Reviewer's report


Version: 2  Date: 22 March 2015

Reviewer: Raymond Viola

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General Comments

This is a well-written description of a proposed pilot study protocol to explore the feasibility and acceptability of a community-based social and practical support intervention for palliative care patients living in the community and their main caregiver and possibly to test the effectiveness of this intervention on instrumental activities of daily living and other outcomes. It is generally complete and detailed and follows the CONSORT guidelines.

Major Compulsory Revisions - None

Minor Essential Revisions

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?

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?

   b) How long would this be available for participants, if they accept the offer?

   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?

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?

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.)?

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?

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.

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).

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.

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.

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”.

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:”.

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?

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.

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.
Minor Issues Not for Publication

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

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.”

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…”.

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.”

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…”

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”.

21. In line 350 in the sub-section Visit One of the section The Intervention, add the word “on” before “a formula”, so the line reads: “…perhaps agreeing on a formula of words…”.

22. In line 379 in the section The Trial: Data Collection, remove the letters “ated” after “groups” (these appear to have been missed when the manuscript was edited previously).

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

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”.

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”.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.