

Efficacy of an Internet and mobile phone-based integrated smoking cessation and binge drinking intervention compared to a smoking cessation only intervention for smoking cessation in young people

Submission date 27/08/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/09/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/12/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Smoking is very common among adolescents with lower educational levels. This is a serious public health problem. A previous study tested the appropriateness and effectiveness of a fully automated text messaging-based intervention for smoking cessation (quitting smoking) in young people. It showed that this intervention could reach a high proportion of smoking vocational school students and reduce their cigarette consumption. However, it did not keep them from smoking for long. Problem drinking, particularly binge drinking, is very common in adolescent and young adult smokers and relapses after successful smoking cessation are often associated with alcohol consumption. Therefore, a combination of an integrated smoking cessation and binge drinking intervention is expected to be more effective than a smoking cessation only intervention. The aim of this study is to test the effectiveness of an internet and mobile phone-based integrated smoking cessation and binge drinking intervention compared with a smoking cessation only intervention.

Who can participate?

Daily and occasionally smoking vocational school students in the German-speaking part of Switzerland aged 16 and older who own a mobile phone.

What does the study involve?

Study participants are randomly allocated to one of two groups. Participants of both groups initially participate in a survey about their tobacco smoking and drinking behaviour. Participants in group 1 then receive the integrated smoking cessation and binge drinking intervention. They will get customised web-based feedback on their drinking behaviour, mobile phone text messages to encourage drinking within low-risk limits over a time period of 3 months, mobile phone text messages to support smoking cessation over a period of 3 months, and have a chance to register for a more intensive program providing strategies for smoking cessation

around a self-defined quit date. Participants in group 2 will receive a smoking cessation only intervention including customised mobile phone text messages to support smoking cessation over a time period of 3 months and a chance to register for a more intensive program providing strategies for smoking cessation around a self-defined quit date. Participants are then followed up 6 months after the initial survey.

What are the possible benefits and risks of participating?

We expect that the participants who received the integrated intervention will smoke less than the participants who receive the smoking cessation only intervention. There are no risks.

Where is the study run from?

Swiss Research Institute for Public Health and Addiction (Switzerland).

When is the study starting and how long is it expected to run for?

September 2014 to December 2016

Who is funding the study?

Swiss Tobacco Prevention Fund (Switzerland).

Who is the main contact?

Dr Severin Haug

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Efficacy of an Internet and mobile phone-based integrated smoking cessation and binge drinking intervention compared to a smoking cessation only intervention for smoking cessation in young people: a two-arm cluster randomised controlled trial

Study objectives

The main objective of the planned study is to test the efficacy of an integrated smoking cessation and binge drinking intervention compared to a smoking cessation only intervention for smoking cessation in young people. Our main hypothesis is that the integrated intervention will be more effective than the smoking cessation only intervention for reducing cigarette consumption and achieving smoking abstinence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the Philosophical Faculty of the University of Zurich, Switzerland, 13/08/2014

Study design

Two-arm cluster-randomized single blind controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Tobacco smoking

Interventions

Integrated smoking cessation and binge drinking intervention

1. Individually tailored mobile phone text messages to support smoking cessation and addressing (a) the risks of smoking, (b) the monetary costs of smoking, (c) the social norms of smoking, (d) outcome expectancies, (e) motivation to reduce cigarette consumption, (f) motivation to use social support for smoking cessation, (g) strategies to cope with craving situations, (h) tips for preparing for smoking cessation, (i) reward for staying abstinent.

Participants will receive two weekly text messages over a time period of 3 months.

2. Possibility to register for a more intensive program providing strategies for smoking cessation around a self-defined quit date. Participants will receive one or two text messages per day for a period of 4 weeks.

3. Web-based feedback including individually tailored information on (a) the number of drinks consumed per week in relation to the age- and gender-specific reference group, (b) financial costs of drinking, (c) calories consumed with alcoholic drinks, and (d) number of binge drinking occasions in relation to the age- and gender-specific reference group.

The participants will receive a single web-based feedback immediately after the baseline assessment.

4. Individually tailored mobile phone text messages to stimulate drinking within low-risk limits. Only participants with binge drinking (five or more drinks on one occasion in the last 30 days for male and four or more drinks on one occasion in the last 30 days for female participants) at the baseline assessment will receive these messages (one message per week) over a time period of 3 months.

Smoking cessation only intervention

1. Individually tailored mobile phone text messages to support smoking cessation and addressing (a) the risks of smoking, (b) the monetary costs of smoking, (c) the social norms of smoking, (d) outcome expectancies, (e) motivation to reduce cigarette consumption, (f) motivation to use social support for smoking cessation, (g) strategies to cope with craving situations, (h) tips for preparing for smoking cessation, (i) reward for staying abstinent. Participants will receive two weekly text messages over a time period of 3 months.

2. Possibility to register for a more intensive program providing strategies for smoking cessation around a self-defined quit date. Participants will receive one or two text messages per day for a period of 4 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. 7-day point prevalence smoking abstinence (i.e., not having smoked a puff within the past 7 days) assessed at 6-month follow up

2. Cigarette consumption assessed at 6-month follow up (number of cigarettes smoked on a typical day for daily smokers, typical number of smoking days per month and number of cigarettes smoked on a typical smoking day for occasional smokers)

Secondary outcome measures

1. 30-day point prevalence smoking abstinence (i.e., not having smoked a puff within the past 30 days) assessed at 6-month follow up

2. Stage of change according to the Health Action Process Approach (Schwarzer et al. 2008, Applied Psychology) assessed at 6-month follow up

3. Quit attempt within the previous 6 months assessed at 6-month follow up

4. Alcohol consumption assessed at 6-months follow up by a 7-day drinking calendar for which participants are asked to think about a typical week in the past month and, for each day, to record the number of standard drinks they typically consume on that day.

Overall study start date

01/09/2014

Completion date

31/01/2017

Eligibility

Key inclusion criteria

1. Daily cigarette smoking or occasional cigarette smoking (at least four cigarettes in the previous month and at least one cigarette in the previous week)
2. Aged above 15 years
3. Possession of a mobile phone

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

675 per study group resulting in a total of n=1350 study participants

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2014

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

Switzerland

Study participating centre

Konradstrasse 32

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Switzerland

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Sponsor information

Organisation

Swiss Research Institute for Public Health and Addiction (Switzerland)

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Sponsor type

Research organisation

ROR

<https://ror.org/02crff812>

Funder(s)

Funder type

Research organisation

Funder Name

Swiss Tobacco Prevention Fund (Switzerland) (Ref. No. 13.006402)

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	05/11/2014		Yes	No
	results				

[Results article](#)

01/11/2017

Yes

No