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Evaluation of the effectiveness of a text-based mHealth smoking cessation intervention among high school students in Sweden

Submission date
10/10/2017

Recruitment status
No longer recruiting

Registration date
13/10/2017

Overall study status
Completed

Last Edited
21/11/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Each year, thousands of children and adolescents in Sweden start smoking. Tobacco use increases with age and the earlier one starts smoking, the higher the risk to become addicted to nicotine and develop illnesses due to smoking. Although recent figures show that around two thirds of high school smokers want to quit, only about one in ten seek or gain access to evidence-based interventions. The evidence for the effectiveness of text messaging interventions to reduce smoking behaviour is well-established, yet there is still a great need for studies targeting high school pupils. The smoking cessation program NEXit Junior is a 12-week innovative text-based mHealth smoking cessation intervention based upon fully automated short mobile phone text messages. The messages are built from key elements of existing effective interventions, officially recommended practice manuals and guidance from smoking cessation experts. The effectiveness of the original NEXit intervention (targeting university students) was evaluated in a previous study including 1590 university students. Students who received the intervention were almost twice as likely to quit smoking. The aim of this study is to determine the effectiveness of the text-based smoking cessation intervention among high school pupils.

Who can participate?
High school students who smoke at least one cigarette a week and want to quit smoking

What does the study involve?
Participants are randomly allocated to either the intervention group or treatment as usual group. The intervention starts with a motivational phase of one week. In this first phase the participants receive text messages containing motivating information relevant for quitting, e.g. symptoms to expect after quitting, tips to avoid weight gain, tips to cope with cravings, avoiding smoking triggers, motivational support, and how to distract one’s mind from smoking. Participants also receive messages in order to prompt them to get rid of cigarettes, ashtrays and lighters, to avoid environments where they could normally smoke, and encourage them to overcome challenges of quitting. After 1 week the core intervention begins and runs for 12 weeks. Participants receive up to four text messages per day during the first few weeks, and then the number of messages per day decreases. During the last weeks of the program a single

message per day is sent, with a few exceptions when participants do not receive any messages. Messages encourage participants to not begin smoking again and focus on their success so far. They are offered coping messages for handling cravings, motivational messages, and support with withdrawal symptoms. Follow-ups are conducted after 3, 6 months and 12 months to find out whether the participants have stopped smoking.

What are the possible benefits and risks of participating?
Participants may benefit from stopping smoking. There are no anticipated risks.

Where is the study run from?
High schools in Sweden

When is the study starting and how long is it expected to run for?
November 2017 to July 2019

Who is funding the study?
Linköping University (Sweden)

Who is the main contact?
Dr Ulrika Müssener

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The effectiveness of a text-based mHealth smoking cessation intervention among high school students: a randomized controlled trial

Acronym
NEXit Junior study

Study objectives
The study aims to evaluate the effectiveness of an innovative text-based mHealth smoking cessation intervention employing a single-blind two-arm randomized controlled trial (RCT) design with an intervention group and a treatment as usual group. Outcome measures will be assessed at 3 months in order to estimate immediate effects, as well as intermediate and long term effects at 6 and 12 months. The primary hypotheses are that participants in the intervention group will report significantly higher cessation rates, measured as prolonged abstinence and 4-week point prevalence of smoking abstinence, at follow-up compared with participants in the control group. Secondary hypotheses are that the intervention group will report significantly higher rates of 7-day point prevalence of smoking abstinence, higher mean number of quit attempts since taking part in the study, fewer number of uses of other smoking cessation services since first invitation to the study and lower numbers of cigarettes smoked weekly if still smoking at follow-up, compared with the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee in Linköping, 19/09/2017, Ref: Dnr 2017/388-31

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

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

Interventions
After signing on and completing a baseline questionnaire, participants will be randomized to the intervention or treatment as usual group. Randomization will be fully computerized and automated. No strata or blocks will be used during randomisation, each participant has equal probability of being randomised to either the intervention or control group.

The intervention starts with a motivational phase of one week. In this first phase the participants receive text messages containing motivating information relevant for quitting, e.g. symptoms to expect after quitting (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 one’s mind from smoking. Participants will also receive messages in order to prompt them to get rid of cigarettes, ashtrays and lighters, to avoid environments where they could normally smoke, and encourage them to overcome challenges of quitting.

After one week the core intervention begins and runs for 12 weeks. Participants will receive up to four text messages per day during the first few weeks, and then the number of messages per day decrease. During the last weeks of the program a single message per day is sent, with a few exceptions when participants will not receive any messages. Messages will encourage participants to not begin smoking again and focus on their success so far. They will be offered coping messages for handling cravings, motivational messages, and support with withdrawal symptoms.

Follow-ups will be conducted at 3, 6 months and 12 months after enrolment.

Intervention Type
Other

Primary outcome(s)
Measured at 3, 6 and 12 months after enrolment:
1. Self-reported prolonged abstinence, defined as having not smoked more than five cigarettes in the last eight weeks
2. Self-reported 4-week point prevalence of smoking abstinence (no cigarettes smoked in the past 4 weeks)

Key secondary outcome(s))
Measured at 3, 6 and 12 months after enrolment:
1. Self-reported 7-day point prevalence of smoking abstinence
2. Mean number of quit attempts since taking part in the study
3. Number of uses of other smoking cessation services since first invitation to the study e.g. prescribed medication, nicotine replacement medication, counselling, calling helpline or any other help
4. Numbers of cigarettes smoked weekly (for participants still smoking at the time of follow-up only)

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. High school students
2. Smoking consumption of at least one cigarette a week
3. Willingness to make an attempt to quit smoking
4. Ownership of a mobile phone

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
535

Key exclusion criteria
Non-smokers and pupils who are not willing to attempt to quit smoking

Date of first enrolment
08/01/2018

Date of final enrolment
30/07/2018

Locations

Countries of recruitment
Sweden

Study participating centre
All high schools in Sweden will be asked to partake in the RCT. The trial will be conducted at those high schools which accept to advertise the trial to their pupils.
Sweden
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Sponsor information

Organisation
Linköping University

ROR
https://ror.org/05ynxx418

Funder(s)

Funder type
University/education

Funder Name
Linköpings Universitet

Alternative Name(s)
Linköping University, Linköping University, LiU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ulrika Müssener.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	3-month primary outcome findings	06/03/2020	15/06/2020	Yes	No
Results article	Six-month outcomes	21/11/2021	21/11/2023	Yes	No
Protocol article	protocol	22/11/2018		Yes	No