Author’s response to reviews

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

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Author’s response to reviews:

Janet Hanley, PhD
BMC Family Practice

Dear Dr. J Hanley

We read with enthusiasm you letter giving us the option of resubmitting our manuscript entitled “Effectiveness of a motivational intervention on overweight/obese patients in the Primary Healthcare: a cluster randomized trial” to BMC Family Practice.

We have responded to the comments and quarries of the reviewer. Responses are enclosed and in the new version of the manuscript are shown in bold. We believe that the manuscript has been improved with the reviewer suggestions and hope that with these clarifications our manuscript will be now acceptable for publication in BMC Family Practice.

We confirm that this paper is not under consideration elsewhere, none of the paper's contents have been previously published, and all authors have read and approved the manuscript.
Looking forward to a prompt and favorable final review process,

We thank you in advance for your time and effort.

Kind regards,

Dr. Esther Peña

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Reviewer #3:

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.

We agree with you. There is a large variability among the number of patients in each cluster. There were 12 clusters (centers: Basic Health Areas) in which the patients did not have treatment and 12 clusters in which the patients were treated. Although we considered the reduced number of patients included in each center can produce inefficient estimations we added a column in
table 2 with the multilevel results. As the reviewer can observe the estimation of the effect differ briefly.

SEE TABLE 2.

(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.

The intra-cluster correlation coefficient is 0.08 for the bodyweight, so only the 8% of the variability is due by the center.

(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?

To avoid overburden the doctors, and nursing staff, patient recruitment and follow up were done in stages during the first six months of the study. The first five patients who meet the study inclusion requirements and who present none of the exclusion criteria were enrolled.

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

Yes.

(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.

We apologize if we have not communicated properly our design. To increase the variability of patients included, in each stage (4-6 stages in the first 6 months) only the first five patients were included in the study in each stage. This also avoids overburden doctors and nursing staff.

We apology for this mistake.
(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?

We apologize if we have not communicated properly our design. Yes, each IMOAP participant has provided written informed consent using procedures reviewed and approved by the EECC review board. Patients located in the same building were assigned to the same group (control or intervention). Patients knew after intervention was applied they group, but not before. We have clarified the design in the methods section of the new version of the manuscript (highlighted in bold).

(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.

We have been included 95% CI (Table 2) in the new version of the paper.

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

Yes, we include this in the new version of the manuscript (highlighted in bold).

(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.

We appreciate the reviewer’s comment. Accordingly, we have changed this in the new version of the manuscript.

(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.

We appreciate the reviewer’s comment. Accordingly, we have changed this in the new version of the manuscript.