A Smoking Prevention Program Delivered by Medical Students to Secondary Schools in Brazil Called "Education Against Tobacco": Randomized Controlled Trial

**ABSTRACT**

**1b-i) Key features/functionality/components of the intervention and comparator in the METHODS section of the ABSTRACT**

Yes. "The study groups comprised randomized classes receiving the standardized EAT intervention (90 minutes of mentoring in a classroom setting) and control students in the same schools (no intervention)."

**1b-ii) Level of human involvement in the METHODS section of the ABSTRACT**

Yes. "A Smoking Prevention Program Delivered by Medical Students to Secondary Schools in Brazil"

**1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT**

Yes: "A Smoking Prevention Program Delivered by Medical Students to Secondary Schools in Brazil"

**1b-iv) RESULTS section in abstract must contain use data**

Yes: "This study aimed to determine the long-term effectiveness of the school-based EAT intervention in reducing smoking prevalence among secondary school students in Brazil, as per the study protocol [42]."

**1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials**

Yes. Besides addressing this point in our manuscript, we also cite our previously published study protocol (JMIR Research Protocols, 2017) which addresses all of these points in more detail. Quotes from the manuscript:

"Most school-based tobacco control programs are ineffective, but data from Brazil remain scarce [3-5]. Recent trials on tobacco prevention in the school setting have focused on including school teachers in the intervention [6-8], with others involving families [9,10]. However, these studies concluded that the students' environment (ie, peer group as well as parental behavior and school policies) plays a role in smoking initiation in adolescence."

Regardint the EAT intervention: "A German quasi-experimental study showed the school-based intervention resulted in a significant reduction in smoking prevalence among secondary school students at 6-month follow-up [17,18]. A randomized follow-up study in Germany indicated effectiveness at the 12-month follow-up. However, the results were not significant because of a large loss-to-follow-up effect [19]."

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**METHODS**

**3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio**

Yes. Besides addressing this point in our manuscript, we also cite our previously published study protocol (JMIR Research Protocols, 2017) which addresses all of these points in more detail. Quote from the manuscript:

"A randomized controlled trial was conducted among 2384 adolescents in grades 7 to 11 from secondary schools in Brazil from February 2017 to June 2018 (Figure 1). All predefined time points were met. Details of the study design and the development of the questionnaire are outlined in our previously published study protocol [42]."

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**4a-i) Computer / Internet literacy**

Yes. The participants (school adolescents) were recruited from public secondary schools in Brazil. The trial included face-to-face components (the entire intervention is described in detail in our previously published study protocol, besides being entirely available in our website). Pencil-and-paper questionnaires were used for data collection.

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**4b) CONSORT: Settings and locations where the data were collected**

A pencil-and-paper questionnaire was used for data collection. Class teachers supervised their classes during the completion of the questionnaire and sealed them right after completion for confidentiality reasons. The subsection "Data Collection" of our previously published study protocol (JMIR Research Protocols, 2017) addresses it in more detail.

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**5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered**

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**5-ii) Describe the history/development process**

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**5-iii) Revisions and updating**

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**5-iv) Quality assurance methods**

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Yes, as mentioned in the subitem 8a.

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

School (group allocation was 1:1). The subsection “Randomization” of our previously published study protocol (JMIR Research Protocols, 2017) addresses this in more detail.

7a-i) CONSORT: How sample size was determined

The primary outcome was the difference in smoking prevalence from baseline (t1) to 12 months of follow-up (t3) in the control group versus the difference from t1 to t3 in the intervention group. The differences in smoking behavior (smoking onset, quit attempts) between the two groups were studied as secondary outcomes, along with gender-specific effects.

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/developed

6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored

7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons

A pencil-and-paper questionnaire was used for data collection. Class teachers supervised their classes during the completion of the questionnaire and sealed them right after completion for confidentiality reasons. The subsection “Data Collection” of our previously published study protocol (JMIR Research Protocols, 2017) addresses this in more detail.

7a) CONSORT: How sample size was determined

"The primary outcome was the difference in smoking prevalence from baseline (t1) to 12 months of follow-up (t3) in the control group versus the difference from t1 to t3 in the intervention group. The differences in smoking behavior (smoking onset, quit attempts) between the two groups were studied as secondary outcomes, along with gender-specific effects."

8a) CONSORT: Method used to generate the random allocation sequence

Randomization was externally and centrally performed via computer by a statistician from the University of Gießen, Germany, on the class level within each school (group allocation was 1:1). The subsection “Randomization” of our previously published study protocol (JMIR Research Protocols, 2017) addresses this in more detail.

8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)

Yes, as mentioned in the subitem 6a.

9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Yes, as mentioned in the subitem 8a.

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Yes, as mentioned in the subitem 8a.

11a) CONSORT: Blinding: If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

Yes. We addressed the losses after randomisation as well as we used statistical analysis to evaluate attrition bias. We also made it clear that “Reasons for loss to follow-up included identifier code notassignable, change of school, unauthorized absence from class (truancy), illness, or grade retention.”

12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses

Yes, as mentioned above in the subitem 12a.

13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

"Data analyses were based on the originally assigned groups (Table 1). There were 744 students in the intervention group and 609 in the control group who participated in the survey at both baseline and at 12-month follow-up that could be identified (baseline sample N=2348; prospective sample: n=1353; lost to follow-up: n=980)."

13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons

Yes. We addressed the losses after randomisation as well as we used statistical analysis to evaluate attrition bias. We also made it clear that “Reasons for loss to follow-up included identifier code notassignable, change of school, unauthorized absence from class (truancy), illness, or grade retention.”

14a) CONSORT: Dates defining the periods of recruitment and follow-up

Yes. "Baseline data (t1) were collected from February 2017 to May 2017. Follow-up data (t2 and t3) were collected 6 and 12 months after that (from August 2017 to June 2018)."

14a-i) Indicate if critical “secular events” fell into the study period

14b) CONSORT: Why the trial ended or was stopped (early)
15) CONSORT: A table showing baseline demographic and clinical characteristics for each group
Yes: this data is in Table 1, as well as in Multimedia Appendix 1 and Multimedia Appendix 2.

15-i) Report demographics associated with digital divide issues
N/A

16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Yes. The denominator is present throughout all tables and text of the Results section.

16-ii) Primary analysis should be intent-to-treat
Yes.

17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
Yes. The 95% CI was calculated and is present throughout the tables and text of the Results section.

17a-i) Presentation of process outcomes such as metrics of use and intensity of use
No harms/unintended effects were identified.

18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Yes. We address all these results in the "Results" section: all analyses were pre-specified and are detailed both in this manuscript as well as in our previously published study protocol (JMIR Research Protocols, 2017).

18-i) Subgroup analysis of comparing only users
Yes. The manuscript has a "Limitations" subsection that addresses it, for example: "As our research was not conducted multinationaly, we cannot generalize our results to different countries and cultural backgrounds. However, the similarity between the results found here and the ones found in our German studies [17, 19] increases the international validity of our research. Also, as this study was performed in the setting of Brazilian public schools, the results might not be generalizable to private schools."

19) CONSORT: All important harms or unintended effects in each group
None.

19-i) Include privacy breaches, technical problems
Yes.

19-ii) Include qualitative feedback from participants or observations from staff/researchers
Yes.

DISCUSSION

20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses
Yes.

20-i) Typical limitations in ehealth trials
Yes.

21) CONSORT: Generalisability (external validity, applicability) of the trial findings
No harms/unintended effects were identified.

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting
No.

22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Yes. "To our knowledge, this is the first randomized trial on school-based tobacco prevention in Brazil that showed significant (P<.01) results in favor of the intervention. From baseline to the 12-month follow-up, the smoking prevalence increased from 11.0% to 20.9% in the control group and from 14.1% to 15.6% in the intervention group. This effect was increased for students with low educational background (ie, with low academic performance), which suggests that the intervention may contribute to reducing social inequalities among Brazilian adolescents, which are enhanced by tobacco addiction [44-45]."

23) CONSORT: Registration number and name of trial registry
Yes.

24) CONSORT: Where the full trial protocol can be accessed, if available
Yes.

25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders
A grant from the German Heart Foundation provided funding for the Smokerface App and a grant from the German Center for Lung Research funded the CO measurement device and the Samsung tablets. The Federal University of Ouro Preto contributed to the project providing logistic support and copies of the questionnaire to be distributed to every participating student. All this information is addressed in the study protocol. All these funders had no role in the design and conduct of this study nor in the preparation, review, or approval of this manuscript.

Other information

26) CONSORT: Other information
N/A

26-i) Outline informed consent procedures
N/A

26-ii) Safety and security procedures
N/A

27) CONSORT: State the relation of the study team towards the system being evaluated
N/A