Author's response to reviews

Title: Developing an Intervention for Fall-Related Injuries in Dementia (DIFRID): an integrated, mixed-methods approach

Authors:

Alison Wheatley (alison.wheatley@ncl.ac.uk; alison.wheatley@newcastle.ac.uk)
Claire Bamford (claire.bamford@ncl.ac.uk)
Caroline Shaw (c.a.shaw@hotmail.co.uk)
Elizabeth Flynn (Elizabeth.Flynn@nuth.nhs.uk)
Amy Smith (amy.smith16@nhs.net)
Fiona Beyer (fiona.beyer@ncl.ac.uk)
Chris Fox (Chris.fox@uea.ac.uk)
Robert Barber (Robert.Barber@ntw.nhs.uk)
Steve Parry (Steve.Parry@nuth.nhs.uk)
Denise Howel (denise.howel@ncl.ac.uk)
Tara Homer (tara.homer@ncl.ac.uk)
Louise Robinson (a.l.robinson@ncl.ac.uk)
Louise Allan (L.Allan@exeter.ac.uk)

Version: 1 Date: 15 Jan 2019

Author's response to reviews:

Ellen Freiberger (Reviewer 1):
The authors developed an intervention improving fall related outcomes for older persons with dementia by using an integrated mixed-methods approach. This manuscript targets an important topic regarding the increase of falls and dementia in older persons and will therefore add to the existing literature. Although the manuscript is of importance there are several major comments to be addressed before the manuscript can be considered for publication. Overall the length of the manuscript does exceed normal manuscript. The authors are encouraged to shorten their manuscript.

Thank you for your positive feedback on our work. We have reduced the length of the manuscript by approximately 1000 words while at the same time adding additional material as recommended by the two reviewers.

1. The title does not reflect the thorough full development of the intervention. The reviewer would suggest to mention either that the intervention is based on a theory or that an integrated mixed method is used.

   We have changed the title as suggested.

2. In the introduction of the abstract the authors stated that they developed a theory for an intervention. It is not clear for the reviewer what the aim of the intervention should be: reduction of fall related injuries or long-term outcomes. This is only being mention later on in the abstract (line 48).

   The aim of the intervention is to improve outcomes following a fall requiring healthcare attention; this encompasses both short-term recovery and reducing the likelihood of future falls. We have now clarified this.

3. The authors present their stage model for development of the theory but in the abstract they do not present a "theory" but more consensus related information and components of the intervention. This information does not fit precisely the introduction in the abstract.

   Thank you for pointing out this inconsistency. We have edited the abstract to be more consistent with the contents of the manuscript.
4. The authors use different terms for their approach: (p 5 line 39-40) is stated that effective models are missing for complex intervention and in (p 6 line 10) about theoretical mechanism whereas the authors talk about a theory in the abstract (p 4 line 19) and theory development (p 6 line 46). The reviewer would suggest to either stick to one term or define both terms and present some rational for the different terms.

We have edited to clarify that our emphasis was on identifying causal factors and change mechanisms to inform a new intervention. We have standardised the terminology used.

5. In the introduction the authors should add a short paragraph about the different impact of falls or injurious falls. As it reads now the authors compare outcome of falls and injurious falls similar, which is not the case. Please specify why the authors are concentrating on injurious falls only.

A sentence has been added to compare the outcomes of injurious and non-injurious falls.

6. Furthermore, the authors talk about fall preventive intervention in older persons with dementia but the reviewer is missing the Hauer group being mentioned there e.g. Hauer et al., 2018 Gerontology; Dutzi, I., et al., Cognitive Change in Rehabilitation Patients with Dementia: Prevalence and Association with Rehabilitation Success. J Alzheimers Dis, 2017. 60(3): p. 1171-1182; Hauer, K., et al., Physical training improves motor performance in people with dementia: a randomized controlled trial. J Am Geriatr Soc, 2012. 60(1): p. 8-15.)

We have incorporated the suggested papers into this section.

7. The reviewer would suggest to split the described third goal in this manuscript (p 6 line 12-15) "the development of a logic model and intervention materials" into two separate goals. The development of a logic model is somehow different to the development of intervention materials. Furthermore, Figure 1 shows that the both points are separated.

This has been separated into two points as suggested.

8. The authors are to congratulate for their in-depth methods of developing the new intervention. Nevertheless the reviewer question the part "Theory development" (p 6 line 47) as different terms have been used before.

We have changed the wording to be consistent, here and in accordance with point 4.
9. Please explain why the area of "context" "mechanism" and "outcome" (p 7 line 8-12) were chosen as they have not been mentioned before. The reviewer assumes that in the step before "grouping emerging themes" this is the result of but that has not been described. This is also the case for stating the categories "reasoning" and "resources". No information how these categories arise are given.

We have elaborated the meaning of context, mechanism and outcome (these are a standard framework in realist methodology for presenting this type of data) and added definitions for ‘resource’ and ‘reasoning’.

10. For the reviewer from the search strategies it is not clear if the authors also differentiated to setting e.g. Nursing Homes or Community-dwelling as this is going to have an impact on the development of the intervention later on e.g. with respect to possible frequency and duration as well as education of provider (p. 8 line 6-12).

We have clarified in the introduction that the intervention is focused on people with dementia who live in the community. However, literature from varied settings was included in the realist review and these contexts taken into account.

11. For the reviewer it is not clear if in the Consensus meeting 1 all experts got the same information or were split right away into three groups which would make a difference. Please explain (p 9 line 22-30).

As stated on pg 9, the panel received the information to read prior to the meeting. However, we have clarified that all groups discussed all issues, rather than each group tackling a separate issue.

12. Please provide information if all 24 panel members responded in the Delphi Round or if some members only responded to some question and how the authors handled missing answers (pa 9 line 37-47). The reviewer wonders if the 2/3 majority would include all 24 panel members or the panel members taking part in the Delphi round.

We have clarified the response rates to the two rounds of the Delphi survey and added a sentence indicating that all responses were complete.
13. Please explain how stakeholders could be informed about possible intervention if the process of intervention development was under way (p 10 line 2-14).

The intervention presented to the stakeholders was the proposed intervention following the first round of the survey. We have clarified that the stakeholder interviews/focus groups explored a preliminary version of the intervention.

14. The authors are to congratulate for their methods to develop the logic model. To the current knowledge of the reviewer, no other research group has gone through such an intensive methodological way of developing an intervention (p 10 line 33-43)

Thank you for this encouraging comment.

15. The paragraph "preparation of intervention resources" comes for the reviewer "out of the blue" as no description of this theme has been described before (p 10 line 48-56). Please reconsider for clarification or moving to somewhere else in the manuscript.

We have edited the manuscript to clarify that the resources emerged from the process of developing the protocol and logic model. We feel this is in the correct position in the text as it was the final phase of intervention development.

16. The literature given for the CM0 c2 is mostly based on hip fracture patient. As the authors address "injurious falls" the reviewer wonders if the authors have focused on hip fracture as the most important injury but have not stated these focus earlier in the manuscript. Please explain. (p 12 line 34-56)

The intervention itself is not focused on a specific type of injury. Unfortunately, hip fracture has been the main focus of the literature on fall-related injuries. A line clarifying this has been added.

17. Furthermore in the CMOc2 no information on Nursing home setting is presented. The reviewer wonders if this has not been a topic of the Delphi round.

Indeed, the focus was on community-dwelling people with dementia, as clarified in point 10.
18. The reviewer would like to suggest of rephrasing the heading of CMO c3 as the variables of interest "social isolation" and psychosocial factors could not be subsumed under comorbidities (13 line 25)

Thank you for highlighting this issue. We have changed the heading to ‘developing a holistic approach’

19. In addition the statement by the stakeholder is about "falls" not injurious falls adding to the confusion of what the goal of the authors are (p 13-14 line 55-6). Please review.

While we appreciate the potential for confusion when different terms are used, we have to use the words as spoken by participants.

20. By looking at table 2 (p 14) the reviewer wonder if actually all necessary assessments are in place to obtain all the relevant information. By being familiar with fear of falling and nutrition, to the knowledge of the reviewer, no such instruments exist for older persons with dementia, or are this information obtained by proxy? Then the authors should state how the information could be obtained.

We generally did not include formal structured tools in the assessment. Most assessments were carried out by skilled observation and/or verbal report from patient and carer. Fear of falling was formally assessed as an outcome measure for the study using the M-FES.

21. Although the reviewer is familiar with the OTAGO Program it is not clear how the authors relate their future intervention to the OTAGO without mentioning this exercise program before throughout their manuscript. This information should be added to the background, that the OTAGO program is most effective and used in Nursing homes.

A reference to OTAGO has been added to the Background section.
Nevertheless again, the inconsistency which setting is addressed does show up here as the quote presented is from the hospital setting or a nursing home? (p 16 line 20-36). Again, the reviewer wonders in which setting the future intervention should be applied.

We have deleted the quotation. As previously clarified in point 10, the intervention is to be delivered in the community. Nevertheless, we did include professionals from hospitals and intermediate care as they have valuable and relevant experience in managing injuries in people with dementia.

22. The question about duration or ongoing support (CMO c5) does not address the international recommendation of required session to be effective e.g. Burton et al., 2015. Furthermore, this section needs shortening.

We have shortened the section as suggested.

Both stakeholders and consensus panel members highlighted the tension between meeting the individual needs of people with dementia for ongoing and longer term follow up with effective use of resources. This issue, however, does not seem to be addressed in the suggested Burton (2015) paper.

23. Interestingly to the reviewer in CMOc7 the aspect of huge fluctuation of staff is not mentioned. Did this topic not arise during the consensus meeting? Fluctuation of staff is one of the major barriers for implementing effective fall prevention programs in an EU country not UK. Please comment.

Continuity of care is discussed in CMOc5 and was identified as a barrier in the qualitative work, though not by the consensus panel. We have added a short elaboration of this to the CMOc5 section.
24. The section of Design and feasibility adds again to the confusion of the reviewer (p 24 line 31). As the reviewer suspected it the authors are changing from now from an intervention to prevent injurious falls to a more simple fall prevention. This has not been addressed in the background or before. Please review and comment carefully.

We have clarified in the abstract that the study aim was to improve outcomes for people with dementia following a fall, but should also reduce the likelihood of future falls. The focus on injurious falls was a requirement of the funding and was contested by a number of study participants, who argued that all falls should be included. This led to a slight modification of the eligibility criteria for the feasibility study, where we changed from injurious falls to those requiring healthcare attention. More radical change of the criteria was not supported by the TOC (see pg 23).

25. In the outcome measure section (p 25 line 24) the authors are defining, as an outcome "falls" not even injurious falls. With regard to the short intervention period (mentioned before) the reviewer doubt if the intervention will show any effects, and why the authors are not looking on functional benefits, or is this outcome measure being obtained in the feasibility study? Then please comment and add this information.

There was considerable discussion about appropriate outcome measure within the qualitative work and consensus meetings, with eventual agreement that falls was the most important outcome. We did, however, include a range of outcome measures, including functional outcomes, and have amended the text to clarify this.

26. The reviewer wonders why international recommendation for fall prevention are not cited here (e.g. Sherrington et al., 2016 or Gillespie et al., 2012), as these international recommendation are setting the frame in other health care systems, and should be acknowledged.

Gillespie et al 2012 is referenced in the introduction. We have not referenced these recommendations in the discussion because the intervention is not solely a falls prevention intervention. We feel that to add this would add to the confusion surrounding the focus of the intervention.
27. The information about attendance of the panel members and response rate should be provided earlier in the method section (see comment above) (p 27 line 42-46).

We have added details of meeting attendance and survey response rates to the methods section, as per point 12.

Please provide a short summary of the effectiveness narrative review (p7 line 30-35) as well as for the realistic synthesis (pa 7 line 40).

A short summary of the effectiveness review has been added. The findings of the realist synthesis are integrated with the account of each CMOc.

As not many future readers might be familiar with the approaches the authors used please specify the term "searches were carried out inductively" (p 7 line 45).

We have deleted this, as it is explained later in the paragraph.

Please spell the abbreviation of PWD (p 9 line 12) if used for the first time.

PWD has been spelled out throughout.

Please also spell abbreviation MDT (p 19 line 37). The reviewer assumes multidisciplinary team but is not sure.

This is spelled out in the section under Consensus Meeting 2 (pg 11), where it was referred to for the first time.

Susanne Saal (Reviewer 2):

Thank you very much for the invitation to peer review the manuscript entitled "Developing an Intervention for Fall-Related Injuries in Dementia (DIFRID)". The authors developed a complex intervention aimed to reduce fall-related injuries in people with dementia. An appropriate framework and a range of appropriate methods were used. The results of the developing steps are described detailed and are supported by a bunch of additional files. However, the description of the final intervention is somehow rudimentary. The manuscript is comprehensive, but might benefit from a more concise description of the preliminary development stages and a more pronounced discussion section.
Thank you for your comments. The paper is intended to describe the development of the intervention, since this is often a neglected area and the need for greater transparency over the process of intervention development has been emphasised (see e.g. Hoddinott, 2015). We have added a sentence to this effect to the text at the end of the introduction.

We have not included a detailed description of the final intervention due to limitations of space. Full details will be available in the final report which has now been submitted to the funding body.

In the methods section the employment of observation is mentioned, but the main manuscript does not report on the observation anymore. Was the observation part of the study? On the other hand, the effectiveness review is not mentioned in the abstract, but discussed in the main text.

We have clarified this both in the abstract and on page 8 lines 22-24. The observation was part of the broader qualitative work that was presented to the consensus panel but did not form part of the initial theory generation as it had not yet been conducted. The effectiveness review was also added to the abstract.

The results section might benefit from a data presentation following the single methodological steps. No information on the participants enrolled in the single methodological steps is presented. The authors mention that a number of modifications have been made after two rounds of Delphi surveys. The authors should briefly comment on the modifications.

We have added details of the number of participants in each stage.

Trial registration: Please add the date of registration.

This has been added.

In line 20, evidence from interventions preventing accidental falls in older people without dementia is reported, but the cited papers (6,7) deal with patients with cognitive impairment.

We apologise for this; clearly we made an error when editing the manuscript. The correct citations have been added.
On page 6, line 52 semi-structured interviews and focus groups are mentioned. The authors refer to an unpublished manuscript. The authors should therefore provide some more details on the content of the semi-structured interviews, e.g. was an interview guide used?

This paper is now published and the reference has been updated accordingly.

On page 10, section Stakeholder feedback: What was the reason for conducting additional stakeholder feedback interviews, when stakeholder were already involved in the Delphi survey? Where are the results of the stakeholder feedback interviews reported in the manuscript?

The intention was to reengage with participants from the early qualitative work to ensure that their views had been correctly represented in the draft intervention. However, due to difficulty recruiting people with dementia and carers, we involved a smaller number of new participants. This was crucial since the consensus panel only included professionals. The findings of the stakeholder feedback are integrated throughout the discussion of CMOcs, as described at the beginning of the results section on page 11.

On page 10, line 55, a Programme Management Group is mentioned. What was the role of this group?

We have removed the reference to the PMG and have instead referred to the group of co-investigators.

Overall, the results on the intervention development should be presented in a more concise manner.

We have reduced the word count of the main body of the manuscript from 6950 to 6080.

Results are reported according to the emerging themes. This approach provides a good overview about modifications during the process regarding the themes, but in some points, it is difficult to identify from which source (Delphi survey or Stakeholder feedback) the given information is drawn.

We have attempted to clarify all instances of consensus panel vs stakeholder feedback throughout this section.
Information on the characteristics of the final intervention should be part of the results section. Information on the "dosage" of the intervention components is sometimes missing, e.g. the duration of the staff training programme. In Additional file 6 and the interventions' description, the differentiation between "what" should be implemented and "how" the intervention should be delivered is somehow weak. A checklist like the CICI framework generic checklist (https://doi.org/10.1186/s13012-017-0552-5) might be helpful to be more clear in terms of intervention characteristics and implementation strategies.

Having now considered the CICI checklist, we feel that this is not a relevant checklist to describe our intervention and are confident that the TIDieR checklist (as used in Additional File 6) is a more appropriate tool. However, we have taken on board this feedback and added further clarification to Additional File 6, particularly regarding dosage.

The discussion section is rather short. Although there are a number of studies, which use a comparable methodological approach or contribute to the body of evidence dealing with falls in people with dementia, the authors do not discuss their findings on the background of the existing evidence. The discussion of the finding should be embedded in the already existing bulk of evidence of studies dealing with fall prevention programmes for people with dementia.

An additional paragraph has been added to the discussion section.