Reviewer's report

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

Version: 3 Date: 15 January 2013

Reviewer: Kirsten J Coppell

Reviewer's report:

Thank you for asking me to review the revised version of this paper. Overall this second version is much improved, but could be improved further. Further detail is required about how and what advice was given to each of the two groups. The paper would benefit from improvements in grammar and sentence structure, and being written more concisely. Specific comments are:

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.

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. 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.

MINOR ESSENTIAL REVISIONS
ABSTRACT

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

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%’.

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

BACKGROUND

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

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

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

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.

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…’

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

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’.

METHODS

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

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

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)’.

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?

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

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.

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.

DISCUSSION

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

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.

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.

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?

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 drop out 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.

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

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests