Reviewer's report

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

Version: 5 Date: 17 March 2013

Reviewer: Kirsten J Coppell

Reviewer's report:

Overall my previous comments have been incorporated into the paper. Further clarity is required about the dietitians in the methods section. I am not a statistician, and assume that the statistical methods have been appropriately reviewed. There are still some paragraphs/sentences that could be worded better and some grammatical errors, a few of which I have noted, but further checking would be required. My comments are as follows:

MAJOR

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. Please clarify these points.

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.

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.”)

* 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).”

* For the sentence “A food frequency questionnaire (FFQ)….82 foods (FFQW82) (10).” ‘an FFQ’ should be ‘a FFQ’.

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

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

* 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.

* 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.”

* 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’.

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.”

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.

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.

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

* 2nd paragraph - the 5th sentence would benefit from slight rewording, a suggestion being, “For dietary fibre intake, a statistically significant increase was…….ITT/LOCF.”

* 2nd paragraph - the 5th sentence would benefit from slight rewording, a suggestion being, “No statistically significant changes were shown.....total energy.”

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?

* Page 14, 2nd paragraph, 1st sentence - please review this sentence, as the focus is on prevention of diabetes rather than the main subject of the paper, improved glycaemic control in T2DM.

* Strengths and limitations of the study, Page 17 - the last paragraph continuing onto page 18 appears to be repetitive, and deletion is suggested.

* 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.

* 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.

* 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.

* 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.”

**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.