Author's response to reviews

Title: Efficacy of a 3-month lifestyle intervention program using a Japanese-style healthy plate on body weight in overweight and obese diabetic Japanese subjects: A randomized controlled trial

Authors:

Keiko Yamauchi (yamauchi@nuas.ac.jp)
Tomomi Katayama (t-katayama@takara-univ.ac.jp)
Takahiro Yamauchi (tary0916@yahoo.co.jp)
Kazuhiko Kotani (kazukotani@jichi.ac.jp)
Kokoro Tsuzaki (ktsuzaki@kyotolan.hosp.go.jp)
Kaoru Takahashi (seika@hyogo-yobouigaku.or.jp)
Naoki Sakane (nsakane@kyotolan.hosp.go.jp)

Version: 4 Date: 10 November 2014

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

Title: Efficacy of a 3-month lifestyle intervention program using a Japanese-style healthy plate on body weight in overweight and obese diabetic Japanese subjects: A randomized controlled trial

Referee 1:
Minor Essential Revisions
1. P6, L11-15: Dietary intake and steps were assessed only in the intervention group. It should be shown.

As suggested, we added the sentence: Dietary intake and walking steps were measured only in the intervention group (Page 6, line 11, Page 7, line 29, and Page 7 line 33).

2. P6, L32-35: There were no participants lost to follow-up. ITT using last observation carried forward was not necessary. The sentences should be deleted.

As suggested, we deleted.

3. P7, L6: Table 1 => Table 2

Sorry, we changed the sentence (Page 7, line 6).

4. P7, L26-29: Dietary intake was assessed only in the intervention group. It should be shown.

As suggested, we changed the sentence (Page 7, line 29).

5. P8, L13-34: References 29-34 => 31-36

Sorry, we change the reference number (ref 28-24 => 30-36).

6. P9, L8-9: An additional study should compare the dietary intervention with the healthy plate with the dietary intervention without the healthy plate.

As suggested, we added the sentence (Page 9, line 8-10).
Referee 2:
Major Compulsory Revisions
Clarify whether N of 18 in sample size estimation is for only the intervention group or the two group together. As it is written now, it appears 18 is needed for the intervention group. If the same sample size for the control group is needed, then the total needed would be 36. The study only had 10 and 9 in each group, which makes the study significantly under-powered.

A sample of 18 subjects was calculated based on detecting a difference of 3 kg and a standard deviation (SD) of 2 kg in weight loss at the 3 month follow-up between intervention and control group, with 80% power and 5% significance.

As suggested, we changed the sentence (Page6, lines24-27).

Referee 3:
Minor essential revisions:
Page 4, lines 6-8. Regarding the inclusion criteria of participants in the study, the text points out that ONE of the following criteria should be met: 20-70 years of age, diabetes mellitus type 2, or IMC ≥24 kg / m2. What is not clear is why the selection is based only on one of the characteristics since the manuscript title refers to a RCT in overweight or obese and diabetic subjects.

Sorry, as suggested, we changed the sentence: Those who met the following criteria were recruited: 1) aged 20-70 years, 2) type 2 diabetes mellitus or 3) body mass index (BMI) ≥24 kg/m2 (the overweight level was defined based on previous studies [18-21]) (Page4, lines6-8).

If dietary and physical activity assessment was done only in the intervention group, as stated by the authors in the response to the first review, this should be mentioned in the manuscript.

Dietary and physical activity assessment was done only in the intervention group because of practical troubles.
We added the sentence (Page6, line11, Page7, line29, and Page7 line33).