

Efficacy of a web-based computer-tailored smoking prevention intervention for Dutch adolescents

Submission date 16/07/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/09/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/10/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

To reduce tobacco-related disease it is crucial to prevent adolescents from starting smoking. Web-based interventions are suitable for health education and their effectiveness has been demonstrated across a wide range of conditions. They provide tailored feedback based on an individual's answers to a questionnaire. These messages are more likely to influence the person's behaviour. The aim of this study is to test a new web-based program called Smoke Alert at schools and to assess its effectiveness for the prevention of smoking uptake among adolescents.

Who can participate?

Students from high schools in the Netherlands, aged between 12 and 30.

What does the study involve?

Schools are randomly allocated into either the experimental group or the control group. The experimental group complete an online questionnaire and receive tailored advice. The control group complete a short questionnaire that measures smoking behaviour and intention to start smoking. Age, gender and educational level are also assessed. The students in the control group do not receive any advice. Assessments are made at the start of the study and after six months.

What are the possible benefits and risks of participating?

Students participating in this study have the opportunity to obtain free personal tailored advice with information on how to refuse a cigarette or how to stop smoking. Students in the control group were offered the chance to take part in the Smoke Alert intervention six months later. This way, all students who are participating are offered the Smoke Alert intervention. There are no risks of participating in this study.

Where is the study run from?

University Maastricht (Netherlands).

When is the study starting and how long is it expected to run for?

April to December 2011.

Who is funding the study?
Dutch Ministry of Health, Welfare and Sport (Netherlands).

Who is the main contact?
Sanne de Josselin de Jong (sanne@stivoro.nl).
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Study website
<http://www.smokealert.nl>

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effects of a randomized web-based computer-tailored smoking prevention trial for Dutch adolescents: a cluster randomized controlled trial

Study objectives

The personalized feedback messages that adolescents receive on their computer screen in the tailored condition result in lower uptake of smoking after six months compared to no feedback messages.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Based on the guidelines of the local Ethics Committee (no treatment is involved and filling out the questionnaire do not cause mental load), medical ethical approval is not sought. The students, their parents and teachers receive written information on methods. The students voluntary take part in the intervention and they are guaranteed anonymity.

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Smoking initiation

Interventions

The study compares the effect of a web-based tailored smoking prevention intervention with a control condition.

Participants in the experimental condition receive a web-based tailored intervention called 'Smoke Alert', consisting of a questionnaire followed by a tailored advice. The intervention incorporates concepts from several cognitive models. Smoke Alert measures attitude towards smoking and quitting, perceived social influence -consisting of social pressure, social modeling and social norms- and self-efficacy not to smoke. Smoke Alert also tailors to intention to start or quit smoking and actions plans to quit smoking or refuse a cigarette. Other factors that are assessed in the Smoke Alert-questionnaire are age, gender, educational level and level of physical activity.

After filling out the questionnaire, respondents receive personal, automatized feedback. This feedback is provided on each specific determinant and the students' response to specific items is used for this (e.g. a chapter for feedback on action plans with a short advice for each specific action plan).

Participants in the control condition do not receive a tailored advice.

Intervention Type

Behavioural

Primary outcome measure

Smoking behaviour - Respondents are asked to select a statement that best described their behaviour. They are categorised as non-smokers if they indicate to have never smoked a puff; to have tried smoking but not anymore or to have stopped smoking.

Baseline assessment and follow-up measurement at six months

Secondary outcome measures

Intention to start smoking. The students are asked to select a statement that best described their situation with options ranging from 'I think I will start smoking within 1 month' (7) to 'I know for sure I won't ever start smoking' (1).

Baseline assessment and follow-up measurement at six months

Overall study start date

01/04/2011

Completion date

31/12/2011

Eligibility

Key inclusion criteria

Participants in this study were students from high schools in the Netherlands, aged between 12 and 30.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

1940 students

Key exclusion criteria

Self-reported smoking and previous exposure to the intervention

Date of first enrolment

01/04/2011

Date of final enrolment

31/12/2011

Locations**Countries of recruitment**

Netherlands

Study participating centre**University Maastricht**

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Sponsor information**Organisation**

University Maastricht (Netherlands)

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Sponsor type

University/education

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Government

Funder Name

Dutch Ministry of Health, Welfare and Sport (Netherlands)

Alternative Name(s)

Dutch Ministry of Health, Welfare and Sport, VWS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/03/2014		Yes	No