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Evaluation of the effectiveness of a SMS based smoking cessation intervention among university students in Sweden - the NEXit trial

Submission date
16/10/2014

Recruitment status
No longer recruiting

Registration date
04/11/2014

Overall study status
Completed

Last Edited
10/03/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Smoking tobacco is a significant cause of death and illness. It can result in, among other things, a variety of cancers, stroke, heart disease and lung conditions such as emphysema. Nearly 100,000 young people start smoking worldwide. For every death related to smoking, more than 20 other people will suffer from at least one serious smoking-related illness. Smoking is still the most important underlying factor for preventable illness and death in Sweden. Identifying ways (interventions) to help young people to quit smoking would have a major impact on population health. Although primary healthcare services do offer proven interventions to stop people from smoking, they may not be really suitable or acceptable to younger people. Here, we want to test out a new quit smoking intervention aimed at getting young people to stop smoking. The program is called NEXit, Nicotine exit. It is a 12-week program based upon fully automated short mobile phone text messages. The messages are built from key elements of existing effective interventions as well as from officially recommended practice manuals and other literature and guidance from experts.

Who can participate?
Young people studying at colleges and universities in Sweden who smoke on a daily or weekly basis, who are willing to set a date to stop smoking within a 4-week period.

What does the study involve?
All participants are asked to choose a day to stop smoking (quit day). They are then randomly allocated into one of two groups. Those in group 1 receive motivational messages (the intervention) five times a day for three days before their stated quit day and then continue to receive 3-5 motivational text messages per day for week 1, 2-4 messages per day for the next 2-4 weeks, and then 10 messages per week for the remaining 8 weeks. Those participants in group 2 do not immediately receive the intervention. Instead, they have to wait until group 1 have completed the program before being able to access it themselves. We then assess the success of the program by looking at how many participants from either group have stopped smoking,

compare the number of attempts made to stop smoking and, in cases where the participants are still smoking, compare the number of cigarettes smoked on a daily basis after the trial has finished.

What are the possible benefits and risks of participating?
The possible benefits for the participants are support to stop smoking. There are no known side effects.

Where is the study run from?
Linköping University (Sweden)

When is the study starting and how long is it expected to run for?
October 2014 to April 2015

Who is funding this study?
The Swedish Research Council (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1

Study information

Scientific Title
SMS-based smoking cessation intervention among university students - the NEXit trial: a two-arm randomized controlled trial from Sweden

Acronym
NEXit

Study objectives
The study aims to evaluate the effectiveness of a SMS based quit smoking application, employing a randomized controlled trial (RCT) design with an intervention group (group 1) and a waiting list control condition (group 2) that first will have access to the intervention after a 4 months follow-up. Four main hypotheses have been outlined:
1. Proportion of participants reporting prolonged abstinence or 4-weeks/7-days point prevalence of abstinence will differ in group 1 and 2, with group 1 having a higher proportion of participants having quitting smoking measured immediately after the end of the 12 week intervention
2. Quit attempts will differ, with group 1 having more quit attempts compared to group 2 measured since the time of randomization (19 weeks)
3. Utilisation of other smoking cessation services will differ with group 1 having used more other smoking cessation services since the time of randomization (19 weeks)
4. The number of daily smoked cigarettes at the time of follow-up will be lower in group 1 among those who still smoke at the time of follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethics Committee in Linköping, 17/06/2014, ref Dnr: 2014/217-31

Study design
Two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.nexit.nu (in Swedish only)

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

Interventions

After randomisation and signing on, the intervention starts with a motivational phase of between one to four weeks depending on when the participants set a quit date. The participants are given an opportunity to set a quit date every week during this 4 weeks motivational phase. If no active quit date is set with this 4 week period the participant is given a quit date immediately after the 4 week motivational phase in accordance with the inclusion criteria and informed consent.

In this first motivational phase the participants receive 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.

Before the quit day the participants will receive dedicated messages five times a day during three days immediately before the quit date in order to prepare the smokers for quitting smoking. These messages will prompt participants to get rid of cigarettes, ashtrays and lighters and to avoid environments where they could normally smoke, and encouraged to overcome challenges of quitting

After setting a quit date the core intervention runs for twelve weeks. The participants will receive 3-5 text messages per day for the first week, 2-4 messages the next 2-4 weeks, and then 10 text messages per week the following eight weeks. Messages will encourage participants to persevere with the quite attempt and focused on their success so far. They will be prepared with coping messages for handling cravings, motivational messages, encouragement to preserve with the quit attempt, and assistance with withdrawal symptoms.

The intervention includes a function where the participants could ask for more SMS when having problems with craving, relapse or weight gain. By texting the word crave participants with cigarette cravings received instant messages to distract or support them during these episodes. By texting the word lapse, participants received a series of text messages that encourage them to continue with their quit attempt. By texting weight, participants received tips on how to avoid weight gain.

Follow up will be performed immediately after the end of the 12-week intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Self-reported prolonged abstinence (defined as having not smoked more than 5 cigarettes the last 8 weeks)
2. Self-reported 4 weeks point prevalence of smoking abstinence (not having smoked a single cigarette).

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 since the first invitation to the study (19 weeks)

3. Use of other smoking cessation services (medication, counselling, calling help line etc.), since the first invitation to the study (19 weeks).
4. Number of daily smoked cigarettes at the time of follow-up among those who still smokes at the time of follow-up.

Overall study start date
20/10/2014

Completion date
19/04/2015

Eligibility

Key inclusion criteria
All students (age range approx 18-30) that are daily or weekly smokers and willing to set a quit date for stop smoking within a 4 weeks period. There is no restriction on the use of other smoking cessation treatments or methods.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
To achieve a power of 80% with a significance level of 0.05 (two-sided), each group needs 474 people. If 30% attrition in the follow-up measurement, each group needs 677

Total final enrolment
1590

Key exclusion criteria
Non-smokers/occasional smokers not smoking every week and smokers not willing to set a stop date within 4 weeks after informed consent to participate.

Date of first enrolment
20/10/2014

Date of final enrolment
19/04/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Linköpings University IMH/SAM
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Sponsor information

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The Swedish Research Council (Sweden)

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Sponsor type
Research council

ROR
https://ror.org/03zttf063

Funder(s)

Funder type
Research council

Funder Name
The Swedish Research Council (Sweden), Box 1035, SE-101 38 Stockholm, Sweden, +46 (0)8 54644000

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?
Protocol article	protocol	08/04/2015		Yes	No
Results article	results	01/03/2016		Yes	No
Results article	results	02/04/2019		Yes	No
Results article	results	05/03/2020	10/03/2020	Yes	No