Author’s response to reviews


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Author’s response to reviews: see over
Response to Reviewers Comments

1. Since the study cannot be blinded, will there be a process to prevent contamination of the control group, or at least to monitor for contamination by the intervention?
   *A question will be included for the control group at the eight week interview to determine if they have been in contact with anyone who has received or provided the intervention.*

2. In lines 298-299 in the section Services as usual (control), the plan to offer the intervention to participants in the control group after 8 weeks in the study is explained. Can the investigators please comment on the following:
   a) Will the intervention be available to participants in the intervention group after 8 weeks in the study as well?
      *Yes, it will and this has now been clarified in the manuscript.*
   b) How long would this be available for participants, if they accept the offer?
      *A second cycle of 8 weeks will be made available and this has been clarified in the manuscript.*
   c) Will there be assessments during the time period after 8 weeks, if the offer is accepted, as a follow-up of the main study?
      *Yes, this will be a follow up of the main study and this has been clarified in the manuscript.*

3. Please clarify the following: if the patient leaves home to go into hospital or hospice, will participation in the study, including the intervention if the patient is in that group, continue?
   *Yes, it can with their consent. This has been addressed in the manuscript.*

4. What are the study end-points for patients/carers, other than completing the T2 assessment (e.g. death, patient/carer request to withdraw from study, etc.)?
   *The end points have been more clearly defined in the revised manuscript as suggested.*

5. Change in volunteers’ death anxiety and confidence in communication will be analyzed, as explained in lines 415-416 in the Data Analysis section. How will these outcomes be measured?
   *Measures have now been outlined in the manuscript.*

6. At several spots in the Abstract, main text and Figures, abbreviations are used without explanation. I suggest that full terms be given the first time each abbreviation is used, with the abbreviation following in brackets. Abbreviations include: RCT, INSPIRE, MRC in the abstract and UK, NHS, HOME, SAIATU, A&E, OPD, MRC, INSPIRE, RCT, HSE, CONSORT, PI, ASI, AMA in the main text and PI in Figure 2.
   *Completed as suggested.*
7. In line 242 in the Randomization section, I suggest adding the word ‘patient’ before the word ‘gender’, to clarify that the group balance sought relates to the patients’ demographics (which I have presumed).

_This section has been revised._

8. Labeling of Figures 1 and 2 needs to be clarified. In the version of the manuscript I reviewed, Figures 1 and 2 were each two pages long and were identical. I suspect that the first page of each Figure is meant to be Figure 1 and the second page of each Figure is meant to be Figure 2.

_This has been addressed._

**Discretionary Revisions**

9. The title is long. I suggest shortening it, such as: INSPIRE: Investigating Social and PractIcal supports at the End of life. Pilot randomized trial of a community social and practical support intervention for adults with life-limiting illness: Study protocol.

_This has been addressed._

10. I wonder if there is a missing word in line 168 in bullet # (4) in the third paragraph of the Aim and Objectives section, right after “Increase the size of”.

_No change was made._

11. In line 170 in the fourth paragraph of the Aim and Objectives section, the term “Within Phase I/II of the study” is unclear at this point in the manuscript, since phases have not been described yet. I suggest removing this and replacing with: “The research team will also seek to:”.

_Ammended._

12. In line 265 in the Sample Size section, “study timeframe” is mentioned, but an actual timeframe is never specifically mentioned in the manuscript. Is it possible to give the reader an expected timeframe?

_Ammended._

13. In line 298 in the section Services as usual (control), “T1” and “T2” are mentioned and the reader is referred to later in the manuscript to understand what these mean. I suggest replacing these terms with “4 weeks” and “8 weeks” in this line, or moving the whole section so it comes after the next section in which the intervention is described.

_Ammended._

14. In Figure 2, the number of participants in each group is given as “n=80”, followed by the clarification that this includes both Carers and Patients, and preceded by “2 x”. The main text is quite clear in line 259 in the Sample Size section that the overall sample size is “up to 80”, presumably referring to patients only. I suggest that Figure 2 be changed to indicate that the goal is for (40 Carers and 40 Patients) to be included in each group. If this change is made, then “2 x” and “n=80” could be removed from each box.

_Ammended._
15. In line 114 in the third paragraph of the Background section, there is a spelling error for ‘interventions’ immediately following: “Such community-led”. Ammended

16. In lines 216-217 in the first paragraph of the Phase I – Modelling sub-section of the Methods section, I suggest considering the following rewording of the sentence: “A mechanism of volunteer support must also be developed.” Ammended.

17. In line 261 in the Sample Size section, I suggest replacing “the” with “permit”, so that the line reads: “...and retention of the participants, and permit calculation of appropriate sample sizes...”. Ammended.

18. In line 303 in the section The Intervention, add the word “to” just before “help”, so the line reads: “...making links with those living close-by who would like to help.” Ammended

19. In line 318 in the third bullet of the second paragraph in the section The Intervention, add the word “be” before “confident”, so the line reads: “The ability to be confident and out-going...” Ammended

20. In line 323 in the seventh bullet of the second paragraph in the section The Intervention, add the word “the” before “purpose”, so the line reads: “A good sense of personal boundaries and a clear understanding of the purpose of the role”. Ammended

21. In line 350 in the the word “on” before formula of words...”. Ammended

22. In line 379 in the after “groups” (these edited previously). sub-section Visit One of the section The Intervention, add “a formula”, so the line reads: “...perhaps agreeing on a section The Trial: Data Collection, remove the letters “ated” appear to have been missed when the manuscript was Ammended

23. In line 458 under word testing. This needs to be removed. Authors’ Contributions, there is a question mark after the Ammended

24. In Figure 1, the second bullet in the second box labeled “Phase I – Modelling” needs to be reworded as follows: “Design, implement and evaluate a brief
training programme that aims to help volunteers fulfill their role, build confidence in communication and potentially reduce death anxiety”.

Ammended

25. In Figure 1, the fourth bullet in the second box labeled “Phase I – Modelling” needs to be reworded as follows: “Develop and agree on mechanism of volunteer support”.

Ammended

Reviewer 2
The abstract is not completely clear about the fact that this paper concerns a research protocol, and that this protocol only concerns the first 3 phases of the MRC Framework (phase 0, 1 and 2)

Addressed in revised submission

The paper is well written, but there are some spelling mistakes: e.g. the word 'interventions' (line 114) or 'interventions' (line 158)

Addressed

Please check the completeness of the references at the end of the paper (for instance in the first reference of De Roo et al. the last co-author A.L. Francke is missing). Furthermore, the reference style is not always consequent

Addressed