Author's response to reviews

**Title:** Feasibility study of an optimized person-centred intervention to improve mental health and reduce antipsychotics amongst people with dementia in care homes: study protocol for a randomized controlled trial

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**Author's response to reviews:** see over
Dear Barry Davis

Re: Response to peer review comments from Anne Margriet Pot on Manuscript 9401811017349731 (Feasibility study of an optimized person-centred intervention to improve mental health and reduce antipsychotics amongst people with dementia in care homes: study protocol for a randomized controlled trial)

In response your email dated 22\textsuperscript{nd} October 2012, we have addressed the comments provided by peer review and have revised our manuscript using ‘tracked changes’ in the text.

The following provides a point-by-point response to the concerns raised:

1. \textit{Will the study design adequately test the hypothesis?}
   a. \textit{Please add the comparison group (Person-Centred Care alone) in the hypotheses.}
   The comparison group Person centred care is already included in all the hypotheses (page 7 “Specifically the hypotheses are that compared to Person-Centred Care alone.”)
   Our design cannot tackle the question does PCC alone reduce antipsychotic prescription as there is no true control available. To include such a control we judge would require a different experimental design, which then would not answer the questions we are assessing in this pilot. However we appreciate the point the reviewer is making and will ensure that change from baseline in the PCC group is discussed in the descriptive analysis (addition page 15).

   b. \textit{For the second hypothesis, a subgroup is defined for which the intervention is assumed to be especially beneficial. I would suggest to do the same for the other two hypotheses, or, if the authors decide not to do so, to describe why not.}
   We have no power to perform the subgroup analysis suggested by the referee in a meaningful way in this pilot study but thank the reviewer for the helpful observation. We intend to make these subgroup analyses a feature of the main study where we will have sufficient power for such exploratory substudies.

2. \textit{Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?}
a. A short summary of the Person-Centered care program would be helpful. I assume that PCC training is delivered to all staff in the participating nursing homes? Description of the Person-Centred care intervention provided. Clarification provided that this intervention will be delivered to all staff in participating homes (page 8).

Does the same hold for the other interventions? Please clarify.

The study uses a factorial design, as shown in Figure 1. For example, care homes 1 and 9 will receive PCC only, while care home 4 will receive Social Interaction and Exercise in addition to PCC and care home 13 will just receive Antipsychotic Review in addition to PCC. Staff will receive training in the interventions allocated to the care home, with all care homes receiving training in the Person-Centred care intervention (page 10).

b. Treatment fidelity of the therapists will be measured. The actual care provided by other professionals involved (staff / general practitioners) might be worthwhile too. Whilst the treatment fidelity of the therapists will be measured more formally as part of trial monitoring procedures, the care provided in line with the study interventions will be observed and recorded by WHELD therapists on a more informal basis, as part of the ongoing process evaluation for the trial.

c. In what way will the homes not already known to the researchers be selected?

The care homes not known to researchers will be identified from all care homes in the research area rated as ‘adequate’ or better on the CQC register. All care homes listed in the CQC register that meet the study’s inclusion and exclusion criteria will be entered into a study database. Next, this list of eligible care homes will be randomised and the homes approached in the order of appearance on the randomised list (page 13).

I suppose the 12 residents who will be selected will live on different wards of a ‘traditional’ nursing home? Or are homes providing small group living care also included?

Residents will be selected from registered care homes with 60% or more residents with dementia (a minimum of 12 residents) (page 13).

3. Is the planned quantitative and qualitative analysis appropriate?

a. The authors write: “Findings of the qualitative study will contribute to the optimization of the interventions, the training and the implementation approaches in the larger RCT, WP5.” This qualitative study may also shed more light on the specific outcomes and mediators (working mechanisms) of the interventions that need to be taken into account in the planned RCT (as described on page 7). Please add.

The qualitative evaluation certainly seeks to do this. This has been added to the Qualitative data management and analysis section (page 16).

b. Why are the assumed mediating factors not measured in the quantitative study?

Including questionnaires on staff beliefs and attitudes might add important information on the use of these instruments for the planned RCT.

This issue was considered in the study design stage and it was decided that the qualitative methodology selected would be more appropriate for the purposes of the trial than a quantitative study of staff attitudes and beliefs. These are not primary outcomes for the study and, as we are collecting large amounts of outcome data on
residents, using care staff as informants, it was considered that administering additional staff measures could prove to be excessively burdensome. In addition, the investigators’ previous work on a trial of a person-centred care intervention (Fossey et al, 2006), in which staff attitudes were measured using a quantitative approach, did not provide useful information about mediating factors. Therefore, a qualitative approach was chosen to directly elicit staff concerns.

c. I suppose the outcomes are measured on an individual level. Please make more explicit.
With the exception of the QUIS observational study, which is conducted at a group level, all outcome data will be collected at an individual level for the individual participants (page 15).

d. With regard to the follow-up period of nine months: how will be dealt with attrition? Although we have set a minimum recruitment target of 12 individuals with dementia per care home, all residents within the care homes, who meet the study’s eligibility criteria will be invited to participate, which will help to account for the potential loss of participants during the course of the study (page 10). The original power calculation made allowance for predicted trial attrition but accurate assessment of this rate is a part of the pilot element of the study. (Please see top of page 7)

4. Is the writing acceptable?
a. The authors describe a complex design in a very comprehensible way. My only suggestion would be to take a bit more international perspective for the introduction.

Introduction has been updated to include European and American perspectives (pages 4 and 5).

I hope that the above addresses the reviewer’s concerns adequately. If there are any further areas for clarification please do not hesitate to contact me.

Yours sincerely

Jane Stafford
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