Reviewer's report

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

Version: 4  Date: 20 August 2009

Reviewer: Erik Cobo

Reviewer's report:

In general, authors have addressed the suggestions.

Major compulsory revision:
One question related to previous concerns arose: the number of patients allocated to each intervention arm is unbalanced. The chi-square test for a discrete uniform distribution (df=2) has a 4.71 value (P=0.095), but if we concentrate on the first two categories, the results would be significant (X2=4.69, P=0.03). Of course, those data driven, a posteriori, tests should only be interpreted as exploratory.

But as this unbalance may be surprising to some reader, the authors should argue carefully it. Please note that the second results sentence still suggesting selection bias, that is, that patients were included only if the allocated arm fitted with their treatment expectations. At least, those concerns should be addressed on the discussion. If, for example, patients retired they consent after they knew the allocated arm, at least this fact should be reported. This reviewer thinks (but this is not shared by anyone) that once informed consent is done, patients may change their mind and they may deny the (consent to) allocated treatment (specially if they are not blinded), but they cannot deny the (consent to) analyze and to publish their data. Following my point of view, those patients should also be included. But the ethical committee or the authors may think that those patients should be excluded (Declaration of Helsinki doesn’t differentiate between consent to treatment and consent to data).

Discretionary revisions:
Please note that Friedman et al suggested 10 “cases with event” per variable, nor 10 cases. (‘Event’ should be read as the less frequent outcome category.). As it is just a thumb rule and it refers to simultaneously included variables, I would not be worried about this.

Please note that in table 4, only one mean and only 1 IQR limit has 1 decimal number (I suggest all numbers except the counts having just 1 decimal).

Level of interest: An article of importance in its field

Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests’ below