Author's response to reviews

Title: A pharmacist-led intervention for increasing the uptake of Home Medicines Review (HMR) among residents of retirement villages (PHARMER): protocol for a cluster randomized controlled trial

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Author's response to reviews: see over
Thank you for the feedback on our submission to BioMed Central Health Services Research. Please see below our responses to the reviewer’s queries/comments.

1. Reference 3, cited in the paper (Background, para 4) indicates previous work by the research team in Retirement Villages and with key stakeholders in the HMR process. Will this prior engagement influence outcomes of this study?

   The work we carried out previously (postal survey of retirement village residents) is unlikely to affect the outcomes of this study. Reasons for this include:

   i. the retirement village population we target in PHARMER trial will be different from those who participated in our previous survey. Our previous survey was conducted 3 years ago and targeted residents who were members of Residents of Retirement Villages of Victoria Inc. (RRVV), whereas this study targets all residents from the selected retirement villages. Only 30% residents of the selected retirement villages are RRVV members; and

   ii. the survey asked participants whether they had received a HMR in the last 12 months and had heard of HMR but did not provide any information on the HMR service. Therefore, the educational intervention we propose to test in this study is unlikely to be affected by our previous work.

   In the unlikely event that our previous work influences the outcomes of this study, both groups (intervention and control) would equally be affected.

2. I was uncertain how the statement (under Methods/Design; Study design) where the authors state that “Five to ten villages......will be recruited” reconciles with the statement (under Identification and selection of retirement villages para 1, line 5) that “a convenience sample of ten retirement villages was selected” and the statement (under Recruitment of retirement villages) that “Written permission was obtained from each village manager at the time of recruitment of each village”. This variation in tense is confusing and important to clarify before comments can be made about the adequacy of the sample. If only 5 Villages are recruited there may not be sufficient diversity of sites to account for the regional variations in HMR rates pre-intervention.

   We have rephrased the above statements in the text using future tense. To ensure consistency, we have used future tense for other similar phrases in the text. Please see track changes in the
Methods/Study design, under Study setting, Identification and selection of retirement villages, and Recruitment of retirement villages.

We have also made it clear in the text that we aim to recruit 10 retirement villages for the study. Initially, we will select ten retirement villages in consultation with the Residents of Retirement Villages of Victoria Inc. (RRVV). The representatives of these selected villages (also known as Resident Liaison Officers [RLOs]) will be asked to assist us in recruiting their retirement village for the study (e.g. obtain permission from their village manager). If any of the selected RLOs are unable to assist, we will select new retirement villages and approach the RLOs of these newly selected villages. This process will continue until we recruit 10 RLOs and their retirement villages. This information has been included in the text. Please refer to the track changes in the Methods/Study design, under Study setting and Recruitment of retirement villages.

The issue of regional variation is covered in response to the next question.

3. The reason for trying to ensure representativeness from non-metropolitan area is unclear. It seems the regions both have “metropolitan” and “non-metropolitan” retirement villages. I would have thought representativeness would have related more to the profile of residents in terms of their likely need for a HMR, their ability to access medical practitioners, the workload of the medical practitioners and the availability and competency of accredited pharmacists to undertake the review.

We take the point about ‘representativeness’. Our intent was to have diversity rather than representativeness; hence we have selected a site from a regional centre in each cluster. We have amended the text relating to this by removing the phrase describing the inclusion of retirement villages from non-metropolitan areas to ensure representativeness. Please refer to the track changes in the Methods/Design, under Identification and selection of retirement villages.

4. The wording of the paragraph on Cluster randomisation is unclear: my interpretation is that retirement villages in each geographic area will be randomly allocated to PIG or UCG. Are there 5 participating retirement villages participating from each geographic area? How is the “15km apart” rule implemented?

We have rephrased the description of the cluster randomisation and group allocation. Geographical regions (northeast or southwest) will be randomised to intervention group (PIG) or control group (UCG). Retirement villages and residents will be in intervention group or control group based on the geographical location of their RV. We have also explained the reasons for randomising by geographical location rather than individual residents or individual retirement villages (e.g. to avoid contamination). Please refer to the track changes in the Methods/Study Design, under Identification and selection of retirement villages, and Cluster randomisation.

We plan to have five retirement villages in each of the groups (PIG and UCG). We have included a sentence explaining this in the text. Please refer to the track changes under Identification and selection of retirement villages.

To reduce the chances for contamination, we will have a minimum distance of 15 km between the PIG and UCG retirement villages. We will use Google Maps (available online) to measure the distance. We have rephrased the sentence relating to this measure in the text. Please refer to the track changes under Identification and selection of retirement villages.

5. The reason for excluding people who have had a HMR in the previous 12 months needs to be explained (Exclusion criteria dot point 1). The HMR rules allow more than one HMR/year if patient circumstances (eg hospitalisation, new chronic condition) demand a review.

According to the HMR criteria, a General Practitioner (GP) can initiate a HMR for an eligible patient only once a year, unless the patient’s condition changes (e.g. has a recent hospitalisation) and requires more frequent review. The majority of patients who have received a HMR are unlikely to be eligible to receive another one in the next 12 months. This study is aimed at improving the uptake of HMR in retirement village residents using an intervention. Residents and
6. Under “Sample size”, has any consideration been given to replacement of participants who leave the study, given the likelihood of high attrition rates in this elderly population?

Participants in our randomised controlled trial cannot be replaced after the intervention has occurred because the intervention happens at one time point only in each retirement village.

We have minimised the effect of loss to follow up by inflating sample size by 20% and we intend to use the intention-to-treat principle to analyse the data. These points have already been mentioned in the text (see Data analysis and Sample size).

7. Under “Base-line data collection” it may be important to consider issues such as complexity of the medication regimen, use of high risk medicines such as warfarin, number of chronic conditions, dementia, time since last hospitalisation and number of hospitalisations in the previous 12 months as key resident markers for a HMR.

We are already collecting the above information (e.g. medication-related risk factors) suggested by the reviewer in our baseline questionnaire and have clarified this in the manuscript. Please refer to the track changes under Interventions in the pharmacist intervention group and Baseline data collection.

8. It is unclear to me why “secondary outcome measures” (under Six-month follow up, second to last sentence) are suddenly announced. How will normal age-related changes in health-related QOL be accounted for over the study period. I don’t believe inclusion of these secondary outcome measures is appropriate unless they are formally included in the a priori aims of the study and appropriate methods of measuring these outcomes and appropriate epidemiologic study techniques described to avoid confounding.

We have made some minor changes in the text to make our outcome measures clearer, such as adding an extra sub-heading defining our primary and secondary outcome measures, and removing the phrases describing these measures in other parts of the text. Please refer to the track changes under Outcome measures, Three month follow up and Six month follow up.

We agree with the reviewer regarding the measure for health-related quality of life. In addition to the reviewers’ point about the possibility of normal age-related changes in this population, the study timeframe may be too short for assessing changes in participants’ health-related quality of life. Therefore, we have removed health-related quality of life as a secondary outcome measure, but will collect this information at baseline and six months to describe the participants. Please refer to the track changes under Outcome measures and Six month follow up.

Our secondary outcome measure will be change in medication adherence. We have also included this measure as the secondary aim of our study. Please refer to the track changes in the Background and under Outcome measures.

We are using the Morisky scale to measure participants’ medication adherence. This is a validated scale widely used in medical research for this purpose. To control for potential confounding, we will use multivariate statistical techniques in our data analysis. This approach is commonly used in epidemiologic studies.

In addition, we have made some minor revisions in the abstract to make it consistent with the text. Please refer to the track changes in the Abstract. To make it easier for you to review, we have also
attached two versions of the revised manuscripts – one version with the track changes shown, and the other version with the track changes accepted.

Thank you for your consideration. We look forward to receiving your favourable response.

Yours sincerely,

\[Signature\]

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