PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK pragmatic hybrid effectiveness-implementation type 1 randomised controlled trial
AUTHORS	Hassett, Leanne; Tiedemann, Anne; Hinman, Rana S.; Crotty, Maria; Hoffmann, Tammy; Harvey, Lisa; Taylor, Nicholas; Greaves, Colin; Treacy, Daniel; Jennings, Matthew; Milat, Andrew; Bennell, Kim; Howard, Kirsten; van den Berg, Maayken; Pinheiro, Marina; Wong, Siobhan; Kirkham, Catherine; Ramsay, Elizabeth; O'Rourke, Sandra; Sherrington, Catherine

VERSION 1 – REVIEW

REVIEWER	Prof.dr. M.W.G. Nijhuis-van der Sanden Radboud university medical center Research Insttitute for Health Sciences IQ Healthcare 114 PO Box 9101^6500 HB Nijmegen The Netherlands
REVIEW RETURNED	20-Oct-2019

GENERAL COMMENTS	The target group of this study is: adults with self-reported mobility limitations (n=600). Study design: randomized controlled trial with three arms: a) enhanced 6-months intervention package; b) less intensive intervention package and c) waiting list control group (receiving intervention b after 6 months). Comparison: a-b, a-c and b-c, 6 months after randomization. Primary outcome: average steps per day, measured with the StepWatch activity monitor over a one-week period. Secondary outcomes: physical activity measures, difficulty walking, overall function and disability, individualised mobility goal attainment, mental wellbeing, quality of life Cost-effectiveness and cost-utility of the interventions compared to no intervention and to each other and a process evaluation (published elsewhere). In general: this is an interesting relevant study, however I needed some time to get a correct overview on the study design, and I need to say that the research protocol as provided in the appendix was

	more clear for me. So I will provide some suggestions to increase the readability for readers, not aware of your previous research and experience. I used The SPIRIT as guidance. **General remarks:** My first question is why do the authors mention this trial a pragmatic trial: what do they mean ? Moreover, this is a randomized controlled trial which is not consistently mentioned see for instance line 22 abstract. Be consistent in the total paper. Another important point is the trial period: In the article it is mentioned that the first inclusion was February 2019, in the appendix 2018 is mentioned. Moreover there are 50 participants included between February and October (600/50 = 12), so this would mean an inclusion period of 8 years. As mentioned in the protocol (appendix) inclusion over 30 months was planned so this would mean an inclusion in 8 months of 160 participants. So it is really important to mention the study period (started later?) and strategies to guarantee the recruitment and inclusion. This because the study will loose a lot of power if the n= 600 is not reached. I wondered if a short discussion part with some reflection on the choices made by the research team would be helpful to make these choices more transparent (for instance not measuring the performance measures like strengths, aerobic fitness etc or why not using the step watch at 12 months, or why including the General Practioner, what is expected of the involvement). **Title:** It would be more clear in the title to describe the target population as adults with self-reported or identified mobility limitations, see inclusion criteria and inclusion procedure. **Abstract**: In the introduction the involvement of physical therapist is mentioned but not the central coordinated health coach. Is this always a physiotherapist? And the aim/objective of the study is not mentioned. In the methods section the design is not clear, please provide the measurement time points, the recruitment of the participants, the duration of the waiting list period, and target population. The primary outcome is measures at baseline and 6 months? The secondary outcomes are mentioned in a list without any connection for the reader to the research question and the measurement time points. Some seem to be related to physical activity outcome and maintenance at 12 months, some related to the costs calculation etc, please order this in an understandable way. **Strengths and limitations:** It is important to include the target population in this part and some information why this is a pragmatic evaluation. Moreover, it would be nice to get transparent the contrast between intervention a and b, what is the strengths (or limitation) of the 3-arm trial? Why do you mention this intervention multidisciplinary? For me the

	involved disciplines are not transparent. Moreover, the developmental process of the intervention is not described in the introduction. And why do you mention the 6 month time frame while the a and b group are also measured at 12 months… **Introduction** In the introduction it is clearly explained Why physical activity in the chosen target group is important. In sentences 54-57 , page 4 it is explained that aerobic capacity etc increase, but this is not measured in the trial so may be better to focus on the outcomes as measured in this study. From line 39 page 5 I recognized the behavioral change model as mentioned in the TIDieR, COM-B. The use of the Behavioral change strategies and the choices made between these theories should be more clearly described in the introduction to recognize the elements in the intervention: like motivation, goal-setting etc. Now the reader needs to find them in the TIDieR. Another important point is the rationale why to include a Physiotherapist (PT) (line 58, page 5). What will the PT do in the first assessment and which information will be added to the advises? For instance specific training (fitness or strengths or…) and how will this be integrated in the coaching procedure and activity tailoring. This is not clearly described. And how can this be done by a telephone assessment? In which way is this comparable or not to the physical assessment at home. At page 6 line 8, it is stated that the intervention packages are developed in consultation: It needs a little bit more explanation about this trajectory and which steps were undertaken (see for instance the MRC frame work. Was there already some pilot testing ? The interventions a and b are the result of the developmental process as described above. So it would be logical to present table 1 with both interventions here. This makes the readability of the study better. Moreover, table 1 needs a better presentation to get insight in the differences and similarities in both intervention strategies related to the theoretical framework. Reading the appendices I had a lot of questions in table 1 and then I found the TIDieR description that was really much more transparent so I suggest to use this table to describe both interventions. Therefore I will not sent the comments to table 1 (much more than to the TIDieR table). Related to this TIDieR I have some remarks: The *What procedures row* 1: where is the assessment in intervention a performed, by which PT and what do you mean with a handover if possible??? Moreover for me it is not clear if the coaching will be done by the intake PT or the central PT? and if so how do you prevent contamination between both interventions a and b if these are delivered by the same central PT? Moreover, it seems to me more logical to present the development of tailored intervention directly after the intake , because the monitoring is focused on this plan. In the *WHAT materials row* you mention in intervention 2 that each participant needs a mobile phone for the messages etc, but this is the same for intervention 1 I guess, because in this intervention also

	activity apps etc are used. Please provide before the hypothesis formulation the objectives/research questions of the study and include also the cost-effectiveness and cost-utility as second research objective. Moreover, it would be nice to deepen the contrast between the intervention a and b in your hypotheses. Which factors are responsible for the contrast and influence the better outcome? And do you expect that the lower costs will lead to comparable cost-effectiveness? **Methods section** Please start this section with a clear explanation of the trial design including type of trial, the subgroups, allocation ratio, randomization procedure, and framework. The start and end of the inclusion, the measurement time points and the combination of effectiveness and costs utility analysis. The readability will be increased if you already described the intervention a and b as suggested above, the description of i) etc can be shortened. At page 8 line 3-17 should be described after the second aim of this study as described in line 17-24. Moreover, it would be helpful to present the implementation procedure and recruitment methods in the paper. Here I read you will evaluate these separately however, for the trial design we need insight in these procedures. In line 24 you introduce figure 1 as describing the overall logic of the study. I am sorry to say that this figure was not very logical for me: in the intervention components I would expect the elements contrasting the interventions, which are not clearly described, moreover, there is information in this figure which I miss in the text, like the patient characteristics, staff training etc, the short term outcomes are not ordered by timepoints and the long-term outcomes are included in the figure but not part of the study. Moreover, I find some information in the feedback loops which should have mentioned in the hypothesis (eg. Therapeutic relationship as facilitator or moderator). So I suggest to skip this figure and include some info in the TIDieR and add the figure 6.1 flowchart of the study included in the study protocol which is much more transparent. The information on the inclusion should be part of the design see before. See also the question about the status of recruitment (50 instead of 160). **Participants:** Please start this section with some information on the study setting, where participants are recruited/invited. Were their also eligibility criteria for the participating centres? The in-and exclusion criteria are clear, however I miss information on the recruitment and enrollment procedures. When potential participants are interested what happens then? I found the information in the study protocol fig 6.2 this needs to be added in the protocol article. **Assessments/outcomes** For me this was a confusing part in the protocol study: firstly it

	appeared that there were outcomes mentioned that were not mentioned in the assessment protocol. So I found it quite difficult to get an overview on WHAT was measured at WHICH time point, HOW and WHY (what I mean is to answer which research question). So I would prefer a table with time points and primary and secondary outcomes and which of the measurements are used as background info (eg characteristics of the participants), which are used as effect outcomes and which as effect modifiers and which are used for the cost evaluation. See table 3 and 4 in the provided protocol. These were much more transparent for me. If you describe the StepWatch Activity Monitor: can you provide some more information on the pale participant wear this activator? Day and Night? Because this is the primary outcome it is important to get some details. What needs to be added is the measurement procedure and who performed the measures. Moreover, the other measures page 9, line 44), are these related to the effectiveness study or related to the process evaluation which is described elsewhere? I would suggest to only describe the measurements you will use in this study and later on in describing the results. If you include these in the analyses (eg PACES and WAI as modifiers) then it is okay to include them. But for each measure included it should also be described for which research question it will be used in the statistical analysis. **Intervention** See remarks before. What needs to be described more clearly is who is involved in the intervention. Which professional is doing what during recruitment, inclusion and delivery of the intervention. And what I miss is a transparent overview which activities were performed by whom during the implementation of the intervention. Were there eligibility criteria for the providers/PTs? Were the PT's at the centers trained in Motivational interviewing and coaching? Were the PT's trained to perform a telephone interview and to develop a tailored health intervention? Which aspects in the interview/ cq physical assessment guided their decisions on the goals, and training exercises. Who is involved in the text messages and role modeling video's? How is the website introduced to both the coaches and the participants, are the coaches trained and informed about the possibilities of the website. Apps etc. So please describe the implementation and which strategies will be used if the recruitment or adherence is not as expected. At page 14 line 31 the involvement of patients and public is described. You emphasize the role in the development of the intervention, however is there also a role in the recruitment phase, the evaluation phase and the interpretation of the findings: so in the trial itself.

	Sample size and statistical analysis: The sample size calculation seems appropriate, however, the number of 600 is rather ambitious. The statistical analysis is straight forward, however, the subgroup analysis on age and severity of mobility limitation seems to be related and I guess this will be the self-reported limitation, please add this information. The secondary analysis focusses on the effect of adherence. For me it is not clear how adherence will be defined because of the different factors in the intervention like using activity apps, visiting the website, visiting the video models etc etc how is adherence defined to perform these analyses? Moreover, I miss information on handling missing data and do not understand what is mentioned with range checks? **Ethics and dissemination** I miss some information on the informed consent procedure, the anonymization of data, and the data protocol. It is described that all authors have full access to the data, but I hope to the anonymized data? I read dissemination to the international public but are there plans to communicate trial results to participants, other healthcare professionals, and the target group ? And when? Is the data base als available to other researches or the public after the publication of the own research? **Author contributions** The Role of the authors related to their background would provide some more insight. For instance was a statistician involved in the study? How is the composition, roles, and responsibilities of the coordinating centre? Who are involved in a steering committee? Who is involved in the data management team, and other individuals or groups overseeing the trial? Who are responsible for the education of the providers of the intervention? And who is responsible to monitor the progress of the study?

REVIEWER	Amal A. Wanigatunga Johns Hopkins Bloomberg School of Public Health, USA
REVIEW RETURNED	15-Jan-2020

GENERAL COMMENTS	The authors present a study protocol for a single blinded, two intervention (versus comparison group) study primarily aimed to increase walking steps per day in those with mobility limitations. Overall, I believe the protocol is generally well-written but there is need to review for grammar. Comments by section are detailed below: Abstract -In the introduction, mobility limitation is not disability in it of itself – disability is mobility limitations in social context. See two references below:

	Nagi SZ. Some conceptual issues in disability and rehabilitation. In: Sussman MB, editor. Sociology and rehabilitation. Washington, DC: American Sociological Association; 1965. World Health Organization. The International Classification of Impairments, Disabilities, and Handicaps—a manual relating to the consequences of disease. Geneva: World Health Organization; 1980. -The method section is worded a bit awkwardly as the outcome is presented first before the intervention details. Could this be written more clearly? Strengths and limitations – -One limitation is that recruitment is based on self-reported mobility limitation and mobility limitations are not directly observed or standardized (e.g., using a performance test). Introduction -Same comment as abstract introduction on the mobility limitation versus disability. Mobility limitations put persons at HIGH risk for mobility disability (e.g., dismobility) or major mobility disability. To me, the rationale should be around this point. The interventions examined will try to put persons away from being at high risk for dismobility (high enough walking impairment that affects social involvement). -The LIFE study should be referenced for reference 12 (https://jamanetwork.com/journals/jama/fullarticle/1875328). The current reference in reference 12 slot is not the actual reference. As a side note, the LIFE study reference has a similar rationale to your study – recruit those with mobility limitations and infuse physical activity into daily lifestyles to protect against transitioning into disability states. Methods and analysis -Under Randomization, the group allocation for stratification is not clear. Please provide more detail into how randomization for group allocation is stratified. -Under Assessments, it is not clear how the ankle devices are returned to study staff. -Under Assessments, it is not clear how “data for all outcomes will be collected for those who cease to participate, where possible”? Please provide 1-2 sentences explaining how. -I find the adverse event section a bit lacking. There are other adverse events that may occur without hospitalization but may be potentially serious (e.g., angina, shortness of breath long after exercise). Also, it would be helpful if the authors can succinctly address how the study deals with exercise effects on muscle (e.g., soreness) and other discomforts. Some of these details can be drawn from the actual protocol provided. -Under Interventions, the authors took care to explain the step activity monitor does not provide feedback to the participant, yet the six-component intervention provides either a FitBit or pedometer to capture and provide feedback on steps/day to the participant. This is very confusing and requires detailed explanation on how this affects or does not affect primary outcome (average steps/day), especially since the texting intervention not the waiting list comparison arm do not offer these electronic devices. -There seems to be no mention of adherence and compliance and related evaluation metrics. I do see a small mention of adherence in

	the actual study protocol (not in the manuscript) but not in the manuscript. Can the authors add a description on how adherence and compliance are evaluated?

REVIEWER	Dawn Mackey Simon Fraser University Canada
REVIEW RETURNED	20-Feb-2020

GENERAL COMMENTS	This is a thoroughly described and well-written study protocol for the ComeBACK trial. I appreciate the opportunity to review it and make constructive suggestions for further improvement. The ComeBACK intervention aims to increase physical activity among adults with self-reported mobility limitation through a physiotherapist-led package. The 3-arm trial (n=600) will compare effects on objectively-measured physical activity of an enhanced 6-month intervention package, a less intensive 6-month intervention package, and no intervention (wait-list control). As appropriate, the authors followed reporting recommendations for trial protocols, for instance by describing the intervention using the TIDieR format. Consistent with this being a study protocol, my comments focus on clarity of the reporting. Major Comments I like that the authors acknowledge the importance of scalability and state that they have designed the intervention with scalability in mind. I wonder, however, about the scalability of interventions delivered by physiotherapists, mostly because of cost considerations but also because of access considerations in rural and remote areas. Can you address this, from an Australian context, in the paper? Are health care providers normally paying for physiotherapist-led programs for community members? Have physiotherapist-led exercise programs been shown to be cost-effective, even if for different target populations? Recognizing the complexity of exercise prescription and behaviour change among adults with mobility limitations, would other allied health professionals such as Kinesiologists or Exercise Physiologists be suitable for delivering the program? Consultations with consumers, clinicians, and policy makers are mentioned a few times throughout the paper (e.g., Abstract, page 2; Introduction, page 6; Methods, Interventions, page 10). Please describe these consultations in greater detail. Were separate consultations held with each group? How many people participated in each group? How were people recruited for the consultations. What were the guiding questions asked and addressed at each consultation? Minor Comments Abstract Add “for adults with self-reported mobility limitations” to the end of the sentence, “In consultation with consumers, clinicians, and policy makers, we have developed two affordable and scalable intervention packages designed to enhance physical activity.” Strengths and limitations of this study

	Suggest revising the first bullet point to be more specific: “Addressing the important and growing health problem of mobility limitation.” Introduction Page 4, third para, last sentence. Please include the magnitude of step count increase that was associated with reduced risk of mortality from ref #8. Methods and Analysis Overview, page 6. Please describe the features of the trial that make it pragmatic, with appropriate references to trials methods literature. Overview, page 7. It’s a strength that the study design is a hybrid design (Type I) to capitalize on the opportunity to collect preliminary information about implementation outcomes. It is stated in the paper that the protocol for the nested process evaluation will be described elsewhere. However, I would like to see a few things clarified in this current paper: --The authors state they will use quantitative and qualitative methods to explore uptake and acceptability of the intervention. By whom? Please clarify the groups among which uptake and acceptability will be assessed. --In the section on ‘Other measures’ (page 9), many (if not all) of the implementation outcomes are mentioned, including participant impressions, enjoyment of the intervention, relationship between participant and health coach, experiences and attitudes of stakeholders. As these are implementation outcomes that will be reported separately in the process evaluation, I suggest omitting mention of them here in this paper to avoid confusion. Overview, page 7. In addition to stating the date of first participant recruitment, also include the anticipated timeline for full recruitment and whether there are specific recruitment goals for each study site? Participants, page 7. Please clarify the justification for defining mobility limitation as self-reported difficulty or inability to walk 800 m, as the definition used is different from that commonly used in studies of older adults. For instance, among older adults, inability to walk 400 m constitutes ‘mobility disability,’ which is more severe than ‘mobility limitation.’ For instance, see LIFE Trial by Pahor M et al. 2014 JAMA. Self-reported difficulty walking outside on level ground for 2-3 blocks (about 400 m) or up one flight of stairs without resting constitutes ‘mobility limitation’ in older adults. For instance, see Simonsick EM et al. 2008 JGMS. Outcomes, page 9. Please include rationale for choice of primary outcome, including choice of one-week measurement period. Other measures, page 9. Describe the methods that will be used to assess health and community service utilization as part of the economic evaluation. What processes are in place to track these outcomes over time? Adverse events, page 10. The Data Monitoring Committee, not the study investigators, should likely be responsible for the review of the adverse events to make decisions about continuation of the research. In addition, please further explain the size and composition of the Data Monitoring Committee, as well as their roles and responsibilities, including whether there will be any interim

	analyses. Page 11, Group 1: Coaching to ComeBACK. Clarify if participants will be asked to record and track their physical activity choices. Page 12, Section iv mentions the physical activity plan will be shared with the participant's GP. At what point is the plan developed and finalized. This needs clarification in section ii. Page 12, Group 2: Texting to ComeBACK. Clarify the duration of the tailored advice phone calls. Statistical analysis. It is mentioned that sub-group analyses will be conducted by severity of mobility limitation, but measurement of severity of mobility limitation is not described earlier in the paper. Please address. Ethics and Dissemination Will study results be disseminated to participants, and if so, how? Consider adding a paragraph to this section (to end the paper) to summarize the significance and potential implications and applications of this study. Table 1. I was not clear on the meaning of "centralized coaching delivery." Is there a particular organization in NSW or elsewhere in Australia that will provide centralized coaching for this trial? Or will study-specific staff be hired and act as coaches? If the latter, what organization(s) could function in this capacity later on during broader implementation?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Prof.dr. M.W.G. Nijhuis-van der Sanden

Comment 1. In general: this is an interesting relevant study, however I needed some time to get a correct overview on the study design, and I need to say that the research protocol as provided in the appendix was more clear for me. So I will provide some suggestions to increase the readability for readers, not aware of your previous research and experience. I used The SPIRIT as guidance

> **Author Response:** We are grateful for the positive comments and suggestions for improvement.
>
> **Alterations to Manuscript:** Outlined below

Comment 2. Why do the authors mention this trial a pragmatic trial: what do they mean?

> **Author Response**: Loudon et al (BMJ, 2015) provide a clear description of the distinction between pragmatic and explanatory trials "A pragmatic randomised trial is undertaken in the "real world" and with usual care and is intended to help support a decision on whether to deliver an intervention. An explanatory randomised trial is undertaken in an idealised setting, to give the initiative under evaluation its best chance to demonstrate a beneficial effect." We have added this information and given this reference in the manuscript.

Alterations to Manuscript: New sentence line 166 "The trial is more pragmatic than explanatory in that it uses recruitment and intervention strategies relevant to the "real-word" and is intended to help support a decision on whether such interventions should be delivered. A more explanatory trial would be undertaken in an idealised setting, to give the intervention its best chance to demonstrate a beneficial effect" (new ref 26).

Comment 3. Moreover, this is a randomized controlled trial which is not consistently mentioned see for instance
line 22 abstract. Be consistent in the total paper.

Author Response: We have added the words **"**randomised control" in several places to increase consistency.

Alterations to Manuscript: Line 33 and Table 2 Title: **"…**pragmatic randomised control trial (n=600) will…" and "Table 2: Intervention description of the ComeBACK randomised controlled trial…"

Comment 4. Another important point is the trial period: In the article it is mentioned that the first inclusion was February 2019, in the appendix 2018 is mentioned. Moreover there are 50 participants included between February and October (600/50 = 12), so this would mean an inclusion period of 8 years. As mentioned in the protocol (appendix) inclusion over 30 months was planned so this would mean an inclusion in 8 months of 160 participants. So it is really important to mention the study period (started later?) and strategies to guarantee the recruitment and inclusion. This because the study will loose a lot of power if the n= 600 is not reached.

Author Response: We find it beneficial to commence trial recruitment slowly to be sure procedures are all in place. Therefore the early recruitment rate is not indicative of the final recruitment rate. Recruitment rate had increased significantly until the global COVID-19 pandemic. We are confident that we will reach 600 participants but do not consider it wise to give a timeframe for this at this time of uncertainty. We have added current recruitment numbers to the manuscript as it is some months since we submitted this manuscript (October 2019).

Alterations to Manuscript: Recruitment numbers updated on line 185 "The first participant was recruited on 13 February 2019 and at the time of submission of this manuscript 156 participants had been randomised."

Comment 5. I wondered if a short discussion part with some reflection on the choices made by the research team would be helpful to make these choices more transparent (for instance not measuring the performance measures like strengths, aerobic fitness etc or why not using the step watch at 12 months, or why including the General Practioner, what is expected of the involvement).

Author Response: We do not consider it possible to reflect on all of these choices given the space constraints. However, we have justified our reasoning for sending the tailored activity plan to the General Practitioner within Table 1: "credible and trusted source reinforcing behaviour changes suggested by health coach". We have now also added this information within the text of the manuscript. We are now aso collecting *Stepwatch* data at 12 months and have included this in the manuscript.

Alterations to Manuscript: Line 138: "Both interventions involve the development of a goal-based tailored physical activity plan (made in conjunction with a physiotherapist and sent to participants and their primary care physician (referred as a General Practitioner (GP)) to reinforce physical activity participation).."

Comment 6. It would be more clear in the title to describe the target population as adults with self-reported or identified mobility limitations, see inclusion criteria and inclusion procedure.

Author Response: We agree this would be clearer but consider this would make the title too long.

Alterations to Manuscript: None**.**

Abstract:
Comment 7. In the introduction the involvement of physical therapist is mentioned but not the central coordinated health coach. Is this always a physiotherapist? And the aim/objective of the study is not mentioned.

Author Response: The health coaches are all physiotherapists, we have made this clearer. We consider the first part of the methods section of the abstract is a clear representation of the study aims "This pragmatic randomised control trial (n=600) will be undertaken among adults with self-reported mobility limitations. It aims to estimate the effects on physical activity…"

Alterations to Manuscript: Addition of "from a physiotherapist" after mention of phone coaching on line 37 and 39.

Comment 8. In the methods section the design is not clear, please provide the measurement time points, the recruitment of the participants, the duration of the waiting list period, and target population. The primary outcome is measures at baseline and 6 months? The secondary outcomes are mentioned in a list without any connection for the reader to the research question and the measurement time points. Some seem to be related to physical activity outcome and maintenance at 12 months, some related to the costs calculation etc, please order this in an understandable way.

Author Response: We have clarified that the less intensive and waiting list groups will also last 6 months. We have added an additional table (Table 3) which indicates the time points for the primary and secondary outcomes.

Alterations to Manuscript New text underlined: "It aims to estimate the effects on physical activity of: i) an enhanced 6-month intervention package (one face-to-face physiotherapy assessment, tailored physical activity plan, physical activity phone coaching from a physiotherapist, informational/motivational resources and activity monitors) compared with a less intensive 6-month intervention package (single session of tailored phone advice from a physiotherapist, tailored physical activity plan, unidirectional text messages, informational/motivational resources); ii) the enhanced intervention package compared with no intervention (6-month waiting list control group); iii) the less intensive intervention package compared with no intervention (waiting list control group)." (line 38 and 41)

Strengths and limitations:
Comment 9. It is important to include the target population in this part and some information why this is a pragmatic evaluation. Moreover, it would be nice to get transparent the contrast between intervention a and b, what is the strengths (or limitation) of the 3-arm trial?

Author Response: We do not consider that there is sufficient space for these additions especially given the editor's request to shorten the bullet points.

Alterations to Manuscript: None**.**

Comment 10. Why do you mention this intervention multidisciplinary? For me the involved disciplines are not transparent. Moreover, the developmental process of the intervention is not described in the introduction. And why do you mention the 6 month time frame while the a and b group are also measured at 12 months…

Author Response: The investigator team is multidisciplinary, the intervention is delivered by physiotherapists. We have made this clearer. The intervention lasts for 6 months, the 12-month follow-up is to examine lasting intervention effects in the two groups who received the intervention first but does not involve the comparisons with the control group.

Alterations to Manuscript: Bullet point "Multi-disciplinary theory-based intervention design…" changed to "Theory-based intervention informed by...." (line 59)

Line 136/7: “In consultation with consumers, clinicians, and policy makers, our multidisciplinary investigator team...”

Introduction

Comment 11. In the introduction it is clearly explained why physical activity in the chosen target group is important. In sentences 54-57 , page 4 it is explained that aerobic capacity etc increase, but this is not measured in the trial so may be better to focus on the outcomes as measured in this study.

Author Response: We consider the broader context/aims of the trial intervention to be useful so would prefer to leave this as it is.

Alterations to Manuscript: None**.**

Comment 12. From line 39 page 5 I recognized the behavioral change model as mentioned in the TIDieR, COM-B. The use of the Behavioral change strategies and the choices made between these theories should be more clearly described in the introduction to recognize the elements in the intervention: like motivation, goal-setting etc. Now the reader needs to find them in the TIDieR.

Author Response: We do not consider that there is sufficient space to describe behaviours theories but have referred the reader of this section to Table 1.

Alterations to Manuscript: New text underlined “In consultation with consumers, clinicians, and policy makers, our multidisciplinary investigator team developed two intervention packages based on behaviour change theories as outlined in the logic model (Fig.1) and Tables 1 and 2” (line 136-138)

Comment 13. Another important point is the rationale why to include a Physiotherapist (PT) (line 58, page 5). What will the PT do in the first assessment and which information will be added to the advises? For instance specific training (fitness or strengths or…) and how will this be integrated in the coaching procedure and activity tailoring. This is not clearly described. And how can this be done by a telephone assessment? In which way is this comparable or not to the physical assessment at home.

Author Response: We do not consider there to be space to discuss this issue in more detail in this section. This information is provided in the Intervention section and Table 2, and the rationale is provided in Table 1.

Alterations to Manuscript: None**.**

Comment 14. At page 6 line 8, it is stated that the intervention packages are developed in consultation: It needs a little bit more explanation about this trajectory and which steps were undertaken (see for instance the MRC frame work. Was there already some pilot testing?

Author Response: We do not consider there to be space to address this point.

Alterations to Manuscript: None**.**

Comment 15. The interventions a and b are the result of the developmental process as described above. So it would be logical to present table 1 with both interventions here. This makes the readability of the study better. Moreover, table 1 needs a better presentation to get insight in the differences and similarities in both intervention strategies related to the theoretical framework. Reading the appendices I had a lot of questions in table 1 and then I found the TIDieR description that was really much more transparent so I suggest to use this table to describe both interventions. Therefore I will not sent the comments to table 1 (much more than to the TIDieR table).

Author Response: We do not consider there is space in the TIDieR table to add all the detail from Table 1 so would prefer to leave both as they are.

Alterations to Manuscript: None.

Comment 16. Related to this TIDieR I have some remarks: The What procedures row 1: where is the assessment in intervention a performed, by which PT and what do you mean with a handover if possible??? Moreover for me it is not clear if the coaching will be done by the intake PT or the central PT? and if so how do you prevent contamination between both interventions a and b if these are delivered by the same central PT? Moreover, it seems to me more logical to present the development of tailored intervention directly after the intake , because the monitoring is focused on this plan.

Author Response: This is a good point. We have edited to make the distinction between the physiotherapist who does the assessment (who may be the treating physiotherapist or may be the study physiotherapist depending on the recruitment method) and the central phone coaching physiotherapist clearer. Contamination is prevented by the employment of staff to work on the project and clear staff training and procedures. We have moved the position of the "physical activity plan" sentences.

Alterations to Manuscript: New/moved text underlined.

"Group 1

- Initial physiotherapy assessment (by local or study physiotherapist) to identify mobility status, safety issues, medical, social and environmental influences on mobility. Three-way (participant/health coach physiotherapist/ assessment physiotherapist) handover at end of session if possible.
- Development of tailored physical activity plan.
- Fortnightly patient-centred health coaching from a physiotherapist trained in health coaching incorporating behaviour change strategies including goal-setting, problem-solving, building social support, experiential learning and motivational interviewing."

"Group 2.

- One-off phone-based tailored advice from a physiotherapist trained in health coaching to provide expert assessment of capability, identifying appropriate physical activity opportunities and to build motivation. Follow-up email to summarise and reinforce advice.
- Development of tailored physical activity plan.
- Pre-scheduled text messages with some personalisation and tailoring (based on the physical activity plan) commencing at 5 times/week to provide motivation support, planning support, problem-solving and maintenance support."

Comment 17. In the WHAT materials row you mention in intervention 2 that each participant needs a mobile phone for the messages etc, but this is the same for intervention 1 I guess, because in this intervention also activity apps etc are used.

Author Response: No this is not required for Intervention 1 as participants can use a pedometer instead of activity apps. This is part of the tailoring of the intervention.

Alterations to Manuscript: None

Comment 18. Please provide before the hypothesis formulation the objectives/research questions of the study and include also the cost-effectiveness and cost-utility as second research objective. Moreover, it would be nice to deepen the contrast between the intervention a and b in your hypotheses. Which factors are responsible for the contrast and influence the better outcome? And do you expect that the lower costs will lead to comparable cost-effectiveness?

Author Response: For simplicity, we would prefer to stick with the primary questions for this section.

Alterations to Manuscript: None

Methods section

Comment 19. Please start this section with a clear explanation of the trial design including type of trial, the subgroups, allocation ratio, randomization procedure, and framework. The start and end of the inclusion, the measurement time points and the combination of effectiveness and costs utility

analysis. The readability will be increased if you already described the intervention a and b as suggested above, the description of i) etc can be shortened.

> **Author Response:** We have re-ordered and expanded the overview paragraph that starts the methods section.
>
> **Alterations to Manuscript:** Underlined text is new or has been moved.

"This pragmatic superiority trial (n=600) will use 1:1 concealed on-line randomisation to allocate adults with self-reported mobility limitations to a 6-month enhanced intervention, a 6-month less intensive intervention or a waiting list control group (who will receive the less intensive intervention after 6 months). Between-group comparisons will be undertaken at 6 months (all groups) and at 12 months (comparing two intervention groups).

The study primarily aims to establish the effects of the interventions, compared to each other and to control, on objectively-measured physical activity at 6-months (*Stepwatch*, steps per day). Secondary outcomes include other physical activity measures, measures of health and functioning, individualised mobility goal attainment, mental wellbeing, quality of life, rate of falls, health utilisation and intervention evaluation. Secondary analyses will explore differential effects on the basis of recruitment source (health professional referral versus community advertising), assess implementation outcomes, and establish the cost-effectiveness and cost-utility.

The trial is more pragmatic than explanatory in that it uses recruitment and intervention strategies relevant to the "real-word" and is intended to help support a decision on whether such interventions should be delivered. A more explanatory trial would be undertaken in an idealised setting, to give the intervention its best chance to demonstrate a beneficial effect.[26] A hybrid effectiveness-implementation design (Type 1)[27] will be used to collect implementation outcomes at the same time as effectiveness outcomes. A nested process evaluation will use both quantitative and qualitative methods to explore uptake by participants and acceptability of the intervention (to participants, health coaches and other stakeholders). The protocol for the process evaluation will be described elsewhere. The PRACTIS guide[28] to implementation and scale-up of physical activity interventions was used to ensure that the interventions (and study recruitment methods) were as potentially scalable in future as possible. Future scale-up of the interventions, if found to be effective, will be guided by the model developed by Milat et al,[29] along with the implementation outcomes and other aspects of the process evaluation. An economic analysis, which will be conducted alongside the trial, will aim to establish the cost- effectiveness and cost-utility of the interventions compared to no intervention and to each other to assist funders of preventive health interventions to assess the value of such an approach for future investments. Table 1 shows the reasons for choice of different components, Table 2 overviews the intervention in TIDieR format and Figure 1 shows the overall logic and broader context for the trial. The first participant was recruited on 13 February 2019 and at the time of submission of this manuscript 156 participants had been randomised.
The primary comparisons will assess the effect on objectively measured physical activity at 6 months of the

i) enhanced intervention package (*Coaching to ComeBACK* group: one face-to-face assessment from a physiotherapist, tailored physical activity plan sent to participant and GP, physical activity phone coaching from a physiotherapist, activity monitors and/or apps, booklet and access to on-line resources) compared with a less intensive intervention package (*Texting to ComeBACK* group: single session of tailored advice by phone from a physiotherapist with health coaching training, tailored physical activity plan sent to participant and GP, unidirectional text messages, booklet and access to on-line resources);
ii) the enhanced intervention package (*Coaching to ComeBACK* group) compared with no intervention (*Texting to ComeBACK Later* waiting list control group);

iii) the less intensive intervention package (*Texting to ComeBACK* group) compared with no intervention (*Texting to ComeBACK Later* waiting list control group)."

Comment 20. At page 8 line 3-17 should be described after the second aim of this study as described in line 17-24. Moreover, it would be helpful to present the implementation procedure and recruitment methods in the paper. Here I read you will evaluate these separately however, for the trial design we need insight in these procedures.

Author Response: We would prefer to leave this text where it is since it refers to the primary outcome and the secondary aims have been more clearly described in the overview as helpfully suggested above.

Alterations to Manuscript: None**.**

Comment 21. In line 24 you introduce figure 1 as describing the overall logic of the study. I am sorry to say that this figure was not very logical for me: in the intervention components I would expect the elements contrasting the interventions, which are not clearly described, moreover, there is information in this figure which I miss in the text, like the patient characteristics, staff training etc, the short term outcomes are not ordered by timepoints and the long-term outcomes are included in the figure but not part of the study. Moreover, I find some information in the feedback loops which should have mentioned in the hypothesis (eg. Therapeutic relationship as facilitator or moderator). So I suggest to skip this figure and include some info in the TIDieR and add the figure 6.1 flowchart of the study included in the study protocol which is much more transparent. The information on the inclusion should be part of the design see before. See also the question about the status of recruitment (50 instead of 160).

Author Response: Logic Models are considered to be an essential component in the development and evaluation of complex interventions [Moore G, et al. Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance. London: Medical Research Council; 2014.]. They provide a basis not only for outlining the key hypothesised therapeutic process of the intervention, but also for process evaluation (and future intervention refinement). We would therefore prefer to keep Table 1, Table 2 and Figure 1 as they are as we consider them to be complementary. Figure 1 is intended to represent the logic of the intervention design in broader terms and is not intended to link directly to the outcomes. The different roles of the tables and figures has been made clearer.

Alterations to Manuscript: We have re-ordered the relevant text to read "Table 1 shows the reasons for choice of different components, Table 2 overviews the intervention in TIDieR format and Figure 1 shows the overall logic and broader context for the trial" (lines 182-184)

Participants:

Comment 22. Please start this section with some information on the study setting, where participants are recruited/invited. Were their also eligibility criteria for the participating centres? The in-and exclusion criteria are clear, however I miss information on the recruitment and enrolment procedures. When potential participants are interested what happens then? I found the information in the study protocol fig 6.2 this needs to be added in the protocol article.

Author Response: Additional text has been added to the "Participants" section.

Alterations to Manuscript: "Participants with a range of health conditions who report difficulty or inability to walk 800m will be recruited. The process evaluation will explore differences in feasibility and efficiency of recruitment in each of the settings to inform future implementation strategies." (lines 206-209)

Assessments/outcomes

Comment 23. For me this was a confusing part in the protocol study: firstly it appeared that there were outcomes mentioned that were not mentioned in the assessment protocol. So I found it quite difficult

to get an overview on WHAT was measured at WHICH time point, HOW and WHY (what I mean is to answer which research question).

> **Author Response:** We have added Table 3 to overview outcomes and timepoints and included this in the outcomes section.
>
> **Alterations to Manuscript:** New sentence: **"**Table 3 overviews the trial outcomes and measurement timepoints." (line 254)

Comment 24. So I would prefer a table with time points and primary and secondary outcomes and which of the measurements are used as background info (eg characteristics of the participants), which are used as effect outcomes and which as effect modifiers and which are used for the cost evaluation. See table 3 and 4 in the provided protocol. These were much more transparent for me.

> **Author Response:** This is a good idea. Table 3 from the protocol has been included in the manuscript as Table 3.
>
> **Alterations to Manuscript:** New Table 3 added.

Comment 25. If you describe the StepWatch Activity Monitor: can you provide some more information on the pale participant wear this activator? Day and Night? Because this is the primary outcome it is important to get some details.

> **Author Response:** This device is worn during waking hours. This information has been added to the manuscript.
>
> **Alterations to Manuscript:** New text underlined.
> "The matchbox-sized *StepWatch* Activity Monitors used to objectively measure physical activity (primary outcome 6-month, secondary outcome 12 month) will be mailed to participants with reply-paid envelopes and clear instructions for use and will be worn at the ankle during waking hours for periods of seven consecutive days." (line 240)

Comment 26. What needs to be added is the measurement procedure and who performed the measures. Moreover, the other measures page 9, line 44), are these related to the effectiveness study or related to the process evaluation which is described elsewhere? I would suggest to only describe the measurements you will use in this study and later on in describing the results. If you include these in the analyses (eg PACES and WAI as modifiers) then it is okay to include them. But forach measure included it should also be described for which research question it will be used in the statistical analysis.

> **Author Response:** The measurement procedure is described within the Assessment section. It includes information about blinding of outcome assessors.
>
> **Alterations to Manuscript:** None**.**

Intervention
Comment 27. See remarks before. What needs to be described more clearly is who is involved in the intervention. Which professional is doing what during recruitment, inclusion and delivery of the intervention. And what I miss is a transparent overview which activities were performed by whom during the implementation of the intervention. Were there eligibility criteria for the providers/PTs? Were the PT's at the centers trained in Motivational interviewing and coaching? Were the PT's trained to perform a telephone interview and to develop a tailored health intervention? Which aspects in the interview/ cq physical assessment guided their decisions on the goals, and training exercises. Who is involved in the text messages and role modeling video's? How is the website introduced to both the coaches and the participants, are the coaches trained and informed about the possibilities of the website. Apps etc. So please describe the implementation and which strategies will be used if the recruitment or adherence is not as expected.

> **Author Response:** We do not consider there to be space to add this detail into the text of the manuscript. This information is provided as part of the TIDieR checklist in Table 2.

Alterations to Manuscript: None**.**

Comment 28. At page 14 line 31 the involvement of patients and public is described. You emphasize the role in the development of the intervention, however is there also a role in the recruitment phase, the evaluation phase and the interpretation of the findings: so in the trial itself.

Author Response: We do not have involvement of patients and public in the trial itself.

Alterations to Manuscript: None**.**

Sample size and statistical analysis:
Comment 29. The sample size calculation seems appropriate, however, the number of 600 is rather ambitious.

Author Response: Ambitious but achievable given our previous studies and recruitment rate to date.

Alterations to Manuscript: None.

Comment 30. The statistical analysis is straight forward, however, the subgroup analysis on age and severity of mobility limitation seems to be related and I guess this will be the self-reported limitation, please add this information. The secondary analysis focusses on the effect of adherence. For me it is not clear how adherence will be defined because of the different factors in the intervention like using activity apps, visiting the website, visiting the video models etc etc how is adherence defined to perform these analyses? Moreover, I miss information on handling missing data and do not understand what is mentioned with range checks?

Author Response: These details will be defined as part of the Statistical Analysis Plan to be developed prior to the end of data collection. This has been added to the manuscript.

Alterations to Manuscript: A detailed Statistical Analysis Plan will be developed and signed off by all investigators prior to analysis. (lines 433-434)

Ethics and dissemination
Comment 31. I miss some information on the informed consent procedure, the anonymization of data, and the data protocol. It is described that all authors have full access to the data, but I hope to the anonymized data?

Author Response: We will follow all usual ethical requirements and will certainly not provide access to identifiable data. All data are stored in REDCap which allows different level access for investigators and research staff dependent on their role in the study. We consider the existing information to be sufficient “Written informed consent from all participants will be obtained by study staff prior to study enrolment (see sample consent form in supplementary material). Participant confidentiality will be maintained at all times and all data will be stored securely” but have edited the data access statement.

Alterations to Manuscript: New word underlined: “All authors will have full access to de-identified study data.” (line 461)

Comment 32. I read dissemination to the international public but are there plans to communicate trial results to participants, other healthcare professionals, and the target group ? And when?

Author Response: We state that our dissemination plan includes dissemination to clinicians and consumer meetings. We have edited our text to specify healthcare professionals and added participants.

Alterations to Manuscript: Line 455: **“**Dissemination will be via publications, conferences, newsletter articles, letters to participants, talks to healthcare professionals and consumers…”

Comment 33. Is the data base also available to other researches or the public after the publication of the own research?

Author Response: Information on data access will be included in the final publication.

Alterations to Manuscript: None**.**

Author contributions
Comment 34. The Role of the authors related to their background would provide some more insight. For instance was a statistician involved in the study? How is the composition, roles, and responsibilities of the coordinating centre? Who are involved in a steering committee? Who is involved in the data management team, and other individuals or groups overseeing the trial? Who are responsible for the education of the providers of the intervention? And who is responsible to monitor the progress of the study?

Author Response: We do not consider it possible to include this information given the space constraints.

Alterations to Manuscript: None

Reviewer: 2
Amal A. Wanigatunga

Comment 1. The authors present a study protocol for a single blinded, two intervention (versus comparison group) study primarily aimed to increase walking steps per day in those with mobility limitations. Overall, I believe the protocol is generally well-written but there is need to review for grammar.

Author Response: Thank you.

Alterations to Manuscript: None

Abstract

Comment 2. In the introduction, mobility limitation is not disability in it of itself – disability is mobility limitations in social context. See two references below:

Nagi SZ. Some conceptual issues in disability and rehabilitation. In: Sussman MB, editor. Sociology and rehabilitation. Washington, DC: American Sociological Association; 1965.

World Health Organization. The International Classification of Impairments, Disabilities, and Handicaps—a manual relating to the consequences of disease. Geneva: World Health Organization; 1980.

Author Response: We agree that disability has a social component. We are using the broader definition of disability from the guide on the WHO ICF website which states that "disability is an umbrella term for impairments, activity limitations and participation restrictions" (https://www.who.int/classifications/icf/icfbeginnersguide.pdf?ua=1). For simplicity we have edited the introduction of the abstract to remove mention of disability but will include our definition in the introduction.

Alterations to Manuscript:
Previous version: Mobility limitation is a common and serious form of physical disability often resulting from neurological and musculoskeletal health conditions, ageing and/or physical inactivity.

New version: Mobility limitation is common and often results from neurological and musculoskeletal health conditions, ageing and/or physical inactivity. (line 25-26)

Comment 3. The method section is worded a bit awkwardly as the outcome is presented first before the intervention details. Could this be written more clearly?

> **Author Response:** We have attempted to express the aims of the study in PICO format. We have now split this sentence into two to assist readability.
>
> **Alterations to Manuscript:**
> Previous version: "Among adults with self-reported mobility limitations, this pragmatic trial (n=600) aims to estimate the effects on physical activity of: i) an enhanced 6-month intervention package (one face-to-face physiotherapy assessment, tailored physical activity plan, physical activity phone coaching, informational/motivational resources and activity monitors) compared with a less intensive intervention package (single session of tailored phone advice, tailored physical activity plan, unidirectional text messages, informational/motivational resources); ii) the enhanced intervention package compared with no intervention (waiting list control group); iii) the less intensive intervention package compared with no intervention (waiting list control group). The primary outcome will be average steps per day, measured with the StepWatch activity monitor over a one-week period, 6 months after randomisation.
>
> New version: This pragmatic randomised control trial (n=600) will be undertaken among adults with self-reported mobility limitations. It aims to estimate the effects on physical activity of: …." (line 33)

Strengths and limitations

Comment 4. One limitation is that recruitment is based on self-reported mobility limitation and mobility limitations are not directly observed or standardized (e.g., using a performance test).

> **Author Response:** We do not consider that the use of a performance test would be feasible for scale-up so deliberately chose not to include such a test. Nonetheless we have added this point to the strengths/limitations.
>
> **Alterations to Manuscript:** Line 64: Recruitment is based on self-reported mobility limitation rather than a standardised measure.

Introduction

Comment 5. Same comment as abstract introduction on the mobility limitation versus disability. Mobility limitations put persons at HIGH risk for mobility disability (e.g., dismobility) or major mobility disability. To me, the rationale should be around this point. The interventions examined will try to put persons away from being at high risk for dismobility (high enough walking impairment that affects social involvement).
-The LIFE study should be referenced for reference 12 (https://protect-au.mimecast.com/s/gZMSCzvOWKiMMzn0Dt40Op2?domain=jamanetwork.com). The current reference in reference 12 slot is not the actual reference. As a side note, the LIFE study reference has a similar rationale to your study – recruit those with mobility limitations and infuse physical activity into daily lifestyles to protect against transitioning into disability states.

> **Author Response:** As mentioned above we are using the broader definition of disability from WHO ICF website which states that "disability is an umbrella term for impairments, activity limitations and participation
> restrictions" (https://www.who.int/classifications/icf/icfbeginnersguide.pdf?ua=1). We have made this clearer in the manuscript.
>
> We are a bit confused by the comment about reference 12.
> Reference 12 in the submitted version is: Pahor M, Guralnik JM, Ambrosius WT, et al. Effect of structured physical activity on prevention of major mobility disability in older adults: the

LIFE study randomized clinical trial. JAMA. 2014;311(23):2387-2396. This appears to be the same as the one at the link given by the reviewer.

Alterations to Manuscript: New first sentence added (underlined text below).
Disability is an umbrella term for impairments, activity limitations and participation restrictions (new ref 1, WHO, ICF guide). Mobility limitation (i.e., difficulty or inability to walk) is a particularly common [2] and serious form of physical disability. (lines 68-70)

Methods and analysis

Comment 6. Under Randomization, the group allocation for stratification is not clear. Please provide more detail into how randomization for group allocation is stratified.

Author Response: Randomisation to groups will be stratified by whether participants were recruited from the general community (via advertising etc) or from health services. We have made this clearer.

Alterations to Manuscript: Line 232-233:

Old text: "Group allocation will use stratification to ensure balance by recruitment source (health service or community)."

New text: "Randomisation to groups will be stratified by whether participants were recruited from the general community (via advertising etc) or from health services".

Comment 7. Under Assessments, it is not clear how the ankle devices are returned to study staff.

Author Response: The ankle device will be returned to study staff via reply-paid envelopes. This is mentioned on line 211.

Alterations to Manuscript: No alterations to manuscript

Comment 8. Under Assessments, it is not clear how "data for all outcomes will be collected for those who cease to participate, where possible"? Please provide 1-2 sentences explaining how.

Author Response: This sentence has been revised to be clearer.

Alterations to Manuscript: Lines 246-248: Where possible, data for all outcomes will be collected for all participants including those who cease participation in the interventions, unless the participant wishes to withdraw from the study.

Comment 9. I find the adverse event section a bit lacking. There are other adverse events that may occur without hospitalization but may be potentially serious (e.g., angina, shortness of breath long after exercise). Also, it would be helpful if the authors can succinctly address how the study deals with exercise effects on muscle (e.g., soreness) and other discomforts. Some of these details can be drawn from the actual protocol provided.

Author Response: The manuscript has been edited to include the other adverse events mentioned by the reviewer. Our protocol acknowledges that participants may experience muscle soreness at the start of the physical activity program. This will be minimised by advice to increase activity levels gradually and to seek professional advice if soreness lasts for more than three days or interferes with daily activities. This information has been added to the manuscript.

Alterations to Manuscript: Line 288-289, additional text underlined: Adverse events will be defined as an unwanted and usually harmful outcome (e.g. exercise-related falls, musculoskeletal injury, angina, shortness of breath or cardiovascular event).
Line 304 additional text: Participants may experience muscle soreness at the start of the physical activity program. This will be minimised by advice to increase activity levels gradually

and to seek professional advice if soreness lasts for more than three days or interferes with daily activities.

Comment 10. Under Interventions, the authors took care to explain the step activity monitor does not provide feedback to the participant, yet the six-component intervention provides either a FitBit or pedometer to capture and provide feedback on steps/day to the participant. This is very confusing and requires detailed explanation on how this affects or does not affect primary outcome (average steps/day), especially since the texting intervention not the waiting list comparison arm do not offer these electronic devices.

Author Response: The step activity monitor used for outcome assessment (the *Stepwatch*) does not provide feedback to participants and is used to enable blinded outcome assessment using the same procedures for all groups. The devices used as part of the intervention (*FitBit* or pedometer) are designed to give feedback and this feedback is part of the intervention.

Alterations to Manuscript: None**.**

Comment 11. There seems to be no mention of adherence and compliance and related evaluation metrics. I do see a small mention of adherence in the actual study protocol (not in the manuscript) but not in the manuscript. Can the authors add a description on how adherence and compliance are evaluated?

Author Response: We are measuring adherence to the intervention in a number of ways (e.g. number of health coaching sessions attended) but would prefer not to describe these here as we are drafting a separate protocol paper for the process evaluation which will include this information.

Alterations to Manuscript: None**.**

Reviewer: 3
Dawn Mackey

Comment 1. This is a thoroughly described and well-written study protocol for the ComeBACK trial. I appreciate the opportunity to review it and make constructive suggestions for further improvement.

Author Response: Thank you.

The ComeBACK intervention aims to increase physical activity among adults with self-reported mobility limitation through a physiotherapist-led package. The 3-arm trial (n=600) will compare effects on objectively-measured physical activity of an enhanced 6-month intervention package, a less intensive 6-month intervention package, and no intervention (wait-list control).

As appropriate, the authors followed reporting recommendations for trial protocols, for instance by describing the intervention using the TIDieR format. Consistent with this being a study protocol, my comments focus on clarity of the reporting.

Major Comments

Comment 2. I like that the authors acknowledge the importance of scalability and state that they have designed the intervention with scalability in mind. I wonder, however, about the scalability of interventions delivered by physiotherapists, mostly because of cost considerations but also because of access considerations in rural and remote areas. Can you address this, from an Australian context, in the paper? Are health care providers normally paying for physiotherapist-led programs for community members? Have physiotherapist-led exercise programs been shown to be cost-effective, even if for different target populations? Recognizing the complexity of exercise prescription and behaviour change among adults with mobility limitations, would other allied health professionals such as Kinesiologists or Exercise Physiologists be suitable for delivering the program?

Author Response: This program could be delivered by any allied health professional with appropriate skills. In Australia Kinesiologists and Exercise Physiologists have similar costs to physiotherapists. We therefore do not consider the use of physiotherapists to limit the scalability of the intervention.

Alterations to Manuscript: None**.**

Comment 3. Consultations with consumers, clinicians, and policy makers are mentioned a few times throughout the paper (e.g., Abstract, page 2; Introduction, page 6; Methods, Interventions, page 10). Please describe these consultations in greater detail. Were separate consultations held with each group? How many people participated in each group? How were people recruited for the consultations. What were the guiding questions asked and addressed at each consultation?

Author Response: This input was gained from a) input from our multidisciplinary study team that includes health service managers and clinicians; b) from many informal discussions over the years with health service managers, health professionals, health service users, community members and those delivering intervention in our previous trials, c) formal qualitative work from our previous trials (eg Hamilton C, McCluskey A, Hassett L, Killington M, Lovarini M (2018). Patient and therapist experiences of using affordable feedback-based technology in rehabilitation: a qualitative study nested in a randomised controlled trial. Clinical Rehabilitation. 2018 Sep; 32(9):1258-1270, other manuscripts under review) and our systematic reviews of qualitative studies. We do not consider there is space to add this detail to the manuscript.

Alterations to Manuscript: None**.**

Minor Comments

Abstract

Comment 4. Add “for adults with self-reported mobility limitations” to the end of the sentence, “In consultation with consumers, clinicians, and policy makers, we have developed two affordable and scalable intervention packages designed to enhance physical activity.”

Author Response: We have made this change as suggested.

Alterations to Manuscript: Line 28: “**…** we have developed two affordable and scalable intervention packages designed to enhance physical activity <u>for adults with self-reported mobility limitations.”</u>

Strengths and limitations of this study

Comment 5. Suggest revising the first bullet point to be more specific: “Addressing the important and growing health problem of mobility limitation.”

Author Response: We have actually deleted this bullet point in response to the editor comment about the need to focus on the methods.

Alterations to Manuscript: None**.**

Introduction

Comment 6. Page 4, third para, last sentence. Please include the magnitude of step count increase that was associated with reduced risk of mortality from ref #8.

Author Response: This has been added.

Alterations to Manuscript: Line 91: New text underlined **"**For example, taking a greater number of steps per day was associated with lower all-cause mortality over a 10-year follow-up period (adjusted hazard ratio (AHR) for all-cause mortality 0.94; 95% CI, 0.90 to 0.98 per 1 000 steps; p = 0.004).[8] In those who increased daily steps there was a substantial reduction in mortality risk after adjusting for baseline daily step count (AHR, 0.39; 95% CI, 0.22 to 0.72; p = 0.002).[8]"

Methods and Analysis

Comment 7. Overview, page 6. Please describe the features of the trial that make it pragmatic, with appropriate references to trials methods literature.

Author Response: See response to Reviewer 1 on this issue. We do not consider there to be space to describe all the features but have added the following text and a reference.

Alterations to Manuscript: Lines 166-168: "The trial is more pragmatic than explanatory in that it uses recruitment and intervention strategies relevant to the "real-word" and is intended to help support a decision on whether such interventions should be delivered. A more explanatory trial would be undertaken in an idealised setting, to give the intervention its best chance to demonstrate a beneficial effect.[25]"

Comment 8. Overview, page 7. It's a strength that the study design is a hybrid design (Type I) to capitalize on the opportunity to collect preliminary information about implementation outcomes. It is stated in the paper that the protocol for the nested process evaluation will be described elsewhere. However, I would like to see a few things clarified in this current paper:

The authors state they will use quantitative and qualitative methods to explore uptake and acceptability of the intervention. By whom? Please clarify the groups among which uptake and acceptability will be assessed.

Author Response: Additional information has been provided in the text.

Alterations to Manuscript: line 171: "A nested process evaluation will use both quantitative and qualitative methods to explore uptake by participants and acceptability of the intervention (to participants, health coaches and other stakeholders)."

Comment 9. In the section on 'Other measures' (page 9), many (if not all) of the implementation outcomes are mentioned, including participant impressions, enjoyment of the intervention, relationship between participant and health coach, experiences and attitudes of stakeholders. As these are implementation outcomes that will be reported separately in the process evaluation, I suggest omitting mention of them here in this paper to avoid confusion.

Author Response: Given the hybrid nature of the study we would prefer to leave these measures in this manuscript.

Alterations to Manuscript: None**.**

Comment 10. Overview, page 7. In addition to stating the date of first participant recruitment, also include the anticipated timeline for full recruitment and whether there are specific recruitment goals for each study site?

Author Response: This is unfortunately not possible given the current global pandemic situation.

Alterations to Manuscript: None**.**

Comment 11. Participants, page 7. Please clarify the justification for defining mobility limitation as self-reported difficulty or inability to walk 800 m, as the definition used is different from that commonly used in studies of older adults. For instance, among older adults, inability to walk 400 m constitutes

'mobility disability,' which is more severe than 'mobility limitation.' For instance, see LIFE Trial by Pahor M et al. 2014 JAMA. Self-reported difficulty walking outside on level ground for 2-3 blocks (about 400 m) or up one flight of stairs without resting constitutes 'mobility limitation' in older adults. For instance, see Simonsick EM et al. 2008 JGMS.

Author Response: Firstly**,** we are using the more recent and broader WHO ICF definition of disability that includes mobility limitation. "Disability is an umbrella term for impairments, activity limitations and participation restrictions (new ref 1, WHO, ICF guide)." We have added this information to the manuscript.
Secondly, we consider mobility limitation to be on a continuum and have chosen difficulty walking 800m to be an extent of mobility limitation worthy of intervention. This enables earlier intervention than a 400m cut-off would. The 800m (half mile) distance was also chosen as it is an item within the Fried pre-clinical disability screening tool.

Alterations to Manuscript: Line 68: Disability is an umbrella term for impairments, activity limitations and participation restrictions (new ref 1, WHO, ICF guide).

Comment 12. Outcomes, page 9. Please include rationale for choice of primary outcome, including choice of one-week measurement period.

Author Response: The manuscript currently justifies the choice of the Stepwatch as the primary outcome measurement tool. It states "This device was chosen as prior research by the present authors30 found it to be the most accurate device for step measurement in people with mobility impairment with average 98% (SD 12%) agreement with investigator-observed steps over a 6-minute period as opposed to 17% (SD 19%) for the more commonly-used Actigraph device. The StepWatch Activity Monitor is simple to use, can be mailed to participants and does not give feedback to the wearer.

We do not consider it necessary to add justification for the one-week period as It is generally considered best practice to objectively measure physical activity for a period of 7-days (Matthews C.E. 2012; MSSE). This is because there is likely to be intra-participant variability from day-to-day as to how much physical activity is conducted and so the average over a few days to a week is likely to be a better reflection of current physical activity levels.

Alterations to Manuscript: None**.**

Comment 13. Other measures, page 9. Describe the methods that will be used to assess health and community service utilization as part of the economic evaluation. What processes are in place to track these outcomes over time?

Author Response: This will be collected via paper based or online monthly calendars over the 12-month period, with phone follow-up as necessary. This is mentioned under assessments (lines 243-246). The sentence in "other measures" has been amended to further reflect this.

Alterations to Manuscript: Lines 282-283: **"**Intervention costs and health and community service utilisation, as collected by monthly calendars…"

Comment 14. Adverse events, page 10. The Data Monitoring Committee, not the study investigators, should likely be responsible for the review of the adverse events to make decisions about continuation of the research. In addition, please further explain the size and composition of the Data Monitoring Committee, as well as their roles and responsibilities, including whether there will be any interim analyses.

Author Response: Any adverse event occurring will be reported to the DMC by study coordinator (SO). There are no interim analysis planned.

Alterations to Manuscript: None

Comment 15. Page 11, Group 1: Coaching to ComeBACK. Clarify if participants will be asked to record and track their physical activity choices.

Author Response: Yes, they will. This will be discussed in more detail in the process evaluation paper.

Alterations to Manuscript: None**.**

Comment 16. Page 12, Section iv mentions the physical activity plan will be shared with the participant's GP. At what point is the plan developed and finalized. This needs clarification in section ii.

Author Response: This is developed after the first coaching call or physical assessment. This has been made clearer.

Alterations to Manuscript: Addition of words "soon after it is developed" (line 361 & 391) to the relevant section and changing order in in the TIDieR table.

Comment 17. Page 12, Group 2: Texting to ComeBACK. Clarify the duration of the tailored advice phone calls.

Author Response: These calls take 50-60 minutes. This information has been added.

Alterations to Manuscript: Line 376-377: **"***Single session of tailored advice provided by phone by a physiotherapist*. This call will last 50-60 minutes, will…"

Comment 18. Statistical analysis. It is mentioned that sub-group analyses will be conducted by severity of mobility limitation, but measurement of severity of mobility limitation is not described earlier in the paper. Please address.

Author Response: This will be based on data collected in the baseline questionnaires about extent of difficulty walking.

Alterations to Manuscript: None

Ethics and Dissemination

Comment 19. Will study results be disseminated to participants, and if so, how?

Author Response: Participants will receive a letter outlining the study results. This information has been added to the manuscript.

Alterations to Manuscript: Lines 456-457: "Dissemination will be via publications, conferences, newsletter articles, letters to participants..."

Comment 20. Consider adding a paragraph to this section (to end the paper) to summarize the significance and potential implications and applications of this study.

Author Response: We have inserted the following two sentences.

Alterations to Manuscript: Lines 464-468: "This study will address a key evidence gap regarding realistic scalable ways to enhance physical ability in people with impaired mobility. Trial results will provide direct information about the costs and benefits of the intervention approach compared with current practice to enable funders of preventive health interventions to decide whether such approaches are worth investing in as a population health intervention."

Comment 21. Table 1. I was not clear on the meaning of "centralized coaching delivery." Is there a particular organization in NSW or elsewhere in Australia that will provide centralized coaching for this

trial? Or will study-specific staff be hired and act as coaches? If the latter, what organization(s) could function in this capacity later on during broader implementation?

Author Response: Study-specific staff will be hired to act as coaches. Health services could take on this role if the intervention is found to be effective.

Alterations to Manuscript: This has been made clearer in the table.

VERSION 2 – REVIEW

REVIEWER	Amal A. Wanigatunga Johns Hopkins Bloomberg School of Public Health
REVIEW RETURNED	15-May-2020

GENERAL COMMENTS	My comments were addressed. The only thing I recommend is that the authors justify and/or cite the selection of "800m" to determine mobility limitations. In older adults, 1/4 mile or 400m is used to determine mobility disability (not limitations) but in this protocol, younger adults are recruited (probably part of the justification). However, the rationale for the 800m selection should be explicit in the protocol. Vestergaard, S., Patel, K. V., Walkup, M. P., Pahor, M., Marsh, A. P., Espeland, M. A., ... & Guralnik, J. M. (2009). Stopping to Rest During a 400-Meter Walk and Incident Mobility Disability in Older Persons with Functional Limitations. Journal of the American Geriatrics Society, 57(2), 260-265.

REVIEWER	Dawn Mackey Simon Fraser University Canada
REVIEW RETURNED	23-May-2020

GENERAL COMMENTS	Thank you for the thorough responses and revisions you provided following the first round of review. There are three remaining items I would like to see incorporated in the manuscript. 1. As scalability is cited as a strength of the intervention, please add text to the manuscript to support the scalability of the intervention, considering both issues of cost and access. 2. Please add text to the manuscript to describe the consultations that were conducted with consumers, clinicians, and policy makers, similar to what was included in the first response to reviewer comments. 3. Please state the size and composition/expertise of the Data Monitoring Committee in the manuscript.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1 (comments from first round that were not addressed)
Prof.dr. M.W.G. Nijhuis-van der Sanden

Comment 1. I wondered if a short discussion part with some reflection on the choices made by the research team would be helpful to make these choices more transparent (for instance not measuring the performance measures like strengths, aerobic fitness etc or why not using the step watch at 12 months.

> **Author Response:** We have added a justification of not including performance measures. We have actually added a stepwatch measurement at 12 months since the original protocol submission in October 2019 and included this in the previous revision.
>
> **Alterations to Manuscript:** New paragraph under a new heading "discussion". **"**It would have been useful and interesting to measure performance outcomes such as mobility, balance and strength at 6 and 12 months, but the size of the trial, geographic spread of participants and budget constraints preclude this." (Lines 496-498)

Introduction

Comment 4. In the introduction it is clearly explained why physical activity in the chosen target group is important. In sentences 54-57 , page 4 it is explained that aerobic capacity etc increase, but this is not measured in the trial so may be better to focus on the outcomes as measured in this study.

> **Author Response:** We have re-considered this point and still feel that the current introduction relates appropriately to the trial outcomes given the inclusion of "For example, taking a greater number of steps per day was associated with lower all-cause mortality over a 10-year follow-up period (adjusted hazard ratio (AHR) for all-cause mortality 0.94; 95% CI, 0.90 to 0.98 per 1 000 steps; p = 0.004)."
>
> In this sentence "People with health conditions affecting mobility can obtain additional benefits from physical activity including better mobility, fewer falls and less risk of hospitalisation.[10] Physical activity enhances mobility through improved aerobic capacity, muscle strength, balance and coordination.[11]" we discuss aerobic capacity as one of the mechanisms for improving mobility. We are measuring mobility behaviour through steps and self-reported.
>
> **Alterations to Manuscript:** None**.**

Comment 5. From line 39 page 5 I recognized the behavioural change model as mentioned in the TIDieR, COM-B. The use of the Behavioral change strategies and the choices made between these theories should be more clearly described in the introduction to recognize the elements in the intervention: like motivation, goal-setting etc. Now the reader needs to find them in the TIDieR.

> **Author Response:** We consider the current text in the intervention section and tables to be sufficient and do not consider it necessary to repeat information from Tables 1 and 2 in the main text. The intervention section reads: "The COM-B (Capability Opportunity Motivation –> Behaviour) model of behaviour change[16] was used to guide the intervention design, with self-determination theory[24] and social cognitive theory[25] further underpinning the motivational component. Table 1 overviews the aspects of the COM-B addressed by each aspect of the intervention packages."
>
> **Alterations to Manuscript:** We have added that author Prof Greaves (Prof of Psychology Applied to Health) guided this aspect of the intervention in the author contribution section. (Lines 505-522)

Comment 6. Another important point is the rationale why to include a Physiotherapist (PT) (line 58, page 5). What will the PT do in the first assessment and which information will be added to the advises? For instance specific training (fitness or strengths or…) and how will this be integrated in the coaching procedure and activity tailoring. This is not clearly described. And how can this be done by a telephone assessment? In which way is this comparable or not to the physical assessment at home.

Author Response: We consider that the current text is sufficient: "a single face-to-face one-hour assessment of mobility status, safety issues, medical, social and environmental influences on mobility, will be undertaken during a home visit by a physiotherapist (employed locally). Where a home visit is not possible, a video conference will be conducted as an alternative. At the end of the assessment, a phone or videoconference call will be made to the health coach with both physiotherapist and the participant present to introduce and handover to the health coach and discuss any particular issues." Our staff report that a telephone or video assessment works well enough to guide the intervention. We will explore this issue more fully in the process evaluation.

Alterations to Manuscript: None**.**

Comment 7. At page 6 line 8, it is stated that the intervention packages are developed in consultation: It needs a little bit more explanation about this trajectory and which steps were undertaken (see for instance the MRC frame work. Was there already some pilot testing?

Author Response: This change has been made with the addition of the below text to the Patient and public involvement section.

Alterations to Manuscript: "Consultations with consumers, clinicians, and policy makers assisted in the design of intervention and study methods. This input was gained from a) input from our multidisciplinary study team that includes health service managers and clinicians; b) from informal discussions with health service managers, health professionals, health service users, community members and those delivering interventions in our previous trials[42-44], c) formal qualitative work involving participants in our previous trials[45,46] and our systematic reviews of qualitative studies[47,48].

The study protocol and choice of intervention and assessment tools (including the burden on participants) was further guided by feedback from consumers obtained as part of the endorsement of the trial by the Australia & New Zealand Musculoskeletal Clinical Trials Network (ANZMUSC)". Study results will be disseminated to participants via email or paper letters. (Lines 414-427).

Comment 8. The interventions a and b are the result of the developmental process as described above. So it would be logical to present table 1 with both interventions here. This makes the readability of the study better. Moreover, table 1 needs a better presentation to get insight in the differences and similarities in both intervention strategies related to the theoretical framework. Reading the appendices I had a lot of questions in table 1 and then I found the TIDieR description that was really much more transparent so I suggest to use this table to describe both interventions. Therefore I will not sent the comments to table 1 (much more than to the TIDieR table).

Author Response: We consider the TIDieR table would have too much information which would detract from readability to add all the detail from Table 1 so would prefer to leave both as they are.

Alterations to Manuscript: None.

Comment 9. Please provide before the hypothesis formulation the objectives/research questions of the study and include also the cost-effectiveness and cost-utility as second research objective. Moreover, it would be nice to deepen the contrast between the intervention a and b in your hypotheses. Which factors are responsible for the contrast and influence the better outcome? And do you expect that the lower costs will lead to comparable cost-effectiveness?

Author Response: For simplicity, we would prefer not to make changes to the primary questions detailed in the Overview section.

Alterations to Manuscript: None

Methods section

Comment 10. At page 8 line 3-17 should be described after the second aim of this study as described in line 17-24. Moreover, it would be helpful to present the implementation procedure and recruitment methods in the paper. Here I read you will evaluate these separately however, for the trial design we need insight in these procedures.

Author Response: We would prefer to leave this text where it is since it refers to the primary outcome and the secondary aims have been more clearly described in the overview in response to a different reviewer comment.

Alterations to Manuscript: None**.**

Intervention

Comment 11. See remarks before. What needs to be described more clearly is who is involved in the intervention. Which professional is doing what during recruitment, inclusion and delivery of the intervention. And what I miss is a transparent overview which activities were performed by whom during the implementation of the intervention. Were there eligibility criteria for the providers/PTs? Were the PT's at the centers trained in Motivational interviewing and coaching? Were the PT's trained to perform a telephone interview and to develop a tailored health intervention? Which aspects in the interview/ cq physical assessment guided their decisions on the goals, and training exercises. Who is involved in the text messages and role modeling video's? How is the website introduced to both the coaches and the participants, are the coaches trained and informed about the possibilities of the website. Apps etc. So please describe the implementation and which strategies will be used if the recruitment or adherence is not as expected.

Author Response: This information is provided as part of the TIDieR checklist in Table 2.

Alterations to Manuscript: None**.**

Author contributions

Comment 12. The Role of the authors related to their background would provide some more insight. For instance was a statistician involved in the study? How is the composition, roles, and responsibilities of the coordinating centre? Who are involved in a steering committee? Who is involved in the data management team, and other individuals or groups overseeing the trial? Who are responsible for the education of the providers of the intervention? And who is responsible to monitor the progress of the study?

Author Response: We have expanded on the author contribution section as outlined below.

Alterations to Manuscript: All authors contributed to the design of the study and preparation of the study protocol. This manuscript was drafted by author Sherrington who oversees all aspects of the study. Author Hassett oversees the intervention aspects of the study and the Sydney sites. Author O'Rourke oversees data collection and integrity and privacy. Author van den Berg oversees the South Australian sites. Authors Hinman, and Taylor oversee the Victorian sites. Author Hoffman oversees the Queensland sites. Authors Sherrington, Hinman, Crotty, Hoffman, Harvey, Taylor, Hassett and Tiedemann were Chief Investigators on the Grant application. Authors Milat. Treacy, Bennell, Howard and Jennings were Associate Investigators on the Grant application. Associate Investigator Herbert is not an author on this paper but will guide statistical analysis. Authors Treacy, Jennings and Milat are senior clinicians and/or policy leaders. Author Pinheiro will undertake the economic evaluation under guidance from author Howard. Author Greaves guided the use of behaviour change theory in intervention design. Author Milat will guide the use of the scale-up tool he developed. Authors ORourke, Kirkham and Ramsay are employed to work on the study. Authors Kirkham and Ramsay are the physiotherapists who deliver the health coaching interventions and assisted with the design of the interventions. Author Wong is a PhD student who will lead the implementation/process evaluation (to be reported separately). We are grateful to study participants and to the patient advisors who helped shape the intervention. (Lines 506-522)

Reviewer: 2
Amal A. Wanigatunga

Comment 1. My comments were addressed. The only thing I recommend is that the authors justify and/or cite the selection of "800m" to determine mobility limitations. In older adults, 1/4 mile or 400m is used to determine mobility disability (not limitations) but in this protocol, younger adults are recruited (probably part of the justification). However, the rationale for the 800m selection should be explicit in the protocol.

Vestergaard, S., Patel, K. V., Walkup, M. P., Pahor, M., Marsh, A. P., Espeland, M. A., ... & Guralnik, J. M. (2009). Stopping to Rest During a 400-Meter Walk and Incident Mobility Disability in Older Persons with Functional Limitations. Journal of the American Geriatrics Society, 57(2), 260-265.

> **Author Response:** We chose 800m in the inclusion criterion about mobility limitation as it has been used in a number of large cohort studies. For example this analysis of data from the Women's Health and Aging Study II (Weiss et al 2007) uses a primary outcome of "self-reported limitation walking one-half mile". Of course 800m is the metric version of one-half mile.
>
> **Alterations to Manuscript:** This reference has been added to the manuscript. (Line 210)

Reviewer: 3
Dawn Mackey

Thank you for the thorough responses and revisions you provided following the first round of review. There are three remaining items I would like to see incorporated in the manuscript.

Comment 1. As scalability is cited as a strength of the intervention, please add text to the manuscript to support the scalability of the intervention, considering both issues of cost and access.

> **Author Response:** This change has been made with addition of the below text to the discussion.
>
> **Alterations to Manuscript: "**The trial interventions are designed to be tailored yet scalable. The interventions are designed by health professionals and involve individualised health professional input, but have minimal face to face contact in an effort to minimise travel time, increase availability and enable greater efficiency. The use of a central centre to deliver the interventions is a model designed to be implemented if found to be effective. The inclusion of the lower intensity (text message) group aims to ascertain whether there is sufficient benefits from this less resource intensive model." (Lines 488-494)

Comment 2. Please add text to the manuscript to describe the consultations that were conducted with consumers, clinicians, and policy makers, similar to what was included in the first response to reviewer comments.

> **Author Response:** This change has been made with the addition of the below text to the "Patient and public involvement" section.
>
> **Alterations to Manuscript:**
> "Consultations with consumers, clinicians, and policy makers assisted in the design of intervention and study methods. This input was gained from a) input from our multidisciplinary study team that includes health service managers and clinicians; b) from informal discussions with health service managers, health professionals, health service users, community members and those delivering interventions in our previous trials[42-44], c) formal qualitative

work involving participants in our previous trials[45,46] and our systematic reviews of qualitative studies[47,48].

The study protocol and choice of intervention and assessment tools (including the burden on participants) was further guided by feedback from consumers obtained as part of the endorsement of the trial by the Australia & New Zealand Musculoskeletal Clinical Trials Network (ANZMUSC)". Study results will be disseminated to participants via email or paper letters. (Lines 414-427).

Comment 3. Please state the size and composition/expertise of the Data Monitoring Committee in the manuscript.

Author Response: This change has been made.

Alterations to Manuscript: "Unintended events will be reported to the 3-person independent Data Monitoring Committee that has been established for this trial and comprises one medical professional and two allied health professionals experienced in the care of people with mobility limitations. Unintended events will…" (Lines 304-307)

VERSION 3 – REVIEW

REVIEWER	Amal A. Wanigatunga, PhD, MPH Johns Hopkins Bloomberg School of Public Health
REVIEW RETURNED	31-Aug-2020

GENERAL COMMENTS	Great job!