Reviewer’s report

Title: Implementing the theory-based advance care planning ACP+ programme for nursing homes: study protocol for a cluster randomised controlled trial and process evaluation

Version: 0 Date: 11 Jul 2019

Reviewer: Susan Hickman

Reviewer's report:

Overall, an interesting paper describing a rigorous intervention to improve advance care planning (ACP) in nursing homes. The trial design description is generally clear and easy to follow. The tables and supplemental materials are great additions that complement the text. However, there are a few areas that require clarification to strengthen the manuscript as noted below.

Introduction

1. The first paragraph is a little confusing and might be clearer if ACP is defined first, prior to talking about why it is important in nursing homes.

2. Line 15 references "high-quality methods" - could use a little more specificity.

3. The end of the long sentence in lines 16-20 implies ACP in the USA is "potentially less effective" but it is unclear what it is being compared to or the evidence supporting this assertion. (Less effective than what?)

Methods

4. What is their function of volunteers in relation to this intervention? What data is collected from volunteers? They do not seem to be part of the intervention or assessment, so it is unclear why they are repeatedly mentioned. In particular, I'd remove the reference to volunteers from the abstract, as it suggests their inclusion is more important than it appears to actually be (after reading the full protocol).

5. In the description of the outcome measurements (line 138-243), I got a little lost. The authors describe developing a questionnaire based on a study from Detering, but it is unclear what the questionnaire assesses. Please include sample items in the text and clarify the purpose of the questionnaire.

6. I'd like to see the "other measures" mentioned in lines 166-195 removed from the text and presented in table format. It would be a lot easier to digest this information in a table format.
7. In the description of the recruitment process (page 12), it is unclear how facility matching is taken into account during recruitment, which creates some confusion about the recruitment process as well as raising questions about the matching process. How did it work out so perfectly that you had enough matching facilities? What was the selection process to arrive at your final sample?

8. How are the process evaluation measures being taken into account in the analysis? I do not see any plan to include these variables in an analysis, but it seems likely that the information gathered as part of the process evaluation is relevant to outcomes (as is suggested by the authors in the discussion on lines 457-459). They seem to be the closest measure you have to assess "dose."

9. There seems to be a lot of staff data collection and it is unclear whether it benefits residents or is just for the study. What is the purpose of the google forms diary and what exactly is collected? What, if anything, is recorded in the clinical record? How long does this take?

10. It seems pretty central to the trial design that the trainer is external. However, this is not apparent until page 15. It should be mentioned earlier.

11. What is happening in the control facilities? I was unable to find a description of the plan for these facilities. And what is being assessed in these facilities? Just the baseline and 8 month outcomes? Ideally, the methods would be clear about each condition and what is happening in each arm of the study.

12. On pages 19-21, the discussion of ethical considerations needs some work. There are two categories of participants: staff/volunteers and residents/family members. It seems like the harms as well as issues related to protecting confidentiality are different for each category of participant. Please address each type of participant in the ethical considerations discussion separately.

Discussion

13. An important additional study limitation is the assumption that changes in staff knowledge leads to changes in both behavior as well resident outcomes. The statement that improving staff level outcomes is a necessary precondition before being able to change outcomes for residents (lines 487-490) has face validity, but what is the evidence to support this assertion? I do not think there is good evidence to support this statement.

14. On line 494, there is a reference to economic outcomes. The sentence implies there will be an economic outcomes assessment, but just not simultaneously. Should this be in the methods? Outcome?
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

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Not relevant to this manuscript

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