Author’s response to reviews

Title: What is important to people living with dementia?: the ‘long-list’ of outcome items in the development of a core outcome set for use in the evaluation of non-pharmacological community-based health and social care interventions

Authors:

Andrew Harding (a.harding5@lancaster.ac.uk)
Hazel Morbey (h.morbey@lancaster.ac.uk)
Faraz Ahmed (a.ahmed5@lancaster.ac.uk)
Carol Opdebeeck (C.Opdebeeck@mmu.ac.uk)
Reena Lasrado (reena.lasrado@manchester.ac.uk)
Paula Williamson (P.R.Williamson@liverpool.ac.uk)
Caroline Swarbrick (Caroline.Swarbrick@manchester.ac.uk)
Iracema Leroi (Iracema.Leroi@manchester.ac.uk)
David Challis (david.j.challis@manchester.ac.uk)
Ingrid Hellström (ingrid.hellstrom@liu.se)
Alistair Burns (alistair.burns@manchester.ac.uk)
John Keady (John.Keady@manchester.ac.uk)
Siobhan Reilly (s.reilly@lancaster.ac.uk)

Version: 2 Date: 13 Feb 2019

Author’s response to reviews:

Thank you for your helpful comments on our manuscript.

The table below provides a point-by-point response to show how each recommendation has been actioned in the amended and re-submitted manuscript: “What is important to people living with dementia?: the ‘long-list’ of outcome items in the development of a core outcome set for use in the evaluation of non-pharmacological community-based health and social care interventions” (BGTC-D-18-00600R1).
Amendments to the original manuscript are highlighted in yellow in the re-submitted manuscript and copied in to this table for each comment.

Recommendations - Reviewer 2

Response

1. More information on how individuals were recruited to participate in the study is need. I realize the authors cite a protocol paper that presumably contains some of this info, but the current manuscript should provide a bit more info so that it can stand alone.

   As the reviewer correctly states, a protocol paper (in another BMC journal – Trials - that is open access) is cited where the recruitment process for each of the five groups (people living with dementia, care partners, health & social care professionals, policymakers and researchers) is outlined in significant detail. While this information is of course relevant in this manuscript, our concern here is that it would add significant text – and it is already available in a BMC open access journal. We are happy to add an edited version of this text or provide a hyperlink in the text as a quick link, if the editor thinks prudent.

2. Is this list of outcomes specific to the UK setting or can it be applied cross nationally?

   Although the qualitative data collection was limited to the UK, the studies that we included in the extraction of outcomes were international. This is now clarified in the methods and discussion sections.

   We have clarified in the methods section relating to the UK location of participants in the qualitative data and international scope of interventions in the literature:

   “Participants were based across the UK, although mostly in the North West of England” (page 6)

   “Any UK based or international non-pharmacological intervention focusing on people living with dementia at home, which aimed to support people living with dementia in their neighbourhoods and communities.” (Page 8)

   We have also updated the discussion section based on this point:

   “Given the participants in the qualitative data were based in the UK the ‘long-list’ has particular relevance for the UK context as well as being of international interest. That said, although the trials reviewed were international, more work is needed to ensure that the outcome items are as equally applicable for an international context.”
3. The literature search was limited to the ALOIS database. I am not familiar with this database and it is unclear how studies enter the database. A more comprehensive search should be conducted of existing databases (e.g., embase and medline).

As stated in the manuscript, the ALOIS database is managed by the The Cochrane Dementia and Cognitive Improvement Group located at The Medical Sciences Division at Oxford University. ALOIS is an established database that is used in numerous dementia reviews. We have provided more information in the manuscript about how ALOIS is managed, specifically focusing on how studies enter the database (page 7). ALOIS constitutes a comprehensive search of existing literature in relation to this study given that it includes many existing databases:

“ALOIS is updated by monthly searches of Medline, Embase, PsycINFO, Web of Science Core Collection, ClinicalTrials.gov, World Health Organisation International Clinical Trial Registry Platform meta-registry, Cochrane Controlled Register of Controlled Trials (CENTRAL) and LILACs (via Bireme) input into ALOIS.”

This has been added to the text to provide readers with assurances that a search of ALOIS constitutes a thorough search strategy.

4. The specific key words and search terms used to search the database should be provided.

Key words or search terms were not used to search the database. On page 8 we state that:

“The advanced search function allows users to search by study aim, study design, intervention type or whether records are Cochrane studies. In January 2016 the ALOIS database was used to extract outcomes adopted in existing non-pharmacological interventions, applying the following inclusion criteria:”

However, perhaps it is not clear from the above text that ALOIS allows searches by intervention types that are non-pharmacological. On that basis, we have clarified which intervention types ALOIS allows you to search for. The text now reads:

“The advanced search function allows users to search by study aim, study design, intervention type (Any, Non-pharmacological, Pharmacological, Unclear or Both) or whether records are Cochrane studies. In January 2016 the ALOIS database was used to extract outcomes adopted in existing non-pharmacological interventions, applying the following inclusion criteria:”

5. Data was extracted from 50% of the identified studies. Some validation work should be done against the studies that were not extracted to ensure the 50% sample is representative of the entire literature.

The purpose of the literature review was to locate outcomes to complement outcomes extracted from the qualitative data. Furthermore, extracting outcomes from 50% of studies was
decided based on initial screening where it became apparent 50% of identified studies would be sufficient. We have clarified this in the manuscript on page 8.

“The purpose of the literature review was to determine the outcomes used in existing research to complement the outcomes identified from interviews and focus groups with people with dementia, their care partners, health and social care professionals, and policymakers, commissioners and research leaders. As such, we extracted outcomes from a 50% random sample of the identified studies. During the outcomes extraction process we observed that no new outcome was added and that we had reached a saturation point at 50%.”

6. It is unclear why costs and economic outcomes were excluded from the list of outcomes.

Simply put, the aim of the study addresses significant weaknesses in the literature concerning people living with dementia. It is not the aim of the study to look at costs and economic outcomes, and as such they were not part of the research question.

An addition to the text at the end of the discussion section that is outlined below in point 7 addresses this point.

7. I question if excluding caregiver outcomes is a reasonable assumption. Most community based dementia interventions also impact caregivers. A separate list of caregiver outcomes should be considered. If not for this manuscript, then the authors should note that this will be done for a future analysis.

As above in relation to point 6, care partner outcomes while interesting and clearly important in the sphere of community based interventions, are not part of the aim, objectives or research question linked with this study.

However, as recommended, care partner (the term we use in the N&D study), costs and economic outcomes are areas of interest and quite rightly this manuscript should highlight this. The following text has been inserted at the end of the discussion section:

“The ‘long-list’ reported here does not include outcomes relating to care partners, delivery of care or processes, costs or economic related outcomes. Research focusing on care partner related outcomes is warranted as a separate study and clearly an area of interest for further research.”

8. The discussion should comment a bit more on the connection between these outcomes and specific measures. While inconsistencies in the collection and reporting of outcomes is a challenge another major challenge is measurement of each outcome. The authors have a great opportunity to not only report the key concepts but also provide some inventory on the measures that can be used to capture the outcomes.
This manuscript focuses on the first phase of a multi-phase study. After the Delphi survey in phase 2 (the results of which are being written now), the list of 54 will reduce to outcome items that are deemed core by key stakeholders. Phase 3 will review existing outcome measurement instruments in relation to their fit with the core outcomes. While this will highlight existing specific measures in the context of core outcomes, it will also highlight all existing measures that are used in the field. This will act as the “inventory” mentioned by the reviewer. We have clarified this in the conclusion section:

“In a further phase we will review existing outcome measurement instruments in order to highlight how (if at all) measurement instruments measure the core outcomes identified.”