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
COVER LETTER

April 10, 2013

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

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.

We are submitting two versions of this paper, both of which are the same except in presentation. The first is a clean copy with no strike-out marks. Red font reflects areas where changes were made. The second version shows the changes and additions in red font and the deletions in blue using the strike-out feature. Perhaps you will want to supply the reviewer with both versions.

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. We are submitting two versions of this paper, both of which are the same except in presentation. The first is a clean copy with no strike-out marks. Red font reflects areas where changes were made. The second version shows the changes and additions in red font and the deletions in blue using the strike-out feature. Perhaps you will want to supply the reviewer with both versions.

We hope that the corrections are satisfactory. Responses to specific comments are as follows.

MAJOR COMPULSORY REVISIONS

Methods
* A little more explanation is required about the registered dietitians. It is not clear whether some primary health care clinics already employ or have a visiting dietitian, and this would be useful to know so as to ascertain the level of dietary intervention possible in primary care prior to the study. Also, it states 11 clinics did not have a registered dietitian prior to the study, how many of these clinics were intervention clinics and how many were control clinics? Were 11 different dietitians allocated to these clinics or did one dietitian visit more than one of these clinics? From the sentence, “Five registered dietitians were in charge of both groups.” is it meant that five dietitians only were involved in the study.

Nine primary health care clinics (4 for IG, 5 for CG) already employed registered dietitian and 11 clinics did not. Therefore, 6 registered dietitians for IG and 5 registered dietitians for CG were randomly allocated. Four registered dietitians were in charge of both groups. As we already mentioned, training of registered dietitians was conducted based on an instruction manual and thus did not differ between those at the intervention clinics and control clinics.

Accordingly, as for the explanation about the clinics without dietitians, we corrected this information as follows: (11 clinics; 6 for IG, 5 for CG). Further, “Five registered dietitians were in charge of both groups” was corrected to “Four registered dietitians visited more than one of these clinics.”
Discussion
*Page 15, 1st paragraph - please provide appropriate references for 1st and 2nd sentences. It should be clear from the first point that ‘normal’ BMI range for Asians is less than other groups, and thus are at risk of developing T2DM at a lower BMI. This is not clear from the current wording, and additional sentences may be required to explain the authors’ point. Also, it should be clear as to whether just obesity is being referred to, or obesity and overweight.

Thank you for bringing this important point to our attention. We corrected the 1st and 2nd sentences by adding two new references (19,20) as follows:

“Although mean changes between the two groups were not significant for BMI, this might be an understandable result considering that ‘normal’ BMI range for Asians is less than other groups of Europeans and Americans (19,20), and thus are at risk of developing type 2 diabetes patients at a lower BMI.”

MINOR
Background
* To improve the structure and flow of this section, I suggest moving the sentence, “In Japan, approximately 8.9 million people.......for type 2 diabetes (3).” to follow the 3rd sentence of the 1st paragraph (“Type 2 diabetes is responsible.......viewpoint of medical economics.”)

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

* I suggest deleting the sentence about diabetes prevention as it is not directly relevant. This sentence is “Meta-analyses of randomized controlled........tolerance to type 2 diabetes (4,5).”

Following your suggestion, we deleted the reference (5) and corrected this sentence.

* For the sentence “A food frequency questionnaire (FFQ)........82 foods (FFQW82) (10).” ‘an FFQ’ should be ‘a FFQ’.
We have made this correction. Thank you.

* In the following sentence “Using the FFQW82, we.....from registered dietitians.” Delete ‘program’ which comes just before ‘(SILE)’.

We made this correction.

* In the sentence “The main current…..3 levels of physical activity.” ‘3’ is usually written as ‘three’.

We made this correction.

* I am not sure if it is an error or a misunderstanding, but I think it is worth keeping the deleted portion that describes the JDS dietary recommendations. I agree with the deletion of the ADA recommendations.

Thank you for bringing this point to our attention. We have made this correction and included the deleted portion that describes the JDS dietary recommendations.

* I also think it would be relevant to still include the deleted sentence “Our SILE program basically follows the guidelines of the JDS........strategy than the JDS recommendations.”

We have made this correction.

* In the 1st sentence of the last paragraph “The aim of this study is to examine....dietary intakes.” ‘study is to’ should be ‘study was to’ and ‘date’ should be ‘data’.

We made these corrections.
Methods
* Outcome measures, 2nd paragraph – suggested rewording of 3rd and 4th sentences. “Our protocol stated that waist circumference would be a secondary outcome measure, but waist circumference measurements were missing for some patients, and there appeared to be large variations in the measurements for some individuals. Thus we eliminated waist circumference from the analysis.”

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

Results – page 12
* As HbA1c is the primary outcome measure, I suggest putting this result which is currently in paragraph 3, before the results stated in paragraph 2.

Following your suggestion, we corrected this.

Results – page 13
* 2nd paragraph - the 2nd sentence needs to be re-worded to improve clarity, and some parts have been deleted which I think should still be included. The main points to be included are that it has to be clear the authors are referring to ‘energy intake at dinner’, there was a statistically significant difference when all models were used for both the LOCF and CDS analyses, but not MI.

Thank you for your suggestion. We included the parts which have been deleted and re-worded these sentences.

* 2nd paragraph - the 3rd sentence, add ‘statistically’, to read “There was a statistically significant….Model 3).”

We have made this correction.
For dietary fibre intake, a statistically significant increase was........ITT/LOCF.”

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

No statistically significant changes were shown.....total energy.”

According to your suggestion, we corrected this.

Discussion
* Page 14, 1st paragraph, 5th sentence (“These results were.....dietary outcome measures.”) Please review as it does not appear to make sense – is there a ‘not’ missing?

Thank you for bringing this important point to our attention. We corrected this.

“reduce the incidence of” to “improve the glycemic control with type 2 diabetes patients”.

Strengths and limitations of the study, Page 17 - the last paragraph continuing onto page 18 appears to be repetitive, and deletion is suggested.
Following your suggestion, we deleted this sentence.

* Page 18, 3rd paragraph, 1st sentence - ‘completion’ has been replaced by ‘dropout’, but the stated percentages later in the sentence have not been changed accordingly. Please correct.

We have made this correction.

* Page 20, 2nd paragraph, 1st sentence - is it intended to talk about prevention of diabetes, when the focus of the study is improved glycaemic control? I suggest this paragraph be revised accordingly.

Thank you for your appropriate suggestion. We have corrected “in the prevention of diabetes” to “in order to improve glycemic control “.

* Page 20, Implication, last sentence - reference is made to prevention of diabetes, when the focus of the study is improved glycaemic control? I suggest this sentence be revised accordingly.

Following your suggestion, we have corrected this.

* Page 20, Conclusions, 1st sentence - ‘dietitian delivered’ should be added as that was an important component of the intervention, so as to read, “The dietitian delivered structured individual-based lifestyle…….type 2 diabetes.”

Thank you for this helpful suggestion. We changed the sentence accordingly.