Author's response to reviews

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

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Author's response to reviews: see over
Reviewer's report

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Version: 2 Date: 18 July 2012

Reviewer: Karen Walker

Reviewer's report:

Minor essential revisions:

Page 5, lines 9-10: The wording in the sentence concerning the exclusion criteria is not clear. This needs redrafting to more clearly indicate why the exclusion criteria were considered inappropriate.

Health care divisions, in which study team members are directly involved as industrial physicians, were excluded.

Please see Page 4, line 8-9.

As suggested, we changed the word.
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.

We rewrote the part of “Recruitment of health care divisions” on page 5 as indicated in red. We used the word “group” instead of “cluster” in the revised manuscript.

Please see Page 5, line 13-18: A large health care division, covering many distant areas, was divided into groups. This process was done by the health care division itself mainly based on the area and number of examinees. A total of 43 groups were thus formed from 17 health care divisions. The number of groups formed in each health care division ranged from 1 to 10. Each group included 700 to 6,000 annual examinees. Some groups that were small were pooled with others.

The health care divisions # 17 and # 16 were combined to make one group. Please see attached Table.
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 via 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.

As suggested, we added more information.
The questionnaires are mailed out to the participants from the lifestyle support center with self-addressed envelopes. If a completed questionnaire is not sent back to the lifestyle support center within two weeks, the participant will be contacted first by mail and then by telephone. We made a manual for this process.

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

We deleted this sentence and added a new sentence “They were all approved by the steering committee”. This is what we meant in the previous manuscript.

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 23 – 24: Allocation was done by stratified randomization with seven strata of companies or communities. A randomization list was prepared by an independent statistician by using PROC MULTTEST with seed = 4989.

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

This sentence was deleted in the new manuscript.

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).

The intervention was outsourced to three private companies that are all engaged in the healthcare business, such as lifestyle supporting services by public nurses and dietician. It was difficult for us to standardize the intervention schedule among the companies. Each company uses its own intervention schedule and the intervention is standardized within each company. We, therefore, set the minimum essentials for the intervention. The goals were the same. Body weight and the number of footsteps were measured every day using the same device. The staff monitored the achievement of participant’s goals regularly and gave telephone counseling with motivational interviewing.

As shown in the Table 1, there were considerable differences in the quantity of services among the companies. This might be unfavorable to the study, but could provide us with an opportunity to analyze how these differences affect the intervention effects.

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.

According to the comments, these points have been clarified in the method section of the revised manuscript.
Please see Page 5, lines 22-31.

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).

Public health nurses and registered dieticians employed by the lifestyle support centers have college degree and at least 5 years work experience in the intervention.

Minor essential revisions

Abstract
All items pointed out have been changed in the revised manuscript.

Methods
Throughout the papers we have used an intervention arm and a control arm instead of an intervention cluster or a control cluster.

Health check ups
We have moved the description of BMI to where it was first mentioned.

Characteristics of study participants
We have added “was” between “BMI” and “substituted”

Sample size
Reference numbers have been given.
We have changed these points according to the comments in the new manuscript.

Statistical analyses
We deleted the p-values in Table 2.
We deleted the sentence: We will do some explanatory data analysis using the clustering effect such as sex ratio and mean age.

Results
We deleted the ICCs.
Discussion
As suggested, we changed the sentence.

Discretionary revisions
As suggested, we changed “study group” to “study team” to avoid confusion.