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: 20 February 2014

Reviewer: Hazel Gilbert

Reviewer’s report:

This paper describes the development of an intervention for an RCT to reduce smoking in adolescents, and includes preliminary descriptive data about the participants. The intervention is theoretically driven and consists of several components, and is comprehensively described. The paper is very well written.

There are however, some points where additional description is needed.

Major Compulsory Revisions

1) Recruitment

The spread and characteristics of the municipalities participating is an important consideration and, although mentioned on page 14, for international readers a brief description of what constitutes a municipality, and the size and make up in terms of urban/rural populations, and how many schools on average would be in each municipality would aid understanding. How representative of the general population were the ones agreeing to participate?

2) Randomisation and Baseline characteristics

As the randomisation was by school, as well as those of the individual participants, the characteristics of the individual schools are also needed. Again, for the international reader, a short description of the school system in Denmark would clarify whether they are similar in terms of academic level, but also the size, area (urban/rural) ses level and ethos of the school is important.

Drawing lots to randomly allocate is a rather crude method, but at the very least, the randomisation should have been stratified within each municipality.

3) Analysis and Power calculations

What was the basis for the expected 25% reduction prevalence of smoking?

Was the same questionnaire used at baseline and at all follow-ups?

More information is needed on the analysis and statistical tests to be used. This planned analysis should take into account the longitudinal nature of the study and the nested design of pupils within schools.

It is an ambitious aim to examine the relative effect of different components, normally this is not possible without a factorial design, which is of courses not
possible with this kind of complex intervention. It will be interesting to see the results of this.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**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