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#Smokefree: testing a school-based active involvement intervention to reduce smoking among adolescents.

Submission date	Recruitment status	[_] Prospectively registered
05/04/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/04/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2026	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In Belgium, the average of smoking initiation is 15.1 years, with tobacco use increasing as adolescents mature. Concurrently, there is a rising trend in electronic cigarette usage, particularly among younger age groups. This trend is concerning as adolescent smoking habits often continue into adulthood, contributing significantly to cancer incidence. Various factors, including positive outcome expectations, positive attitudes, and inflated norms influence these behaviors. Recent research suggests that television and social media also play pivotal roles in shaping these thoughts and behaviors, with adolescents being particularly susceptible to glamorized depictions of smoking and vaping in the media. This study aims to evaluate an intervention designed to mitigate pro-smoking cognitions and prevent smoking initiation among adolescents. The term smoking in this context includes both regular cigarettes and e-cigarettes.

Who can participate?
Belgian adolescents aged between 13 and 15 years

What does the study involve?
The intervention group will receive a school-based curriculum incorporating age-appropriate education, youth empowerment and community-based learning. Guided by the theory of active involvement, the intervention comprises two main components. The first component involves educational sessions where participants learn about the determinants and consequences of smoking/vaping and develop critical media literacy skills to analyze pro-smoking portrayals in popular media. The second component focuses on designing and implementing anti-smoking campaigns, allowing participants to create and disseminate their own intervention messages. Participants will complete questionnaires assessing smoking/vaping cognitions, behaviors, and media literacy components. The control group will undergo the same procedures but will receive the intervention after completion of the questionnaires.

What are the possible benefits and risks of participating?
Participation in the intervention equips individuals with knowledge and skills to resist smoking /vaping influences, potentially sustaining their non-smoking status or reducing their smoking

uptake in the long term. Moreover, since the intervention aligns with mandated learning objectives set by the Flemish government; participating schools also benefit. Risks include potential discomfort discussing smoking/vaping topics and completing related questionnaires. To mitigate these risks, the primary researcher (Sofie Vranken) will carry out the intervention and be present when individuals fill out the survey. The primary researcher has expertise in social sciences and health-risk behaviors, making her attentive toward potential signs of discomfort. Furthermore, participants will receive detailed information on the questionnaire content and assurances of anonymity, privacy, and confidentiality.

Where is the study run from?
1. KU Leuven (Belgium)
2. Upsala University (Sweden)

When is the study starting and how long is it expected to run for?
September 2023 to June 2025

Who is funding the study?
Flemish Fight Against Cancer Agency (Kom op tegen kanker)

Who is the main contact?
Sofie Vranken, sofie.vranken@univie.ac.at

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Public, Scientific

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Additional identifiers

Protocol serial number
KotK_KUL/2018/11827/1

Study information

Scientific Title

#SmokeFree: Developing and testing an active involvement prevention intervention incorporating social media to reduce smoking initiation among adolescents

Acronym
#Smokefree

Study objectives
This project aims to investigate the short- and long-term effectiveness of an active involvement intervention in (a) reducing favorable cognitions related to smoking/vaping, and (b) sustaining a non-smoking status.

Hypotheses:
Overall, it is hypothesized that individuals who followed the interventions show less favorable attitudes towards smoking/ vaping, a decrease in descriptive and injunctive norms toward smoking/vaping, less positive outcome expectations, more negative outcome expectations, lower intention and willingness to engage in smoking/vaping compared to those who did not follow the intervention.
Furthermore, it is also expected that non-smokers who participated in the intervention sustain their non-smoking behavior, and smokers show a higher intention to quit smoking/vaping compared to non-smokers and smokers in the control group.

Research question:
Finally, the aim is to investigate whether the effectiveness in decreasing favorable cognitions and sustaining a non-smoking status is visible in the long run.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/05/2023, Social and Societal Ethics Committee (SMEC) (Dekenstraat 2 - box 3700, Leuven, 3000, Belgium; +32 (0)16 32 71 39; smec@kuleuven.be), ref: G-2020-2267-R6(AMD)

Primary study design
Interventional

Study design
Quasi-experimental pre/posttest design

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of smoking and vaping initiation among Belgian 14-15- year-olds

Interventions
Potential participants were recruited through the secondary schools they were enrolled in. To mitigate contamination effects, classes from the same school were assigned to the same condition. Allocation of participants to conditions was based on the region where the school was

located and the educational track of pupils, ensuring a close match between groups as possible. Participants were unaware of their assigned condition. As both the intervention and the questionnaires take place within secondary schools, the study is considered multicenter.

To test the impact of the active involvement intervention, a quasi-experimental research design comparing a control group and intervention group will be employed. Participants will be assigned to groups based on school availability. The groups were also matched according to the educational track of the students and the geographical location of the schools. Only the researchers are aware of the participants' assigned conditions.

The control group receives usual care. Using the theory of active involvement, the intervention group will follow a school-based curriculum in which they learn about the determinants of smoking/vaping (e.g., attitudes, outcome expectations, norms) and the consequences of these behaviors, learn to critically analyze portrayals of smoking and vaping across popular series, movies, and on social media, and plan/design their own anti-smoking campaign. The curriculum will last 3 hours and is administered by the principal investigator on this project.

All participants are required to fill out three online questionnaires: a baseline measurement (September 2023), a follow-up questionnaire (October to November 2023) and a delayed follow-up questionnaire (April to May 2024) at the same time.

Participants in the control group fill out the same questionnaires at the same time as the control group. They will receive the school-based curriculum after having completed the final questionnaire.

Intervention Type
Behavioural

Primary outcome(s)
The following measures will be assessed in the baseline, posttest and delayed posttest questionnaire. The scales will be used for smoking/vaping separately.
1. Attitudes toward smoking/ vaping assessed using six 7-point semantic differential items (based on Mesman et al., 2020)
2. Injunctive norms toward smoking/vaping assessed using a 7-point Likert scale, indicating participants' agreement with three statements regarding the perceived approval of important others related to smoking behaviors (based on Mesman et al., 2020)
3. Descriptive norms toward smoking/vaping assessed using a slider ranging from 0% to 100% to assess the perceived number of peers engaging in these behaviors (based on Greene et al., 2021)
4. Positive outcome expectations toward smoking and vaping assessed using a 7-point Likert scale, indicating agreement with 7 statements regarding the positive consequences of smoking (Based on Barker et al., 2019; Dalton et al., 1999)
5. Negative outcome expectations toward smoking/vaping assessed using a 7-point Likert scale, indicating agreement with five statements regarding the negative consequences of smoking (Barker et al., 2019, Dalton et al, 1999)
6. Willingness to smoke/vape assessed using a 7-point Likert scale, indicating agreement with four statements that assert the willingness to take/decline cigarettes based on a fictitious scenario (based on Gerrard et al., 2005; Vogel et al., 2021)
7. Intention to smoke/vape assessed using a 7-point Likert scale, indicating agreement with three statements that assess the intention to engage in smoking (adapted from Mesman et al., 2020)

Key secondary outcome(s)

The secondary outcome measures consist of smoking/vaping frequency and quantity questions, as well as some media literacy questions. Furthermore, some other components related to the intervention will be assessed.

Smoking/vaping frequency and quantity at immediate post-test measurement:
1. In the immediate posttest survey, participants will be asked whether they have engaged in smoking/vaping during the last month.
2. In the immediate posttest survey, participants who have engaged in smoking/vaping will be asked how often they engaged in this behavior (based on Rosiers et al., 2023).
3. In the immediate posttest survey, participants who have engaged in smoking/vaping will be asked how many cigarettes/vapes they have smoked.
4. Participants will be asked how likely it would be that they would quit smoking/vaping in the next 6 months using a 7-point semantic differential scale (self-developed).

Smoking/vaping frequency and quantity at delayed post-test measurement:
1. In the delayed post-test survey, participants will be asked whether they have engaged in smoking/vaping during the last 6 months
2. In the delayed post-test survey, participants who have engaged in smoking/vaping will be asked how often they engaged in this behavior (based on Rosiers et al., 2023)
3. In the delayed posttest survey, participants who have engaged in smoking/vaping will be asked how many cigarettes/vapes they have smoked
4. Participants will be asked how likely it would be that they would quit smoking/vaping in the next 6 months using a 7-point semantic differential scale (self-developed)

Media literacy components at baseline, immediate post-test and delayed post-test:
1. Critical thinking about source and message assessed using a 7-point Likert scale with 6 statements (Based on Austin et al., 2015)
2. Reflective thinking about the role of media assessed using a 7-point Likert scale with 4 statements (based on Pinkleton et al., 2007)
3. Perceived similarity assessed using a 7-point Likert scale with 5 items (based on Pinkleton et al., 2007)
4. Perceived realism assessed using a 7-point Likert scale with 4 items (based on Pinkleton et al., 2007)
5. Perceived desirability assessed using a 7-point Likert scale with 6 items (based on Pinkleton et al., 2007)
6. Wishful identification assessed using a 7-point Likert scale with 3 items (based on Pinkleton et al., 2007)
7. Skepticism about the media assessed using a 7-point Likert scale with 6 items (based on Pinkleton et al., 2007)
8. Self-efficacy to influence others assessed using a 7-point Likert scale with 3 items (based on Pinkleton et al. 2017)
9. Inform others about the risks of media assessed using a 7-point Likert scale with 4 items (Based on Pinkleton et al., 2017)

At immediate posttest, participants in the intervention condition will also be assessed:
1. Engagement assessed using a 7-point Likert scale with 9 items (Based on Greene et al., 2015)

Completion date
05/06/2025

Eligibility

Key inclusion criteria
1. In 2nd - 3rd year of secondary school (ages 13-15 years)
2. Dutch-speaking

Participant type(s)
Learner/student, Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 Years

Upper age limit
15 Years

Sex
All

Total final enrolment
1189

Key exclusion criteria
1. Missing data on multiple of the relevant variables
2. Non Dutch-speaking
3. Participants who fail one out of the two attention checks in each of the questionnaires
4. Participants in the intervention group who did not provide any correct answer on the condition-specific attention check (I.e., indicating which activities they undertook during the intervention)

Date of first enrolment
25/05/2023

Date of final enrolment
04/06/2024

Locations

Countries of recruitment
Belgium

Study participating centre
KU Leuven
Parkstraat 45
Leuven

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Study participating centre
Heilig-Hartcollege Heist-Op-Den-Berg
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GO! Atheneum Schilde
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Sponsor information

Organisation
Fight Against Cancer (Kom op tegen Kanker)

Funder(s)

Funder type
Charity

Funder Name
Fight Against Cancer (Kom op tegen Kanker)

Results and Publications

Individual participant data (IPD) sharing plan
The cleaned dataset excluding participants' personal information will be shared publicly via the Open Science Framework (OSF). Furthermore, the raw and cleaned data will be shared in a non-publicly available repository of the authors' university.
The type of data stored: The researchers will store the cleaned data files related to participants' responses on the pretest, immediate posttest and delayed posttest. This data consists of survey data.
The process of requesting access: The data will be stored on the Open Science Framework, which is freely available via https://osf.io/5b4ed/.
The researchers will also store the data on a protected network drive of our research group, which only grants access to individuals who are affiliated with the research group. This aligns with the internal policies of the group. Notwithstanding, the analytical dataset will be available to the general public via the provided OSF link.
Dates of availability: Data will be shared once data collection has been finalized, and the data have been cleaned/ analyzed. The data will be made publicly available upon submission of manuscripts to peer-reviewed journals. The estimated data would thus be June 2024 – June 2025.
Active consent was obtained from all participants. Furthermore, active consent was obtained from school principals and passive consent from parents.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	content analysis	01/10/2025	05/08/2026	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes