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Mobile phone-based smoking cessation intervention for patients with elective surgery

Submission date
17/08/2018

Recruitment status
No longer recruiting

Registration date
04/10/2018

Overall study status
Completed

Last Edited
27/03/2019

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Several large studies have shown that the risk of cardiovascular (heart), respiratory (lung), and wound-healing complications (including death) within 30 days of surgery is greater for smokers than non-smokers. However, there is evidence that even short-term smoking cessation may reduce morbidity (illness) after surgery. Structural problems and scarcity of time and resources lead to patients at most Swedish surgical departments simply being told that they should quit, and perhaps being referred to a primary health care clinic. An SMS (text message)-based smoking cessation aid can be effective in helping individuals quit smoking, but is also a very simple and time efficient tool for surgical departments to administer. The aim of this study is to fill the knowledge gap on whether or not an SMS-based smoking cessation intervention can be effective at helping patients stop smoking before surgery. This study aims to assess the effectiveness of the SMS-based intervention on smoking behaviour as an additional tool on top of current routine treatment.

Who can participate?
Adult patients undergoing elective surgery

What does the study involve?
Participants are randomly allocated to one of two groups. One group is given access to the new SMS intervention, while the other group is not given access to the intervention. Both groups have access to the surgical departments' current routine for smoking cessation before surgery. Smoking outcomes are measured through questionnaires after 3, 6, and 12 months.

What are the possible benefits and risks of participating?
This trial will collect data on the effectiveness of the intervention, increasing the evidence on SMS-based interventions for smoking cessation. One group is given a new intervention which is hoped to improve their chances of quitting smoking, but the researchers are not withholding any other treatment that individuals in the intervention or control group wish to use. All participants are free to use any service currently existing, but only the intervention group will receive the new intervention. There are therefore no immediate risks, but a potential benefit for patients that are allocated to the intervention group.

Where is the study run from?
20 surgical departments in south-east Sweden

When is the study starting and how long is it expected to run for?
September 2017 to October 2021

Who is funding the study?
Kamprad Family Foundation (Sweden)

Who is the main contact?
Dr Marcus Bendtsen

Study website
http://www.nexit.nu/opr

Contact information

Type(s)
Scientific

Contact name
Dr Marcus Bendtsen

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http://orcid.org/0000-0002-8678-1164

Contact details
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58183

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Mobile phone-based smoking cessation intervention for patients with elective surgery – a randomised controlled trial

Acronym

NEXit OPR

Study objectives
Smoking cessation rates will be higher among individuals given access to a mobile phone-based intervention, compared to individuals without access.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regionala etikprövningsnämnden i Linköping: avdelningen för prövning av övriga forskning, 10 /10/2018, dnr 2018/316-31

Study design
Two-arm parallel-group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Smoking among patients with elective surgery

Interventions
All patients with elective surgery will be invited to the trial. One group will be given access to the mobile phone-based program delivered via SMS, including interactive component, while the other group will be told that they will not be given access to the intervention. Both groups will be told that they have access to the surgical departments' current routine for smoking cessation prior to surgery. Smoking outcomes will be measured through questionnaires at 3, 6, and 12 months after randomisation.

Intervention Type
Behavioural

Primary outcome measure
Measured at 3, 6 and 12 months after randomisation using self-reported questionnaires:
1. Prolonged abstinence (not smoking more than 5 cigarettes the past 8 weeks). 8 weeks is adjusted to 5 and 11 months at 6- and 12-months follow-up
2. Point prevalence (not smoking any cigarette the past 4 weeks)

Secondary outcome measures
Measured at 3, 6 and 12 months after randomisation using self-reported questionnaires:
1. 7-day point prevalence (no cigarettes the past 7 days)
2. The number of quit attempts since joining the study
3. Number of cigarettes smoked per week (if still smoking)

Overall study start date
01/09/2017

Completion date
15/10/2021

Eligibility

Key inclusion criteria
All patients undergoing elective surgery will be invited to the trial (not children or neonatal)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
434

Key exclusion criteria
Not owning a mobile phone or non-smoker

Date of first enrolment
15/10/2018

Date of final enrolment
15/10/2020

Locations

Countries of recruitment
Sweden

Study participating centre
20 surgical departments in south-east Sweden
Sweden
581 83

Sponsor information

Organisation
The Kamprad Family Foundation for Entrepreneurship, Research & Charity

Sponsor details
Familjen Kamprads stiftelse, Västra Esplanaden 3
VÄXJÖ
Sweden
352 30

Sponsor type
Charity

Website
http://familjenkampradsstiftelse.se/in-english/

ROR
https://ror.org/03qb1q739

Funder(s)

Funder type
Charity

Funder Name
Familjen Kamprads Stiftelse

Alternative Name(s)
Kamprad Family Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Publication and dissemination plan

A trial protocol will be submitted for review prior to the first patient being recruited. Data from the 3-month follow-up will be used to author an efficacy article regarding short-term effects in the beginning of 2020. Data from 6- and 12-month follow-up will be used to author an efficacy article regarding long-term effects in the beginning of 2022.

Intention to publish date

01/01/2022

Individual participant data (IPD) sharing plan

Data will be archived on university servers. Due to GDPR the trialists are not allowed to hand over data.

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	protocol	26/03/2019	27/03/2019	Yes	No