Author’s response to reviews

Title: Can a tailored exercise and home hazard reduction program reduce the rate of falls in community dwelling older people with cognitive impairment? Protocol paper for the i-FOCIS randomised controlled trial.

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Author’s response to reviews: see over
Dear Giulia Mangiameli,

Re: Can a tailored exercise and home hazard reduction program reduce the rate of falls in community dwelling older people with cognitive impairment? Protocol paper for the i-FOCIS randomised controlled trial

JCT Close, J Wesson, C Sherrington, KD Hill, S Kurrle, SR Lord, H Brodaty, K Howard, L N Gitlin, SD O'Rourke, L Clemson.

MS: 7147579831370250 Study protocol BMC Geriatrics

Dear Editorial staff

Thank you for your response to our recent submission to BMC Geriatrics. We have addressed the following as requested

1. Ethical and Funding Approval Documentation

Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system.

We can confirm that the following documents have been forwarded to BMCSeriesEditorial@biomedcentral.com.

A copy of all Ethics approval documents which include:

1) Copy of overall study approval letter dated 7th May 2014
2) Copy of Site specific approval letter for the Prince of Wales Hospital site dated 23rd May 2014
3) Copy of Site specific approval letter for the Hornsby Ku-Ring-gai Hospital site dated 28th May 2014
4) Copy of Site specific approval letter for Neuroscience Research Australia dated 23rd May 2014
5) A copy of Funding approval document from the Australian Government National Health and Medical Research Council letter
6) Budget Release Confirmation from the UNSW Grants management office dated 3rd June 2014
2. Funding

A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body?

This study is funded by an Australian National Health and Medical Research Council Project Grant (Reference Number: NHMRC ID: 1060191).

A copy of Funding approval document from the Australian Government National Health and Medical Research Council letter

3. Study status

The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

Our study commenced on the 1st July 2014 and is ongoing. Investigators can confirm we are still collecting data.

4. Related Articles

Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal? If so, can you please provide a list of the related articles?

No publications containing the results of this study have already been published or submitted to any journal.

Kind regards
Sandra O'Rourke
We believe the topic to be of interest to the readership of the BMC Geriatrics, as our current randomised controlled trial will examine whether a novel approach to delivery on an individually tailored exercise and home hazard reduction program, which focuses on preserved cognitive abilities, can reduce the rate of falls in cognitively impaired older people.

Dementia has consistently been shown to increase the risk of falls in older people, with rates twice that found in cognitively intact older people. A fall is the most common cause of hospitalisation in people with dementia. No studies have been effective in preventing falls in community dwelling older people with dementia. Such negative findings suggest that simply applying an intervention shown to work in cognitively intact people is unlikely to yield benefits.

The study outlined in the protocol paper will determine the impact of this tailored intervention in reducing the rate of falls in community dwelling older people with cognitive impairment as well as the cost-effectiveness and adherence to the program. The results will have direct implications for the design and implementation of interventions for this high-risk group of older people.

The study protocol has not been published previously and is not under consideration for any other publication. All authors listed above have made substantial contributions to the conception or design
of the research and contributed to and agree with the content of the final protocol paper. The authors have no financial disclosures to report.

Thank you in advance for considering this study protocol.

Sincerely,

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