Author’s response to reviews

Title: Peer volunteers in an integrative pain management program for frail older adults with chronic pain: study protocol for a single group trial

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Response to the reviewer

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Thank you for providing your comments and advice. The manuscript had been sent for English editing. Also, we have addressed the issues that you raised and have made corresponding changes which are highlighted in blue in the manuscript. Please also refer to the point-by-point response as follows, in which the changes are in italic:

Abstract
#1 Discussion section states that older adults “do not prefer taking pain medications.” While it is likely true that many adults prefer not to take pain medications, this statement may be stated in too general of a manner, since it is also likely not true of all older adults.

Response: Thank you for the comment. We agree that this statement may be too general and we therefore have revised the statement as follows:

In view of the high prevalence of chronic pain among older adults and its adverse impacts, it is important to provide older adults with tools to control their pain. We propose the use of peer volunteers to enhance….

Background
#1 3rd paragraph, 2nd sentence, same comment as above related to a generalized statement about older adults’ preferences regarding medication use.

Response: We agree that not every older adult would prefer not to use pain medication. We have now made the statement less general:

However, some older people prefer not to use pain medication and often request them only when the pain reaches an intolerable level.

#2 7th paragraph, 2nd sentence seems to start referring to one particular study. If that is the case, what “interventions” are being referred to here? In general it may be helpful to be clearer that this sentence is talking about the study that you continue to describe in the next couple of sentence.

Response: Sorry for the confusion. The second sentence was meant to refer to general social support interventions in the community, rather than to any particular study. We have now clarified the sentence:

…and will lead to a greater exercise adherence to such activities, as well as result in a higher level of enjoyment of them [12]. Social support interventions in community settings focus on changing physical activity behavior through building, strengthening, and maintaining social networks that provide supportive relationships for behavioral change. In general, these interventions involve making a “contract” ….

In a study conducted in the United States, 81 sedentary adults were randomly assigned….
#3 7th paragraph, last sentence, how are the results of “enhanced long-term maintenance of physical activity” and “significantly more physical activity….after 18 months” different

Response: We apologize that the last sentence did not contain enough details. “Long-term maintenance” was meant to refer to the differences in physical activity within the group over time (i.e. baseline vs. at 16 weeks vs. at 18 months), while “significantly more physical activity” referred to the differences in physical activity between the control group and the group with peer support at a particular time point. We have now added more details on the results of that study:

No significant difference in moderate-to-vigorous physical activity (MVPA) minutes/week at week 16 were found between the two groups, but both reported significantly more MVPA minutes/week relative to baseline at week 16. Moreover, peer volunteers (PVs) enhanced the long-term maintenance of physical activity, as the active intervention group was able to maintain and slightly increase their PA behavior by the 18-month follow-up session, while the standard community intervention group began to return to their baseline levels. There was significantly more physical activity among the group with peer support relative to the standard community intervention group after 18 months of follow up [13].

#4 8th paragraph, 2nd sentence, recommend removing “showed a tendency for” and just stating that the peer group had a 27% decrease… Perhaps the statement of “tendency” is referring to a lack of statistically significant difference, but the way it’s worded here doesn’t seem completely correct.

Response: Thank you for the comment. The use of “tendency” referred to a lack of statistically significant difference. Because this word might be confusing, we have now removed the words “showed a tendency for”:

…participants (n=52, aged 65-94) in the peer-led group reported a 27% decrease in falls and more weekly walking for 34 minutes compared with the control group…

#5 10th paragraph, 1st sentence, recommend removing or changing the word “effectiveness” since a preliminary study like this really doesn’t test effectiveness.

Response: Thank you for the suggestion. The word “effectiveness” has now been removed as this is a pilot study to test the feasibility of the program. The sentence has been revised as follows:

The aim of this study is to determine the feasibility of PVs in an IPMP for Hong Kong older adults with chronic pain.

#6 10th paragraph, I’m not sure what is meant by a “dose-response relationship.” This is described later, but typically a dose-response relationship refers to how much of an intervention someone received (e.g., people who received the whole intervention vs. drop out before completion), rather than the time-course of changes, as it seems to mean here. Recommend revising this terminology here
and later in the manuscript. Minimally, explain clearly up front what you mean by dose-response in this context.

Response: Thank you for the comment. We have now added an explanation of the meaning of “dose-response relationship” in our study. The revised sentence is as follows:

… we would also like to examine the dose-response relationship of an IPMP with PVs in this study (i.e. the possibly non-linear association between intervention duration and pain intensity score).

Method
#1 Recommend adding a brief description of how participants will be recruited.

Response: Thank you for the suggestion. Details on the recruitment of the subjects have now been added:

The participants will be recruited from one nursing home in Hong Kong. The home-in-charge nurse will be approached and invited to participate in the study. Older adults in the nursing home who are interested to participate will be recruited according to the inclusion criteria. The present study will be a pilot study with 30 participants.…..

PVs will be recruited from a pool of regular members in the IAA. The IAA staff will announce and promote this study to those members. Those members who are interested will be invited to register and participate in the study. A total of 30 will be recruited.

# 2 Describe whether there may be a ‘learning effect’ or other potential methodological issues with repeating the measures so many times during the intervention

Response: We agree that the measure of pain intensity in the beginning of all 16 training sessions may induce a so-called “learning effect”, which will familiarize the participants with the measuring instrument in the study. Ideally, to control for this and other potential effects, we should include a control group. However, as the IPMP has been shown to be effective and this study aims to evaluate the effect of peer volunteers, introducing a control group may not be appropriate. We have acknowledged this as a limitation and suggest further studies with randomized controlled trial design to adjust this so-called “learning effect”.

#3 Data analysis section – explain what is meant by “mid-intervention effect”
Response: Sorry for the confusion. By “mid-intervention effect,” we were referring to the effect of our intervention on the pain score during weeks 1 to 8 (P1). Other outcomes, such as functional mobility, physical activity, etc., will not be collected before the completion of the 8-week intervention. For clarity, we have decided not to use the term “mid-intervention effect,” but rather “intervention effect”.

#4 Describe how any issues of non-normal data will be handled (e.g., alternatives to a t-test).
Response: If the data do not follow a normal distribution, we will use the Wilcoxon Signed-rank test and the Mann-Whitney U test for within-group and between-group comparisons respectively. We have included the following lines:

... a t-test will be used to compare the mean pain intensity, functional mobility, physical activity, loneliness and happiness levels and use of non-pharmacological methods collected at four time points, i.e., between P0 and P1, P1 and P2, P1 and P3 (for pain only) and between P0 and P2, P0 and P3, and P2 and P3 (for other variables). The Kolmogorov-Smirnov normality test will be used to examine the normality of the outcome variables. If the data do not follow a normal distribution, we will use the Wilcoxon Signed-rank test and the Mann-Whitney U test for within-group and between-group comparisons, respectively.

Discussion

#1 The overall goal of this research is to see if the PV’s help with long-term adherence. This study involves 12 weeks of measurement, which is not long-term. While this is fine for a pilot study since the real assessment is on feasibility, I recommend noting a limitation regarding the duration of the study, particularly related to its ability to assess long-term changes.

Response: Thank you for the suggestion. We are aware of the limitation, as this is only a pilot study. The limitation of this study has now been added in the discussion section.

... The limitations of this study should be noted. As it is only a pilot study lasting 12 weeks, long-term changes in the outcome measures cannot be evaluated. Moreover, there may be a “learning effect”, which will familiarize the participants with measuring instrument in the study as there will be a repeated measure of pain intensity in the beginning of all 16 training sessions. This study provides evidence for future, larger studies that utilize a randomized controlled design and a possibly longer follow-up time to adjust this “learning effect” and to investigate whether PVs should be integrated in programs for older adults with chronic pain. This will help to promote health among older adults in the long-term.

#2 2nd paragraph states that if the study is positive, PVs should be integrated… However, this is only a pilot study, and the true effectiveness will be evaluated in a larger trial. Therefore this remark should probably be revised a bit.

Response: Thank you for the comment. We agree that this is only a pilot study to test the feasibility of integrating PVs into a pain management program and that the true effectiveness of this measure needs to be further evaluated in larger trials with a randomized controlled design. Therefore, we have now revised the relevant lines to read:

This study provides evidence for future, larger studies that utilize a randomized controlled design and a possibly longer follow-up time to adjust this “learning effect” and to investigate whether PVs should be integrated in programs for older adults with chronic pain. This will help to promote health among older adults in the long-term.