Author's response to reviews

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

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Response to reviewer Maria Rosaria Galanti.

Major compulsory revisions:

1. Structure of the paper
   We thank the reviewer for this careful and insightful comment. We acknowledge that the structure of the paper can be confusing and have restructured the paper as suggested by the reviewer and according the journal guidelines.

2. Thank you for commenting the theoretical model for the intervention. We agree that the model is complicated as we, as the reviewer points out, include the variables tackled by the intervention in the theoretical frame. We have although tried to simplify the model by removing the bullet points. The model is based on the theory by Flay et al. (1995), and the different factors are structured according to their model. We also agree that the word contextual can cover more arenas and therefore, we renamed the contextual influences as environmental influences, as was done by Klepp et al. (2005). Furthermore, we changed the word ‘ultimate’ to ‘distal’.

3. Study design. The X:IT study consists of a cohort study, where the same students were followed from baseline in the beginning of year 7, and with follow-up data collected in the end of year 7, 8 and 9. We followed the students by their name, birthday, class and school. As students in Denmark follow the same class/group of children through all nine years of schooling, it is rather simple to follow students over years. Students who changed school were omitted from the survey as they would not attend either an intervention or control school. In the data file students were anonymized. This has been clarified in the text, page 11, paragraph 3 and 4.

   Within each municipality schools were allocated to either intervention or control school by drawing lots, e.g. if a municipality enrolled 5 schools in the study, six lots were made, three with intervention and 3 with control. The allocation is a result of this random procedure.

4. Study population. We understand the reviewer’s concerns. In the results section (page 13) we mention the larger imbalances between the experimental groups. Randomization guarantees equal distribution of covariates across intervention and control groups. An observed imbalance can happen in any randomization, but a statistical significant distribution is unlikely to influence the effect of the intervention. Therefore, there should be no testing of homogeneity (ref: Senn 1989). This has been added to the text, page 15, paragraph 2. To avoid misunderstandings we deleted the description of potential implications in the discussion.

5. 48 schools (26 intervention and 22 control schools) could not comply with the demand of being completely smoke-free. This has been added to the text, page 5, paragraph 3. The criterion of invisible smoking was assessed through direct questions to the school coordinators and to questions the pupils asking how often they see teachers smoke at school grounds.
6. a. Thank you for this suggestion. We have simplified table 2 and added numbers to the table to meet the reviewer’s suggestion of adding additional information on the cohort and follow-up.

b. Table 3. This advice has been addressed in point 4.

7. Language. We changed the title according the reviewer’s comment and scrutinized the language.

Minor revisions

1. Time constraints are the main reason for the delay of publication of this report. We have been very busy running the intervention and collecting large amounts of data among many schools and pupils. Furthermore, the report was submitted to BMC in February 2013 and we received the review comments 4 weeks ago.

2. Thank you for drawing our attention to these unclear statements. We have clarified the text. The concept of smoke free dialogues has been described at page 6, paragraph 4. The expression “prevalence reduction” has been changed to “lower the prevalence in intervention than in control group”, page 13, paragraph 3. The discussion of the unequal distribution of SEP has been deleted from the text. We acknowledge that to correctly examine the relative effect of the different component, we would need a factorial design. We have deleted this scoop from the text.

Response to reviewer Hazel Gilbert.

Major compulsory revisions:

1. Recruitment.

The reviewer asks for a brief description of what constitutes a municipality. Thank you for this suggestion. We have elaborated the text, page 9, paragraph 1. Denmark has 98 municipalities and with a population of 5.6 million the average size is around 57,000 people pr. municipality. The municipalities in the X:IT study varies between 35,000 and 295,000 inhabitants, and five of the ten largest municipalities in Denmark are present in the study. They are spread all over Denmark. According to Eurostat (European Commission) Denmark is one of the least urbanized countries in Europe with only 22% of the population living in urban regions compared to 41% in average in all European countries. There would be around one school pr. 5,000 inhabitants in a municipality.

2. Randomization and baseline characteristics

A short description of the Danish school system would also be helpful. This has also been added to the text, page 9, paragraph 1. The Danish public school consists of year 0 (preschool class) and year 1-9. All 10 years are mandatory. The Danish children start at school the year they turn 6. Children who start together in the same class at year 0 will belong to the same class/group of children through all ten years of schooling. There is a limit of 28 children pr. class. Schools with year 7-9
pupils have 2-4 parallel tracks. There is no grouping after abilities in the Danish schools i.e. that all children have joint lecturing. 85% of all Danish children attend the public school and the schools are area-based, which means that they have a wide socioeconomic composition. We measure individual and school level socioeconomic position in order to be able to take that into account in the analyses.

Randomization was stratified within each municipality. Allocation was performed by drawing lots, e.g. if a municipality enrolled 5 schools in the study, six lots were made, three with intervention and 3 with control. This has been clarified in the text, page 9, paragraph 4.

3. Analyses and power calculations. Thank you for these comments; we have clarified the text accordingly:

The X:IT project is mainly based on two Nordic projects, which showed effects sizes between 30-50%. The 25% reduction in prevalence of smoking was expected to be realistic in Denmark, page 13, paragraph 5.

We used the same questionnaires for baseline and follow-up surveys, although we added relevant evaluation questions to the follow-up version, e.g. questions on how many lessons the students have had this year using the X:IT-material. This information has been added to the text, page 10, paragraph 3.

For the analyses of first follow-up data we will use multilevel logistic regression models with adjustment for smoking at baseline. Furthermore, we will perform available case and intention-to-treat analyses, the latter with multiple imputation of missing data. In the analysis of second follow-up a mixed model with repeated measures will be used. The random effects will handle the covariance within schools and classes. The fixed effects will include an interaction between time and intervention indicator. This has been added to the text, page 14, paragraph 2.

We acknowledge that to correctly examine the relative effect of the different component, we would need a factorial design. We have deleted this scoop from the text.