PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	IMPLEMENTATION OF THE StandingTall PROGRAMME TO PREVENT FALLS IN OLDER PEOPLE: A PROCESS EVALUATION PROTOCOL
AUTHORS	Taylor, Morag; Todd, Chris; O'Rourke, Sandra; Clemson, Lindy; Close, Jacqueline; Lord, Stephen; Lung, Thomas; Berlowitz, David; Blennerhassett, Jannette; Chow, Jessica; Dayhew, Julia; Hawley-Hague, Helen; Hodge, Wendy; Howard, Kirsten; Johnson, Pamela; Lasrado, Reena; McInerney, Garth; Merlene, Marita; Miles, Lillian; Said, Catherine; White, Leanne; Wilson, Nicola; Zask, Avigdor; Delbaere, Kim

VERSION 1 – REVIEW

REVIEWER	Pérez-Ros, Pilar Universidad Católica de Valencia San Vicente Mártir, Nursing
REVIEW RETURNED	10-Feb-2021

GENERAL COMMENTS	The present manuscript is a study protocol on a home-based exercise program using TeleHealth. Falls remain a highly prevalent geriatric syndrome. Exercise is the main prevention strategy, but adherence to the programs and follow-up of exercise performance after completion of the programs is a knowledge gap yet to be resolved. This project will endeavour to recruit 300 participants across threesites in Australia and 100 participants in the United Kingdom. The aim of the study is to evaluate the implementation of StandingTall into the community and health service settings in Australia and the United Kingdom. The nested process evaluation will use both quantitative and qualitative methods to explore uptake and acceptability of the StandingTall program and associated resources. The primary outcome is participant adherence to the StandingTall program over 6-months I feel it is an ambitious and very well designed project. The authors have considered all aspects related to adherence to the programs. As a suggestion I am sending you this document in case it would be useful for any point: Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol. 2004;23(5):443-451 I would recommend some suggestions Please could the authors change the wording of line 86 to a conditional verb tense, as their intervention has not yet been evaluated. Methods,

	Line 112 I have reviewed the website, I think it provides a lot of information. I have a personal question. Do the seniors who participated in this study access the program in the same way or from a direct link? Line 122 Could you change: 60 years and older? Inclusion criteria: Hearing impairment would have to be added? After the start of the program, the professional, either face-to-face or virtually, who instructs on how to perform the exercises, I understand that he/she makes sure that they are done correctly. Is there a procedure to reevaluate the subject after several sessions to see if he/she is still doing it correctly? How is the subjects' technological skills assessed? All the best in your submission!

REVIEWER	Edgren, Johanna University of Jyväskylä, Gerontology Research Center, Department of Helath Sciences
REVIEW RETURNED	22-Feb-2021

GENERAL COMMENTS	The rationale of the study is clearly presented and the research is highly relevant and important. Additionally, the manuscript is fluent and well written in general. However, I have some notifications for the authors. 1. SPIRIT checklist: Please, follow the SPIRIT checklist for the minimum content of a clinical trial protocol and attach the filled SPIRIT checklist to the manuscript. This would make the review process more fluent and transparent. 2. Time schedule remains unclear: I would prefer a schematic diagram describing the time schedule of enrolment, intervention, assessments, and visits for participants (please, see details in the SPIRIT checklist). 3. Statistics: I think that the statistical methods should be described more explicitly for analyzing primary and secondary outcomes or give reference to where other details of the statistical analysis plan can be found, if not in the protocol. E.g. the planned cost-benefit analysis should be described in the statistics section. 4. Figure 1: The font size is too small to read. Please, redo the figure with larger font size.

REVIEWER	Taylor, Lynne The University of Auckland
REVIEW RETURNED	24-Feb-2021

GENERAL COMMENTS	This study is a clearly articulated, ambitious and complex program of work. The only section that needed clarifying for me were lines Lines 199-219. It took me a while to figure out this section related to Table 1. Can you refer to Table 1 in the text here? Also, reorder the explanatory text to match table 1? i.e. fidelity, acceptability, adoption etc. I'm sure the methodological approach and the results will be of great interest to many. I look forward to reading the results.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments

1. As a suggestion I am sending you this document in case it would be useful for any point:

Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol. 2004;23(5):443-451

Authors' response: Thank you for this recommendation, it will be a valuable resource when reporting the findings of the study.

2. I would recommend some suggestions Please could the authors change the wording of line 86 to a conditional verb tense, as their intervention has not yet been evaluated.

Authors' response: The intervention has been evaluated in a large 2-year RCT which was submitted at the time of our submission but has since been accepted and published. However, in light of the reviewers comments we have revised the manuscript, please see below:

'…StandingTall will provide a novel solution to the fall epidemic by providing older people with an effective…'

3. Line 112 I have reviewed the website, I think it provides a lot of information. I have a personal question. Do the seniors who participated in this study access the program in the same way or from a direct link?

Authors' response: The participants, exercise therapists and support persons complete their training and training quiz via the website and access resources (e.g. the programme manual). However, the web version of the programme is through a direct link which is provided on the website, in the programme manual (available on the website) and/or via email. Login details are required to access the programme as it is not yet publicly available.

4. Line 122 Could you change: 60 years and older?

Authors' response: The manuscript has been revised to say 60 years or older, please see below:

'The study will involve consenting community-dwelling older people, aged 60 years or older with sufficient English….'

5. Inclusion criteria: Hearing impairment would have to be added?

Authors' response: Hearing impairment is not actually an exclusion criterion for the study, however, we agree that this may be an issue for some people.

6. After the start of the program, the professional, either face-to-face or virtually, who instructs on how to perform the exercises, I understand that he/she makes sure that they are done correctly. Is there a procedure to reevaluate the subject after several sessions to see if he/she is still doing it correctly?

Authors' response: We recommend participants have an initial setup session with an exercise specialist (e.g. physiotherapist/physical therapist, exercise physiologist, fitness instructor) with experience in delivering exercise to older people. The *StandingTall* programme has animated video demonstrations, a tips & hints page and a quick refresh page (with still images of the exercise) for each exercise – participants use this information to complete the exercises (included in manuscript). Participants may choose to have additional session/s with an exercise specialist, but this is not required for the study. Exercise specialists are also able to view participants exercise progress in the back-end CMS and modify their exercises as required (included in manuscript). Participants are also able to access support through a study helpline (this has been added to the manuscript), please see below:

'If participants need programme support during their 6-month intervention period, they can contact a central study helpline and/or their exercise specialist.'

7. How is the subjects' technological skills assessed?

Authors' response: Technological skills were not assessed as part of this implementation trial. The programme is easy to follow, the participants have a setup session with an exercise specialist to take them through the program and they can contact their exercise specialist or a central study helpline for technical support. Survey questions, now provided for peer review via the open science framework (please see our response to point 3), should help elicit any technological difficulties experienced by participants. Additionally, the programmes usability (system usability scale) has previously been tested and rated highly (Delbaere 2021 BMJ).

Reviewer 2 comments

8. SPIRIT checklist: Please, follow the SPIRIT checklist for the minimum content of a clinical trial protocol and attach the filled SPIRIT checklist to the manuscript. This would make the review process more fluent and transparent.

Authors' response: While the authors agree that the SPIRIT checklist should be used for a full trial protocol, not all of the information can be included in a published protocol. In fact, the SPIRIT statement suggests that the full protocol should be submitted to an institutional review board, not to a journal for publication. We have provided additional details in the manuscript, as well as the SPIRIT checklist, but do not feel that every point in the SPIRIT checklist can be addressed in the published protocol while still adhering to the journal word limit requirements. Please see below and the Open Science Framework link:

'Participants are not restricted regarding concomitant care, interventions or activity.'

'Adverse events are reported to the data monitoring committee and unexpected and serious adverse events are reported to the governing site and/or Research Ethics Committee, as appropriate and in accordance with the local mandatory reporting policies.'

'Missing data will be left missing; no imputation methods will be used.'

'Participant confidentiality and privacy will always be maintained, and all data will be stored securely. Data access will only be provided to study staff and investigators.'

9. Time schedule remains unclear: I would prefer a schematic diagram describing the time schedule of enrolment, intervention, assessments, and visits for participants (please, see details in the SPIRIT checklist).

Authors' response: We have revised the manuscript to include a participant flow diagram and have referenced this figure throughout the manuscript, for example, please see below:

'Figure 1 demonstrates participants flow through the study.'

'Participants are contacted by phone if their adherence drops below 85% for two consecutive weeks to discuss any problems or issues and to encourage adherence (Figure 1).'

'The data collection time-points for participants are presented in Figure 1.'

10. Statistics: I think that the statistical methods should be described more explicitly for analyzing primary and secondary outcomes or give reference to where other details of the statistical analysis plan can be found, if not in the protocol. E.g. the planned cost-benefit analysis should be described in the statistics section.

Authors' response: Considering this is an implementation trial and therefore we do not have a reference/control group, data will be reported as described i.e. total exercise minutes and mean or median weekly exercise minutes and compared to previous literature. Similarly for survey responses, the number and proportion for responses will be reported.

We have removed the section on cost-benefit analysis as we are unsure whether we will have sufficient power to undertake this analysis. With the COVID-19 pandemic, our recruitment rate is less than expected and as a result we will likely have a reduced sample size. Implementation costs will be evaluated as part of the process evaluation.

11. Figure 1: The font size is too small to read. Please, redo the figure with larger font size.

Authors' response: We have revised Figure 1 (now Figure 2) and increased the font size.

Reviewer 3

12. The only section that needed clarifying for me were lines Lines 199-219. It took me a while to figure out this section related to Table 1. Can you refer to Table 1 in the text here? Also, reorder the explanatory text to match table 1? i.e. fidelity, acceptability, adoption etc.

Authors' response: Thank you for this feedback. We have revised the manuscript to add additional references to Figure 1 (now Figure 2) and Table 1 in the section the reviewer has referred to and have reordered the text and table so that their orders are matching (Adoption, Appropriateness, Acceptability, Fidelity, Coverage, Feasibility, Sustainability, Implementation Cost). Please also see below:

Using this approach, every element of the model is written as an outcome and outcomes are connected. It shows the logical connections between inputs, outputs and outcomes using a type of 'if-then' logic. Figure 2 illustrates the model inputs and how effective programme delivery will be achieved if these inputs are sufficient.

There are three kinds of outcomes streams for StandingTall – (i) outcomes for participating organisations, which are expected to contribute to increased system capacity to support falls prevention; (ii) outcomes for study participants, which are expected to contribute to fewer falls among older people; and (iii) outcomes for health professionals, which are expected to contribute to more stakeholders recognising that exercise is key to falls prevention (Figure 2). Outcomes are categorised as short (3-6 months), medium (12 months) and longer term. Short-term outcomes relate to adoption, appropriateness, acceptability, fidelity and coverage (Table 1). Medium and long-term outcomes include

fewer falls among older people and increased system capacity to support falls prevention, and relate to feasibility, sustainability and implementation cost (Table 1).

VERSION 2 – REVIEW

REVIEWER	Pérez-Ros, Pilar Universidad Católica de Valencia San Vicente Mártir, Nursing
REVIEW RETURNED	16-Jun-2021

GENERAL COMMENTS	The authors have improved the manuscript and clarified the elicitation, assessment and analysis of outcomes.

REVIEWER	Taylor, Lynne The University of Auckland
REVIEW RETURNED	01-Jul-2021

GENERAL COMMENTS	Thankyou for revising the "Programme logic model" section and accompanying Table and figure. I find this much clearer. I have no further suggestions. All the best.