Reviewer's report

Title: Japan Diabetes Outcome Intervention Trial-1 (J-DOIT1), a nationwide trial of type 2 diabetes prevention by telephone-delivered lifestyle support for high-risk subjects detected at health checkups: Rationale, design, and recruitment

Version: 1 Date: 2 March 2012

Reviewer: Karen Walker

Reviewer's report:

The paper reports on the protocol and recruitment for the Japan Diabetes Outcome Intervention Trial-1 (J-DOIT1), a cluster, randomised controlled trial to examine the effects of lifestyle coaching delivered via the telephone on the development of type 2 diabetes in Japanese adults with elevated fasting plasma glucose. The title and abstract indicate that this is the scope of this research paper.

This is an important study which will extend knowledge of how to deliver an effective program for diabetes prevention. Some methodology could be reported more clearly. The data reported appear sound although some consideration is needed to methods of analysis for non-parametric data. Due consideration has been given to study limitations. The writing is clear throughout although a number of minor changes can be made to avoid small grammatical errors.

- Major Compulsory Revisions

1. Page 3 lines 14-15: The Introduction poses the question – ‘What are effective and efficient methods to identify subjects at risk for diabetes?’ However, the paper then describes how participants were selected for J-DOIT1 based where possible on a fasting plasma glucose of 100-125 mg/dL (5.6-6.9 mmol/L) (page 4, line 31). Only one criterion has been used to identify most subjects at risk and the comparison of screening methods posited in the Introduction is not addressed by outcomes presented. The text in the Introduction should be refocussed.

2. Page 3 lines 33 to 35: presumably the clusters of 200-300 participants all came from the same area or community or company setting. Or was the cluster based on the lifestyle support centre that was closest? The nature of the cluster needs to emerge more clearly here.

3. The abstract states that ‘A large cohort was successfully randomised’ but in discussing recruitment and allocation of clusters, no detail is provided on the method used for randomisation (page 3, lines 34-35). Were the clusters stratified by setting and then randomised?

4. Page 4, Health check-ups. The information provided on anthropometric and biochemical methods appears unnecessarily brief. Who carried out the anthropometric assessments and what equipment was used? Calculation of BMI
might be mentioned. If blood was withdrawn from people who had not fasted how are these data treated?

5. Participant eligibility- could be based on fasting plasma glucose or on casual plasma glucose. How many participants were enrolled based on the latter criterion? Also page 4 line 34- if correct- it should be stated rather than inferred that women with a history of gestational diabetes could be enrolled.

6. Page 6 lines 25 and 26: CPG # 144 mg/dL (8.0 mmol/L) . If symptoms are not present, it can be questioned whether this definition includes many people who do not actually have diabetes? Was their status confirmed by a second test?

7. Page 8 line 5 and Figure 1. As participants were screened for eligibility after they were enrolled, the number of people considered ineligible might differ a great deal between clusters. What was the range in cluster size before and after screening for eligibility? Did cluster size differ between the control group and the intervention group?

8. Page 8, line 8 and Table 2. Earlier (page 7, line 30) it is stated that all analysed variables are non-parametric. How was this tested? Where measures given in Table 2 are parametric they should be provided as mean ± Sd and where they are non-parametric they can then be given as the median (interquartile range). Where these data are non-parametric use of a t-test for group comparisons is not appropriate and the relevant non-parametric test should be applied.

9. In the discussion of the relatively low incidence of high BMI in this Japanese population- it would be useful here to comment on the utility of a waist circumference in detecting abdominal adiposity in Asian populations and an explanation might be given here as to why this measure was not employed.

10. Page 11 line 7: add to the discussion a comment on strategies that might be used to capture women more equally in studies of this type.

- Minor Essential Revisions

Page 3, lines 25026: Where is this Ethics Committee based?
Page 3, line 31: change ‘method’ to ‘methods at’
Page 3 line 32: ‘being 2000 or more examinees annually’ rewrite for better clarity
Page 4 line 10: Change ‘is well trained’ to ‘are well trained’
Page 4 line 17: ‘anonymous’ might be better as ‘de-identified’ and again page 7 line 6.
Page 4 lines 18-20. Sentence on Ethics approval- remove as it duplicates lines 25 and 26 on page 3.
Page 4 lines 34-35: Why is an HbA1c of #6.5% equivalent to #6.1%? This seems a confusing statement.
Page 5 line 4- was this a medical history questionnaire forming part of the baseline questionnaire? Clearer here if explicitly stated.
Page 5 line 8: change ‘the questionnaire’ to ‘a questionnaire’
Page 5 line 10: indicate meaning of BMI on first use.
Page 5, line 13; change 'metabolic syndrome' to 'the Metabolic Syndrome'. And again below in page 5 line 17; page 8, line 15; page 10 line 13; page 10 line 14; page 10 line 18; page 10, line 20; page 11 line 3;
Page 5 lines 17-19: use SI units here also.
Page 5 line 23: 'The goals of lifestyle changes' better as 'The goals for lifestyle change'
Page 5 line 29: clarify that '23 g' is 23g per 'go'?
Page 6 line 7: 'mails' better as 'written information delivered by mail'?
Page 6 line 7 and Table 1: it would be useful to include the number of participants counselled by each of these three groups
Page 6 line 17: Change 'lifestyles' to 'lifestyle'
Page 7 line 11: 'will observe' would be better as 'is likely to observe'
Page 7 line 12 change 'than control cluster' to 'than in the control cluster'
Page 7 line 32: indicate the version of SPSS used.
Page 8 line 7: state proportion who gave consent in control group and percent who gave consent in the intervention group
Page 8 lines 8-13: the text is repetitive with respect to Table 2 and should be cut.
Page 8 line 26: change 'actions' to 'action' and 'lifestyles' to 'lifestyle'
Page 8 line 33: change 'follow-ups' to 'follow-up'
Page 9 line 21: change 'modifications' to 'modification'
Table 3 first column on left-hand side: correct 'Mets rsik'

- Discretionary Revisions
Page 3, line 20 'from the thoughts that as a national project' is clumsily worded
Page 4, lines 17-18 ‘The lifestyle support centers…’ This sentence might be better earlier when initially describing the centers.

Page 5 line 1: the grounds defining “suspicion” might be indicated or better as ‘evidence for ‘
Page 6 lines 19-20: consider use of # and also lines 25, 26
Page 10 line 23: ‘There are’- better as ‘This study has’

Figure 1: In boxes headed ‘Exclude (n=5851)’ and ‘Exclude (n=5488)’- it would be useful to add in numbers who met exclusion criteria versus numbers who were eligible but refused

Level of interest: An article of importance in its field

Quality of written English: Acceptable
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