Reviewer's report

Title: Design of a multicomponent school-based randomized trial to reduce smoking among 13-15 year olds, the X:IT study

Version: 3 Date: 18 October 2013

Reviewer: Maria Rosaria Galanti

Reviewer's report:

General comment: The article reports on the development of a multi-component intervention of smoking prevention in school and corresponding evaluation design, a praxis very recommended in experimental studies dealing with outcome evaluation of interventions. The topic is of relevance for public health and the investigators succeeded in recruiting a sufficient sample. The study design is straightforward and the authors seem to be aware of the possible shortcomings in this kind of community experiments.

However, there are numerous (both major and minor) methodological problems that should be addressed in order to make the study completely trustable.

Major compulsory revisions

1. Structure of the paper: The paper now contains a number of headings and subheadings in no logic structure. I suggest the following hierarchy in headings: Background and rationale for the study; Intervention, with sub-headings: Theoretical model; development of the intervention; components and content; Evaluation, with subheadings: Design; Population; Instruments; Data collection; Statistical aspects; Discussion

2. Theoretical model for the intervention and construct definition – I find the description of the theoretical model depicted at page 4 and in figure 2 rather difficult to follow and unnecessary complicated. First: I do not understand the difference between “Attitudinal” “Social” and “Contextual” influences. Family is a context through which social influences are conveyed, as it is the case for school and community: why should the first be labeled as “social” and the others as “contextual” is not clear. Second, it is difficult to understand the logic used by the authors to group under these headings very different factors (i.e. structural-social and cognitive factors, factors pertaining to the individual and factors pertaining the environment). For instance, why are knowledge/expectations/attitudes (typically individual cognitive traits) be classified as attitudinal and skills as intra-personal influences?

The confusion is probably due to the effort of putting together a theoretical frame (causal chain of influences), institutional levels, and study-specific operative variables. I suggest that the authors simplify their scheme listing behavioral influences coming from different social environments (family, school and community), as distal influences and individual factors (i.e. mediators) as proximal influences leading to the outcome. Also, it would be very nice to the
reader to put in evidence (for instance in bold, or bold frame) which of these influences are tackled by the intervention

3. Study design – it is not clear whether the study population consists of a cohort or of repeated cross-sectional samples, with outcome only assessed at the group level. In the first case, a description of the individual follow-up procedures should be given (including the tracing and survey of pupils changing school, see paragraph population suggested above). In the latter case, details on the planned analysis should be given – for instance how control for potential confounders will be pursued. Also, the authors should explain why a higher number of schools were randomized to the intervention compared to the control group (53 vs. 44), page 9

4. Study population- there was an imbalance between experimental groups concerning several characteristics potentially predicting the outcome. At page 13 3rd paragraphs the authors acknowledge some of them, but avoid describing the implications of this imbalance, although the majority of the differences would point towards an anti-conservative bias, i.e. would favor the alternative hypothesis of effectiveness of the intervention.

5. Protocol violations- It seems clear (page 5) that some schools were allowed to skip the application of an important intervention component (environmental prevention). It would be nice to know: a. how many schools among those participating in the trial had this problem, and their distribution between intervention and control group b. how could the investigators assess that the criterion “teachers smoking …must be invisible to the pupils” was actually respected

6. Tables
a. Table 2: very difficult to read in the present form. I suggest to omit the first column and to simply write in the cells the activities corresponding to the time points highlighted in the frame row
b. Table 3: a notation of whether the observed differences between groups were statistically significant would be desirable

7. Language - I strongly suggest that the manuscript undergoes a careful language scrutiny by an English speaking professional, because in the present form the comprehension is seriously limited by grammar and terminology problems, above all an improper use of scientific English. This affects the whole manuscript, to begin with the title (e.g. it is not the trial that is multi-component and reduces smoking, but the intervention that the trial is designed to evaluate). Other example: when talking about behavioral influences the usual terms are “distal” and “proximal” influences, rather than “ultimate” and “intermediate”.

Minor essential revisions
1. Timeline of the study – According to the timeline reported in table 2, the study should have been completed during the past spring. One wonders why so much
time elapsed before this basic report was submitted. Also, at this point, it would be nice to have some additional information on the cohort at follow-up (i.e. proportion students retained, procedures for follow-up in case of school change)

2. In several points there are unclear statements and imprecisions that should be addressed, such as:

- Smoke free dialogues (page 5 line 4): definition?
- Power calculation (page 8, last paragraph): in developmental ages, where the prevalence is constantly increasing, it is improper to speak about “prevalence reduction”. The proper expression would be “lower prevalence in intervention than in control group”
- Page 15, 2nd paragraph : the unequal SEP distribution in the trial arms IS likely to result in a bias, even if one of the strata is not different. The argument that smoking prevalence is higher in the stratum not differing is misleading, since the size of the strata is also a factor.
- Scope of the study, page 15 next to last paragraph. How do the authors plan to analyse the effect of single program components? To do so, they would have randomized to these components as well.

**Level of interest:** An article of importance in its field

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests