Reviewer's report

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

Version: 3 Date: 8 July 2009

Reviewer: Erik Cobo

Reviewer's report:

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.)

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.)

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).

Consort 13. Please, provide the distribution of the 287 volunteers among the 3 groups.

Consort 14. Please, specify the start and end dates for recruitment and follow up.

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.

Consort 16. Please, provide the overall number of patients as well as absolute numbers together with percentages.

Consort 17. Please, do all the CI calculations again (at least ARR and NNT are wrong: too precise for this sample size).
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.

Consort 5. Please, specify what are the intended comparisons among the three interventions.

Consort 11. Please, clarify whether or not the evaluators of the outcome were masked.

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.

Consort 19. Please, provide information regarding any adverse event.

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).

**Level of interest:** An article of outstanding merit and interest in its field

**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