Reviewer’s report

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

Version: 0 Date: 16 Nov 2016

Reviewer: Richard Parker

Reviewer's report:

Major comments:

1. The title of the manuscript should include "cluster randomised trial" in the title as per the CONSORT statement. Please refer to the CONSORT extension to cluster trials checklist: http://www.consort-statement.org/extensions?ContentWidgetId=554

2. The description of the trial design could be improved. In particular, please clarify in the Methods section that the trial has a cluster randomised design and that the centres were randomised. How many clusters were randomised and what was the average size per cluster? What was the rationale for doing a cluster randomised trial?

3. Where exactly was the study conducted and how were the centres selected for inclusion in the study? What was the eligibility criteria for inclusion of clusters?

4. Were patients recruited after the centres were randomized? Was any allocation concealment done at either the cluster or individual levels?

5. The primary outcome appears to have changed from the protocol paper. In the protocol paper (page 4) it suggests that the primary outcome is the proportion of patients showing a 5% reduction in weight loss, whereas this seems to have been changed to "change in continuous weight loss" in this results paper. Please explain the reasons for this change.

6. It is not clear whether the 12 months weight loss outcome is primary or the 24 months outcome. The primary outcome is not clearly defined.

7. No sample size calculation is provided. If this is in the protocol paper then it should at least be referenced or reproduced in the current paper.

8. Please give details about the randomisation method and type of randomisation. In the methods section there is a heading "Screening and randomization", but no details about the randomisation method are included beneath it. Please follow the CONSORT extension for cluster trials statement and describe who generated the randomization allocation sequence, who enrolled clusters etc.
9. Page 8 (statistical methods). "For categorical variables, mean and standard deviation were used..." It is not appropriate to calculate the mean and standard deviation of categorical data.

10. Page 8: "multilevel statistical techniques". Please explain in more detail about the statistical analysis method. What variables were included in the models, and how was clustering taken into account?

11. For table 2, standard errors should be reported instead of standard deviations.

12. If the p-value=0.05, then I interpret this result as being of borderline significance rather than statistically significant.

13. Why were so many patients lost to follow-up between 12 and 24 months follow-up (figure 1), particularly in the control group? 34% were lost to follow-up between 12 and 24 months compared to only 10% in the intervention group. Overall, drop-out was as high as 53% in the control group and 40% in the intervention group. Could the differential drop-out between trial arms have introduced bias into the analysis results at 24 months? What were the reasons for the differential drop-out? Was the drop-out similar across centres? Could the authors perform a missing data analysis to investigate possible predictors of the missing data? This should also be mentioned as a important limitation in the discussion section. Although "adherence was better in the intervention group" (page 13), this does NOT necessarily "confirm the long-term efficacy of the group motivational approach among patients" if the results are biased due to differential drop-out (e.g. if control patients with moderate or high weight loss were dropping out of the study).

14. How was missing data dealt with in the primary analysis? The proportion of patients with missing primary outcome data is very high in this trial.

Minor comments:

15. Page 8: The statement "The hypothesis used to compare was the null hypothesis". doesn't make sense.

16. Please report the intra-cluster correlation coefficient for the primary outcome.

17. It would be more informative if 95% confidence intervals were reported for at least the primary outcomes.

18. Page 9: "statically" should be "statistically".

19. Page 9: The statement "A significant reduction of the weight..." is vague. I think you mean "5% reduction in weight"?
20. It is not recommended to use significance tests to compare baseline differences in RCTs (see for example Knol MJ, Groenwold RHH, & Grobbee DE (2012). P-values in baseline tables of randomised controlled trials are inappropriate but still common in high impact journals. European journal of preventive cardiology, 19(2), 231-232).

21. Very small p-values should be reported as $<0.0001$ rather than 0.0000 in Table 3.

22. Page 11: Presumably "increased to 28.9%" should be "increased to 26.9%" as shown in Table 2?

23. First sentence of discussion: Significantly more patients achieved a reduction of 5% or more of the initial weight.

24. Page 12, lines 5 - 29. Which study is this paragraph referring to?

25. I could not see references for 29 to 31.

26. Since the intervention was in addition to usual care, should "rather than the regular follow-up appointments" (page 13, line 14) be changed to "in addition to the regular follow-up appointments"?

27. The Abstract states that "1,200 overweight/obese patients [were] randomly assigned", but I think you mean that 864 were randomly assigned. 1,200 were prescreened.

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.

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