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Effects of a text messaging smoking cessation intervention among online help seekers and primary healthcare visitors in Sweden

Submission date
23/07/2020

Recruitment status
No longer recruiting

Registration date
27/07/2020

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
In Sweden, researchers have previously conducted studies of smoking cessation interventions among high school and university students. They found consistent evidence that a text message intervention was effective in increasing the prevalence of smoking abstinence. They are also currently conducting a study of a text message smoking cessation intervention tailored to patients with elective surgery. However, these interventions have recruited participants from well-defined contexts, i.e. high schools, university campuses, and surgical departments, but have not taken a broader approach to recruitment in the general population. Also, there have not been any studies in Sweden of text message smoking cessation interventions targeting the general population. The aim of this study is to validly estimate the effects of a text message smoking cessation intervention as a complement to treatment as usual in the general population of Sweden. In addition, the study aims to gain knowledge on the differences between individuals recruited from two distinct settings: online advertisement and primary healthcare.

Who can participate?
People aged 18 or older who are smokers and have a mobile phone (with a Swedish phone subscription)

What does the study involve?
Participants are randomly allocated to one of two groups. Both the intervention and control group will be given treatment as usual, and neither will be restricted from using other available smoking cessation aids. Participants who are allocated to the intervention group will in addition receive text messages for 12 weeks which aim to help them quit smoking. Participation involves answering questionnaires at the start of the study and follow-ups.

What are the possible benefits and risks of participating?
The researchers have not identified any risks from participation, but they believe that those who are given access to the intervention will benefit from it.

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

When is the study starting and how long is it expected to run for?
October 2020 to January 2023

Who is funding the study?
Region Östergötland (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LIO-896081

Study information

Scientific Title
Effects of a text messaging smoking cessation intervention among online help seekers and primary healthcare visitors in Sweden: a randomized controlled trial

Acronym
NEXit PV

Study objectives
1. Participants with access to a 12-week text messaging smoking cessation intervention will report a higher prevalence of smoking abstinence at follow-up
2. Intervention effects will be moderated by mode of recruitment (passively online vs proactive in primary healthcare)
3. Intervention effects will be mediated through self-efficacy, importance and know-how
4. Participants recruited through online advertisements will be demographically different than those recruited through primary healthcare

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/06/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: Dnr 2020–01427

Study design
Two-arm parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Internet/virtual, Telephone

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Allocation will be done according to a computer-generated random sequence. Participants will prior to randomization be stratified according to which of the two versions of the intervention is appropriate (general or surgery). Block randomization will be used to ensure an equal number of participants in each group within stratum. Random block sizes of 2 and 4 will be used in order to prevent subversion of allocation concealment. Randomization will be done immediately after responding to the baseline questionnaire, which is done by participants on their mobile phone.

Once responses are received by the backend server, automatic randomization will take place and participants will be told about group allocation via a text message. Research personnel will not be able to affect the allocation.

Both the intervention and control group will be given treatment as usual, and neither will be restricted from using other available smoking cessation aids. The intervention group will in addition be given access to a text message intervention.

Treatment as usual will in this trial be defined as follows:
1. For participants recruited through online advertisements: referral to national quit lines (sluta-röka-linjen) and general information about smoking and health.
2. For the individuals recruited through primary healthcare units: referral to national quit lines (sluta-röka-linjen) and referral to general information about smoking and health. In addition, primary healthcare units will offer all smokers to meet with a nurse or smoking cessation specialist to have a conversation about smoking cessation and health.

Participants allocated to the intervention group will be given access to a text message intervention. Two versions of the intervention exist: one for the general population and one which has been tailored specifically for individuals with elective surgery. Both versions are based on findings from previous research. The elective surgery intervention will be allocated to participants in the intervention group who report having elective surgery planned in the next 3 months.

Both versions of the intervention consist of a 12-week text message program with messages sent to participants mobile phones on a daily basis. Two to four messages will be sent per day during the first few weeks, which will be reduced to two per day during the middle part of the intervention, and further reduced to one message per day during the latter part of the intervention.

Unique for the elective surgery version is that some of the messages include hyperlinks that take the participants to interactive web-based modules. There are a total of nine such modules and, throughout the intervention period, participants will be reminded to revisit previously completed modules.

The intervention period will be 3 months, after which a follow-up questionnaire will be sent to participants. A final follow-up questionnaire will be sent to participants 6 months after randomization, and then the trial will close out.

Intervention Type
Behavioural

Primary outcome measure
1. Prolonged abstinence measured using a questionnaire at 3 and 6 months, following the Russell standard definition of not having smoked more than 5 cigarettes in the past 8 weeks (thus allowing for a 4-week grace period). The abstinence period will be adjusted to 5 at the 6-month follow-up.
2. Point prevalence of smoking abstinence measured using a questionnaire at 3 and 6 months, defined as not smoking any cigarette the past 4 weeks, as recommended by the Society for Research on Nicotine and Tobacco.

Secondary outcome measures

1. Seven-day point prevalence of complete smoking abstinence, measured using a questionnaire at 3 and 6 months
2. Number of cigarettes smoked weekly (if still smoking), measured using a questionnaire at 3 and 6 months
3. Number of quit attempts since baseline, measured using a questionnaire at 3 and 6 months
4. Number of uses of other smoking-cessation aids since baseline, measured using a questionnaire at 3 and 6 months

Overall study start date
01/01/2020

Completion date
01/01/2023

Eligibility

Key inclusion criteria
Smokers aged 18 years or older

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A Bayesian group sequential design will be used, thus no fixed target exists. The researchers expect no more than 1000 participants, but there are target posterior probabilities that will dictate this.

Total final enrolment
1012

Key exclusion criteria
Non-smokers or aged less than 18

Date of first enrolment
01/10/2020

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University
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Sponsor information

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University/education

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https://ror.org/05ynxx418

Funder(s)

Funder type
Government

Funder Name
Region Östergötland

Results and Publications

Publication and dissemination plan
A protocol for the trial will be submitted to a peer-reviewed journal. Results will be published in peer-reviewed open access journals.

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
The dataset cannot be made publicly available due to GDPR. It is not possible for the researchers to guarantee that the data generated from this trial cannot be combined with other registries to identify individuals. The data will be stored at Linköping University.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/12/2020	10/01/2022	Yes	No
Results article		04/10/2023	05/10/2023	Yes	No
Results article		09/07/2024	09/07/2024	Yes	No