Reviewer's report

Title: The role of gender in a smoking cessation intervention: a cluster randomized clinical trial

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Reviewer: Iñaki Galán

Reviewer's report:

This work is a secondary analysis of a cluster randomized clinical trial assay to evaluate the effectiveness of a stepped smoking cessation in primary health care, based on a broad sample of health centers, involving about 3000 people in 11 Spanish regions. The study design has been published in this journal in 2009.

Major compulsory revisions:

The main limitation of the study comes from the analysis of the data. In my opinion, the design used is not the most appropriate to meet the objectives. To evaluate the role of gender as a predictor of smoking cessation within the community trial, the authors include all participants in the study, the intervention group and control. By including the controls do not evaluate the intervention process of trial and the results shown reflect the likelihood of smoking cessation (in a mixture of people involved in the intervention and those not receiving specific intervention) by gender. In my opinion the authors have two options to evaluate this objective: 1) Analyse the whole sample but including an interaction term between study group (intervention and control) and gender, 2) select only the intervention group.

Another confusing aspect should be clarified is the statistical analysis used. The authors point out in the Methods section (data analysis) that they have used a random-effects logistic regression. Actually it is a mixed effects (fixed and random) multilevel logistic regression analysis. The random effects corresponding to the primary care centers and the fixed effects to the predictor variables. However, this reviewer does not understand the purpose of using this analysis since the absence of significant predictors at the primary care level that could explain the observed variability between centers (contextual variables). The results as shown in Table 3 only describe a residual variability between centers (variance adjusted for the effect of individual variables). This reviewer, taking into account the type of cluster design and purpose of the study, would have preferred a logistic regression model which takes into account the sample design to estimate the standard errors, using the module of Stata Survey Data, which is the program that the authors have used.

The logistic regression model is poorly specified. Its not define what variables are included in the model (the number of variables in Table 1 is much greater than that of Table 3). It is not include any mention to the selection steps of variables in
the model. It is assumed that all variables of Table 3 are introduced simultaneously but it is unknown whether there is an initial selection process.

Physical activity is not defined (e.g. leisure-time, at work, whether or not includes household activities, etc.). This variable is classified in two categories that do not follow any recommendations known.

The information in Table 2 should be restructured. If the aim is to compare in a bivariate way gender differences at baseline and one year follow-up stratified by intervention group and control, should be restricted to individuals from whom information is available at one year. Thus, the information would be more comparable avoiding differential bias due to loss to follow-up.

Minor essential revisions:

Abstract (Background): Change "The aim of our study was to analyze the role of gender in a specific intervention of conducted smoking cessation in Spain" for this one "The aim of our study was to evaluate the role of gender in the effectiveness of a specific intervention of smoking cessation conducted in Spain".

Abstract (Methods): Write Spain instead of SPAIN.

Key words: Include "Clinical Trials".

Background: At the end of the first paragraph, the phrase "In the same year, 27.2% of woman and 19.4% of men reported an increase of tobacco consumption with respect to 2004" is out of context and lack of appropriate citation. It seems to indicate an increase in consumption compared to 2004 but at a fraction of the population. This information should be linked to the third paragraph, but rather to provide international data focus on the situation in Spain.

Methods:

Data collection:

On page 7, lines 12-22, the paragraph about treatment could be excluded since it is not used in the analysis. Related to treatment rather than to exclude this variable (it is questionable the problem of overfitting) would have been interesting to assess whether there are gender differences in response to different treatments because, as the authors note in the case of nicotine replacement therapies, there seems to be less effective in women than in men. This information would be useful in assessing the therapeutic strategy for primary health care. In any case it would be interesting to know the distribution of treatments by gender.

The last paragraph of this section refers to variables measured only in women?

Data analysis:

There are a large number of subjects lost to follow-up. Classified all of them as smokers it is questionable. For this reason, an analysis including these subjects could be performed to ensure that the results do not change (to quote these results in the text, no need to include tables).
Results:

Lines 17-19, page 10, mentioned data not shown "It was observed that women had more smoking cravings confronted with difficult situations when such as depression, anger ... ....." This information, if relevant, should have been included in the overall analysis of the study. Otherwise adds more confusion.

Page 11, lines 5-8 ".... was adjusted for age, group ... ", should be included at the end of the phrase "at baseline".

Page 11 lines 10-21: the data are not shown in tables. If this information is relevant should be accompanied by the appropriate table.

Discussion:

Page 12, lines 10-11: "was... but this effect due to the high of our study sample size". This statement must be qualified as many of the differences are clinically significant and can not be attributed to the sample size.

Page 13, lines 4-6, quoted in the text the Bohadana and Pogun studies (references 24 and 27) but it lacks the authors of quotations 28 and 29.

Tables:

Report to three decimal places for the p-values and p <0.001.
Label the variables exactly the same in all tables.
Follow the same order of variables in all tables.
Table 3 should include the p-value in the estimation of the variance.

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests