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Efficacy of a smoking cessation intervention using smartphones

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
15/05/2018

Overall study status
Completed

Last Edited
10/09/2021

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 remains one of the main preventable causes of early death worldwide. Despite the knowledge about the negative consequences of smoking, every fourth person aged 15 and older smoked in Switzerland in 2016. High relapse rates indicate the major challenge of stopping smoking (cessation). External resources such as social support might buffer the daily stress smokers experience while quitting. As most relapses occur in the first three weeks after the quit attempt, social support seems highly relevant during that sensitive time period.
As part of the tobacco prevention campaign in Switzerland, the Federal Office of Public Health (FOPH) and its partners developed a mobile phone application (the SmokeFree Buddy app) to encourage smokers' intention to quit and to offer social support interactively from a buddy while quitting. Mobile interventions have the potential to intervene at any time, in tailored manner and during actual experiences in people's everyday life.
This study aims to test the effectiveness of the smoking cessation mobile intervention "SmokeFree Buddy app" in a real-life setting from one week before to three weeks after a self-set quit date and six months later.

Who can participate?
Adult smokers aged 18 years or older trying to quit smoking

What does the study involve?
The participants are randomly assigned to one of two study groups: the intervention or the control group.
The participants in the intervention group announce a self-set quit date and choose a buddy (self-chosen from the personal social network), who supports them using the smoking cessation application (SmokeFree Buddy app) during the quit attempt.
The participants in the control group also announce a self-set quit date, however try to stop smoking on their own and without the mobile smoking cessation intervention "SmokeFree Buddy app".
In both groups, participants measure their daily exhaled carbon monoxide with a personal mobile Smokerlyzer and fill out daily end-of-day diaries during seven days before and three weeks after the self-set quit date. Six months after the self-set quit date, there is a follow-up diary period of three consecutive days.

What are the possible benefits and risks of participating?
Participants have the chance to become smoke free. With quitting or reducing smoking participants may experience positive health consequences. In addition, the participants receive a personal iCO Smokerlyzer (Bedfont Scientific Ltd.), a carbon monoxide monitor for the smartphone, with a value of CHF 60. With completion of the study participants take part in a lottery (main prize with a value of CHF 200, 40x CHF 50-shopping voucher).
Participants in the role of the buddy are reimbursed with CHF 50 with completion of the study.
Participants in both groups do not encounter any risks, inconveniences or disadvantages.

Where is the study run from?
University of Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
June 2017 to March 2020

Who is funding the study?
University of Zurich (Switzerland)

Who is the main contact?
Mr Philipp Schwaninger (Scientific)
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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
Nil known

Study information

Scientific Title
Efficacy of a randomized controlled trial to promote smoking cessation using mobile applications

Acronym
SWAPP

Study objectives
1. Is the SmokeFree Buddy app an effective intervention to promote daily abstinence rates and to reduce daily number of cigarettes smoked in adult smokers at the self-set quit date, three weeks (end of intervention) and six months later in comparison to a control group, based on daily diary data?
H1.1. Adult smokers in the intervention and control group will show higher daily abstinence rates and lower daily number of cigarettes smoked at the self-set quit date, three weeks later (end of intervention) and six months later compared to baseline, and the intervention group will show higher daily abstinence rates and lower daily number of cigarettes smoked compared to the control group at all three measurement points.

2. What are the trajectories over time of daily smoking abstinence rates and daily number of cigarettes smoked in the intervention compared to the control group, based on daily diary data?
H2.1. In both groups, from baseline to the self-set quit date daily abstinence rates will increase and daily numbers of cigarettes will decrease over time, with higher increase in daily abstinence rates and higher decrease in daily number of cigarettes smoked over time in the intervention group than the control group.
H2.2. In both groups, from the self-set quit date until three weeks later (end of intervention) daily abstinence rates will decrease and daily number of cigarettes smoked will increase over time, with lower decrease in daily abstinence rates and lower increase in daily number of cigarettes smoked in the intervention than the control group.
H2.3. In both groups, from three weeks after the self-set quit date (end of intervention) until six months later daily abstinence rates will decrease and daily numbers of cigarettes smoked will increase over time.

3. Does the SmokeFree Buddy app increase social and self-regulatory processes in daily life and do they serve as mediating mechanisms explaining the effect of the SmokeFree Buddy app?
H3.1. Smokers in the intervention group will report higher intensity and quality of social support at the self-set quit date, three weeks later (end of intervention) and six months later compared to the control group.
H3.2. Smokers in the intervention group will report higher self-efficacy at the self-set quit date, three weeks later (end of intervention) and six months later compared to the control group.
H3.3. Smokers in both the intervention and control group will report higher action control at the self-set quit date and three weeks later (end of intervention) compared to baseline.
H3.4. Changes in intensity and quality of social support, and self-efficacy will mediate the positive effects of the intervention on abstinence rates and numbers of cigarettes smoked at all three measurement points.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Faculty of Arts and Social Sciences of the University of Zurich, 13/12 /2017, ref: 17.12.13

Study design
Single-blind two-arm parallel-group randomized controlled trial with longitudinal design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (in German)

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

Interventions
Participants are randomly allocated to the intervention or control group.
All participants attend a "background assessment" session at the University of Zurich. They are instructed to use a breathalyzer to measure exhaled carbon monoxide, and are instructed to announce a self-quit date.
All participants receive an end of day diary (short questionnaire) which is filled out daily from 7 days before their quit date until 21 days after their quit date, and a breathalyzer to measure carbon monoxide output daily during this period.
Participants are also followed up with a daily diary for three days, six months after their quit date.

Participants in the intervention group are additionally instructed to use the “SmokeFree Buddy app” during 28 consecutive days (7 days prior to the quit date and 21 days afterwards). More information on the “SmokeFree Buddy app”: https://www.smokefree.ch/en/buddy-app/
With the SmokeFree Buddy app participants also have to identify a personal buddy (self-chosen from the personal social network). These buddies get an instruction on how to connect with the target person and to use the “SmokeFree Buddy app“ during the 28 consecutive days to support the smoker in his/her cessation process.

Participants in the control group will have the same setting, but do not receive the mobile intervention “SmokeFree Buddy app” and therefore do not have a supporting buddy.

Intervention Type
Behavioural

Primary outcome measure
1. Smoking abstinence is measured daily during the 28 day quitting period and for a three day period six months after the quit date, using
1.1. Subjective self reporting (daily diary questionnaires) of abstinence and and number of cigarettes smoked
1.2. Objective exhaled carbon monoxide (in parts per million [ppm]) via Smokerlyzer (iCO Smokerlyzer; Bedfont Scientific Ltd)

Secondary outcome measures
1. Intensity and quality of social support is measured daily using self-reporting diary questionnaires throughout the 28 day quitting period and for three days six months after the quit date.
2. Self-efficacy and action control is measured daily using self-reporting diary questionnaires throughout the 28 day quitting period and for three days six months after the quit date.
3. Positive and negative effect is measured daily using self-reporting diary questionnaires throughout the 28 day quitting period and for three days six months after the quit date.

Overall study start date
01/06/2017

Completion date
20/03/2020

Eligibility

Key inclusion criteria
Adult smoker:
1. 18 years or older
2. Daily smoker (at least one cigarette per day)
3. Intention to quit smoking
4. Own a smartphone with access to mobile internet and daily use
5. Fluent in the German language

Buddies:
1. 18 years or older
2. Current non-smoker (at least 6 months abstinence of tobacco and e-cigarettes)
3. Own a smartphone with access to mobile internet and daily use
4. Fluent in the German language

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Overall: 240 participants (n=160 smokers: 80 smokers each condition and n=80 buddies)

Total final enrolment
243

Key exclusion criteria
Adult smoker:
1. Younger than 18 years old
2. Less than daily smoking
3. 24-hour shift work
4. Simultaneous participation in a professional smoking cessation program or active use of a smoking cessation application
5. Insufficient comprehension of the German language.

Buddies:
1. Current smoker
2. 24-hour shift work
3. Younger than 18 years old
4. Insufficient comprehension of the German language

Date of first enrolment
15/04/2018

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Zurich, Department of Psychology
Zürich
Switzerland
8050

Sponsor information

Organisation
University of Zurich

Sponsor details
Department of Psychology, Applied Social and Health Psychology
Binzmühlestrasse 14 / Box 14
Zurich
Switzerland
8050

Sponsor type
University/education

ROR
https://ror.org/02crff812

Funder(s)

Funder type
University/education

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal.

Intention to publish date
28/02/2021

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. Corina Berli

Applied Social and Health Psychology
Address: Binzmühlestrasse 14 / Box 14, CH-8050 Zürich
corina.berli@psychologie.uzh.ch

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/10/2019	31/10/2019	Yes	No
Results article		09/09/2021	10/09/2021	Yes	No