Author's response to reviews

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

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Dear Editors of BMC Public Health

Thank you for your email dated 13 February concerning our paper “Design of a multi成分ent school-based randomized trial to reduce smoking among 13-15 year olds, the X:IT study”. With this letter I hope to answer your questions satisfactorily.

We kindly ask you to peer review the study protocol. This study is a collaboration between Centre for Intervention Research and The Danish Cancer Society. Trygfonden and The Danish Cancer Society funded the center, but have not been involved in peer review of the separate studies only the total center application with limited information on design details. Proof of external funding is attached.

In Denmark conduct of surveys and interventions that do not include examination of human biological material or clinical examination of individuals do not need approval from the Danish committee System on Biomedical Research Ethics. I asked them today to provide evidence that the X:IT study does not need any approval, and I will forward this to BMC Public Health as soon as possible.

The X:IT study is registered at the Danish Data Protection Agency, reference number: 2010-54-0930.

The X:IT study is also registered at Current Controlled Trials ISRCTN77415416. This information has been added to the abstract as well as the manuscript.

This is the first paper from the X:IT study. So far no other manuscripts have been submitted.

Baseline data in the study protocol are provided with the purpose of examining to which degree the randomization of intervention and control schools resulted in comparable groups. We think that proving whether the randomization was successful or not is an important part of assessing the validity of the study.

All authors have been personally and actively involved in the work leading to this paper. All ethical safeguards have been met and there are no conflicts of interest. The paper has not been submitted before.

I look forward to your reply.

Sincerely yours,

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