reference to table 1 now refer to sub-studies, hopefully clearly differentiating between the steps and sub-studies involved.

Consider using the term "health impairments" or "sensory impairments" rather than "ill health".

Thank you. All instances of term ‘ill health’ have been updated to impairment in the revised manuscript.

Although stages 1-3 of the research are important and contribute substantially to the development and implementation of stage 4; the focus of the research should be on the feasibility stage. The level of detail in stages 1-3 (pages 10-18) can likely be reduced to provide a broad overview of the research with the main focus of the article on stage 4. Additionally, Table 1 provides succinct information of what is involved at each of the stages. No further revisions have been provided for pages 10-18 as the recommendation is to reduce the text in this section.
Thank you for this comment. The protocol for the field trial is complex and multi-faceted and is described in detail in a separate publication which is in preparation. The purpose of the current manuscript is to detail the process involved in the development of the field trial.

Please review the grammar within the text. There are instances where a singular is used for a plural and vice versa, i.e. page 5, line 6, "Furthermore, caregiver burnout and physical exhaustion are amplified due to greater dependency for self-care and other activities of daily living and communication barriers."

We appreciate your attention to detail whilst undertaking this review. We have amended the sentence above and carefully reviewed the article for further grammatical errors. We looked for further examples of singular/plural errors but did not find any. We wonder whether this might be due to the UK/US confusion on this issue – in the UK, collective nouns are (incorrectly) referred to in the plural (i.e. the team are; the staff are; the UK are). The grammatically correct version is (as we have used): the team is; the staff is; the majority is; the UK is etc. I hope this addresses the problem.

Specific Comments:

Abstract:

Please include "Implications" as a part of the "Discussion" section, not on its own.

Please remove the acronym PPV as it is not referred to more than once in the abstract.

Consider rewording the first sentence of the abstraction to read, "Hearing and vision impairments are among the most common and disabling comorbidities in people living with dementia."

Consider rewording the final sentence in the "Background" section to read, "At the end of the development programme, it is anticipated a 'sensory support' package will be ready for testing in a full scale randomised controlled trial."
Primary Objectives:
There are a number of primary objectives listed on page 6, which relate to a stage/step within the research programme. Consider indicating the primary objectives for each stage/step rather than listing them altogether.

Thank you for the attention to detail in your review. All of the above specific comments have been taken on board and amended in the revised version of the manuscript.

Step 4: Field Testing the Draft Intervention

In the methods section it is mentioned that all participants and their caregivers will receive either a full draft intervention package or certain components of the package decided a priori. How will this be determined and what are the certain components that will be provided? What is the rationale for providing some participants with the full package and others with certain components?

Thank you for your question. We have briefly detailed the rationale for giving some individuals the full intervention and others a briefer version.

In the study procedures section, the consent process is unclear. It appears potential participants are pre-screened and consented prior to screening for suitability. What is the screening for suitability? What does it entail? Please clarify. Additionally, are there any special considerations for consenting participants with dementia and sensory impairments?

Details of screening procedures for hearing, vision and cognition have been briefly outlined in the revised manuscript. Information about the consent process and special considerations has also been added.

Refrain from using the word "couple" on page 20, line 43. The previously used term dyad is more appropriate.
Thank you for this comment, the manuscript has been amended to ‘dyad’.

According to the timeline on page 24, field testing should be complete by June 2017. It is mentioned that the final protocol outlining the study procedures and draft intervention to be field tested will be prepared at the end of step 3. Has this been prepared? If so, what does it include? Additionally, what are the specifics of the outcomes you are exploring? i.e. what quality of life measures are included? What are the caregiver indices? What health economic measures are being used?

Please provide details about how demographic and baseline data will be described. Will they be described in means and standard deviations? Frequencies and percentages? Both? It is mentioned that the quantitative evaluation will be a description of the rates of recruitment and retention over the period of the study, tolerability and utility or the assessment procedures and description of the participant reaction to the intervention components and frequency and duration or therapy sessions by a rating scale. What are the measures for these outcomes? How will they be described? How is the rating scale devised? Is it on a scale of 1-10? Further detail is needed to understand how you will be analyzing your study results. Additionally, ensure that the analysis section covers all of the outlined objectives in stage 4.

What would be considered feasible before moving to a larger RCT? i.e. were thresholds considered for acceptability and tolerability of the intervention? Please provide criteria for success of the pilot study.

The points raised by the reviewer are all extremely valid and important issues, all of which we have addressed in a separate protocol for the SENSE-Cog Field Trial, which has just been submitted and is currently under review. The complexity of the study precludes a detailed discussion of the Field Trial protocol in the current paper and is beyond the remit. The current paper focuses on the development of the intervention to the point of being a ‘draft intervention’ ready for field trialling. We have indicated in the revised text that this is the case. We hope that the reviewer will agree that this allows us to include valuable details concerning the different stages of the study.
Stage 4 reads almost as though it is two studies rather than one single mixed-methods study. Integration of the two parts of stage 4 would make the section more cohesive and fluid for the reader rather than reading stage 4 as two separate parts.

Thank you for this suggestion. We have taken the Reviewer’s advice and made this one single mixed-methods study, as reflected in the revised manuscript.

Reviewer #3: This study protocol for intervention development and testing is ambitious and an interesting area of intervention.

I have some comments for the authors on suggested improvements to the manuscript as follows:

1. An aim of the research programme as specified in the background (p6, lines 21-25), and also in the abstract, is to develop and test the intervention so that it is 'ready to be tested' in a full scale definitive RCT. I am concerned about the assumption of the authors that the intervention 'will be ready' to be tested in a full trial after this period of work. What if the field testing phase identifies that the intervention is not feasible for implementation and thus full scale trialling? Have the authors fully considered feasibility testing of the methods to be used in a full scale trial to ensure that the trial itself would be viable? There are aims to identify the most appropriate outcome measures and recruitment and retention rates, but the feasibility and acceptability of randomisation, for example, will not be considered in this study as the field testing does not comprise randomisation (and there is no justification for why this is the case).

The MRC guidance for complex public health intervention development includes two-way links between the development and feasibility phases, and feasibility and effectiveness testing phases, emphasising that sometimes work may need to take a backwards step through this process if data suggests that proceeding to the next phase is not warranted. I would recommend that the wording of this aim of the research is amended throughout the manuscript in a way that adopts a less certain tone, and allows for the possibility that a full scale trial may not be possible without further development/testing. In addition, the authors may wish to outline in what circumstances they would not proceed to a full scale trial, for example, what outcomes at Step 4 would be considered as requiring further development of the intervention prior to trialling?
Thank you for your kind and constructive comments. In relation to acceptability of randomisation, we have based our model upon several trials dealing with similar target populations in which randomisation has proved to be well tolerated.

As well as describing instances in which the trial would not go forward based upon the outcomes of the field testing, we have removed from the manuscript instances in which the assumption of continuing to a full scale RCT is made.

2. Table labelling inconsistencies need correcting. On Page 8 (line 52) the authors refer the reader to 'Table 1' in the text (a description of dimensions of complexity), but the instructions to the editorial team are to insert Table 2 here, and the corresponding table file at the end of the manuscript is labelled as Table 1 in the title, even though the preceding table is also labelled as Table 1 (although the file does not contain a title). There are instructions to insert Table 1 on page 7, but the table is not referred to in the text - the reader needs some guidance on when to refer to this table. This error then carries over into the labelling for Table 3 (which in the file at the end of the manuscript has 'Table 2' in the title and is referred to as Table 2 in the text on page 13, line 2), and Table 4 (which in the file at the end of the manuscript has 'Table 3' in the title and is referred to in the text as 'Table 3' on page 22, line 23).

Thank you for your attention to detail. The tables have been renumbered accordingly, referenced within the text and given appropriate titles throughout the revised manuscript.

3. Page 9, line 51, should the 'g' of 'group' in the 'research user group' be capitalised?

4. Page 11, lines 2-12, it would be useful if the authors could specify the databases that are intended to be used for the systematic literature review.

5. Page 11, line 60, after introducing the acronym for the Expert Reference Group (ERG), the full title is used again in this line.
6. Page 13, lines 48-50, the description of the qualitative analysis of the focus groups is very brief, more information would be useful, for example - why and how will the content analysis be used to interpret the data?

7. Page 14, line 50, remove the word 'for'

8. Throughout the manuscript the authors use British English spellings (e.g. randomised, individualised) for the most part, but there are some exceptions that need correcting for consistency, for example page 15, line 17 (standardized).

9. Spelling mistake on page 16, line 52: Focus Group 'A needs correcting to 'A'

10. Page 18, line 45, the data will be 'subjected' not 'submitted' to content analysis? Again, there is very little detail here regarding how the analysis will be conducted.

11. Page 18, line 53, the word 'to' is missing (will be 'to' field test the draft intervention)

12. Figure 1, the acronym 'PwD' is not described

Thank you for your thorough and constructive comments all the above points have been addressed in the revised manuscript.