PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Comparison of open- and closed-chain exercises in improving the response inhibitory ability of the elderly: a protocol for a randomized controlled clinical trial
AUTHORS	Ke, Liu; Lanlan, Zhang; Jian, Zhang; Jianing, Wei

VERSION 1 – REVIEW

REVIEWER	Snowdon, David Monash University, Peninsula Clinical School
REVIEW RETURNED	14-Jun-2021

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript reporting the protocol for a pilot randomised controlled trial investigating the effects of open and closed chain exercise on improving the inhibitory control ability of the elderly. My primary feedback is that the authors should consider using either the CONSORT extension for pilot randomised controlled trials OR the SPIRIT checklist to ensure that they report on all areas required for pilot trials AND that they structure the content appropriately (i.e. appropriate headings). The authors also need to provide justification for why they are labelling this trial a 'pilot trial'. Introduction: - Page 10 line 38 needs a reference to support the statement. - Page 10 line 48 needs a reference to support the statement. - Page 11 line 25 needs a reference to support the statement. - Page 11 line 25 can you expand on the forms of cognitive function that are improved with open chain exercise (i.e. what is already known in this area of research) in the elderly? Aims - The study protocol you are reporting is a pilot study. The aims need to reflect the fact that this is a pilot study. The aim of a pilot study should not be to determine efficacy. Please justify why this study is labelled a 'pilot study' and refer to the BMJ Open website (author page) for possible reasons and further information on pilot studies. References: Leon et al. The Role and Interpretation of Pilot Studies in Clinical Research. J Psychiatr Res. 2011 May ; 45(5): 626–629. doi:10.1016/j.jpsychires.2010.10.008 Thabane et al. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology 2010, 10:1 http://www.biomedcentral.com/1471-2288/10/1 Methods

	- Please provide details on the randomisation procedure i.e. how exactly will participants be randomised? Will you use a computer generated random number sequence or another method? - Please provide details on the allocation procedure i.e. Who? When? How? - Page 13 line 48: You state 'Before and after the intervention, all groups will have their demographics statistically analyzed for factors such as health status, physical fitness, and cognitive function (Table 1). Intergroup differences will be minimized before the intervention' o Can you please clarify what 'Intergroup differences will be minimized before the intervention' means? o This should be reported in the statistical analysis section. - Under the heading 'evaluation procedures' you have described the interventions and control conditions. I'm not sure how the intervention is an 'evaluation procedure'. I suggest using the CONSORT extension for pilot studies to assist with headings and to ensure that all relevant information is reported. Reference Thabane et al. Methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials Pilot and Feasibility Studies (2016) 2:25 DOI 10.1186/s40814-016-0065-z - The description of the interventions and control is rather brief. I suggest using the TIDIER framework to help with reporting this section and ensuring that all relevant information pertaining to the interventions and control are reported. Reference Hoffman et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014; 348 doi: https://doi.org/10.1136/bmj.g1687 - Regarding the control group: will they be discouraged from exercising? How will you measure or know that they don't participate in any sport? - Why will participants of both groups be required to exercise at 60-70% of max heart rate? Particularly for the table tennis group? This group appears to have a large focus on skill development rather than aerobic fitness. - Further to the point above, on page 15 you state 'The exercise intensity will be monitored, ensuring that the heart rate remains in the range of 60–70% of the maximum heart rate (HRMAX = 220 – age)', then on page 16 you state 'Fit aerobics at 50–60% of the heart rate reserve for the first two weeks, followed by 70–75% of the heart rate reserve'. The heart rate values/range stated are not consistent. - - Will you be measuring compliance/attendance in the intervention groups?

	- Table 1 and Table 2 are unnecessary. Report the specific demographics/outcomes that will be collected in the text rather than a table. - A table outlining the outcomes and the time points at which they are to be collected would be valuable. - References are required for all the outcomes that are reported. - 'Go Reaction Time', 'Stop Response Reaction Time', 'Stop Signal Response Time' and 'Stop Signal Delay' are confusing terms and it would be good to provide a clear definition of each term, early in the outcomes section, to provide the reader with the context required to understand these terms. - Please include a section on outcome assessors. Who are they and will they be blind to group allocation? - Will researchers who analyse the data be blind to group allocation? - Figure 1 is difficult to read with the black background. - Figure 2 and 3 require a legend to help with interpretation of the symbols in each figure. Discussion - BMJ open has clear guidelines on the structure of manuscripts reporting on research protocols. They do not require a discussion and I think that much of the information in the discussion would fit better in the introduction – as it would provide the reader with further background information on the effects of different types of exercise (open and closed chain) on cognitive function. - The limitations section in the discussion should be summarised in the 'Strengths and Limitations' dot points at the beginning of the manuscript. There are no limitations in the dot points of the manuscript, where they should be summarised. - In the discussion you refer to many terms regarding cognitive function, including inhibition, refresh, conversion and transformation ability. It would help the reader if these terms were explained. - In the discussion you also report on previous literature that investigated athletes who engage in open-chain exercises. Where possible, it would be good to provide the reader with a thorough background on the literature investigating the elderly first. This is missing from the manuscript and it is difficult to interpret the literature on athletes when the literature on the elderly is not provided in detail.

REVIEWER	Gluchowski, Ashley The University of Manchester, Health Ageing Research Group
REVIEW RETURNED	28-Jun-2021

GENERAL COMMENTS	In exercise prescription, open and closed exercise also has a different meaning (kinetic chain). Would be worthwhile to distinguish this.

	Your fit aerobics seems to have an element of strength training, which is no longer just 'aerobics' and may be labelled 'multicomponent', consider removing this to make this comparison truly aerobic. Consider more details in methods section (as currently there is not enough to allow for replication). For instance, are participants exercising in groups (socialization, increased adherence) or one-on-one with trainer? Will this impact results? No mention of HRR in table tennis group (but mentioned in fit aerobic group), but mentions HRmax in overall procedures. Please clarify what metric will be used to monitor and compare exercise intensity between groups and make consistent. I can see many other limitations that haven't been presented, consider expanding this section. Consider expanding on randomization concealment, and mechanism.

VERSION 1 – AUTHOR RESPONSE

Responds to the reviewers' comments:
Reviewer: 1
Dr. David Snowdon, Monash University, Peninsula Health
Comments to the Author:
Thank you for the opportunity to review this manuscript reporting the protocol for a pilot randomised controlled trial investigating the effects of open and closed chain exercise on improving the inhibitory control ability of the elderly. My primary feedback is that the authors should consider using either the CONSORT extension for pilot randomised controlled trials OR the SPIRIT checklist to ensure that they report on all areas required for pilot trials AND that they structure the content appropriately (i.e. appropriate headings). The authors also need to provide justification for why they are labelling this trial a ‘pilot trial’.
1

Answer
The the SPIRIT checklist has already been added,include the page/line numbers of my manuscript where the relevant information can be found.

Introduction:
2
- Page 10 line 38 needs a reference to support the statement.

Answer
Relevant references have been added.

3
- Page 10 line 48 needs a reference to support the statement.

Answer
Relevant references have been added.

4
- Page 11 line 25 needs a reference to support the statement.

Answer
Relevant references have been added.

5
- Page 11 line 25 can you expand on the forms of cognitive function that are improved with open chain exercise (i.e. what is already known in this area of research) in the elderly?

Answer
In the process of serving the elderly community, to help the elderly establish health profiles, we were tested such as MOCA, BDI-II, MMSE, etc.We found that compared with the closed chain exercise and the no exercise elderly, the cognitive function of the elderly in the open chain exercise is better.And according to previous studies, it is found that athletes in open chain exercise have better reaction inhibition ability than athletes in closed chain exercise. Therefore, we want to explore whether open chain exercise is more effective in improving the cognitive ability of the elderly.

Aims
6
- The study protocol you are reporting is a pilot study. The aims need to reflect the fact that this is a pilot study. The aim of a pilot study should not be to determine efficacy. Please justify why this study is labelled a 'pilot study' and refer to the BMJ Open website (author page) for possible reasons and further information on pilot studies.
References:
Leon et al. The Role and Interpretation of Pilot Studies in Clinical Research. J Psychiatr Res. 2011 May ; 45(5): 626–629. doi:10.1016/j.jpsychires.2010.10.008
Thabane et al. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology 2010, 10:1 http://www.biomedcentral.com/1471-2288/10/1

Answer
We collated previous studies and found that closed chain exercise athletes and open chain exercise athletes have differences in inhibitory control ability,this difference is seen in both behavior and brain function. Therefore, we assumed that the exercise pattern would be used as an intervention, and wanted to explore whether such a difference would appear in the elderly.

Methods
7 and 8

- Please provide details on the randomisation procedure i.e. how exactly will participants be randomised? Will you use a computer generated random number sequence or another method?

- Please provide details on the allocation procedure i.e. Who? When? How?

Answer
Add the Randomisation section in the article to describe the above information in detail

9
- Page 13 line 48: You state 'Before and after the intervention, all groups will have their demographics statistically analyzed for factors such as health status, physical fitness, and cognitive function (Table 1). Intergroup differences will be minimized before the intervention'
o Can you please clarify what 'Intergroup differences will be minimized before the intervention' means?
o This should be reported in the statistical analysis section.

Answer
‘Intergroup Differences will be minimized before the intervention' means that, in order to ensure no inter-group differences in all test indicators after random grouping, I will carry out independent - sample T test on the grouped data. In the absence of significant differences, continue the next steps.I will add related reports in the Statistical Analysis section.

10
- Under the heading ‘evaluation procedures’ you have described the interventions and control conditions. I’m not sure how the intervention is an ‘evaluation procedure’. I suggest using the CONSORT extension for pilot studies to assist with headings and to ensure that all relevant information is reported.

Reference

Thabane et al. Methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials Pilot and Feasibility Studies (2016) 2:25 DOI 10.1186/s40814-016-0065-z

Answer
Thank you very much for your reference. I have learned the writing method of the CONSORT Extension for Pilot Studies.My title may not be set accurately enough. The title should not be called 'Evaluation Procedures', ' Exercise Intervention 'can summarize the content described in this part.

11
- The description of the interventions and control is rather brief. I suggest using the TIDIER framework to help with reporting this section and ensuring that all relevant information pertaining to the interventions and control are reported.

Reference
Hoffman et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014; 348 doi: https://doi.org/10.1136/bmj.g1687

Answer
The interventions and control has been described with TIDIER framework

12
- Regarding the control group: will they be discouraged from exercising? How will you measure or know that they don’t participate in any sport?

Answer
All the participants are not used to regular exercise before participating in the experiment. The control group just needs to maintain their old habits,and we will visit the control group regularly to evaluate their physical activity, so as to ensure that their physical activity does not meet the exercise standards.

13
- Why will participants of both groups be required to exercise at 60-70% of max heart rate? Particularly for the table tennis group? This group appears to have a large focus on skill development rather than aerobic fitness.

Answer

Because I wanted to make sure that the participants were exercising at the right intensity through heart rate monitoring.

14
- Further to the point above, on page 15 you state ‘The exercise intensity will be monitored, ensuring that the heart rate remains in the range of 60–70% of the maximum heart rate (HRMAX = 220 – age)’, then on page 16 you state ‘Fit aerobics at 50–60% of the heart rate reserve for the first two weeks, followed by 70–75% of the heart rate reserve’. The heart rate values/range stated are not consistent.

Answer
I'm sorry for the inconsistency caused by my writing error. It has been adjusted now.

15
- Will you be measuring compliance/attendance in the intervention groups?

Answer
Yes, we will have coaches to monitor and record their attendance, and if they are absent, they will supplement the training at other times.

16
- Table 1 and Table 2 are unnecessary. Report the specific demographics/outcomes that will be collected in the text rather than a table.
Answer
Thank you for that excellent and insightful series of remarks. Personally, I think the existence of Table 1 and Table 2 is to make the data more clearly presented and facilitate the comparison among different groups. For Table 2, the differences among groups at different time points can also be seen.

17
- A table outlining the outcomes and the time points at which they are to be collected would be valuable.

Answer
The metrics and time points for the secondary results that you want to collect are listed in table2.

18
- References are required for all the outcomes that are reported.

Answer
The results of all reports have been supplemented with references as required.

19
- ‘Go Reaction Time’, ‘Stop Response Reaction Time’, ‘Stop Signal Response Time’ and ‘Stop Signal Delay’ are confusing terms and it would be good to provide a clear definition of each term, early in the outcomes section, to provide the reader with the context required to understand these terms.

Answer
Appropriate explanations have been provided in place, thanks for the tip.

20 and 21

- Please include a section on outcome assessors. Who are they and will they be blind to group allocation?

- Will researchers who analyse the data be blind to group allocation?

Answer
A description of the outcome assessors has been added to the statistical analysis section.

22
- Figure 1 is difficult to read with the black background.

Answer
The background color of the Figure 1 has been replaced.

23
- Figure 2 and 3 require a legend to help with interpretation of the symbols in each figure.

Answer
The figure legends have been added.

Discussion

24
- BMJ open has clear guidelines on the structure of manuscripts reporting on research protocols. They do not require a discussion and I think that much of the information in the discussion would fit better in the introduction – as it would provide the reader with further background information on the effects of different types of exercise (open and closed chain) on cognitive function.

Answer
Part of the discussion has been moved to the introduction

25
- The limitations section in the discussion should be summarised in the ‘Strengths and Limitations’ dot points at the beginning of the manuscript. There are no limitations in the dot points of the manuscript, where they should be summarised.

Answer
The limitations section has been adjusted appropriately.

26
- In the discussion you refer to many terms regarding cognitive function, including inhibition, refresh, conversion and transformation ability. It would help the reader if these terms were explained.

Answer
Related terms have been explained.

27
- In the discussion you also report on previous literature that investigated athletes who engage in open-chain exercises. Where possible, it would be good to provide the reader with a thorough background on the literature investigating the elderly first. This is missing from the manuscript and it is difficult to interpret the literature on athletes when the literature on the elderly is not provided in detail.

Answer

Related literature for the elderly has been added.

Reviewer: 2
Dr. Ashley Gluchowski, The University of Manchester
Comments to the Author:

1
In exercise prescription, open and closed exercise also has a different meaning (kinetic chain). Would be worthwhile to distinguish this.

Answer
Added the content to distinguish between open and closed exercise in exercise prescriptions in the introduction.

2
Your fit aerobics seems to have an element of strength training, which is no longer just 'aerobics' and may be labelled 'multicomponent', consider removing this to make this comparison truly aerobic.

Answer
The part that is easy to make people ambiguous has been deleted. Thank you for your opinion.

3
Consider more details in methods section (as currently there is not enough to allow for replication). For instance, are participants exercising in groups (socialization, increased adherence) or one-on-one with trainer? Will this impact results?

Answer
The details of the method section have been added, and the group exercise method has been explained

4
No mention of HRR in table tennis group (but mentioned in fit aerobic group), but mentions HRmax in overall procedures. Please clarify what metric will be used to monitor and compare exercise intensity between groups and make consistent.

Answer
HRR in the aerobic group has been modified.Exercise intensity will be monitored uniformly using HRmax in the overall program.

5
I can see many other limitations that haven't been presented, consider expanding this section.

Answer
The part about research limitations has been appropriately added

6
Consider expanding on randomization concealment, and mechanism.

Answer
In order to express in more detail and conform to the specification, the TIDIER Framework was adopted to describe the motion intervention

VERSION 2 – REVIEW

REVIEWER	Snowdon, David Monash University, Peninsula Clinical School
REVIEW RETURNED	22-Sep-2021

GENERAL COMMENTS	I thank the authors for addressing most of my comments. It is now clear how participants will be randomized, what intervention the groups will receive (through use of the TIDIER checklist) and that researchers who analyze the data will be blind to group allocation. However, I still have some minor concerns. 1. The aims of your study are not consistent with the aims of a pilot trial. As previously mentioned in my first review of your manuscript, a pilot trial does not aim to investigate the efficacy of an intervention. Please refer to the Thabane et al. (2010) and Leon et al. (2011) references for the aims/purpose of pilot trials (below) or the BMJ Open website for a brief overview. I suggest removing the term 'pilot' from the description of your study design as your aims are not consistent with the aims/purpose of pilot trials. References: Leon et al. The Role and Interpretation of Pilot Studies in Clinical Research. J Psychiatr Res. 2011 May ; 45(5): 626–629. doi:10.1016/j.jpsychires.2010.10.008 Thabane et al. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology 2010, 10:1 http://www.biomedcentral.com/1471-2288/10/1 2. Thank you for clarifying the randomization procedure. However, you have not explained how allocation will be concealed at the point of randomization. Please clarify this in your manuscript. 3. Thank you for clarifying that 'All the participants are not used to regular exercise before participating in the experiment. The control group just needs to maintain their old habits, and we will visit the control group regularly to evaluate their physical activity, so as to ensure that their physical activity does not meet the exercise standards.' Can you please report this information in your manuscript? 4. Thank you for clarifying that 'we will have coaches to monitor and record their attendance, and if they are absent, they will supplement the training at other times.' Can you please report this information in your manuscript? 5. Thank you for clarifying that data will be analyzed by researchers who are blind to group allocation. Can you please clarify whether outcome assessors (i.e. researchers who complete the outcome assessment) will also be blind to group allocation? 6. Regarding your reporting of blinding of researchers who conduct data analysis, I recommend rewording as follows: 'Data will be analyzed by PhD students who are blind to group allocation.'

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Dr. David Snowdon, Monash University, Peninsula Health

Comments to the Author:

I thank the authors for addressing most of my comments. It is now clear how participants will be randomized, what intervention the groups will receive (through use of the TIDIER checklist) and that researchers who analyze the data will be blind to group allocation. However, I still have some minor concerns.

1. The aims of your study are not consistent with the aims of a pilot trial. As previously mentioned in my first review of your manuscript, a pilot trial does not aim to investigate the efficacy of an intervention. Please refer to the Thabane et al. (2010) and Leon et al. (2011) references for the aims/purpose of pilot trials (below) or the BMJ Open website for a brief overview. I suggest removing the term ‘pilot’ from the description of your study design as your aims are not consistent with the aims/purpose of pilot trials.

References:

Leon et al. The Role and Interpretation of Pilot Studies in Clinical Research. J Psychiatr Res. 2011 May ; 45(5): 626–629. doi:10.1016/j.jpsychires.2010.10.008

Thabane et al. A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology 2010, 10:1 http://www.biomedcentral.com/1471-2288/10/1

Answer

Thank you very much for your patience to explain, let me understand the difference between my study and pilot trial, I have deleted the word pilot in the study design.

2. Thank you for clarifying the randomization procedure. However, you have not explained how allocation will be concealed at the point of randomization. Please clarify this in your manuscript.

Answer

The randomization procedure will be completed by professional computer workers after the participants are recruited. They are double-blind with recruitment and grouping.

3. Thank you for clarifying that ‘All the participants are not used to regular exercise before participating in the experiment. The control group just needs to maintain their old habits, and we will visit the control group regularly to evaluate their physical activity, so as to ensure that their physical activity does not meet the exercise standards.’

Can you please report this information in your manuscript?

Answer

This part of the content has been added to the ’Exercise intervention’ section.

4. Thank you for clarifying that ‘we will have coaches to monitor and record their attendance, and if they are absent, they will supplement the training at other times.’

Can you please report this information in your manuscript?

Answer

This part of the content has been added to the ‘Exercise intervention ’section.

5. Thank you for clarifying that data will be analyzed by researchers who are blind to group allocation. Can you please clarify whether outcome assessors (i.e. researchers who complete the outcome assessment) will also be blind to group allocation?

Answer

The outcome assessor will be completed by the designated medical institution (Shanghai Punan Hospital of Pudong New District, Shanghai, China), when the participants go for the assessment, there will be no labels, so the outcome assessors will be blind the group allocation.

I also added this part to the 'Statistical analysis'.

6.Regarding your reporting of blinding of researchers who conduct data analysis, I recommend rewording as follows: ‘Data will be analyzed by PhD students who are blind to group allocation.’

Answer

Thank you very much for your suggestion, it has been modified according to your suggestion

We would like to thank the referee again for taking the time to review our manuscript.

VERSION 3 – REVIEW

REVIEWER	Snowdon, David Monash University, Peninsula Clinical School
REVIEW RETURNED	22-Oct-2021

GENERAL COMMENTS	n/a