Author's response to reviews

Title: SMS-based smoking cessation intervention among university students: protocol for randomised controlled trial (NEXit trial).

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Author's response to reviews:

Dear Editor,

Re: MS: 1686931365148962 25/1-2015

SMS-based smoking cessation intervention among university students: protocol for randomised controlled trial (NEXit trial).

Ulrika Müssener, Marcus Bendtsen, Nadine Karlsson, Ian White, Jim McCambridge and Preben Bendtsen

Response to the comments from the reviewer and editor.

Reviewer 1.

1. In the randomisation and other study procedures section it is stated that only students who are willing to set a quit date within a month are eligible for the study. Can the authors explain why this is compared with allowing anyone who intends to quit to join the study.

This was decided for two inter-related reasons: 1) In order to avoid a high numbers of drop outs from the intervention as was seen in our pilot study; 2) the intervention is not designed to meet the needs of those who are not yet willing to set a quit date. Also, in most effectiveness studies concerning smoking cessation this is a standard inclusion criterion.

2. Under blinding can the authors state whether the participants know which group they are in (it seems obvious that if they are in the SMS group that they will guess this anyway).

Both groups were told before signing up for the study that they would be randomised to an intervention group that would get immediately access to the intervention or a waiting list (control group) that would get access to the
intervention 4 in four month time. All participants randomised to the control group also received a SMS informing them about their allocation as written in the middle of page 6.

3. The authors currently state that the data collection procedures are automated limiting chances to bias results but will the research team be masked to treatment allocations throughout the data collection period?

Yes. The research team per se have no access to the computerized system and will only receive the complete data set after the follow-up. However, one of the research team members is responsible for the design and operation of the computerised system, ensuring that all processes were executed as planned.

4. Why is the allowance for attrition deliberately conservative? Do they anticipate a higher rate of drop outs in this trial to others that might normally go for 20% attrition?

Allowance for attrition is deliberately conservative, as we do not anticipate this level of attrition, but wish to make provision for it in consideration of sample size and planning study design.

5. I would suggest splitting up the section on intervention design and content from the section on earlier work to test feasibility of the intervention.

Thank you for this suggestion. We have now removed the text concerning earlier feasibility work to a new section on page 8: “Earlier work on the feasibility of the intervention” immediately after the section on “intervention design and content”

6. Were the focus groups referred to on page 7 undertaken with the same age group as that used in the trial i.e. were students recruited for this earlier work?

Yes, they were the same age group of students.

7. The data analysis plan says it will be ITT but the primary analysis will be undertaken on complete cases only - can the authors explain this contradiction?

We don't see this as a contradiction, since the incomplete cases will play a full role in the sensitivity analyses. The argument is about what we call the "ITT analysis strategy" and is as follows. In theory, intention-to-treat analysis requires outcome data on all randomised individuals (and an analysis which ignores what treatment was actually received). When some individuals have no observed outcomes, we have a problem. Some analysts would use methods such as last observation carried forward or "missing=failure" which include all individuals, but the validity of the analysis should be judged by the plausibility of the underlying assumptions, not by the inclusion of all individuals. We consider the missing at random assumption more plausible than (for example) "missing = not abstinent" for these data. However, we argue that the inclusion of all individuals is essential in the sensitivity analyses, which will consider (for example) the possibility that missing individuals are half as likely to be abstinent as observed individuals. Our argument is explained more fully in the paper cited as (39) and in a more

We state in the middle of page 10 under the section data analysis.: “Following the intention-to-treat analysis strategy, all analyses will include all participants with follow-up data in their groups as randomised, and sensitivity analyses will include all randomised participants to explore different assumptions about the missing data (ref 39, which is a reference to the above mentioned article).”

Editorial request.

1. The date of the registration of the trial registration has been added in the end of the abstract

2. A statement has been added on page 5 in the methods section under "Randomisation and other study procedures", explaining that we obtained informed consent from each participant.

The sentence now reads: “After having read the information about the study, each participant is requested to click on another link to give informed consent to participate in the study”

3. A list of abbreviations used and their meanings have been added to the manuscript after the “Trial Status”.

4. The figure has been removed from the main manuscript and included as a separate file.

5. A figure title and legend section has been added after the reference list.

Best regards,

Ulrika Müssener