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: 2 Date: 3 August 2012

Reviewer: Patty Chondros

Reviewer's report:

The revised version of the paper gives the reader a better understanding of the health care system in Japan and is much clearer to read. Some of the newer sections, however, need some revision or further clarification.

Major compulsory revisions

Page 4, lines 21-22 and Page 5, line 11-15: How were the 43 clusters formed from the 17 health divisions? The word “clusters” is generic – more information is needed to describe the clusters (e.g. are they companies or community groups?) and how they were identified within the health divisions.

Page 4, line 35: More information is needed in how the questionnaires were (or will be) administered baseline and at each follow up time. Was the questionnaire mailed out to the participants or was it completed over the phone? If by mail, were participants provided with self-addressed envelopes? How were they followed up if they did not return the questionnaire? If via telephone, is it entered directly into a database or data collection forms.

Page 5, line 9-10: The meaning of this sentence is not clear; Needs clarification.

Randomisation

Page 5, lines 16-18: Need to also state the block size(s) within each stratum used for the randomisation schedule. In addition, how was the size of cluster included as a stratification factor (e.g. was it collapsed into categories, if so, what were the groupings)? What was the mechanism used to generate the randomisation schedule (e.g. computer, toss of coin) and who generated the random allocation sequence (e.g. external statistician, team member)? When were the clusters notified of their allocation status? Were the subjects recruited before the clusters were randomised or notified of their randomisation status? See the CONSORT statement checklist for reporting of RCTs.

Page 5, line 18-19: The meaning of this sentence is not clear; Needs clarification.

Page 8, line 9: The sentence suggests that the intervention was not standardised. I assume that the intervention was standardised within each company, but the companies used a different intervention schedule (as
suggested by Table 1)? What was the rationale for using a different intervention schedule in each company? Were whole clusters managed by one company or were the individuals within the cluster split across the three companies? If the whole cluster was allocated, how many clusters did each company manage? Table 1: In addition to the number of individuals, also include the number of clusters included in the three companies (if whole clusters were managed by each company).

Discussion
Page 11, 21-22: Stratified randomisation ensures that there is balance on the risk factors used for stratification between the two study arms; Selection bias can be avoided by recruiting and enrolling the individuals into the study before the clusters are allocated to the study arms (Ref: Eldridge, BMJ 2009;339:b4006); Otherwise, strategies may need to be employed to minimise selection bias if the individuals recruited into the study are not blinded to their study arm status and/or the recruiters are not blinded to the study arm status when recruiting individuals. Figure 1 indicates that the individuals were recruited after the clusters were randomly allocated to the intervention or control groups; It is unclear in the paper whether the individuals or the recruiters were blinded to the allocation status of the clusters at the time of assessing their eligibility and enrolment; This needs to be clarified in the methods section of the paper.

Page 8, lines 5-12: Provide a bit more information about the staff that deliver the intervention. That is, are they health nurses and dietitians employed by the lifestyle support centres who are trained specifically to deliver the intervention and how much training will they receive (days, hrs, number of sessions).

Minor essential revisions

Abstract (page 2)
line 2: “follow-ups” change to “follow-up annually over 3 years”
lines 6-7: remove commas from “cluster, randomized, controlled trials”
line 13: replace “the country” with “Japan”
line 14: “Candidates for study” - add the word “the” before “study”
line 16: “Candidates for study” - add the word “the” before “study”
line 22: Change “intervention cluster” and “control cluster” to “intervention group” and “control group”, respectively.
line 22: Change “control cluster” to “control groups”
line 25: Change “intervention and control clusters” to “intervention and control groups”
line 26: Also add there were no differences in individual characteristics between the study groups
Methods
Page 4, lines 23-24: Change “an intervention cluster or a control cluster” to “an intervention group or control group”; Alternatively, can use the word “arm” instead of “group” when referring to the study groups to which the clusters (and individuals) are allocated to throughout the paper.

Health check ups
Page 5, line 25 and page 31: Move description of BMI from line 31 to line 25 where it is first mentioned.

Characteristics of study participants
Page 7, line 1: Change “intervention or control clusters” to “intervention or control groups”

Page 7, line 7: Add “was” between “BMI” and “substituted”

Sample size
Page 9, lines 12, 13, 19: Change “intervention cluster” and “control cluster” to “intervention group” and “control group”, respectively

Page 9, line 20: Reference for Shoenfeld and Richter is missing

Pages 9, lines 27-28: Rephrase the last sentence to state more explicitly that the sample size calculations were based on the Cox proportional hazard model. Move description of descriptive analysis to statistical analyses section.

Statistical analyses
Page 9, lines 32-35: Description of analysis to compare the means and proportions of the two study groups is not required as the p-values have been deleted from Table 2

Page 10, lines 4-5: What do you mean by “using the clustering effect for sex ratio and mean age”? Will you be using the summary measures within each cluster and then applying standard analytical methods to analyse the data at the cluster level? The exploratory analysis needs some clarification.

Page 10, line 6: Consider changing “multivariate” to “multivariable”

Results
Page 10, line 12: add the word “a” between “to” and “control group”

Page 10, line 21: change “groups” to “study groups.”

Page 10, line 23: change “groups” to “group”

Page 32, line 31: Describe in statistical methods how the ICCs were calculated; Is the description given for “ICC for cluster size” correct as it does not make sense to calculate an ICC for the sample cluster size?
Discussion

Page 11, line 19: Change “interventional effects” to “diluting the effect of the intervention”; Possibly add a sentence on how the contamination could have occurred with individual randomisation e.g. by control subjects receiving part of the intervention if in a shared environment or intervention group not receiving part of the intervention e.t.c.

Telephone-delivered interventions

Page 11, line 29: Expand sentence to “availability of participants for the interview that face-to-face provided support”

Page 11, line 30: Expand sentence to “…support for the participant necessary to promote…”

Page 11, line 36: “coaching by telephone…”; Who will deliver the coaching (Eg health nurses, dieticians)? This can have implications on the generalisability of the study in different settings.

Page 12, line 32: add the word “a” between “in” and “subanalysis”

Page 13, line 21: add the word “cluster” between “nation-wide” and “randomized”

Table 2 – footnote: change “group” to “groups”

Table 3 – Add “group” to the column for the intervention; Describe the acronym “Mets” in the footnote;

Figure 1 – Change “Control clusters” and “Intervention clusters” to “Control group” and “Intervention group”, respectively; Change “1clusters” to “1 cluster”

Tenses and typographical errors

There are inconsistencies in the tenses when describing the study and some typographical errors. I have highlighted some examples here, but the remainder of the paper should also be checked.

Page 3, line 11: “s” to” intervention”

Page 4, lines 16: remove commas from “cluster, randomized, controlled trials”

Page 4, lines 25: delete “or” from “community or settings”

Page 4, line 29: “Those who consented and complete the…”; Change “complete” to “completed”

Page 4, lines 32 and 33: change “receive” to “received”

Also check inconsistent tenses (is, are, do versus was, were, did) in the following paragraphs: Page 4, lines 34-36; Page 5, lines 21-36 and page 6 line 1
Discretionary revisions
Page 5, lines 7 and 9; page 8 line 9: Consider changing “study group” to “study team” to avoid confusion with the term “study groups” when used to refer to the intervention and control groups

**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'