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: 12 March 2012

Reviewer: Patty Chondros

Reviewer's report:

Major compulsory revisions

Although some sections of the paper are clearly described, overall the paper lacks clarity and details about the study design. The manuscript needs to be revised considerably and needs extra information about the study design. Some reorganisation of the flow of information may help improve the clarity.

Some of the issues identified are as follows:

Study design and recruitment

1) A brief description of the health care system in Japan is needed to provide the reader unfamiliar with the health care system in Japan with the context and a better understanding of the clusters. For instance: What are health care divisions in companies/communities? What is their function? Do they differ between the companies and communities? Are the health check-ups conducted through the health care divisions? Can individuals attend more than one division? Do they need to be registered with the health care division?

2) Health check ups – are these part of routine health care in Japan? Do all individuals have an annual health checkup?

3) What are lifestyle support centres? Were they set up for the study itself or are they existing organisations. How are they funded / formed? Similarly, data management center – need more information on their exact role.

Randomisation

4) More detail is needed on the randomisation process. For instance, how was the randomisation sequence generated? Type of randomisation (stratification, minimisation, matching)? If so, details on the approach need to be described? Who and how was the random allocation sequence generated and how was it implemented?

Recruitment

5) More detail is needed about how the clusters were identified and recruited. Were the clusters identified first and then the individuals? Who recruited the clusters and participants? How were the clusters formed from the 17 health
check up divisions?

6) If the intervention is delivered through the life support centres, why did you choose cluster randomisation by health care division rather than individual randomisation? Eg was it to avoid individuals sharing information when working in the same work place or community?

Blinding
7) Who was blinded to the study arm status?

Eligibility criteria
8) What were the inclusion and exclusions criteria for the clusters?

Intervention
9) Why is the implementation of the intervention not standardised across the three life support centres? How will this impact of the effectiveness of the intervention?

Follow-up and outcome
10) Page 6, lines 23 and 24: It is confusing why the individual where CPG was measured diabetes is defined as a secondary outcome. Do you mean that it was used as an alternative outcome measure when FPG was not available?

Sample size
11) Need more information on how the sample size of 1100 individuals was calculated assuming an individually randomised trial. Based on the assumptions given in the manuscript, the remainder of the sample size calculations that allow for the clustering effect and drop-out are correct.

12) Does the sample size allow for testing the interaction between T2DM and metabolic syndrome in IFG subjects (sub-analysis)?

Statistical analysis
13) How will the clustering effect be taken into account in the main outcome analysis? The statistical analysis on individual level data needs to allow for the clustering effect due to randomising the clusters instead of individuals.

14) Do you plan on adjusting for any other possible risk factors or stratification factors? If so, this analysis should be stated in the study protocol.

15) Are there any secondary outcomes? If there are secondary outcomes, how will these be analysed?

16) P-values reported for the baseline comparisons reported Table 2 are unnecessary (See Schulz and Grimes: Allocation concealment in randomised trials: defending against deciphering. Lancet 2002; 359: 614–18)

Minor essential revisions
Results
17) Report average and range of cluster sizes for each study arm. Also, cluster characteristics (if applicable) by study arm status should also be reported to assess for chance imbalance between the study arms of cluster characteristics.

18) If information is available, include a table comparing the characteristics of participants that were invited to participate but declined and those that were included in the study to help assess the generalisability of your sample to the intended population.

Grammar and spelling
19) There are inconsistencies in the tenses and typographical errors in the manuscript that need to be corrected.

Pg 2, line 15; pg 2 line 2
Use alternative words, as “recruited” or “identified”, instead of “extracted”

Page 6, line 29
Suggest change “referring to the primary care physicians in charge of disease” to “referring to the primary care physician of the participant with diabetes” (as an example)

Identify that the trial is a cluster randomised trial in the title of the paper.

Discretionary revisions
Include the rationale for cluster randomisation to be included in the background section (as described in discussion, pg 9 of the manuscript).

Report the intra-cluster correlation of the main outcome at baseline and participant characteristics.

Is the use of “casual plasma glucose” an internationally recognised term for measuring glucose sugar levels?

Dropout and discontinuance - Pg 6, line 36
Participants who have developed diabetes are the individuals where the event has occurred (outcome), thus they are still part of the study and contribute to the analysis. Consider moving point (1) “participants who have developed diabetes” from this section. Suggest moving elsewhere in document, with an explanation that when the event occurred the participants were not followed up any further.

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

Quality of written English: Not suitable for publication unless extensively edited
Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

'I declare that I have no competing interests'