Reviewer's report

**Title:** Effects of lifestyle education program aimed at modifying dietary intake by meals for type 2 diabetes patients in clinics: a cluster randomized controlled trial

**Version:** 1  **Date:** 23 August 2012

**Reviewer:** Kirsten J Coppell

**Reviewer's report:**

The authors pose an interesting worthwhile question – does a structured individualised lifestyle education programme delivered by dietitians in a community clinical setting reduce haemoglobin A1c in type 2 diabetes patients? Overall the writing could be improved, and there are a number of methodological issues that require either more information or clarification.

**Major Compulsory Revisions**

1) Background – I do not think it is correct to state that non-obese patients are less likely than obese patients to comply with lifestyle advice? If this statement is correct, please provide an appropriate reference.

2) 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.

3) Methods – as a study protocol for this study has been published, this section could be shortened by including only the key methodological points and not copying directly from the Study Protocol paper. There is no need to include justification for using a cluster randomised controlled trial study design as this has already been explained in the Study Protocol paper.

4) Methods – in the published study Protocol it states that ‘study subjects are males and females from 20 to 79 years of age who have HbA1c concentrations of 6.1% or over…….’ However in the current paper being reviewed, it is stated that the eligibility criteria for HbA1c was 6.5% or over. Please clarify this discrepancy.

5) Methods – points that require clarification: -

a. Given physical activity was a part of the intervention, please clarify if there were any attempts to assess levels of physical activity at baseline and 6 months? If so, how was exercise measured? Given the statistical analysis section refers to a multivariate-adjusted model which included exercise, it seems that physical activity was measured.

b. Did the training for registered dietitians differ for those at the intervention clinics and the control clinics? Stating whether it was the same or different needs to be explicitly stated.
c. Who took the clinic measures, that is blood pressure, weight, height and waist circumference? Was it the dietitian or general practice clinic staff or someone else? Was appropriate training undertaken prior to anthropometric and blood measures being taken? Were the measures taken in duplicate?
d. I note the Study Protocol paper states that the outcome measures will be log transformed. Was this actually done?
e. For the sample size calculations, was consideration given to potential study participant drop-outs when deciding the final number of participants to be recruited?

6) Results
a. Please explain why patients who had changes to their diabetes medication during the study period excluded after the study was completed. Diabetes medication change is inevitable in the management of patients with less than optimal glycaemic control, and it is not surprising (given the intervention) that a greater number and proportion of study participants in the control group were excluded compared with the intervention group – 9 (10%) v 7 (7%).
b. It is unclear as to why not all study participants (both intervention and control) had complete clinical measures (waist circumference, blood pressure, fasting plasma glucose and lipid profile) at baseline, yet they all had an HbA1c result and had body mass index calculated (see Table 1). Does this mean that not all ‘baseline’ measures were actually measured at study entry, but data were acquired from general practitioner medical notes rather than being measured separately as part of the study? Did this also happen for the end of study 6 month measures? Please describe the number in both the control and intervention groups with complete measures at 6 months, as described in table 1. Knowing the degree of missing data (for primary and secondary endpoint measures) for the 154 who completed the 6 month study is important for interpreting the study results.

7) Discussion
It is more appropriate to comment on the discussion when methodological points have been clarified.

Minor Essential Revisions
1) It may be a systems error, but the beginning of the title states, ‘A sample article’. This needs to be deleted.
2) The title could more accurately reflect the actual intervention, and wording improved.
3) There are a number of typographical and grammatical errors throughout. Examples: -
a. in the abstract background, the aim is currently worded as ‘To evaluate the effectiveness of a structured individual-based lifestyle education (SILE) program by registered dieticians to reduce the haemoglobin A1c (HbA1c) level in type 2 diabetes patients in clinical settings.’ The following is a suggestion as to how the
sentence would read better, ‘To evaluate the effectiveness of a structured individual-based lifestyle education (SILE) program to reduce the haemoglobin A1c (HbA1c) level in type 2 diabetes patients delivered by registered dieticians in clinical settings.’

b. in the abstract methods, ‘Intend-to-treat’ should be ‘Intention-to-treat’

c. in the abstract results, 1st sentence, ‘present’ should read ‘percent’.

4) Non-specific phrases are used in places. It would be better to be more specific or delete the phrase. Examples: -

a. in the abstract methods, ‘The program was implemented through several sessions with trained….’ What is meant by ‘several sessions’?

b. in the abstract methods, ‘other clinical data’. What are the other key clinical data items collected?

5) Table 1 – it would be preferable to include the demographic, smoking and family history data at the top of the table. That is include the number of women, smoking status and family history following age.

6) Table 1 – the family history description appears to be incomplete. Please specify family history of what? Presumably it is diabetes?

7) Figure 1 – please change title to the box currently titled ‘lost to follow-up’ as this does not correctly describe the reasons for non completion of the 6 month study.

8) Figure 2 – axes need to be labelled.

**Level of interest:** An article whose findings are important to those with closely related research interests

**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