Author’s response to reviews

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

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Author’s response to reviews: see over
Dear Editor,

Please find attached our manuscript entitled “The role of gender in a smoking cessation intervention: a cluster randomized clinical trial” which we would like to be reconsidered for publication in BMC Public Health.

The present work is a part of the ISTAPS study, a study that evaluates the effectiveness of a stepped smoking cessation intervention based on a trans-theoretical model of change, applied to an extensive group of Primary Care Centers (PCC) (Cabezas C et al. BMC Public Health 2009;9:48).

The results of this work will contribute to the improvement of an important issue in Public Health because it explores gender as a predictor of smoking cessation. We believe that our work could interest your readers were it to be published in your journal.

On behalf of the co-authors I affirm that neither the manuscript, nor any part of it, has been published or is currently under consideration for publication by any other journal. All authors have read and approved the current manuscript.

Below we have responded to the changes proposed by the reviewers, and we have included the new version of the article in the online application system. All changes that have been made to the article are underlined.

We look forward to hearing your opinion on the suitability of our manuscript for inclusion in the journal.

Yours sincerely,

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Reviewer’s report

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

Reviewer 1: Iñaki Galan

Abstract: line 9, should be changed from “fixed-effects logistic regression model” to mixed-effects logistic regression model” since the model contains both fixed effects and random effects. The same change should be done in line 13.

We agree with the reviewer and have changed “fixed” for “mixed”

Introduction:
In the first paragraph you could update the mortality figures with 2006 data. This information has been published recently:

Following the reviewer’s suggestions, we have updated this information including 2006 data.

The third paragraph of the introduction should be integrated into the first one. Furthermore, this paragraph should be improved because it has been misunderstood the epidemiological pattern of the evolution of tobacco consumption in Spain, providing unreferenced figures. In Spain, consumption in men is down from the mid seventies and women reached a peak in the late nineties, falling slightly in the current decade.

“Over the last decade, global tobacco consumption has decreased progressively in Spain; however, tobacco consumption remains high. According to data from 2006, 21.5% of women and 31.6% of men older than 16 were current smokers in Spain (Ministerio Sanidad y Consumo, 2006). Specifically, until the 1970s, the prevalence of smoking in women was lower than 5%. Tobacco consumption in women has since increased, reaching peak levels around 1995 and 2001, and falling slightly in the following decade. In men, tobacco consumption began to decrease after the mid 1970s (Comité Nacional para la Prevención del Tabaquismo, 2009).”

We have included this paragraph in the introduction.

Methods:

Data analysis.
- Some analyses were stratified by gender (Tables 1-3) but not the main analysis (Table 4). For this reason the heading “Analyses were stratified by gender” (first line of the Results section) should be corrected.

We agree with the reviewer. We have removed this sentence from the beginning of the section and we have specified that analyses were stratified by gender when describing the analysis of tables 1-3 in the data analysis section.

- Paragraph explaining the analysis used in the results described in Table 3 is very confusing, “Linear and/or mixed-effects models (analysis of covariance)”. Do you use
We agree with the reviewer and we have rewritten the paragraph in the statistical analysis section to clarify this aspect:
“Linear regression models were used to assess the independent predictor variables on number of cigarettes consumed last month in men, importance, confidence and readiness to quit at the one-year follow-up in both genders, adjusted for baseline measurement. The standard errors were adjusted for the cluster effect of the BCU. Because significant variability among BCUs was found in the number of cigarettes consumed last month in women, a linear mixed-effects model was performed to assess the independent predictors on number of cigarettes consumed last month. These analyses were stratified by gender.”

We have also reworded the title of Table 3:
Title: “Table 3. Independent predictors of no. cig/day, importance of quitting, confidence in quitting and readiness to quit at one-year follow-up. Linear regression model. ISTAPS study”

Results:

- The last paragraph on page 11 is related to Table 4, however is located in the text before of Tables 3. Given that this information is not presented in tables should be minimized and put in context of the results of Table 4.

As suggested by the reviewer, we have rearranged this section.

- The description of Table 3, which is very complex in its interpretation, is little developed in the text (first paragraph on page 12). Authors should make a longer description of the results of this section.
- The information of Table 3 is very confusing. As mentioned above, it states that it has conducted an analysis of covariance, linear regression and mixed models, but is known exactly where and how they are applied. For example, as stated footnotes at the bottom of the Table 3, “mixed-effects linear models” have been only implemented in the variable “number of cigarettes per day” for women. There are numerous empty cells in the absence of an explanation about it (this reviewer assumes that each of the eight models has different variables selection, but it should be explained at the bottom of the Table 3). The title of the columns 3 and 4 varies for men and women. Also, given the large amount of data, it would be advisable in this table to eliminate the standard errors. It would be enough show p-values.

Following the reviewer’s suggestions and since coefficient estimators are relatively small values, we have decided to study only independent predictors associated to each variable considered, without taking confusion into account, to clarify the results. Final models only present those variables which were significant in the analyses.

We have reworded the text in the statistical analysis section:
“Linear regression models were used to assess the independent predictor variables on number of cigarettes consumed last month in men, importance, confidence and readiness to quit at the one-year follow-up in both genders, adjusted for baseline
measurement. The standard errors were adjusted for the cluster effect of the BCU. Because significant variability among BCUs was found in the number of cigarettes consumed last month in women, a linear mixed-effects model was performed to assess the independent predictors on number of cigarettes consumed last month.”

We have reworded the paragraph explaining Table 3 in the Results section:
“The variables associated with number of cigarettes per day, importance, confidence and readiness to quit of smokers at the one-year follow-up showed differences between men and women (Table 3). The most important difference is that physical exercise reduces significantly the number of cigarettes consumed daily in women. Differences between men and women for the remaining predictor variables are of lesser magnitude. Baseline values for each variable considered are highly significant predictors”.

We have also rewritten the title of Table 3:
Title: “Table 3. Independent predictors of no. cig/day, importance of quitting, confidence in quitting and readiness to quit at one-year follow-up. Linear regression model. ISTAPS study”

We have added a footnote for Table 3 for clarification:
“Final models were adjusted only for significant variables.”

Additionally, we have changed the title for columns 3 and 4 for women.

Because coefficient estimator and standard error values are very small, we have decided to include 2 decimals for the standard errors in order to maintain accuracy in the estimation of confidence intervals; p-values are specified at the bottom of the table.

- The titles of Table 1,2 and 4 should be reduced. Table 3 has a confusing title, only referring to its statistical component.

We have shortened the titles for Tables 1, 2 and 4. We have corrected the title for Table 3, which now reads: “Table 3. Independent predictors of no. cig/day, importance of quitting, confidence in quitting and readiness to quit at one-year follow-up. Linear regression model. ISTAPS study”.

- I recommend including 1 decimal (in some data there is 1 while in others there are two) except for p-values.

We agree with the reviewer and have made these changes, except for Table 3. Because coefficient estimator and standard error values are very small in Table 3, we have decided to include 2 decimals for the standard errors in order to maintain accuracy in the estimation of confidence intervals.

Other comments:
- Replace “autonomous comunities” by “region” since this term does not exist in English.

We have changed as suggested by the reviewer.
Reviewer 2: Joan R Villalbí

The paper has improved with the revision, and is almost fit for publication. Being one of two papers from the same trial, exploring the differential role of gender, perhaps it should be published after the more general study, so it may be referenced. It also could benefit from a review of English style: many expressions even if formally correct are reminiscent of Latin-based language structures. For an international readership, I recommend that “Basic Care Unit” in the abstract could be changed for “family physician or nurse.”

The main article about effectiveness of the intervention at 2 years is now being peer-reviewed for another journal. Because these two studies were conducted more or less at the same time, it is impossible for us to know which one will be published first.

The article has now been reviewed twice. It was reviewed by an American speaker and then by an expert medical translator.

As suggested by the reviewer, we have defined ‘basic care unit’ in the abstract.