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Smoking cessation intervention among university students in Sweden. A study of the effectiveness of a text messaging (short message service [SMS]) based stop smoking application

Submission date	Recruitment status	[ ] Prospectively registered
12/02/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/03/2014	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/01/2019	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Smoking is responsible for more than 60 diseases and globally is the most important preventable cause of ill health and death. So far most public health smoking efforts targeted at young people have been focused on prevention of initiation of smoking, whereas smoking cessation programmes have been targeted at the adult population. There are not many proven effective smoking cessation interventions targeting young people.

The stop-smoking-program NEXit, Nicotine exit, is an 8-12 week smoking cessation intervention based on phone text messages (SMS). The messages incorporate elements from initiatives that have worked, official manuals on smoking cessation, other literature and guidance from smoking cessation experts.

Who can participate?

Eligible participants are all students that are daily or occasional smokers.

What does the study involve?

The students will receive invitation to participate in the study by e-mail. Students who are daily or occasional smokers and who consent to participate are then randomly allocated to an intervention group which will have access to the stop-smoking-program immediately or to a control group that will have access to the intervention after 15 weeks (after follow-up for research purposes).

What are the possible benefits and risks of participating?

The possible benefits are support to stop smoking. There are no known side effects.

Where is the study run from?
The study is carried out by researchers at Linköping University, Sweden, using students from one university, Luleå Technical University in the northern part of Sweden.

When is the study starting and how long is it expected to run for?
The study will start in January 2014 and will end in June 2014.

Who is funding the study?
The study is funded by The Swedish Research Council.

Who is the main contact?
Professor Preben Bendtsen
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Study website
http://www.nexit.nu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Effectiveness of a text messaging (SMS) smoking cessation intervention among university students in Sweden: a pilot randomized controlled trial

Acronym
NEXit (Nicotine EXit) 2.0 study

Study objectives
The study aims to develop a SMS-based stop smoking application, and to undertake a pilot randomized controlled trial (RCT) study to prepare for the evaluation of the effectiveness of such a program in a future main trial. The pilot trial is undertaken with smokers who are students at the University of Luleå in Sweden. The study will randomise smokers willing to participate to an intervention group or a waiting list group that will have access to the intervention after 15 weeks. The primary hypothesis is that a greater proportion of the intervention group will have stopped smoking during the follow-up time than the waiting list group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee in Linköping, 04/03/2013, ref: 2013/406-31.

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Tobacco smoking

Interventions
After randomisation and signing on, the intervention starts with a motivational phase of between 1 to 4 weeks, when the participants are given the opportunity to set a quit date. In this first phase the participants receive two SMS of motivating messages with information relevant for quitting, i.e. symptoms to expect on quitting, in other words biofeedback messages about what happens in the body after a quit attempt, tips to avoid weight gain, tips to cope with cravings, avoiding smoking triggers, motivational support, and how to distract ones mind from smoking. Once a week during this first phase the participants will be asked if they are ready to decide a quit date, and if doing so then pass into a second phase with dedicated messages five

times a day during the three days immediately before the quit date in order to prepare the smokers for quitting smoking. The quit dates are to be set within 1-4 weeks after having signed up. After setting a quit date the core interventions run for 8 weeks. The participants are able to restart the intervention and discontinue the intervention at any time.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Self-reported prolonged smoking abstinence of 8 weeks (defined as having not smoked more than five cigarettes)
2. Self-reported point prevalence of smoking abstinence (not having smoked a single cigarette) in the previous 4 weeks

Secondary outcome measures
1. Self-reported 7-days point prevalence smoking abstinence (defined as not smoking any cigarettes in the past 7 days)
2. Number of quit attempts during the 15 weeks after the invitation to participate
3. Use of other smoking cessation services (medication, counselling, calling help line etc) during the 15 weeks after the invitation to participate

Overall study start date
20/01/2014

Completion date
15/06/2014

Eligibility

Key inclusion criteria
All students who are daily or occasional smokers at Luleå University will be invited to participate via an e-mail, aged 18-65

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
8000

Key exclusion criteria
Non-smokers

Date of first enrolment
20/01/2014

Date of final enrolment
15/06/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Institutionen för Medicin och Hälsa
Linköping
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Sponsor information

Organisation
Swedish Research Council (Sweden)

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Sponsor type
Research council

Website
http://www.vr.se/

ROR
https://ror.org/03zttf063

Funder(s)

Funder type
Research council

Funder Name
Swedish Research Council (Sweden), grant number 2012-39665-92722-49

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

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	01/03/2016	23/01/2019	Yes	No