Author's response to reviews

Title: On Your Feet: Protocol for a Randomized Controlled Trial to compare the effects of pole walking and regular walking on physical and psychosocial health in older adults

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Author's response to reviews: see over
Dear Dr Pafitis,

We thank you for your interest in our paper and we are pleased to submit a revised version of our manuscript entitled: *On Your Feet: Protocol for a Randomised Controlled Trial to compare the effects of moderate intensity pole walking and regular walking on physical and psychosocial health in older adults.*

We have addressed the reviewer’s comments, and a detailed point-by-point response to each is given below. Changes in the revised manuscript are indicated using green highlighter. In addition to revisions based on reviewer’s comments, we have made some other minor revisions which are highlighted in yellow. This is because the study population changed from community-dwelling older adults, to older adults living in assisted living communities. These changes are clarified after our reply to the reviewers’ comments.

The authors have read and agreed to the content of the revised manuscript. There is no conflict of interest. Thank you for considering our revised manuscript; we are looking forward to your response.

Yours sincerely, on behalf of all authors,

Juliette Fritschi
Reviewer(s)' Comments to Author:
Changes in response to reviewer comments are highlighted in the manuscript in green. Other changes are highlighted in yellow.

Reviewer 1: Sylvia Titze

Reviewer's report:

Minor essential revisions

1. In the introduction the paper from Kukkonen-Harjula et al. (2007). Self-guided brisk walking training with or without poles: a randomized-controlled trial in middle-aged women. Scand J Med Sci Sports, 17, 316-323. should be included because they compared walking and pole walking groups and the age of the participating women was 50 to 60 years.

We have added this information to the Background section on p 5:

“These include middle aged, non-obese women, adults with type 2 diabetes, cardiovascular disease, peripheral artery disease, musculo-skeletal conditions, chronic obstructive pulmonary disease, Parkinson’s disease, Sjogren’s syndrome and breast cancer.”

2. Page 6: End of introduction: The variables in the last sentence are vague. The terms “functional fitness” or “physical function” and “physical activity as well as sitting” would be more informative.

We have changed the term “function” to “physical function” and behaviour to “physical activity and sitting time” throughout the paper. The sentence on p 6 now reads:

*Therefore, the aim of this trial is to compare the effects of PW with the effects of RW, on physical function, physical activity and sitting time, and wellbeing, in adults aged 65 years or over.*

3. Why is social support not part of wellbeing?

We agree with the reviewer that social support could be included as part of wellbeing. This measure has however, not been included in the study, as the participants are older adults living in assisted living facilities, rather than community-dwelling older adults. Social support was less relevant because almost all participants are residents of the assisted living facilities. Because of this, and to reduce participant burden, it was decided to no longer include this measure of social support in the study. This has been indicated in the revised manuscript using track changes.

4. Page 7, first paragraph. It is indicated that two of the questions are “phone questions”. If you call the participants why don’t you ask all the questions by telephone? Please clarify.
Thank you for pointing this out. All questions to participants were asked verbally during a face to face interview and the reference to the phone questions on page 7 has been removed.

5. Page 7, Randomization: Is there an age-limit or age range?

There is no upper limit for age. All participants must be over 65 years to be eligible. We have added a description of the inclusion criteria to the “Study sample and recruitment” section on p 7 to clarify the age range and the fact that the study was delivered in assisted care facilities:

“Inclusion criteria are: aged 65 years or older. Exclusion criteria include: medically unfit to participate in a walking program; unable to speak or understand English; having a shoulder or elbow flexion range of motion (ROM) of less than 90 degrees; and having pathological conditions of the upper extremity”

6. Page 9, first paragraph: Please also provide the figures of the metric system

We have added this information on p 9:

“….30-second arm-curl test (the number of times a 2.27 kg (5 lb) weight can be curled fully on the dominant side); 2.44 m (8 ft.) timed up and go test…”

7. Page 9, Behaviour: Please indicate whether the accelerometer will be worn: around the hip or the wrist.

We have added this information to the description of ‘Objectively measured PA and sedentary behaviour’ in the methods section on p 10:

“Participants will be shown by the lead researcher how to position the actigraph accelerometer, which will be worn on an elastic clip-on belt, above the left iliac crest.”

8. Page 10, Last sentence of “self reported PA”: Please indicate that the categorization is “per week”.

We have added this information on p 10:

“…and the sum of all MET.minutes per week is categorized as no PA, (<33), some PA (33-499), meeting PA guidelines (≥500-999), or high PA (≥1000).”

9. Page 11: One idea would be to make “social support” to become a sub-category of wellbeing.

Please see our response to comment no. 3.

10. Page 13, Discussion: Pain is a sub-category of wellbeing and should not be listed separately.

Instead of listing pain as a separate outcome measure, it has now been listed as a subcategory under ‘Wellbeing’ in the methods section. In addition, the subcategory, Hand grip, has been moved from the section on Function, to the section on Physical function under primary measures on p 9 in order
to be more consistent with the categorizations suggested. The section on Function has therefore been deleted.

11. Page 14, last paragraph: In the discussion it is unusual to raise a new topic which has not been introduced in the introduction. I suggest to already include a short paragraph about falls and poles making feel the older people safer with regard to falls.

Thank you for this comment. We have now introduced the topic of poles and balance in the Background section on p 4:

“The use of poles may provide extra stability for walkers and reduce falls or fear of falls. However, to our knowledge, no studies have measured balance and stability during PW.”

Spelling
1. Page 5, in the middle of the second paragraph: ...is more difficult for older people than Exerstriding.
2. Page 5, same line: ...Figard-Fabre et al. found... (full stop after "al"
3. Page 5, last paragraph: “psycho-social” or “psychosocial “ (e.g. abstract) please decide which spelling fits better.
4. Page 8, outcome measures: Shouldn’t it be “…behaviour “ # instead of behavioural (PA levels…)?
5. Page 14, second line and six lines below: Space before [50] and space before [8]

The spelling errors have been corrected as suggested.

Reviewer 2: Garry Tew

Reviewer's report:

Major compulsory revisions:

- Need to state a hypothesis before the methods section

We have added a hypothesis at the end of the Background section on p 6 as suggested:

‘The null hypothesis is that there is no difference in these outcomes between participants in the PW group and participants in the RW group.’

-The study is underpowered as the effect size on which the sample size is based is unrealistically large (20%). I think you will be lucky to see a within-group change from baseline in either group of >20%, let alone a difference in change of this magnitude. I appreciate that the absolute intensity of the training in the PW group may be higher than that of RW, but it is unlikely to be that much higher to induce marked differences in the training responses. It is also unclear exactly how you performed the sample size calculation as not all input parameters were provided (eg, what is the primary outcome and SD on which calculations are performed?). You will need to provide a better justification of the expected effect
size or reframe this as a preliminary pilot study. You will also need to be clearer in your description of the sample size calculations- to the extent that a reader could replicate them.

In order to compare the effects of a PW and a RW program on the primary outcomes, we feel it is critical to use a between group difference that is clinically relevant. For our main outcome measure, the Seniors Fitness Test, clinical relevance is defined as a change of >20%. The only other study comparing PW and RW in frail elderly used a 20% between group difference for the 6 Meter Walking Distance for sample size calculation (14). We based our calculations on normative values for 65-69 year old women for the arm curl test, sit to stand test, 6 minute walking distance test, and up and go test, of the Seniors Fitness Test. This was because it was felt that this would most likely be the most representative population. Using a standard sample size formula \( n=2[z^2s^2/\Delta^2] \), of those subtests, the greatest number of participants needed for a 20 % between group difference was for the arm curl test. We have added these details about the sample size calculation to the manuscript. This sample is not underpowered to detect a clinically relevant difference of 20%. However, the study will likely be underpowered to detect between group differences smaller than 20%. As differences in SFT score of <20% are not clinically relevant, they are of less interest in this study.

Further details are added to the description of Sample size on p 7:

“Sample size estimates were therefore based on the premise that the PW group would achieve changes at least 20% greater than those observed in the RW group, in selected measures of the Seniors Fitness Test (30-second chair-stand test, 30-second arm-curl test, timed up and go test, and a 6-minute walk test) (56). This difference is thought to be a clinically relevant difference in functional status (54). Of those subtests, the largest number of participants needed for a statistically significant 20% difference was for the arm curl test. Based on a 20% difference in normative data for women aged 65-69 years for the arm curl test (mean, 17, SD, 4.1), a power of 0.80 and significance of 0.05, and using the formula, \( n=2[z^2s^2/\Delta^2] \), we estimate that 23 participants per group would be needed to detect a between group difference of 20% (i.e. mean, 3, SD, 4.1) in the change score (54).”

- You need to provide more detail on the randomisation process. Who is responsible for conducting this? Is it simple randomisation or block randomisation? If simple, you wouldn't be guaranteed to end with 30 in each arm. Is it rolling recruitment or will you for example recruit the 15 required people at a given site and the randomise 1:1 for that site?

We have clarified the randomisation process in the methods section on p 8:

“After baseline assessment of eligible participants at one site, the lead researcher will notify an external researcher of the participant identification numbers. The external researcher will randomly assign 50% of the participants to the PW intervention and 50% to the RW intervention using a random number generator in SPSS and inform the lead researcher of group allocation. This process will be repeated for each site separately.”

- Accelerometer assessment: please provide details on how many participants will undergo these assessments, how long they will wear the devices for, what
counts as a valid wear (how many hours in a day), and what cut-offs will be used for classifying sedentary behaviour and other intensities of PA.

We have added this information to the description of ‘Objectively measured PA and sedentary behaviour’ in the methods section on p 10:

“A tri-axial accelerometer (ActiGraph GT3X+) will be used to assess levels of physical activity and sedentary behaviour in all participants in both the PW and the RW groups before, during (week 6), and at the end of the program (week 12). Participants will be shown by the lead researcher how to position the actigraph, which will be worn on an elastic clip-on belt, above the left iliac crest. Participants will be asked to put it on when they first get up in the morning and wear it until going to bed at night. In addition, participants will be asked to complete an activity diary to verify the time that the accelerometer was worn. Valid wear time will be defined as a minimum wear time of 10 hours per day for 4 days\textsuperscript{15,16}. Sedentary behavior will be defined as <200 cpm, light intensity activity as 200-2689 cpm, moderate intensity activity as 2690-6166 cpm, and vigorous intensity activity as >6167 cpm\textsuperscript{17,18}.”

- SF12: please reword so that it’s clear that only the physical and mental component summary scores can be obtained from the SF12, and not the 8 sub-domains that can be scored from the SF36.

This has been clarified in the methods section on page 11 as follows:

“Two summary scales will be derived, the physical and mental summary scales. They will be scored using norm based methods.”

- Intervention methods: need to state 3x/week for 12 weeks; what PA advice is provided for outside of sessions?; there’s no mention of how you will quantify the training load - you state the target RPE, but I suggest you record actual RPE and heart rate responses in both groups; I wonder if some people would be embarrassed to use walking poles in public - could you capture info on this some how?

We have added the frequency and PA advice to the description of Program duration, frequency and intensity in the Intervention section on p 12 as suggested:

“The exercise sessions will take place at outdoor areas adjacent to the facilities which are convenient to the participants. Program duration is 12 weeks, with a session frequency of 3 times per week. Session durations for the PW and the RW groups will be 20 minutes at the start of the program, increasing to 30 minutes by week 6. Participants will be advised not to change other lifestyle habits, including PA during participation in the program.”

We agree that recording RPE would be the ideal situation. However, due to cognitive impairments in many older people, it was felt that accurate feedback would be difficult to capture. Due to financial and logistical constraints, it is unfortunately not feasible to measure heart rate responses. As the majority of the participants are residents in aged care facilities, all walks are conducted in the grounds of the facilities, and thus the issue of public embarrassment is not relevant. We have added session attendance as a measure of program adherence.
- Analysis plan: overall is too simplistic - please provide more details; no need for statistics testing of group similarity in baseline characteristics - there’s several papers on this; what’s the primary analysis?; which covariates in the ANCOVA?

We disagree with the reviewer on the baseline characteristics. It is important to confirm that the randomisation works as intended. This section has been revised on p 14 as follows:

“To ensure that randomization resulted in equal distribution of sample characteristics in both intervention groups, baseline characteristics in the intervention and control groups will be compared using t-tests for normally distributed continuous data, appropriate non-parametric tests for non-normally distributed continuous data and chi square tests for categorical variables. Between group differences in study outcomes will be examined using repeated measures of covariance (ANCOVA), adjusted for significant between-group differences in baseline variables. Data will be analyzed using both intention to treat analysis, including all participants who were enrolled in the study and provided both baseline and follow up data, and per protocol analyses, including only participants who completed the program.”

- What procedures are there for trial management and recording and reporting of adverse events?

We have added these procedures to the description of Group structure and supervision on p13 as follows:

“The trial will be monitored by the study leader, who will visit each of the PW and RW groups once weekly to ensure compliance with study protocols. In the case of adverse events, instructors will contact facility medical staff who will arrange for onsite first aid or other intervention as appropriate. The medical staff will inform the study leader within 12 hours. The study leader will register adverse events with the University of Queensland ethics committee and within 48 hours.”

Discretionary revisions:
- Relating to a previous point, I seriously question how likely it is that you will observe appreciable changes in some of the outcomes. For example, do you really expect 30-a arm-curl performance and grip strength to really change in either group? Please comment.

Please see our response to reviewer comment on pp 4-5.

Other changes to manuscript

Other changes have been denoted in yellow highlighter as follows:

1/ Social support has been deleted from the manuscript as the population changed from being community based older adults, to primarily older adults living in assisted living communities.

2/ The intensity of the PW has been changed from moderate intensity, to comfortable intensity to reflect the population, who are generally more frail than the original intended population.