Author's response to reviews

Title: Effectiveness of intensive group and individual interventions against smoking in primary health care settings. a randomized trial.

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Author's response to reviews: see over
Srs. Editors BMC Public Health:

We send you the manuscript “Effectiveness of intensive group and individual interventions against smoking in primary health care settings” (MS: 8503381042784032) reviewed. Our comments to the reviewers’ recommendations are below.

Yours sincerely,

Maria Ramos
Reviewer's report from Cristina Masuet:

On my opinion the paper could be interesting but there is no integration between Title-abstract-paper. Authors should reconsider to analyse every section following the CONSORT schema. OK, we have done it.

1. Is the question posed by the authors well defined?
The question posed by the authors is not well defined, as in the title, abstract and paper is different (the reader can not exactly specify if the study presents two or three arms to evaluate). OK, we have reviewed it.

2. Are the methods appropriate and well described? Methods are not correctly described as the interventions should be more precisely described. The main outcome is not clearly defined as in the Methods is considered the continued abstinence rate, and in the results (paper and abstract) they give us the point-abstinence rate. OK, we have reviewed it.

As a clinical trial they should specify the sample size estimation, the randomization (sequence generation, allocation concealment, implementation), blinding (if needed). Remember that randomization should be afterwards of signed consent, never before. OK, we have corrected it. It was a writing mistake.

About the flow chart is not correctly described, as it should specify for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome, as well as to describe protocol deviations from study as planned, together with reasons. OK, we have reviewed it, except for number of cases assessed for eligibility, because we didn't collect this information. On the other hand, reasons for discontinuing intervention or leaving during follow-up have been explored in a qualitative sub-study. We want to write another paper with the qualitative results.

3. Are the data sound? Not exactly, data is too small to create a multivariate analysis. Freedman¹ said that sample size should be 10 x number of independent variables + 1. We have 10 independent variables, so sample size for a multivariate analysis should be at least 101 cases.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? The manuscript does not adhere to the relevant standards for reporting and data deposition, so authors could review it following the CONSORT checklist. They should present data analysis by protocol and by intention to treat. We thought that analysis by intention to treat is the optimum way.

to present the results of a randomized trial, and CONSORT has confirmed it to us. Analysis by protocol is not necessary.

5. Are the discussion and conclusions well balanced and adequately supported by the data? The discussion and conclusions are not correctly based on the results, as they present a lot of follow-up population, so the representativity of the results is very limited. We have reviewed the Discussion section, where we explain the problem we have had with lost cases during follow-up.

6. Are limitations of the work clearly stated? Limitations are not clearly stated, they should specify them into the discussion section. OK, we have reviewed it.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? Authors do not acknowledge any work upon which they are building. This study has contributed to raise awareness of primary health professionals about the fight against smoking. In the context of the study, smoking cessation formal training was organized and is still going on. Is it suitable to explain this in the paper?

8. Do the title and abstract accurately convey what has been found? Not appropriate as discussed before. Title should specify how participants were allocated to interventions. OK, we have reviewed the title.


Level of interest: An article of limited interest
Quality of written English: Not suitable for publication unless extensively edited. We are surprised with this affirmation, because translator of this paper is a native English person, who is editor of an English medical journal.

Reviewer's report from Erik Cobo:
This paper presents an RCT of 3 interventions against tobacco in a primary health care setting.
Following the CONSORT reporting guidelines for clinical trials, some comments are provided in order to help the authors improve their paper.

Major compulsory revisions:
Consort 7. Please, clarify the formula and the statistic employed to determine sample size. (Note that precision and confidence refers to estimation, but power to testing.). OK, we have done it.

Consort 8 to 10. Please, clarify all those required items for the randomization process. (Note that the actual wording suggests that consent was asked after randomization, which may explain the differences in the number of patients allocated to each intervention, suggesting selection bias.) Already answered in the previous report.

Consort 12. Please, specify the imputation method for the missing data in order
to perform the ITT analysis (I expect that any patient loss to follow up would have been analyzed as a failure). OK, we have done it.

Consort 13. Please, provide the distribution of the 287 volunteers among the 3 groups. OK, we have done it (figure 1).

Consort 14. Please, specify the start and end dates for recruitment and follow up. OK, we have done it.

Consort 15. Please, note that CONSORT recommends eliminating p values from the baseline data. In your design, some selection bias is expected as previously raised in randomization items. This is almost confirmed by the differences in the intervention preferred by the subject. If this is true, the main advantage from the randomization process (all patients came from the same population) is lost. And it should be raised and discussed as a main limitation of your study. OK, we have reviewed it. Consent was asked before, not after, randomization.

Consort 16. Please, provide the overall number of patients as well as absolute numbers together with percentages. OK, we have done it.

Consort 17. Please, do all the CI calculations again (at least ARR and NNT are wrong: too precise for this sample size). OK, we have reviewed it. Thank you very much.

Minor trusted revision:
Consort 4. Please, specify what is the ‘control’ intervention and what are the ‘experimental’ or comparison ones. Please, be sure that any commonality and any difference among the 3 interventions is completely clear to the reader. OK, we have reviewed it.

Consort 5. Please, specify what are the intended comparisons among the three interventions. OK, we have reviewed it.

Consort 11. Please, clarify whether or not the evaluators of the outcome were masked. OK, we have done it.

Consort 12. Please, clarify the main/primary analysis for the main/primary hypothesis. (Note that the actual wording suggests that more than one test have been done, implying multiplicity.)
Consort 18. Please, address multiplicity. OK, we have done it.

Consort 19. Please, provide information regarding any adverse event. OK, we have done it.

Consort 20-22. Please, try to be concise and to structure your discussion following CONSORT recommendations (some insights from STROBE discussion items can also be employed). OK, we have reviewed the Discussion.

Level of interest: An article of outstanding merit and interest in its field
Quality of written English: Needs some language corrections before being
Published. Already answered in the previous report.