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: 14 October 2012

Reviewer: Jeanine Albu

Reviewer's report:

In this study the authors present the results of a 6 month prospective cluster randomized trial of an intensive structured individualized lifestyle education (SILE) delivered by registered dietitians vs. a control program. One of the goals of the intervention program was changing nutritional intake by meals to promote better glycemic control in patients with type 2 diabetes in primary care setting in Japan. The randomization was done at the clinic/provider level. Patients in both the control and the intervention groups had their food intake analyzed by a food frequency questionnaire (energy intake and food types per meals throughout the day). The intervention resulted in significant modification of the composition and energy of meals with decreased energy intake at dinner and increased the vegetable intake at lunch and breakfast. The rationale was that lower fasting and postprandial blood sugar will reflect in a lower A1C. The study appears carefully planned and conducted and a prior publication presents the original details of the protocol. The main result is a greater A1C lowering in the intervention vs. the control group.

Major issues:

1) In the intervention protocol as presented in the original publication as far as I can interpret, the change in the energy of dinner and vegetable intake at breakfast and lunch was to be only one component, not the main component of the intervention, as stated here. Other changes in other process estimates of the intervention vs. the control should be presented here: estimates of changes in physical activity, estimates of changes in total energy intake, other specific lifestyle issues affecting glycemic control identified by the dietitians in their assessments etc, even if not significantly changed.

2) The way the Title, Abstract, Introduction are written now for somebody who has not read the original design it appears that the intervention was really just to change in the energy distribution by meal and meal composition. I think this is not the case as the Methods section shows. The significant changes found in energy intake at dinner and vegetables at breakfast and lunch were originally planned to be just part of the intervention and this has to be reflected throughout the paper. This paper needs to be consistent with the original publication.

3) Particularly changes in total energy intake and body weight must be reported, it is not sufficient to state that there were no differences. The intervention group had slightly higher BMI and the original intent of the intervention was to produce
weight loss in the overweight individuals. While the difference in weight change between groups may not have been significant, there may have been a significant change in weight within groups; these statistics have to be presented. 

4) Also, were the changes in food intake (lower energy at dinner, higher vegetables at other meals) correlated with the changes in A1C? How about checking whether changes in weight were correlated with changes in A1C?

5) The authors should state how the results of the study differ from the current recommendations (in Japan or United States) for meal breakdown of energy intake (if any) and vegetables and fiber intake by meal (in Introduction, with references). Specific current recommendations must be presented for contrast. Would taking a fiber pill for breakfast and dinner accomplish the same thing? Did the increase in vegetable intake for breakfast and dinner compensate calorically for the decrease in the energy intake at dinner (see point 3 above)?

6) Also I suggest presenting the intensity of the intervention i.e. compliance with the dietitian visits vs. the control group. Was the intervention group also monitoring blood glucose more often?

7) Using the % change of a variable which in itself is expressed as a % and changes in a non-linear fashion is not justified. Given that either way the results are significant I suggest including only the changes in A1C in the model which adjusts for baseline A1C values. It would make the results easier to present (moreover the % change in A1C is not a common way to present results; the authors' proposed effect of 15% change was taken from one of their own publication where 15% was actually the change in glucose not A1C).

8) In Table 1 no statistics are given: were any of the baseline variables different by group? How do you justify the variables entered in the models? Were the variables entered in the models significantly different by groups at baseline?

9) A1C data collection: was this done for the study specifically, at registration, or was it taken from the medical records? If the latter, please describe.

10) How about the 3 months data? It seems there was data collected but it is not presented.

Minor issue: needs some language correction before being published

**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 do not have a conflict of interest