

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

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<b>Registration date</b> 27/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/07/2024	<b>Condition category</b> Other	<input type="checkbox"/> 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?  
Dr Marcus Bendtsen  
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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](mailto: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**

Linköping

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# **Sponsor information**

## **Organisation**

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# **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?
<a href="#">Protocol article</a>		03/12/2020	10/01/2022	Yes	No
<a href="#">Results article</a>		04/10/2023	05/10/2023	Yes	No
<a href="#">Results article</a>		09/07/2024	09/07/2024	Yes	No