Reviewer’s report

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

Version: 3 Date: 6 December 2012

Reviewer: Patty Chondros

Reviewer’s report:

Minor essential revisions

Methods

Randomization

Page 5, Line 23 – What are the 7 strata? There are only three types of companies or communities or mixed or 17 health care divisions.

Page 5, Line 24 – Also include the statistical program used (i.e. SAS software); Is the command given for generating random numbers correct? PROC MULTEST is used to perform multiple comparisons.

Sample size

Page 10, line 4: Suggest changing the word “samples” in “(number of samples in each cluster)” to either “individuals” or “subjects”.

Statistical analysis

Page 10, lines 14-16: Suggested changes are highlighted in blue:
Student’s t-test (or Mann-Whitney U-test according to the frequency distribution of the variable) will be used to compare the means (or the distribution) of the two study arms for continuous variables. Chi-square test or chi-square for trend will be used to compare proportions for categorical variables.

Also, describe how will you adjust for the clustering effect for this analysis?

Discussion

Page 12; lines 3-5: There may be various reasons why it is not possible to recruit/enrol subjects before randomisation in CRTs. I suggest describing the reasons for recruiting/enrolling subjects after randomisation e.g. was it not practical due to the nature of the intervention? too expensive or would have taken too long to recruit individuals first? etc

Pg 12, lines 6-8: The reason for inflating the sample size of an individually randomised trial two-fold was because the groups of individuals were
randomised rather than the individuals. It allows for the clustering effect due to the correlation of outcomes for individuals that belong to the same group (that is usually quantified with the intra-cluster correlation coefficient). In this instance, the inflating the sample size does not to minimise selection bias.

Sometimes it may be possible to employ certain strategies to minimise the effect of selection bias at the design stage and/or provide sufficient information for the reader to draw their own conclusions about the possibility of selection bias of individuals (See reference: Eldridge S, Kerry S, Torgerson DJ. Bias in identifying and recruiting participants in cluster randomised trials: what can be done? Br Med J 2009;339:b4006.) My suggestion is to delete the last sentence, and if no strategies could be employed to minimise selection bias (see reference above), then discuss the likelihood of having selection bias in your sample based on the cluster sizes between the two groups and the comparison of the participant characteristics given in table 2 and 3.

Page 22, Table 2 – add extra word in the footnote “interquartile range”

Page 23: Table 3: Add to the title of the table that it is also by sex, that is, for men and women.

There are a few typographical errors that need to be corrected in the document, e.g. missing full stop (page 9, line 27); delete the word “of” at end of line (page 13, line 13); comma instead of full stop (page 13, line 27).

Discretionary Revisions

Statistical analysis

Consider describing how missing data will be handled in the analysis.

Page 13, lines 18-19: Describe how the sub-analysis will be conducted in the statistical analysis section of the paper.

**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:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests'