

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Design, methodology and baseline characteristics of Tai Chi and its protective effect against ischemic stroke risk in an elderly community population with risk factors for ischemic stroke: a randomized controlled trial
AUTHORS	Zheng, Guohua; Zheng, Xin; Li, Junzhe; Duan, Tingjin; Qi, Dalu; Ling, Kun; He, Jian; Chen, Lidian

VERSION 1 - REVIEW

REVIEWER	Janusz Maciaszek University School of Physical Education in Poznań, POLAND
REVIEW RETURNED	24-Aug-2015

GENERAL COMMENTS	Congratulation of idea. I think that it will be very important study. You can add information about different levels of many studies and papers. Check: Am J Chin Med. 2010;38(2):219-29. The effects of Tai Chi on body balance in elderly people--a review of studies from the early 21st century.
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REVIEWER	Eun Nam Lee Department of Nursing, Dong-A university, Korea
REVIEW RETURNED	26-Aug-2015

GENERAL COMMENTS	The reviewer also provided a marked copy with additional comments. Please contact the publisher for full details.
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Congratulation of idea. I think that it will be very important study. You can add information about different levels of many studies and papers. Check: Am J Chin Med. 2010;38(2):219-29.
The effects of Tai Chi on body balance in elderly people--a review of studies from the early 21st century.

Author's response: Thank you for your suggestion. The reference which you recommended has been cited in the revised manuscript. Please check!

Reviewer: 2

I reviewed your protocol. It is very interesting and impressive subject. It is well written protocol.
I would like to ask you minor revision to the manuscript.

Paper section & topic Page Comments

Introduction 3-4

1) Explain the rationale of protective effectiveness of Tai chi on ischemic stroke risk in detail.

Author's response: We have widely amended the session of "Introduction". We further explained the rationale of protective effect of Tai Chi on ischemic stroke risk, and added eight relevant references in the Background. Please check them. Thanks!

2) Consider stating the study hypotheses before the study objective

Author's response: Following hypotheses was added at ahead of the study objective:

"We hypothesize that individuals with high risk factors of ischemic stroke who receive a 12-week Tai Chi exercise will have greater improvement in controlling risk factors of ischemic stroke, enhancing cerebrovascular and cardiopulmonary function compared to those who keep their usual physical activity as assessed immediately after the 12-week Tai Chi exercise intervention and that these benefits maintain until the end of 12-week follow-up."

Please check. Thanks!

Design 5-10

1) Describe the method taken to conceal the sequence of allocation

Author's response: The sequence of randomized allocation was generated by a statistician who was working at Center for Evidence-based Chinese Medicine in our university using statistical software SAS 9.1. Then the allocation sequence was kept in a research assistant who did not involve in participants' recruitment, and later outcomes assessment and statistical analysis. After participants were assured to meet the study criteria and completed the baseline assessment, this research assistant will inform participant that he/she was allocated either Tai Chi group or control group by telephoning.

Above information has described in the session of "Randomization". The method of allocation which we applied in this study was "Central phone randomization". Please check them. Thanks!

2) Who was blinded after assignment to intervention? Tai-chi instructor? or outcome assessor (particularly, psychological outcome assessor?). It is not clear.

Author's response: It is difficult to blind participants and instructors in this study because of exercise intervention. But we will blind the outcome assessors and statistician. We added following "Blinding" session in the revised manuscript. Please check. Thanks!

"Blinding"

Blinding for participants and Tai Chi instructor was impossible in this study, as both of them knew the allocation result when Tai Chi training began to be conducted. But the outcome collectors and statistic analysts were blinded. Two kinds of blind codes were kept in the research assistant. In the first blind code, the allocation results were replaced by the letter A or B, and the real meaning of the letter A or B were marked in the second blind code. The research assistant will deliver the letter A or B to the statistician after the database is closed, and declare the real meaning of the letter A or B when all analysis of data is completed."

In addition, for blinding the outcome assessors, we have described at the "Measure" session of original manuscript (Page 9).

This sentence "All measures will be obtained by personnel blinded to participants' randomization allocation" has been described in the session of "Measure". Please check.

Thanks.

3) Describe the trial design in detail. Is it a parallel RCT with 1:1 ratio?

Author's response: This study was designed as randomized, parallel controlled trial. 170 eligible participants were randomly allocated into either Tai Chi group or control group with 1:1 ratio. The information has been described in the session of "Randomization". Please check them. Thanks!

Participants 5

Your subjects are ages between 55 and 70 years old. However, I don't think subjects with 55-60 ages

are not elderly population. Consider of inclusion criteria again.

Author's response: Pardon me, because the recruitment of this study has been completed, we can not change the inclusion criteria. But thank you for your comments. We will carefully consider your suggestion in next study.

Intervention 6-7

Explain the intervention in detail including teaching skills to allow replication.

Author's response: There should be very difficult to explain intervention process and teaching skills of Tai Chi in detail. Although 24 forms simplified Tai Chi is consist of 24 styles, the moving trace of each styles, the coherence among different styles and the cooperation of both breathing and movement are very complex. Many academic monographs in China introduce the training method of Tai Chi in detail. In this trial, we used the method of Tai Chi training recommended by Chinese National Sports Commission (The Comprehensive book of Tai Chi Quan. 2nd.Beijing, China: People Sport Press; 2006), and will assign two qualified instructors to teach participants to practice. We also listed 24 forms of Tai Chi in the Figure 1 of manuscript (as following). It should be helpful to replicate.

Outcomes 8-9

1) Describe the method measuring primary and secondary outcomes in detail including when they were assessed, how they were prepared?

Author's response: All primary and secondary outcomes will be measured repeatedly three times at baseline, post-intervention and end of follow-up, respectively. The schedule of measurement for all outcomes was briefly summarized in Table 1 of manuscript. Please check.

The measuring method and implements of each primary or secondary outcome were described in the "Measure" session of manuscript. Please check. Thanks!

Statistics 10-12

1) Consider a statistical method to compare group for primary and secondary outcomes from baseline to follow-up. I'd like to recommend repeated ANOVA.

Author's response: Thanks! We have amended it according to your comment.

Discussion 13

1) Describe the applicability of the trial finding.

Author's response: This trial is an ongoing study. We just completed the recruitment and baseline measurement of participants. Therefore the substantive findings can not be still concluded because of uncompleted whole trial. Nonetheless, we added following description about the applicability of the trial findings in the discussion session.

"If the intervention proves to be effective, the evidence-based findings will be available among community elderly population with risk factors of ischemic stroke. Further we believe that those findings may also be suitable for other elderly adults."