Reviewer’s report

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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Reviewer: Theresa Aves

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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.
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".

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

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.

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."

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.

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?

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?

Refrain from using the word "couple" on page 20, line 43. The previously used term dyad is more appropriate.

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 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 the 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.

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.

**Level of interest**

Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

**Quality of written English**

Please indicate the quality of language in the manuscript:

Not suitable for publication unless extensively edited

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