Reviewer’s report

Title: Effectiveness of a motivational intervention on overweight/obese patients in the Primary Healthcare: a cluster randomized trial

Version: 1 Date: 27 Jan 2017

Reviewer: Richard Parker

Reviewer's report:

The authors have responded to some of my comments well, but others still need addressing.

(1) For cluster randomised trials, adjustment for centre is very important and to use standard methods is invalid because they assume independent patients [e.g. see Campbell MK & Grimshaw JM (1998). Cluster randomised trials: time for improvement. BMJ, 317(7167), 1171-1171]. As you correctly state in your response "the patients of the same center tends to be more similar than patients from other centers". Therefore, I do not agree with the reasons given for presenting the standard student's t-test results instead of the multi-level modelling results. In particular, if you fit cluster as a random effect in a multi-level model then this will NOT "confound the effect of the cluster with the real [intervention] effect…": this will only happen if centre is fitted as a fixed effect. An alternative method to multi-level modelling is to aggregate the information at the centre level and then analyse using standard methods, but this method has the disadvantage that results are no longer at the patient-level. In any case, the centre effect must be taken into account for valid analysis.

(2) Please report the intra-cluster correlation coefficient (ICC) for the continuous bodyweight outcome. This will indicate the degree of clustering in the data. I could not see any ICC in the revised manuscript.

(3) Please clarify what is meant by "Patients were recruited always as the five first who meet the inclusion criteria after centers were randomised"? Why "five" in particular? I thought that the average number of patients per cluster was 20?

(4) Just to confirm, by "center" do you mean "Basic Health Areas"?

(5) Sorry I do not understand the newly inserted section of text on page 7 beginning "To avoid possible biases in the patients recruitment and follow-up…. This was carrying out superior quality control, using smaller sample size than would be possible if we randomized the patients." Also, "first two patients" is mentioned which contradicts the "first five patients" in the response to reviewers.
(6) Page 6: "Patients were never aware of the group in which they were allocated to minimize the effect of bias." But presumably patients knew after the intervention was applied, since there was no way of blinding to the intervention?

(7) I could not see any 95% confidence intervals in the manuscript even though this is mentioned in the methods section page 9 and in my comment on the previous submission.

(8) If the analysis was performed as a "complete cases analysis" then this should be reported in the main paper.

(9) Please report exact p-values to 2 decimal places if the p-value is greater than 0.001. For example, please write p=0.02 instead of p<0.05 if the p-value is 0.02.

(10) I am not sure I understand the reason for keeping the p-values in the paper for comparing the baseline differences. If there is missing data or drop-out post-baseline this is not relevant to the decision to include baseline p-values.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Unable to assess

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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