Author's response to reviews

Title: Measuring the implementation of a group-based Lifestyle-integrated Functional Exercise (Mi-LiFE) intervention delivered in primary care for older adults aged 75 years or older: A pilot feasibility study protocol

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Version: 3
Date: 25 March 2015

Author's response to reviews: see over
March 25, 2015

Re: Response to Reviewers for MS 1865542889157901

Dear Pilot and Feasibility Studies Editorial Team and Reviewers,

We would like to thank the editorial team and the reviewers for your comprehensive review of our study protocol manuscript titled, “Measuring the implementation of a group-based Lifestyle-integrated Functional Exercise (Mi-LiFE) intervention delivered in primary care for older adults aged 75 years or older: A pilot feasibility study protocol” (MS: 1865542889157901).

We greatly appreciate your insightful comments and suggested revisions that have strengthened our manuscript. We have prepared a point-by-point response to your comments and have made the required changes to our manuscript to address the concerns. Please find uploaded on Biomed Central the revised manuscript with tables and the revised additional file 2.

Thank you for your continued consideration of this manuscript for publication in Pilot and Feasibility Studies journal.

Sincerely,

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Response to Reviewers

Reviewer #1:

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

None

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

1. Table 4 – ‘EQ5D’ is stated twice at bottom of the table, is this correct?
Authors’ Response: We revised the footnotes for Table 4 (now Table 1) to remove the additional “EQ5D”. (pg. 42)

2. Tables 5-7 – Could include how many participants are represented by the feedback?

Authors’ Response: We revised the titles for Tables 5-7 to include the number of participants represented by the fidelity evaluation and participant feedback. (pg. 46-48)

3. Possibly use bullet points for the ‘activity status’ list on page 9 to help with readability?

Authors’ Response: Bullet points were used for the description of activity status to help with readability as follows:

“For the first recruitment mode, potential participants will be screened for PA by a nurse and will be asked to choose which statement best describes their current activity status:

1. not physically active beyond moving around or walking during activities of daily living;
2. physically active occasionally or during certain seasons more than others;
3. physically active and participates in ≥30 minutes of moderate-intensity physical activities on ≥5 days/week.

Patients that are physically inactive (option 1) or occasionally physically active (option 2) will be targeted for the current study and told by the nurse or physician that they would benefit from more PA.” (pg. 10-11)

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

4. Introduction

It may facilitate reading and understanding if much of the discussion section were to be moved to the introduction section and information on Mi-Life section as appropriate. Specifically the evidence cited supporting the use of this type of intervention and why it is being used to explore the study objectives e.g. page 28 meta-analysis evidence.

Authors’ Response: We appreciate this suggestion from the reviewer and have moved the evidence cited supporting the use of the LiFE intervention to the introduction section (see below).

“Previous pragmatic trials evaluating the implementation of primary care-based PA interventions in older adults have included exercise referral schemes [24, 25] or PA counseling [15, 21]. Exercise referral schemes, where a physician refers patients to an external health care provider or community program, may increase PA levels in inactive older adults [25]. However, it is unclear whether this strategy promotes long-term adherence to exercise participation or if exercise referral schemes are safe and effective for frail elderly patients [24]. PA interventions where a physician or nurse provides an intensive PA counseling intervention in interdisciplinary family
health teams [15] demonstrated an increase in self-reported PA in healthy adult men and women compared to brief advice from a physician. Implementations of home or facility-based exercise or falls prevention programs in primary care-based settings are also possible strategies to result in higher uptake and more sustainable PA [23, 26-29].” (pg. 6)

“Evidence from meta-analysis and randomized controlled trial (RCT) research demonstrates exercise programs that include challenging balance and muscle strengthening exercises are effective for improving health outcomes and reducing falls [30, 1, 31, 32]. Recent work by Clemson et al. [1] demonstrated that teaching older adults how to integrate exercise into daily life activities over five home-based individual visits (the Lifestyle-integrated Functional Exercise (LiFE) program) was associated with an increase in self-reported PA, a 31% reduction in the rate of falls, and improvements in balance and ankle strength compared to controls. The LiFE program is unique such that participants learn activities, and then plan ways to integrate them into their day rather than perform them as part of a structured exercise program. An example of integrating the LiFE activities into a daily routine consists of doing a tandem walk on the way to the kitchen as a balance challenge [1]. The LiFE program is an alternative to traditional, structured exercise for increased PA and falls prevention with good retention and adherence rates in older adults aged 70 years or older [1, 30]. Therefore, implementing a group-based version of the LiFE program in a family health team practice (seen as a more efficient and realistic use of resources than individual delivery) is proposed as the next step in determining the feasibility and effectiveness of this strategy for chronic disease management and falls prevention.” (pg. 6-7)

5. Intervention
Although there is information provided on the pilot test for the intervention and how the intervention was modified at this point, there doesn’t appear to be any information on how the intervention has been adapted for use in a group-based setting. Was the Clemson et al 2012 intervention delivered to individuals only or small groups? How has it been adapted for group dynamics, for example variation between group members’ abilities? Also if the delivery of the intervention has been adapted whether this has required any specific training or different approach to delivery by the Physio?

Authors’ Response: We agree with the reviewer that further details on how we modified the intervention delivered by Clemson et al. are required. We provided an explanation in the manuscript on how the intervention was adapted for use in a group-based setting (e.g., variation between group members’ abilities, teaching and learning opportunities in group environment):

“Several modifications were made to adapt the LiFE intervention for use in a group-based setting. The group-based version of the intervention was designed to encourage discussion among participants regarding any successes or challenges to performing the activities. In the Mi-LiFE intervention, the activities were planned as a group and ideas for how, when, and where to perform the activities were shared among participants and recorded using the activity planner. Peer-to-peer learning strategies were facilitated by the PT and demonstrating the activities in the group setting allowed participants to observe how others performed the activities. Individualized activity recommendations were provided by the PT throughout the group sessions to accommodate variation among group members’ abilities. For the group-based version of the intervention, we reduced the number of forms participants were asked to complete to minimize
the burden of diary completion and to optimize data collection about adherence, PA, and falls. The activity planner was revised to include page numbers in the manual related to each activity, a comments section to describe successes or challenges experienced performing the activities, and a section to record the initial plan and subsequent progressions for each activity.” (pg. 29-30)

We also clarified that the Clemson et al. intervention was delivered to individuals only and elaborated on our rationale for modifying to a group format in the introduction section:

“Recent work by Clemson et al. [1] demonstrated that teaching older adults how to integrate exercise into daily life activities over five home-based individual visits (the Lifestyle-integrated Functional Exercise (LiFE) program) was associated with an increase in self-reported PA, a 31% reduction in the rate of falls, and improvements in balance and ankle strength compared to controls.” (pg. 6)

“The LiFE program is an alternative to traditional, structured exercise for increased PA and falls prevention with good retention and adherence rates in older adults aged 70 years or older [1, 30]. Therefore, implementing a group-based version of the LiFE program in a family health team practice (seen as a more efficient and realistic use of resources than individual delivery) is a proposed as the next step in determining the feasibility and effectiveness of this strategy for chronic disease management and falls prevention.” (pg. 7)

The current study’s physical therapist received training on the delivery of the LiFE intervention by reviewing the LiFE Trainer’s Manual. We were able to further refine the group-based intervention following feedback from the fidelity evaluation of our video-taped pilot test sessions by Dr. Clemson and Ms. Joanne Munroe (physical therapist that delivered the original LiFE intervention). We added the following information to the methods to clarify the training approach by our physical therapist:

“The PT received training on the delivery of the LiFE intervention by reviewing the LiFE Trainer’s Manual [43] and conducting a pilot test of the intervention sessions in a group of four participants (see “Pilot test of the Mi-LiFE intervention”). The PT was also implemented at least some LiFE activities into her daily routine, which provided personal experiences to share with the participants. Our approach to delivering the intervention is thought to be applicable to PTs, kinesiologists, and other health promoters in family health teams or other primary care settings that may deliver the intervention per protocol using the LiFE Trainer’s Manual.” (pg. 15)

6. Eligibility and consent
On page 10 the study states the researchers won’t be recruiting participants with dementia, but more information on how they will be managing those participants with cognitive impairment who do take part could be beneficial. Particularly, whether they are using a cognitive measure e.g. 6CIT or MMSE, to establish level of cognitive function and how they will manage participants when in the trial. So for example the consent process, the authors indicate that a physician will make the decision on whether someone can take part if they have a carer with them. Will consent be monitored throughout the 6 month intervention in case of a change in cognitive capability? More clarity on this would be useful.
Authors’ Response: We will not use a specific cognitive measure to establish level of cognitive function. As described in the manuscript (pg. 12), we will use a two-stage screening process to determine final clearance for the program regarding cognitive function and capacity to consent and participate. First, the potential participant’s physician will provide clearance for participation by reviewing their eligibility and signing a referral form. If the participant has cognitive impairment, the physician will confirm whether the potential participant would be able to participate if a caregiver attends the sessions and assists with program participation. Second, the participant will be required to recall the purpose and general structure of the program and their responsibilities following review of the information letter and consent form with the research assistant during Study Visit 1.

We will also call the participants before every study visit and intervention session, which will provide participants or caregivers with an opportunity to communicate continued interest in study participation or report any concerns to stop all or parts of participation. We have included a statement in the manuscript to clarify these details of our protocol:

“Participants will receive a phone call reminder from the research staff at least one day prior to each session, which will provide participants or caregivers with an opportunity to communicate continued interest in study participation or report any concerns (e.g., safety, difficulties with the intervention).” (pg. 24)

7a. Fidelity
It may be helpful to further describe (page 20) how the fidelity/adherence videos of the groups will be reviewed. For example will the independent reviewer/observer be using a checklist, a scale or looking for any specific behaviours/actions? Has this method been tested for consistency etc?

Authors’ Response: The fidelity evaluation of the video-taped intervention sessions will be performed by two independent reviewers (not involved in data collection) using a checklist developed by our research team. We aim to test this method for consistency by comparing checklists between the two independent reviewers and a third reviewer will be used to resolve any discrepancies. We have further described our fidelity evaluation in the methods:

“Fidelity will be evaluated by auditing video-taped sessions (individual and group) for the first and last cohorts of participants (5 or fewer individuals each cohort). Two independent reviewers not directly involved in data collection will review the video-taped sessions and provide feedback on the intervention fidelity using a checklist developed by our research team. The checklists will be compared for consistency and a third reviewer will be used to resolve any discrepancies between reviewers.” (pg. 23)

7b. On page 11 under enhancing recruitment, the authors may want to further explain how they will ensure translation is consistent? Assuming translators refers to a family relative or carer? This information would help inform intervention adherence and fidelity.

Authors’ Response: Our trial was designed to be inclusive of a wide range of participants, including non-English speaking individuals, which allows us to meaningfully assess the
feasibility of recruitment and implementation for our intervention. Translators will be encouraged to review the LiFE Participant’s Manual, attend the intervention sessions, and participate in all aspects of the intervention. However, we cannot ensure translation is consistent with the intervention protocol and this may affect intervention adherence and fidelity. We have further explained this point in the methods:

“Non-English speaking individuals will be eligible to participate in the program if they have access to a translator who can review the LiFE Participant’s Manual, attend the sessions, and participate in all aspects of the intervention with the participant that they are assisting. However, we are limited in our capacity to ensure the translation is consistent with the intervention protocol.” (pg. 12-13)

7c. On page 12, for clarity it may be useful to confirm whether those taking part in the study and those not taking part will be part of mixed groups receiving the intervention. If they are, then possibly stating how this will be managed.

Authors’ Response: Individuals taking part in the study and individuals not taking part in the study will be part of mixed groups receiving the intervention. They will be offered all the same elements of the intervention sessions (e.g., participant manual, activity planner), however, individuals not taking part in the study will not have any data collected. We have clarified this point in the methods section:

“Participants who do not consent to their data being collected for research purposes, but who have been referred to participate in the program, will be offered all aspects of the exercise program and materials, but will not have data collected.” (pg. 13)

8. Qualitative data
The authors indicate they will be using thematic analysis for the qualitative data, it would be helpful to know whether a pre-set list of topics would be covered during the interviews such as a schedule, and if so what topics would be covered. Will they be using the qualitative work to inform adherence? i.e. why participants didn’t complete the intervention. If they were to include a schedule of topics or themes they wanted to cover during the interviews this would help support how they will explore their objectives.

Authors’ Response: We thank the reviewer for this recommendation. We will be using a semi-structured interview format to assess reasons why the participant enrolled in the intervention, participant satisfaction with intervention delivery and materials, benefits they experienced from their participation, and adherence to and sustainability of the exercise program. We will use their qualitative feedback to inform their adherence to the intervention and obtain a better understanding of the barriers or facilitators to integrating the exercises into their daily life activities. We have added this information to the manuscript to further explain our analysis of the qualitative data:

“Qualitative feedback on the intervention will be obtained via semi-structured interviews with participants (in the presence of caregiver or translator as necessary) at completion of the intervention and at Study Visit 2. During the semi-structured interviews, we will cover a pre-set
list of topics to assess reasons why participants enrolled in the intervention, participant satisfaction with the intervention delivery and materials, benefits from participation, and adherence to and sustainability of the exercise program. If applicable, the effect of a caregiver or translator on feasibility (recruitment, retention, adherence) and implementation outcomes (intervention satisfaction) will be evaluated.” (pg. 22)

**Reviewer #2:**

**Major compulsory revisions**

1. **The overall aim of the proposed study needs to be clearer - is the intervention targeting increases in physical activity or falls reduction or both?**

Authors’ Response: We have revised the manuscript to clarify the overall aim of the proposed study. The overall aim of the study will be to evaluate the feasibility, effectiveness, and implementation of a group-based version of the LiFE intervention in primary care for older adults aged 75 years or older using the RE-AIM framework. The intervention is primarily targeting increases in accelerometer-measured physical activity; yet, we are also collecting data on falls incidence as a descriptive outcome to inform a future trial.

Our primary objectives and hypotheses will be related to feasibility outcomes (recruitment, retention, and adherence) and secondary objectives will evaluate effectiveness outcomes, such as PA levels, physical performance, and quality of life, and implementation outcomes to inform a larger trial. We have clarified the study aims in the introduction:

“The rationale for the current study was to evaluate whether the LiFE intervention, which has been shown to be effective in reducing falls and increasing self-reported PA in a research setting, could be implemented in a real-world primary care practice. Since the original study [1] did not objectively measure whether the LiFE intervention increased PA levels in older adults, a secondary aim of this study was to evaluate whether the LiFE intervention increases PA levels measured by an accelerometer. RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) is an example of a multi-level evaluation framework that may facilitate the measurement of public health effects and barriers and facilitators to implementation [33]. Thus, we have designed a pilot pre-post feasibility study using the RE-AIM framework to measure the pragmatic implementation of a group-based version of the LiFE intervention, referred to as the Mi-LiFE intervention, in primary care for older adults aged 75 years or older. The Mi-LiFE intervention is proposed as a method to engage older adults in sustainable exercise participation and chronic disease management, and to increase PA levels.” (pg. 7-8)

We also revised the objectives to better reflect our overall aim:

“The overall aim of our pilot study will be to evaluate the feasibility, effectiveness, and implementation of a group-based version of the LiFE intervention in primary care for older adults aged 75 years or older using the RE-AIM framework (Table 1). Our primary objectives and hypotheses will be related to feasibility outcomes (recruitment, retention, and adherence) and include:
(1) to evaluate the number of participants we can recruit to participate in the program from a family health team practice over 6 months; the intervention will be considered feasible without modification if we recruit 30 participants over 6 months based on data collected from the family health team’s geriatric screening program.

(2) to determine intervention retention rates; the intervention will be considered feasible without modification if 75% of the sample completes the 6-month follow-up assessments. This criteria is based on the original LiFE study [1] wherein 78% of participants completed the 6-month follow-up assessments.

(3) to determine adherence to the intervention; the intervention will be considered feasible without modification if 50% of the participants complete balance and strength activities ≥3 days/week over the 6-month study period. Our criteria are based on randomized controlled trial (RCT) data in exercise and falls prevention research wherein completion of balance and strength exercise ≥3 days/week was positively associated with falls outcomes [1, 32, 34-36, 28].

Secondary objectives will evaluate the effectiveness of the intervention by measuring PA levels, physical performance, and quality of life, and implementation outcomes to inform a larger trial. Secondary outcome measures, such as PA levels measured using accelerometry, or challenges recorded in implementation log, will inform the future evolution of the research or implementation. Description of outcomes, hypotheses, outcome measures, and statistical analyses in the study protocol are shown in Table 2.” (pg. 8-9)

2. I am not convinced that the small amount of previous feasibility testing of the intervention and accompanying research instruments is a real indication of what will happen during real world implementation - further feasibility should be woven into the protocol. This is as an opportunity to make further amendments to the intervention and to the intended outcome measures. I am concerned that frail older people will find it very difficult to comply with the extent of recording required.

Authors’ Response: We agree with the reviewer’s comment and acknowledge that amendments to the protocol will likely be necessary following completion of our pilot trial. Therefore, we will be recording challenges to implementation and will analyze the implementation log entries, video-taped sessions, intervention phone calls, and activity planners using thematic content analysis to identify which aspects of the intervention were challenging and which outcome measures were difficult to complete. This information has been added to our methods:

“Barriers and facilitators to implementation reported by the research staff, PT, physicians/clinical staff, and participants will be recorded in an implementation log by the research assistant. The log entries, video-taped sessions, intervention phone calls, and activity planners will be evaluated via thematic content analysis [59] to identify which aspects of the intervention were challenging and which outcome measures were difficult to complete.” (pg. 22)

We also revised the discussion to clarify our decision-making regarding whether or not to move forward with a future larger-scale trial:
“We are collecting data on challenges to implementation of the intervention and intended outcome measures to inform whether or not we move forward with a future larger-scale trial, and to identify possible major or minor modifications to our protocol.” (pg. 31)

3. In a similar vein, the fact that you have one expert deliverer of the intervention does not inform future training and supervision requirements for a greater number of deliverers in a future trial and ability to deliver the intervention per protocol.

Authors’ Response: We agree with the reviewer that having one expert deliverer is a limitation and we will not be able to comment on training and supervision requirements across physical therapists. However, our physical therapist will log challenges to implementing the intervention, which will provide her perspective on barriers to implementation (e.g., training and supervision requirements) for a future larger-scale trial. We have clarified this limitation in the discussion:

“Our findings related to adoption at the organization level are limited to our experience of implementing the intervention in one family health team practice with one expert deliverer. A multi-centre cluster RCT is required to better evaluate acceptance and readiness for adopting the Mi-LiFE intervention in family health team practices, variation of implementation across deliverers and sites, and effectiveness of the intervention vs. a comparator.” (pg. 33-34).

Furthermore, our physical therapist did not receive specialized training or supervision on the intervention delivery beyond reviewing the LiFE Trainer’s Manual and implementing some of the LiFE activities into her daily routine. Therefore, our approach to delivering the intervention is thought to be applicable to physical therapists, kinesiologists, and other health promoters that may deliver the intervention per protocol using the LiFE Trainer’s Manual. We have clarified this point in the methods:

“The PT received training on the delivery of the LiFE intervention by reviewing the LiFE Trainer’s Manual [43]. The PT also implemented some of the LiFE activities into her daily routine, which provided personal experiences to share with the participants. Our approach to delivering the intervention is thought to be applicable to PTs, kinesiologists, and other health promoters in family health teams or other primary care settings that may deliver the intervention per protocol using the LiFE Trainer’s Manual.” (pg. 15)

4. The presentation of primary and secondary outcomes needs changing - recruitment is an indication of study feasibility and is often quoted in stop/ go criteria but is not a primary outcome. The presentation of outcomes in table 4 is correct.

Authors’ Response: We thank the reviewer for this valuable suggestion to improve the presentation of the primary and secondary outcomes. We agree that Table 4 (now Table 1) is a more accurate reflection of the primary and secondary outcomes. We have revised the order of the tables to introduce how the RE-AIM framework was applied to the study outcomes first (Table 1) followed by a summary of the outcomes, hypotheses, outcome measures, and methods of analysis (Table 2).
We have revised the presentation of the outcomes throughout the methods to better reflect the reviewer’s recommendation. We also clarified that recruitment is an indication of the study feasibility not a primary outcome on its own.

5. **Carer assessment is raised but not enlarged upon - also why the age restriction for carer participation in the proposed study.**

Authors’ Response: We did not impose an age restriction for caregiver participation in the proposed study. However, we do have a minimum age criteria of 65 years or older to complete the study assessments in the spouses/partners, family members, or friends attending the intervention. We have clarified this point in the methods:

“If the participant has cognitive impairment, they will be required to attend the intervention sessions with a caregiver, who will assist them with the program. All participants will be encouraged to attend the program with a spouse/partner, caregiver, family member, or friend. If the spouse/partner, caregiver, family member, or friend is ≥65 years, they will be provided the opportunity to complete the assessments.” (pg. 12)

We agree that details on the caregiver assessment require elaboration. We clarified in the methods that we plan to collect qualitative data via semi-structured interview with the participants and caregivers regarding the effect of the caregivers on feasibility (recruitment, retention, adherence) and implementation outcomes (intervention satisfaction, fidelity) (see below).

“Qualitative feedback on the intervention will be obtained via semi-structured interviews with participants (in the presence of caregiver or translator as necessary) at completion of the intervention and at Study Visit 2.” (pg. 22)

“During the semi-structured interviews, we will cover a pre-set list of topics to assess reasons why individuals participated in the intervention, participant satisfaction with intervention delivery and materials, benefits they experienced from their participation, adherence to and sustainability of the exercise program. If applicable, the effect of a caregiver or translator on feasibility (recruitment, retention, adherence) and implementation outcomes (intervention satisfaction) will be evaluated.” (pg. 22-23)

6. **The authors may want to reconsider their stringent criteria for progression; for example analysis of the available accelerometry data.**

Authors’ Response: The criteria for success were established to reduce bias regarding our decisions to move forward with further research or implementation. We will either choose to move forward without modification, move forward with major or minor modification or not move forward. As such, we have added “without modification” to each criteria on pg. 8-9.

We agree with the reviewer that the way the criteria are written implies a yes/no decision. However, our progression may be informed by evaluation of multiple factors, not just the
recruitment, retention and adherence. Therefore, we have added the following sentence to the objectives:

“Secondary outcome measures, such as PA levels measured using accelerometry, or challenges recorded in the implementation log, will also inform the future evolution of the research or implementation.” (pg. 9)

**Minor essential revisions**

7. **The presentation of new literature and arguments for the intervention are at the end of the paper rather than forming the background. The discussion should be concerned with the options going forward.**

Authors’ Response: We agree with the reviewer’s suggestion to move new literature and evidence supporting the study rationale to the introduction (see below).

“Previous pragmatic trials evaluating the implementation of primary care-based PA interventions in older adults have included exercise referral schemes [24, 25] or PA counseling [15, 21]. Exercise referral schemes, where a physician refers patients to an external health care provider or community program, may increase PA levels in inactive older adults [25]. However, it is unclear whether this strategy promotes long-term adherence to exercise participation or if exercise referral schemes are safe and effective for frail elderly patients [24]. PA interventions where a physician or nurse provides an intensive PA counseling intervention in interdisciplinary family health teams [15] demonstrated an increase in self-reported PA in healthy adult men and women compared to brief advice from a physician. Implementations of home or facility-based exercise or falls prevention programs in primary care-based settings are also possible strategies to result in higher uptake and more sustainable PA [23, 26-29].” (pg. 6)

“Evidence from meta-analysis and randomized controlled trial (RCT) research demonstrates exercise programs that include challenging balance and muscle strengthening exercises are effective for improving health outcomes and reducing falls [30, 1, 31, 32]. Recent work by Clemson et al. [1] demonstrated that teaching older adults how to integrate exercise into daily life activities over five home-based individual visits (the Lifestyle-integrated Functional Exercise (LiFE) program) was associated with an increase in self-reported PA, a 31% reduction in the rate of falls, and improvements in balance and ankle strength compared to controls.” (pg. 6)

8. **The paper is overly long and would benefit from editing.**

Authors’ Response: We have edited the manuscript according to the reviewers’ comments and made the manuscript more concise, particularly in the methods and discussion sections.

**Discretionary revisions**

9. **The extent of planned statistical tests are rather excessive for a modest feasibility study.**
Authors’ Response: We have reported the planned statistical tests in accordance with the SPIRIT 2013 Statement reporting guidelines. However, we revised this section to refer to Table 2 for a summary of the planned primary and secondary outcome analyses and removed the excessive explanation in the manuscript to avoid redundancy.