

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Counselling for physical activity, life-space mobility and falls prevention in old age (COSMOS): Protocol of a randomized controlled trial (ISRCTN65406039)
AUTHORS	Edgren, Johanna; Karinkanta, Saija; Rantanen, Taina; Daly, Robin; Kujala, Urho; Törmäkangas, Timo; Sievänen, Harri; Kannus, Pekka; Heinonen, Ari; Sipilä, Sarianna; Kannas, Lasse; Rantalainen, Timo; Teittinen, Outi; Nikander, R

VERSION 1 - REVIEW

REVIEWER	Dawn Mackey Associate Professor Biomedical Physiology and Kinesiology Simon Fraser University Canada
REVIEW RETURNED	05-Mar-2019

GENERAL COMMENTS	<p>Thank you for the opportunity to review this trial protocol.</p> <p>Life-space is an important measure of enacted mobility in older adults that is strongly associated with health outcomes. A considerable amount has been published on the predictors of life-space mobility. To my knowledge, very few interventions that increase life-space mobility in ambulatory older adults have been identified. Thus, there is good potential for positive impact from this study, as it seeks to identify whether a 24-month community-based health and physical activity (PA) counselling intervention leads to improvements in life-space mobility and a reduction in fall rates.</p> <p>The intervention has a unique service delivery model: community-based Health Kiosks and Service Centres in Finland. The intervention is comprised of individualized (1) health counselling that is based on a Finnish guide for preventing falls and fall-related injuries, and (2) PA counselling which involves demonstrations and prescriptions of strength and balance exercises from the evidence-based Otago Exercise Program, referrals to community exercise facilities, and a twice weekly walking prescription.</p> <p>The intervention is targeted and specific for fall prevention. I did not see intervention components that were specifically targeted to increasing life-space mobility (i.e., the extent, frequency, and</p>
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independence of one's daily movement). This leads to important questions that need to be clarified in the manuscript:

1. Why is life-space mobility a primary outcome?
2. What is the proposed mechanism by which the intervention may lead to increases in life-space mobility?
3. Previous intervention studies that have attempted to improve life-space mobility should be summarized in the Introduction.
4. Given the emphasis on PA counselling in the intervention design, why is PA a secondary rather than primary outcome?

Study Design:

Please describe the rationale for the 24-month follow-up. Did you consider a 6-month or 12-month follow-up in addition to or instead of a 24-month follow-up to detect early changes in outcomes after intervention end? My concern is that if outcome variables return to baseline levels by 24 months follow-up, you will not be able to characterize the trajectory of change after the intervention ends.

Outcomes:

Daily completed and monthly returned PA diaries for 24 months present a considerable burden to participants. What preliminary data do you have to suggest that they will be completed? If there are large degrees of missing data from the diaries, what will be the implications for the study, and what mitigation strategies exist?

Will all severities of fall injuries be included together in analyses? Will all injuries be treated equally? Hospital registers will be used to verify severe injuries; what defines a severe injury? I would like to see the different types of injuries specified in the manuscript.

Eligibility:

Please include what constitutes severe cardiovascular, severe pulmonary disease, and severe progressive disease?

For severe functional limitations, why did you choose inability to walk 500 m unaided, when inability to walk 400 m in 15 minutes is a standard definition of major mobility disability, e.g., used in the LIFE Study (Pahor M et al. JAMA 2014).

Screening:

Clarify which eligibility criteria will be assessed during the first phone call? The manuscript text about recruitment (page 8) does not map to the 3 recruitment phases illustrated in the study flow chart (Figure 1). Please make these align.

Intervention:

Participants are asked to exercise three times a week at home (for about 30 minutes per session) and go for a walk at least twice per week. Is there a prescribed walk duration? Participants also receive a referral from the physiotherapist for exercise at the local community facilities. Does this mean they are expected to do additional exercise on top of 2 walks and 3 home-based OEP sessions per week?

The 11 supportive telephone calls would also appear to provide an opportunity to address barriers to exercise that have come up for participants as they progress through the program. Clarify if this will be covered on calls.

	<p>Sample Size: The target sample size of 450 participants appears to be quite large (and possibly infeasible) given the stated size of Ylojarvi municipality of 32,000 residents. How many of the 32,000 residents are 65 years and older and not living in an institution? If a larger population is being drawn on from the surrounding Pirkanmaa District, the same question applies.</p> <p>Include the justification for powering the study to detect effect sizes of 10% (i.e., 10% decrease in rate of falls in INT and 10% in life-space mobility composite score in INT)? Kennedy RE et al. (J Am Geriatr Soc. 2018 Dec 7. doi: 10.1111/jgs.15707. PMID: 30536982) recently published on the minimal important change in the life-space assessment (5 point change in composite score). Consider citing that in your sample size section.</p> <p>Include the justification for estimated 30% participant attrition.</p> <p>Ethics and Dissemination: Will study results be disseminated to participants, and if so, how?</p> <p>Consider adding a paragraph to this section (to end the paper) to summarize the significance and potential implications and applications of this study.</p> <p>Minor Comments: Methods > Interventions (page 9). Clarify/re-write this sentence: "Both intervention programs will be updated to the next level during each face-to-face session."</p> <p>The manuscript is generally well-written, but there are some instances of awkward word choice and sentence structure that would benefit from editing.</p>
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REVIEWER	Juliana S Oliveira The University of Sydney, Australia
REVIEW RETURNED	11-Mar-2019

GENERAL COMMENTS	<p>This protocol describes the design of a randomized controlled trial (RCT) investigating the the effect of a health and PA counselling program on life-space mobility and falls rates in community-dwelling older adults. The manuscript is well written, the methodology is appropriate, clear outcomes, and minor issues need to be addressed.</p> <p>Introduction: - I found the introduction a little long and could flow better. At the moment the disablement process model is described in the first paragraph. Then another issue (falls) is described in the second paragraph. Perhaps the authors could establish a better link/connection between these two paragraphs? - Please spell out physical activity instead of using the acronym PA</p> <p>Methods: - Control group: I am not sure if the terms 'sham' and 'placebo' exercise intervention is appropriate to describe the relaxation exercise in the control group. Please review the use of these terms.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Dawn Mackey

Institution and Country: Associate Professor

Biomedical Physiology and Kinesiology

Simon Fraser University

Canada

Life-space is an important measure of enacted mobility in older adults that is strongly associated with health outcomes. A considerable amount has been published on the predictors of life-space mobility. To my knowledge, very few interventions that increase life-space mobility in ambulatory older adults have been identified. Thus, there is good potential for positive impact from this study, as it seeks to identify whether a 24-month community-based health and physical activity (PA) counselling intervention leads to improvements in life-space mobility and a reduction in fall rates.

The intervention has a unique service delivery model: community-based Health Kiosks and Service Centres in Finland. The intervention is comprised of individualized (1) health counselling that is based on a Finnish guide for preventing falls and fall-related injuries, and (2) PA counselling which involves demonstrations and prescriptions of strength and balance exercises from the evidence-based Otago Exercise Program, referrals to community exercise facilities, and a twice weekly walking prescription.

R: We thank Reviewer 1 for her interest concerning our manuscript as well as for the constructive comments and criticism, and accurate questions. Please, see our response to the comments and questions below.

1. The intervention is targeted and specific for fall prevention. I did not see intervention components that were specifically targeted to increasing life-space mobility (i.e., the extent, frequency, and independence of one's daily movement). This leads to important questions that need to be clarified in the manuscript:

1.1 Why is life-space mobility a primary outcome?

R: This study is a traditional falls prevention study (with a few novel aspects), which aims to detect impairments, functional limitations, disability and social isolation as a form of modern handicap according to international classification of functioning (ICF) and its interpretation. We feel that life-space mobility reflects old adult's ability for independent living with social participation. We try to reduce social isolation and we believe life-space mobility is a good primary outcome with falls rates and mechanism leading both of aforementioned. Very few interventions that increase life-space mobility in ambulatory older adults have been identified.

1.2 What is the proposed mechanism by which the intervention may lead to increases in life-space mobility?

R: We have described the vicious cycle of losing function in the beginning of our manuscript. We believe that our intervention improves participants' lower extremity muscle strength and balance, which support their perceived ability to move safely and reduce their fear of falls when being physically active. In addition, as a part of the physical activity intervention physiotherapist encourages participants to walk at least twice a week and increase the distance as well as the duration of their walks. Participants are also encouraged to attend community exercise facilities (e.g. gym, swimming, water aerobics, yoga, etc.) based on their own interests.

With increased physical activity and improved empowerment, we hope that our participants are encouraged to engage in different type of activities outside their home where they have more possibilities for social contacts than at home. We have clarified this proposed mechanism in the revised manuscript (page 5, lines 24-24).

1.3 Previous intervention studies that have attempted to improve life-space mobility should be summarized in the Introduction.

R: There is only one previous randomized controlled trial assessing the impact of a multifactorial intervention on life-space mobility as a primary outcome in older people (Fairhall et al. 2012). We have added the results of this study in the revised manuscript (page 5, lines 1-2).

Reference:

Fairhall et al. Effect of a multifactorial interdisciplinary intervention on mobility-related disability in frail older people: randomised controlled trial. *BMC Medicine* 2012;15(10):120.

1.4 Given the emphasis on PA counselling in the intervention design, why is PA a secondary rather than primary outcome?

R: Please, see our answer to the question 1.2 above. To clarify, we think that PA is an important but not only factor (e.g. transportation can be utilized) to increase life-space mobility. With our practical trial, we aim to societal impact and we feel that increased life-space mobility with fewer falls would describe well both benefits and adverse effects of a successful real-life exercise and physical activity intervention for old adults with early-phase limitations.

2. Study Design:

Please describe the rationale for the 24-month follow-up. Did you consider a 6-month or 12-month follow-up in addition to or instead of a 24-month follow-up to detect early changes in outcomes after intervention end? My concern is that if outcome variables return to baseline levels by 24-month follow-up, you will not be able to characterize the trajectory of change after the intervention ends.

R: This is a valid point. The primary rationale for the 24-month follow-up is to evaluate the long-term effects of the intervention to determine if any of the benefits can be sustained over time. It indeed would be valuable to detect potential short-term changes even during the first year of the intervention (3- or 6-month measurements). However, several measurements for 450 old adults (who need their time for each measurement) in a real-life environment with limited resources restricted our options.

3. Outcomes:

3.1. Daily completed and monthly returned PA diaries for 24 months present a considerable burden to participants. What preliminary data do you have to suggest that they will be completed?

R: We agree, that monthly returned PA diaries for 24 months is a moderate burden to participants. However, detailed information on long-term adherence rates and knowledge of potential dose-response relationship will be of importance, if we succeed and an effective Health Kiosk concept with Service Center environment will be implemented and the concept disseminated to public in Finland. E.g. In our previous Chaos Clinic trial, the dropout rate was only 13 % despite the fact that these persons were 70 years old or older and at high risk for falls and related injuries (Palvanen et al. 2014). Moreover, adherence to the previous intervention was good in general.

Additionally, a recent study by Fairhall et al. (2012) points out, that future research examining the effects of multi-component interventions on life-space mobility should include a longer follow-up period (+12 months) to determine if the benefits of the intervention are maintained after 12 months.

References:

Palvanen M et al. Effectiveness of the Chaos Falls Clinic in preventing falls and injuries of home-dwelling older adults: A randomised controlled trial. *Injury* 2014;45(1):265-71.

Fairhall N et al. Effect of a multifactorial interdisciplinary intervention on mobility-related disability in frail older people: randomised controlled trial. *BMC Medicine* 2012;10:120.

3.2. If there are large degrees of missing data from the diaries, what will be the implications for the study, and what mitigation strategies exist?

R: If there are large degrees of missing data from the diaries, this will have to be taken into account in statistical analysis. Depending on the degree and generating mechanism of missing data, we will consider accounting for missing responses by imputation or applying maximum likelihood approaches accounting for missing observations. This is clarified in the Statistics section of the manuscript (page 17, line 5-7).

3.3. Falls and injuries:

3.3.1. Will all severities of fall injuries be included together in analyses?

R: We thank the Reviewer for this elaborative question. The final classification of fall injuries is possible to complete only until the data is collected since we do not know what kind of injuries and how many of each there will be in advance. However, we have planned to categorize the fall-induced injuries as follows: 1) soft tissue bruises and contusions, 2) wounds and lacerations, 3) bone fractures, 4) joint distortions and dislocations, 5) head injuries other than fractures, and 6) other injuries. Similar classification has been utilized in a previous Chaos Clinic study (Palvanen et al. 2014). Additionally, all injuries will be categorized based on medical contact and/or treatment. We have also added this information to our revised manuscript (page 13, lines 27-30).

Reference:

Palvanen M et al. Effectiveness of the Chaos Falls Clinic in preventing falls and injuries of home-dwelling older adults: A randomised controlled trial. *Injury* 2014; 45(1):265-71.

3.3.2. Will all injuries be treated equally?

R: Please, see our answer above (3.3.1).

3.3.3. Hospital registers will be used to verify severe injuries; what defines a severe injury?

R: We define severe injury as a fracture or head injury. We have clarified this the in the revised manuscript (page 13, line 26).

3.3.4. I would like to see the different types of injuries specified in the manuscript.

R: We have added the classification plan of different types of injuries to the revised manuscript (page 13, lines 27-30).

4. Eligibility:

4.1. Please include what constitutes severe cardiovascular, severe pulmonary disease, and severe progressive disease?

R: By severe cardiovascular and severe pulmonary disease we mean conditions which are currently either unstable or contraindications for physical exercise and/or need immediate medical attention. In addition, during baseline assessments a research nurse assesses cardiovascular condition based on NYHA classification by the New York Heart Association (NYHA). If NYHA class is IV "Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients", the person is excluded and referred to a physician. By severe progressive disease, we mean conditions such as neoplasm and amyotrophic lateral sclerosis (ALS), which have poor prognosis and presumably poor response or no response to physical exercise. We have clarified this in the revised manuscript (page 7, lines 12-16).

4.2. For severe functional limitations, why did you choose inability to walk 500 m unaided, when inability to walk 400 m in 15 minutes is a standard definition of major mobility disability, e.g., used in the LIFE Study (Pahor M et al. JAMA 2014).

R: We used inability to walk 500 m unaided as a definition of severe functional limitations as sake of consistency between our trials. It is a simple self-report screening method and does not require testing of physical performance. We have used it also in our previous studies ProMo (Sipilä et al. 2011). In our opinion, it is a feasible and suitable screening method for our purposes.

Reference:

Sipilä S et al. Promoting mobility after hip fracture (ProMo): study protocol and selected baseline results of a year-long randomized controlled trial among community-dwelling older people. *BMC Musculoskeletal Disorders* 2011;12(7):277.

5. Screening:

5.1. Clarify which eligibility criteria will be assessed during the first phone call?

R: Three of the eligibility criteria's will be assessed during the first phone call i.e. age, living arrangements, and place of residence. We have clarified this in the revised manuscript (page 7, lines 21-22).

5.2. The manuscript text about recruitment (page 8) does not map to the 3 recruitment phases illustrated in the study flow chart (Figure 1). Please make these align.

R: We thank reviewer for this notification. We have modified the third recruitment phase illustrated in the study flow chart (Figure 1) to match with the manuscript text about recruitment (page 7, lines 18-28).

6. Intervention:

6.1. Participants are asked to exercise three times a week at home (for about 30 minutes per session) and go for a walk at least twice per week. Is there a prescribed walk duration?

R: Participants are instructed to walk at least twice a week for 30 minutes. Walking exercise can also be broken into smaller periods e.g. three ten-minute blocks. We have clarified this in the manuscript (page , lines 24-25).

6.2. Participants also receive a referral from the physiotherapist for exercise at the local community facilities. Does this mean they are expected to do additional exercise on top of 2 walks and 3 home-based OEP sessions per week?

R: This is a good elaborative question. When participants receive a referral for exercise, a physiotherapist will instruct him/her to replace one of the weekly Otago, COSMOS or walking exercises with corresponding exercise. For instance, participant may replace the Otago strength exercise with gym training or by attending a strength-training group. Correspondingly, participant may replace Otago balance exercise with yoga, Pilates, Tai Chi, or other guided balance exercise. Walking exercises can also be replaced e.g. with swimming or 6-12).

7. The 11 supportive telephone calls would also appear to provide an opportunity to address barriers to exercise that have come up for participants as they progress through the program. Clarify if this will be covered on calls.

R: We thank the reviewer for this notification. The barriers to exercise that have come up for participants will be addressed during supportive telephone calls. We have clarified this in the revised manuscript as suggested (page 11, lines 16-17).

8. Sample Size:

8.1. The target sample size of 450 participants appears to be quite large (and possibly infeasible) given the stated size of Ylojarvi municipality of 32,000 residents. How many of the 32,000 residents are 65 years and older and not living in an institution? If a larger population is being drawn on from the surrounding Pirkanmaa District, the same question applies.

R: This is an important comment. We did not use population base statistics when planning the trial. However, we utilized information from two reports concerning the health Kiosk of Lahti (other city in Finland) and Ylöjärvi (Kork A-A et al. 2011, Kork A-A & Vakkuri J. 2013). Based on these two reports, we know that the Health Kiosk has the capacity to reach 10,000 people annually of whom 5,000 have aged 70 years and over.

However, we now also searched information about population statistics in Ylöjärvi: 5,937 (18%) of the 32,983 residents of Ylöjärvi were 65 years and older in 2018 (Statistics Finland's PX-Web databases). Of them, 5,343 (97%) were not living in an institution. In the surrounding Pirkanmaa District, 108,170 (21%) of the 515,095 residents were 65 years and older in 2018 (Statistics Finland's PX-Web databases).

Now, we have done baseline assessments of 392 participants and have approximately 40 participants on our waiting list. Thus, the sample size of 450 participants is feasible to us. Even though, we have limited funding and number of recruited participants will be looked against our lower than expected dropout rate when final decisions will be made.

References:

Kork A-A et al. 2011. Terveyskioski palveluinnovaationa. Lahden terveystioski- hankkeen väliarviointi (Vaihe II). Sitran selvityksiä 55. Helsinki (in Finnish);

Kork A-A & Vakkuri J. 2013. Matalan kynnyksen palvelumalli perusturvan palvelualueella. Ylöjärven terveystioskin jatkotutkimus.
http://www.sitra.fi/julkaisut/muut/Matalan_kynnyksen_palvelumalli_perusturvan_palvelualueella.pdf (in Finnish)

Statistics Finland's PX-Web databases,
https://pxnet2.stat.fi/PXWeb/pxweb/en/Kuntien_avainluvut/?rxid=444223df-f91c-4479-891f-5dcd50b983d2

8.2. Include the justification for powering the study to detect effect sizes of 10% (i.e., 10% decrease in rate of falls in INT and 10% in life-space mobility composite score in INT)? Kennedy RE et al. (J Am Geriatr Soc. 2018 Dec 7. doi: 10.1111/jgs.15707. PMID: 30536982) recently published on the minimal important change in the life-space assessment (5-point change in composite score). Consider citing that in your sample size section.

R: We thank the reviewer for this notice and suggestion. We have based the power calculations of our present study on the results of two previous studies carried out by our own research group (Rantanen T et al. 2012, Palvanen M et al. 2014). We have described the justification for power calculations in detail in the Statistical methods section of the manuscript (page 15, lines 11-32). The power calculations for the present COSMOS study have been carried out in 2014 already. Thus, we have not been able to utilize the information from the study by Kennedy RE et al. published in 2018. However, we thank reviewer for pointing out this study and we will refer to it in the discussion section in our forthcoming publication reporting the effects of the COSMOS trial.

References:

Palvanen M et al. Effectiveness of the Chaos Falls Clinic in preventing falls and injuries of home-dwelling older adults: a randomized controlled trial. *Injury* 2014;45(1):265-71.

Rantanen T et al. Individual and environmental factors underlying life space of older people- study protocol and design of a cohort study on life-space mobility in old age (LISPE). BMC Public Health 2012;12:1018.

8.3. Include the justification for estimated 30% participant attrition.

R: Our previous Chaos Clinic intervention included an extensive battery of health related testing including physician's appointment and dropout rate was approximately 15 % (Palvanen et al. 2014). In the present COSMOS trial, we did not have physician's appointment neither extensive health measurements such as DXA, which could draw people to participate. In addition, for majority of the participants, participation involved travelling across the Pirkanmaa District (distances were even 100 km in each direction), and travelling costs were not covered and transportation was not arranged by COSMOS. Thus, we decided to have a conservative power calculation including attrition rate and between-group differences. We agree that this may have been conservative but given the community-based and long-term nature of this trial wanted to ensure it was adequately powered. However, we have clarified this in the manuscript (page 15, lines 28-32).

Reference:

Palvanen M et al. Effectiveness of the Chaos Falls Clinic in preventing falls and injuries of home-dwelling older adults: a randomized controlled trial. Injury 2014;45(1):265-71.

9. Ethics and Dissemination:

9.1. Will study results be disseminated to participants, and if so, how?

R: Yes. The study results will be disseminated to the participants. We have planned to organize at least two information sessions to all study participants when data of the primary outcomes has been analysed. We have clarified this in the manuscript (page 18, lines 12-14).

9.2. Consider adding a paragraph to this section (to end the paper) to summarize the significance and potential implications and applications of this study.

R: We added a paragraph, which summarizes the significance and potential implications of the study to Ethics and Dissemination section (page 18, lines 15-24).

10. Minor Comments:

10.2. Methods > Interventions (page 9). Clarify/re-write this sentence: "Both intervention programs will be updated to the next level during each face-to-face session."

R: We have re-written the sentence (page 8, lines 30-31).

10.3. The manuscript is generally well-written, but there are some instances of awkward word choice and sentence structure that would benefit from editing.

R: We have used our native author's help in revision process and hope that the language is also fluent for native readers.

Reviewer: 2

Reviewer Name: Juliana S Oliveira

Institution and Country: The University of Sydney, Australia

This protocol describes the design of a randomized controlled trial (RCT) investigating the effect of a health and PA counselling program on life-space mobility and falls rates in community-dwelling older adults. The manuscript is well written, the methodology is appropriate, clear outcomes, and minor issues need to be addressed.

R: We thank Reviewer 2 for her positive comments and help in improving the manuscript. Please, see our point-by-point responses below.

1. Introduction:

1.1 I found the introduction a little long and could flow better. At the moment the disablement process model is described in the first paragraph. Then another issue (falls) is described in the second paragraph. Perhaps the authors could establish a better link/connection between these two paragraphs?

R: We thank reviewer for her suggestion. We have shortened our introduction a bit, and tried to connect paragraphs together better. We hope that the disablement process from health impairments until social isolation have now better opened up (please, see the Introduction section, pages 4-5).

1.2 Please spell out physical activity instead of using the acronym PA

R: We have spelled out physical activity instead of using the acronym PA.

2. Methods:

Control group: I am not sure if the terms 'sham' and 'placebo' exercise intervention is appropriate to describe the relaxation exercise in the control group. Please review the use of these terms.

R: We felt that readers of BMJ Open might be familiar with these terms typical for medicine. However, we have changed the terminology and now use terms "relaxation group" and "control intervention" instead of "placebo" or "sham" exercise.

VERSION 2 – REVIEW

REVIEWER	Dawn Mackey Associate Professor Department of Biomedical Physiology and Kinesiology Simon Fraser University Canada
REVIEW RETURNED	02-Jul-2019

GENERAL COMMENTS	<p>The authors provided thorough and appropriate responses to my comments, and they updated the manuscript in important ways such that the revised version of the manuscript (R1) is improved.</p> <p>I still have concerns about the specificity of the intervention for the primary outcome of life-space mobility. It could turn out that the 'falls prevention' style of the intervention leads to improvements in physical activity and reductions in falls with no corresponding increase in life-space mobility (e.g., if participants do not increase the extent or independence of their daily movement). This is something for the authors to keep in mind when interpreting the eventual results of the study.</p> <p>I also still have concerns about the potential large degree of missing data from the daily-completed, monthly-returned physical activity diaries for 24 months. This may limit the ability to detect potential dose-response relationships and to quantify long-term adherence. Again, these are possible issues for the authors to consider when interpreting the study results.</p> <p>Finally, the authors may wish to update Figure 1, as the control group is still labeled as "Sham exercise group."</p> <p>Good luck with the study, I look forward to following its progress in the future.</p>
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REVIEWER	Juliana S Oliveira The University of Sydney, Australia
REVIEW RETURNED	13-Jun-2019

GENERAL COMMENTS	My few concerns have been addressed by authors.
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 2

Reviewer Name: Juliana S Oliveira

Institution and Country: The University of Sydney, Australia

Please state any competing interests or state 'None declared': None declared

1. My few concerns have been addressed by authors.

R: We thank Reviewer 2 for her earlier constructive comments and are glad that she is pleased with our revision.

Reviewer: 1

Reviewer Name: Dawn Mackey

Institution and Country:

Associate Professor

Department of Biomedical Physiology and Kinesiology

Simon Fraser University

Canada

Please state any competing interests or state 'None declared': None declared

1. The authors provided thorough and appropriate responses to my comments, and they updated the manuscript in important ways such that the revised version of the manuscript (R1) is improved.

R: We thank Reviewer 1 for her earlier constructive comments and are glad that she is pleased with our answers and our revised version of the manuscript.

2. I still have concerns about the specificity of the intervention for the primary outcome of life-space mobility. It could turn out that the 'falls prevention' style of the intervention leads to improvements in physical activity and reductions in falls with no corresponding increase in life-space mobility (e.g., if participants do not increase the extent or independence of their daily movement). This is something for the authors to keep in mind when interpreting the eventual results of the study.

R: We thank Reviewer 1 for her interest concerning our manuscript as well as for the constructive comments and criticism, and accurate observations. We will keep these in mind when interpreting the eventual results of the study.

3. I also still have concerns about the potential large degree of missing data from the daily-completed, monthly-returned physical activity diaries for 24 months. This may limit the ability to detect potential dose-response relationships and to quantify long-term adherence. Again, these are possible issues for the authors to consider when interpreting the study results.

R: We will keep also this matter in mind when interpreting the eventual results of the study.

4. Finally, the authors may wish to update Figure 1, as the control group is still labelled as "Sham exercise group."

R: We thank Reviewer 1 for this notification. We have updated the terminology used in the Figure 1.

5. Good luck with the study, I look forward to following its progress in the future.

R: Thank you. We are also eager to interpret and report the results of the study.