Author's response to reviews

Title: Community-based intervention to improve dietary habit and to promote physical activity among the elderly: A cluster randomized trial

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Version: 4 Date: 11 July 2012

Author's response to reviews: see over
Dear Dr. Neilan,

Please find enclosed our revised manuscript entitled “Community-based intervention to improve dietary habit and to promote physical activity among the elderly: A cluster randomized trial”, which we would like to submit for publication as a research article in BMC Geriatrics.

We thoroughly revised the manuscript on the basis of reviewer’s comments. We thank the reviewers for their careful reading of our manuscript, constructive comments and valuable advice. Please see the Author’s response to reviews.

We confirm that this manuscript has not been published elsewhere and is not under consideration by another journal. All authors have approved the manuscript and agree with submission to BMC geriatrics. The study was a part of the research project, “Project PAN”, International Life Sciences Institute Japan. The authors have no conflicts of interest to declare.

We would be grateful if this manuscript could be re-reviewed to assess its suitability for publication as a research article in BMC geriatrics.

We are looking forward to hearing from you at your earliest convenience.

Yours sincerely,

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Author’s response to reviews

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Version: 2 Date: 10 July 2012

Author’s response to reviews: see over
The Biomed central Editorial team

Object: MS: 1495633130675068 - Community-based intervention to improve dietary habits and promote physical activity among older adults: A cluster randomizes trial. Mika Kimura et al.

Thank you for your consideration of our manuscript for publication in your journal.

We have revised the above manuscript according to your reviewer’s comments.

Reviewer # 1 (Dr. Benedetta Bartali)

Major Compulsory Revisions

1) Specify in the abstract: a) what is TAKE10! Program in the methods and b) what are the food groups with increased consumption in the intervention group.

   We revised “Abstract”, and added a) and b).

2) It is not clear how the participants were enrolled in the study. Why the number of women is substantially higher?

   The participants were recruited by through notifications in the ward bulletin. In Japan, females are more motivated and health conscious than males. Please see “Participants” and “Discussion”.

July 10, 2012
3) Provide information on socio-economical status/education in Table 1 and also on physical activity level and self-reported health at baseline and adjust the analyses accordingly.

We did not have the information on socio-economical status/education.

However, other useful information was added in Table 1.

4) What is the range for the TMIG-Index score? Please clearly specify each item included in the index (e.g.: what are the IADLs included in the score?) and provide a reference to support the validity of this Index.

The range of the TMIG-index is 0-13. The information of TMIG-index was described in “Secondary outcomes”, (page10) The reference provided for validity is [28].

5) Clarify how the DVS score has been created and its range.

The DVS score was developed by Kumagai et al. [27] to evaluate Japanese dietary habits on the basis of Japanese national nutrition survey. In the previous study, although significant correlation with other health factors was not evaluated, relative to the group with a DVS 1-3, the groups with DVS 4-8 and 9-10 displayed significantly lower declines in TMIG-index. The range is 0 to 10 (described in “Main outcomes”).

6) Categories could be grouped for self-reported health (e.g. : very good grouped with good, and not so good with not good) and for food frequency (e.g <=2 times/week; >2 times/week) as it is not meaningful to compare categories with only 1-2 subjects. The same for physical activity.

We regrouped the categories for self-rated health, food frequencies, and exercise frequencies. Please see Table 2, 4, 6, 7, 9 and 10.
Show that the sample size ensures sufficient power to detect clinically meaningful effects of the intervention; if it does not, the limitation related to the lack of power should be discussed.

We added sample size estimation in “Sample size”(page 10)

7) Table 2. Please report each component of the TMIG-Index of competence, as specified in table 1

We added the each component in Table 1

8) Please revise English

We asked a native speaker to check this manuscript.

Minor Compulsory Revisions

1) Clarify this sentence in the background section: “However, realistically, for the community-dwelling elderly, materials are needed to allow which they can keep track of and maintain…”

We rewrote this sentence as below in “Background” (page 4).

However, in a super aging society like Japan, too few resources are available to provide professional advice for every individual and therefore simple health programs that promote a healthy diet are needed for community-dwelling older adults.

2) Please note that there is a typo in the name of the categories for self-reported health in the control group, it should be “very good”, “good”… not “almost everyday”...

We replaced it with correct categories.
3) Please replace the term “self-rated health/self-related health” with “self-reported health” throughout the manuscript.

According to Dr. Rydwik’s suggestion, we used “self-rated health”. We hope this is acceptable.

Discretionary Revision

1) It would be interesting if the authors could show the TAKE10 check sheet, TAKE10 calendar and the DVS variety score sheet as Appendix.

We added TAKE10 check sheet and the TAKE10 calendar as Appendix.

Reviewer # 2 (Dr. Elisabeth Rydwik)

Major Compulsory Revisions

The Background need to be more updated in relation to public health interventions and health promotion strategies.

We revised “Abstract” including health promotion strategies.

State the evidence for how a physical exercise program should be performed in order to improve health and fitness related factors.

We revised “Intervention” in the Methods and described the details of the intervention exercise program. (page 7,8).

In the Method section it needs to be stated during the subheading Subject how the randomization procedure was performed and why it was not a “completely randomized trial” as is stated in the Discussion.
We added a Randomization part in Methods. Participants were assigned to each community center according to their home addresses. Please see Randomization (page 10) and Discussion (page 15, first limitation).

The DVS needs to be more thoroughly described. It is not clear if the frequency is part if the DVS or not. If it is, it doesn't make sense that the total score is 10. Also the DVS and the frequency are reported separately in the tables. Also, the DVS is reported with mean (sd), according to the description of the measure, I cannot judge whether this is appropriate or not.

We added information on DVS in “Main Outcomes”. In the previous study, although significant correlation with other health factors was not evaluated, relative to the group with a DVS 1-3, the groups with DVS 4-8 and 9-10 groups displayed significantly lower declines in TMIG-index. We compared the positive change of the group with DVS 1-3 between the 2 groups.

The description of the physical activity measure needs to be elaborated. The content of the exercise sessions needs to be described. Did it constitute the same type of exercises as in the home-based exercises? This is not clear.

We revised “Intervention” in the Methods and described the details of intervention exercise program. (page8). Participants were required to continue the exercises at home.

The intervention program is not based on the current knowledge following recommendations from health and research organizations. At least, this must be discussed.

We revised “Discussion”, and described the purpose of this intervention program.

Why did the authors evaluate the stretching program with a physical activity measure asking for walking, mild exercise and sports habits?
In this program, we recommended walking as a form of exercise. Therefore we also evaluate the frequency of walking. “Sports habits” was eliminated from this manuscript.

Table 3 is difficult to read since it contains a lot of information and only report frequencies. I suggest either collapsing categories or finding another way of presenting data.

All tables were revised.

I lack a discussion about the content of the intervention and also in relation to the outcome measures used. Also, what might an increase in DVS of 1.2 mean, do the authors consider this to be clinically significant?

We revised Discussion totally. As Dr. Rydwik pointed out, the increase in DVS is not meaningful.

**Minor Essential Revision**

The wording “elderly” is used throughout the manuscript, which implies that the subjects are very old and frail. I suggest using the term “older adults” instead.

We replaced elderly with older adults.

The term self-related or self-rated health is used, which is confusing, the correct wording should be self-rated health.

We replaced self-related health with self-rated health.

In the Background section, the first sentence, the word “and” is used several times; I suggest using it only at the end of the sentence.

We asked a native speaker to check this manuscript, and revised.
“However, realistically…” is not clear to me and need to be clarified.

In the Method section, the sentence starting “Twenty candidates did not satisfy…” should be rewritten, for example 94 is spelled with letters within in the sentence. Also the wording “became the subjects” should be altered to “were included.”.

We rewrote this sentence as below in Background (page 4).

However, in a super aging society like Japan, too few resources are available to provide professional advice for every individual and therefore simple health programs that promote a healthy diet are needed for community-dwelling older adults.

Why has parenthesis been used around the sentence starting “Subjects were allowed…”. Baseline is written as one word.

We revised and asked a native speaker to check this manuscript.

During the sub-heading Outcome measures the TMIG-index should be spelled out the first time it is mentioned.

TMIG-index is Tokyo Metropolitan Institute of Gerontology Index of Competence Score. We spelled out it

In the Result section, I suggest the word parameters should be changed to variables.

We changed word parameters to variables.

The attendance rate “was” 68.1% instead of “is”.

We changed “is” to “was”. 
The Discussion starts with a reference. I suggest starting with a short summary of the results and then discussing the results in relation to other studies.

We started with the summary of the results in “Discussion” part.

Reviewer # 3 (Dr. Taina Rantanen)

Major Compulsory Revisions

1. The research question is not presented very clearly. Already in the abstract it should be made clear that the intervention is educational (a series of seminars). The abstract should be revised and should include more precise information of the study.
   We revised “Abstract”. The purpose of this study was effectiveness of a social program using TAKE10!, and determine whether it could change the long standing habits.

2. I am not sure of the importance of some of the outcome measures such as number of different foods.
   Some studies have shown dietary variety to be associated with health status, so we consider dietary variety to be a simple way to ensure intake of a balance of nutrients and therefore this measure to be a good indicator. We described this in Background (page 6)

3. I am also wondering about whether the participants are of normal weight, overweight or underweight. Do they have nutritional deficiencies?
   The BMI (mean) of participants was around 24. Additional information about the participants was added in Table 1. Their nutritional statuses were not determined.
4. Were the participants selected based on the fact that their eating habits did not meet the recommendations?
   We did not select the participants depending on their dietary or exercise habits. The participants were publicly-offered community dwelling people. (Please see Methods)

5. It is unclear whether the participants are community living or whether they are residents of an assisted living facility. The authors state that they were living in a ward but later indicate that they were living in different parts of town. Please, clarify.
   Participants were community living people, and they were assigned to 6 community centers according to their home address. However, this ward consists of an area of only 13.75 square kilometers, and all community centers are within 2 km. Also, environmental factors did not differ substantially. (Randomization in Methods)

6. The intervention description could be clarified.
   We revised "Intervention" in Methods.

7. Description of data collection is quite vague.
   We revised "Participants" in Methods.

8. Data analysis is not sufficient. The cluster randomization is not taken into account in the analyses.
   An Interaction effects were analyzed using a two-way repeated measure analysis of variance, adjusted for age, sex, cluster, and TMIG-index. (Table 3)

9. The data analyses do not answer the question whether change differed between the groups (no group by time interaction term is reported).
An interaction effect between the two groups was observed for Food Frequency Score, and a positive change in 1-3 scores of DVS between two the groups was significantly different. (Please see Results page 13 and Table 3)

10. Power calculations are missing.
   Please see “Sample size”.

11. Main outcome is not defined.
   We defined main outcomes (Please see Main Outcomes)

12. I do not think that the actual data and analysis support the conclusions.
   We revised the conclusion.

13. The participants are not well described. Did they have specific diseases which reduce their physical activity, such as arthritis, CHD? What is socio-economic status of the participants? Their educational background? Do they cook for themselves? etc.
   The information of participants is described in Table 1
   We did not examine who cooks/prepares meals, but we assumed many participants cook for themselves because the majority of the participants were female (not described in the manuscript)

14. The study was evaluated by an ethical committee. The study does not comply with the standards for reporting randomized controlled trials (Consort Statement).
   Please, consult the instructions and revise accordingly.
   We revised whole parts according to the Consort Statement extension to cluster randomized trials.
15. The authors often use the term ‘improved dietary habits’. I find this rather vague and would prefer the exact improvements to be stated.
   We revised this to be more clear, “improve food intake frequency”

16. The authors list in limitations that randomization was not successful. However, no attempt is made to control for the cluster randomization or the age difference between the groups. Just acknowledging this problem may not be enough.
   We revised Discussion.

17. The authors are citing a number of relevant studies, but do not really acknowledge the theories of health promotion. It would be a bonus to describe the theory of health behavior (change) underlying the development of the intervention.
   We revised Background and Discussion according to Dr. Rantanen’s advice.
   Thank you very much.

18. I recommend that the text is reviewed by a native English speaker.
   We asked native speaker to check this manuscript.