Author's response to reviews

Title: Effects of lifestyle education program for type 2 diabetes patients in clinics: a cluster randomized controlled trial

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Author's response to reviews: see over
Dear Editor:

We would like to express our deep appreciation for the comments and suggestions made by the reviewer. Based on these recommendations, we have revised the manuscript and attached our responses to the reviewer’s comments.

Regarding the wording of plasma glucose, we have now uniformly changed “blood sugar” to “plasma glucose.” Thank you for your kind suggestion. As for a typo on p. 8 (NGSD --> NGSP), we have corrected this. Thank you.

The attached paper has been carefully reviewed by an experienced medical editor whose first language is English and who specializes in the editing of papers written by physicians and scientists whose native language is not English. We are submitting a revised version of this paper. It shows the changes and additions in red font and the deletions in blue using the strike-out feature.

We hope that this revised paper is satisfactory and that our responses are clearly presented so that our revised manuscript will be accepted for publication in *BMC Public Health*. If you require further revisions that would make this paper acceptable, we will be glad to make them. We certainly appreciate your very careful review and will be more than happy to follow any further suggestions.

Thank you again for considering our manuscript. We look forward to hearing from you.

Sincerely yours,

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For Reviewer, Dr. Kirsten J Coppell’s Comments:

Thank you very much for your valuable comments and suggestions concerning our manuscript. We found these most helpful and have revised the manuscript accordingly. In the revised version of the manuscript, the changes and additions are in red font and the deletions in blue using the strike-out feature. We hope that the corrections are satisfactory. Responses to specific comments are as follows.

MAJOR COMPULSORY REVISIONS
1. Some additional methodological detail is required in order to understand the intervention package compared with what was delivered to the control group. This is important in relation to understanding and interpreting the results. The additional detail includes
   (a) what sort of information on dietary intake did the CG receive? How often were these control group patients seen? - see subsection intervention and control groups (2nd paragraph, 1st sentence)
   (b) it is implied that dietitians do not usually provide dietary advice at GP clinics. This should be clarified as the control group may not actually be receiving ‘usual care’ if a dietitian is actually delivering the dietary advice to this group.
   (c) how many dietitians were involved in delivering dietary advice to the two groups? Did the dietitians travel to the different general practices or was there a dietitian assigned to each general practice? Did each dietitian provide advice to both the control and intervention group? And if so, what was put in place to ensure no overlap in advice delivered to participants of each of the two groups?
   (d) the details of physical activity advice for the control group needs to be specified. Did the control group receive physical activity advice? If so, was the physical activity advice the same or different from the intervention group.

Thank you for your very useful comments. We newly added the following sentences in the last part of ‘Intervention and control groups’.
“A consultation by a dietitian was provided once with a month of randomization. The general advice was that which was usually given for glycemic control by a general practitioner or a nurse in a clinic, such as “don’t eat too much at dinner”, “eat more vegetables”, “exercise”, and so on. As for clinics without dietitians (11 clinics), registered dietitians were randomly allocated. Five registered dietitians were in charge of both groups.”

2. The discussion section needs to be better structured. As it is implied in other parts of the paper that dietitians do not usually deliver dietary advice in primary care community settings in Japan, the discussion needs to focus on this, as well as the structured content of the dietary intervention which had a particular focus on increasing vegetable consumption at breakfast and lunch.

Thank you for bringing this important point to our attention. We added the following in the last part of ‘Strengths and limitations of the study’:

“In Japan, lifestyle education by registered dietitians for diabetes patients is provided mainly in hospitals and in only a few clinics. Dietary lifestyle education is important for many type 2 diabetes patients. To conduct a system for effective dietary lifestyle education in clinics should be considered to be warranted in Japan.”

If individual dietitians delivered advice at both control and intervention practices, this needs to be discussed as a study limitation. If the physical activity advice delivered to the each to the two groups was different, this also needs to be discussed.

Related to this, we mentioned that five registered dietitians were in charge of both groups as described in the response to 1(d). However, the dietitians were trained to give advice following the manual. Thus, the contamination of advice was not very likely. As for the advice on activity, the intervention group received more practical advice on activity compared to the control group. In fact, 37% of the intervention group responded that they did more exercise compared to the control group (17%). Therefore, not only dietary education but also practical advice on activity might have affected the results. However, our results showed an improvement in dietary intakes and it is reasonable to
make the interpretation that improvement in dietary intakes brought about the improvement in the plasma glucose level.

We added the following in the last part of the third limitation in the section on “Strengths and limitations of the study” in the Discussion: “Furthermore, we mentioned that five registered dietitians were in charge of both groups. However, because the dietitians were trained to give advice following the manual, the possibility of contamination of advice was less likely. As for advice on activity, the IG had received more practical advice compared to the CG. In fact, 37% of the IG responded that they had performed more exercise compared to the CG (17%). Therefore, not only dietary education but also practical advice on activity might have affected the results. However, our results showed an improvement in dietary intakes, and it is natural to make the interpretation that improvement in dietary intakes resulted in improvements in plasma glucose levels.”

Background - Paragraph 2 is rather long, and not all of the content is directly relevant to the main purpose of the paper. I suggest deleting the parts describing the justification of a narrower BMI range for Asians, and the reasons for the increase in the prevalence of diabetes in Japan, as this information is not directly relevant to the study question.

We agree with your comment and removed the sentence. Thank you.

MINOR ESSENTIAL REVISIONS
ABSTRACT

1. overall the abstract could be written more concisely, particularly the methods section.

Following your suggestion, we shortened the Methods section.

2. in the background, the 2nd sentence should say ‘primary care clinical settings’ rather than ‘clinical settings’ only, as this is the main point of difference being assessed, that is delivery of structured lifestyle education
in a primary care setting versus a secondary care setting.

We have made this correction. Thank you.

3. in the methods, the 2nd sentence includes ‘type 2 diabetes (HbA1c #6.5%)’. Please clearly specify what the HbA1c #6.5% refers to? Presumably patients had to have an HbA1c #6.5% at enrolment into the study? If so, then suggested wording would be ‘type 2 diabetes and HbA1c #6.5%’.

Thank you for your appropriate suggestion. We have corrected this.

4. in the results, the first sentence includes ‘-0.7% decrease’. The ‘-‘ should be deleted.

We made this correction.

BACKGROUND
5. as with the abstract, this section could be written more concisely.

Following your suggestion, we shortened this section.

6. the 2nd paragraph is very long and would be better split into 2 or 3 paragraphs

We have divided the 2nd paragraph into two parts.

7. 2nd paragraph - the 1st sentence of should be referenced.

We added reference (3).
8. 2nd paragraph - the 2nd sentence needs to be re-worded - what is meant by ‘...who are strongly suggested to have diabetes...’? This 2nd sentence could actually be deleted.

According to your suggestion, we deleted the 2nd sentence.

9. 2nd paragraph - the second part of the 4th sentence is unclear - what is meant by ‘....and that glycaemic control improved postprandial plasma glucose levels.’? In the 6th sentence, ‘.....focuses on not restricting total energy but on the way of eating....’ would read better as, ‘.....focuses on the pattern of eating...’

In order to shorten this paragraph, we deleted these sentences.

10. 2nd paragraph - in the sentence towards to the end of page 6 that details total energy from carbohydrate and fat, presumably ‘...from fat less than 25%....’ should be ‘total fat’.

Thank you for this helpful suggestion. We changed ‘fat’ to ‘total fat’.

11. 2nd paragraph - at the end of page 6, the JDS dietary recommendations have been detailed (and are relevant), but the ADA recommendations are not directly relevant to the paper, and could be deleted.

We deleted the information on the ADA recommendations.

12. 3rd paragraph - in the first sentence add ‘primary care’ before clinics so that it is clear the intervention is delivered in primary care and not a secondary care clinic. Please give a couple of examples of the ‘other outcome measures’.
We added “primary care” before “clinics.” Also, we mentioned that in addition to changes in HbA1c levels, we assessed “other clinical data, and dietary intakes.” We took out the words “outcome measures.”

METHODS

13. study design - the sentence ‘Patients with type 2 diabetes were the participants’ should be deleted. This information is not required there.

We deleted this sentence.

14. participants - please include briefly include how GPs were recruited, what the eligibility criteria were, and whether any GPs declined to participate.

We recruited GPs who agreed with the aims and procedures in our study and we assigned a GP in the clinic according to the random number as described in the first sentence in the ‘Participants’ section. We added the following as the first sentence: “Volunteer general practitioners who agreed with our study purposes and procedures were recruited.”

15. participants - towards the end of this section it is stated ‘…..who were receiving treatment by a general practitioner.’? Did the patients receive treatment from another health practitioner, such as a hospital clinic, or were they receiving treatment from only a general practitioner. A small point, in this sentence ‘by’ should be replaced with ‘from’. In the same sentence,’(NGSD)’ needs to be corrected to ’(NGSP)’.

The patients were receiving treatment from only a general practitioner. We corrected this sentence to “…who were receiving treatment by the assigned general practitioner in the primary care clinic.”

16. intervention and control groups (1st paragraph) - with respect to the 2nd sentence, did support for self-management of glycaemic control include dietary advice only or was there other support? Also please detail
what is meant be ‘several sessions’, that is how many sessions?

The self-management of glycaemic control included dietary advice, exercise and stress management and was provided in 3 or 4 sessions. We corrected the sentence accordingly. Thank you.

17. outcome measures (2nd paragraph) - as waist circumference was excluded as a secondary outcome measure because of missing date, then the detail about calculating the mean could be deleted.

We deleted that sentence. Thank you.

18. outcome measures (2nd paragraph) - the sentence, ‘Registered dietitians encouraged the IG group to increase the frequency and intensity of their physical activity.’ could be deleted as information has already been provided and it does not related directly to outcome measures.

We deleted the sentence.

RESULTS
19. last paragraph - less detail could be presented regarding the vegetable intake, as the results for the different models and the p-values are presented in table 4, and are more easily read in the table format.

We agree with you. We deleted the details that are shown in the table format. Thank you.

DISCUSSION
20. 1st paragraph - this could be substantially condensed.

Following your suggestion, we condensed the 1st paragraph.
21. last sentence beginning at the bottom of page 14 and continuing on page 15 - this sentence does not make sense, and should be reworded or deleted.

We appreciate your suggestion. After looking at this information carefully we decided to delete 4 sentences beginning with “This education…” and ending in “more lifestyle changes.”

22. Comparison with other studies (last sentence of 1st paragraph) - ‘Studies (23, 27, 31) with baseline HbA1c levels similar to ours (around 5%) showed….’ 5% seems low - is this correct? Please correct accordingly. Indeed the whole sentence needs to be reviewed, as it does not appear to be correct.

Thank you for your valuable comment. We corrected this information as follows: “Studies (23,27,31) with baseline HbA1c levels (7.3% to 7.7%) similar to ours (7.5%) showed an effect size for the mean change from baseline of -0.7%, -0.5%, and -0.1%, respectively, which did not differ largely from our result of -0.5%.”

23. Strengths and limitations of the study (1st sentence at the top of page 17) – it is stated that blood glucose was not tested more often in the clinical setting in the intervention group, but was home blood glucose monitoring encouraged as part of the intervention and done more often in the intervention group compared with the control group?

We added the following sentence: “In Japan, almost all patients who use insulin are likely to use home glucose monitoring; however, the proportions of patients using insulin were similar (around 10%) between the groups, which could eliminate a significant bias.”

24. Strengths and limitations of the study (1st sentence of paragraph 4) - ‘Secondly, completion rates were relatively small; 80% for the IG ad 75%
for the CG.’ Presumably it is meant that the dropout rates were relatively small?

Yes, you understood correctly. We changed this statement to “the dropout rates were relatively small.”

25. Strengths and limitations of the study (1st sentence of paragraph 5) – this sentence says patients were randomly assigned, but GPs were actually randomly assigned to the IG or CG, and patients at the intervention or control practices were consecutively invited to participate in the study.

We changed ‘patients’ to ‘general practitioners’. Thank you for pointing this out.

26. Strengths and limitations of the study (last paragraph) - this paragraph needs to be re-worded as the meaning is not clear. Is the sentence ‘This is not quite short and may be acceptable for avoiding bias.’ Correct?

This was not correct. We deleted the sentence.

Figure
In Figure 1, I am uncertain what is meant by ‘DM drug changed’. Does this mean a drug was stopped and another started?

We corrected ‘DM drug changed’ to ‘Another DM drug started’.