Reviewer's report

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

Version: 1 Date: 11 July 2011

Reviewer: Andrew Gilbert

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This paper provides details of a proposed multi-centre, prospective, cluster RCT. Such a design will allow testing of the hypothesis that a greater proportion of residents in a retirement village which received a multi-component intervention delivered by a pharmacist will receive a Home Medicines Review (via referral by the resident’s general medical practitioner to an accredited pharmacist) compared to a retirement village which did not receive the intervention.

The main goal of the multi-component intervention appears to be to increase residents’ understanding of the value a Home Medicines Review and consequently increase their demand for the service to be initiated by their medical practitioner.

There are a number of questions that I have about this study which may require “discretionary revision” of the manuscript to address; some arise from lack of information, and some from lack of clarity, in the paper.

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?

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.

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.

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?

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.

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?

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.

8. It is unclear to me why “secondary outcome measures” (under Six-month followup, 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.

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

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

'I declare that I have no competing interests'