

Efficacy of a mobile phone-based life-skills training program for substance use prevention among adolescents

Submission date 17/07/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/07/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/08/2024	Condition category Other	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A method of preventing substance use among adolescents is life skills training within the school curriculum. However, such training is prevented from happening due to their large resource requirements. Therefore, one way to solve this problem might be to provide life skills training via mobile phones, which may be a more cost-effective way to reach large numbers of young people.

This study aims to look at the effectiveness of mobile phone-based life skills training at preventing substance use among adolescents.

Who can participate?

Secondary school students of grades 8 and 9, typically aged between 14 and 16, who own a mobile phone

What does the study involve?

Participants will be randomly allocated into either the intervention or the control group. The intervention group will receive mobile phone-based life skills training, where they receive up to 4 weekly individually tailored text messages over 6 months, designed to improve their social skills, and their ability to cope with stress and resist social pressure. There will also be interactive features, such as quiz questions, message and picture contests and friendly competition between users to collect credits.

Participants of the assessment only control group will receive no intervention.

Participants in both groups will be asked to complete questionnaires relating to substance use and social skills at the beginning of the study as well as after 6 and 18 months

What are the possible benefits and risks of participating?

The possible benefit to participants is that is that the intervention will improve their life skills and prevent substance use. There are no known risks to participants taking part in this study.

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 2018 to September 2022

Who is funding the study?
Swiss National Science Foundation (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10001C_179222/1

Study information

Scientific Title
Efficacy of a mobile phone-based life-skills training program for substance use prevention among adolescents: Study protocol of a cluster-randomised controlled trial

Acronym
SmartCoach

Study objectives

SmartCoach, a mobile phone-based life-skills training program to prevent substance use among secondary school students will be more effective than assessment only, to prevent the onset and escalation of problematic alcohol and tobacco use at 18-months follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Faculty of Arts and Sciences at the University of Zurich, 21/06/2018, 18.6.5

Study design

Interventional two-arm single-blind cluster-randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

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

Substance use, tobacco, alcohol

Interventions

Participants will be cluster-randomised, using school class as a randomisation unit. Due to the heterogeneity of students in the different secondary schools, we will use a separate randomisation list for each school (stratified randomisation). Furthermore, to approximate equality of sample sizes in the study groups, we will use block randomisation with computer generated randomly permuted blocks of 4 cases.

School classes will be randomised into two groups, an intervention and a control group.

Research assistants supervising the baseline and follow-up assessments will be blinded to the group allocation of the participants.

Participants in the intervention groups will receive up to 4 weekly text messages over 6 months in order to stimulate:

1. Positive outcome expectations, such as using self-management skills to cope with stress
2. Self-efficacy i.e. to resist social pressure
3. Observational learning, for example of interpersonal competences
4. Facilitation of strategies to cope with negative emotions
5. Self-regulation, for example by self-monitoring of stress and emotions

These texts will have interactive features to stimulate active programme engagement, such as

quiz questions, message and picture contests, and integration of a friendly competition with prizes, in which programme users collect credits with each interaction.

Participants in the control group will receive no intervention.

There will be follow-up assessments 6 and 18 months after study inclusion, which will include questionnaires addressing life skills (stress, coping behavior, social skills) and substance use (alcohol, tobacco and cannabis use)

Intervention Type

Other

Primary outcome measure

The following will be assessed at the baseline and after 6 and 18 months follow up:

1. Prevalence of problem drinking in the preceding 30 days, assessed using the Alcohol Use Disorders Identification Test (AUDIT-C)
2. Point prevalence rate for smoking abstinence in the preceding 30 days, assessed using the criteria of the Society for Nicotine and Tobacco Research

Secondary outcome measures

The following will be assessed at the baseline and after 6 and 18 months follow up:

1. Prevalence of cannabis use in the preceding 30 days, assessed using an item of the Health Behaviour in School Aged Children (HBSC) study addressing the number of cannabis consumption days
2. Quantity of alcohol use in the preceding 30 days, assessed using the Alcohol Use Disorders Identification Test (AUDIT-C)
3. Quantity of cigarettes smoked in the preceding 30 days by assessing the number of smoking days and the typical number of cigarettes smoked per smoking day, self-reported by participants
4. Perceived stress, assessed using a 4 item version of the Perceived Stress Scale (PSS-4)
5. Interpersonal competences, assessed using the brief version of the Interpersonal Competence Questionnaire (ICQ), addressing the following domains of social competence:
 - 5.1. Initiation of relationships
 - 5.2. Negative assertion
 - 5.3. Disclosure of personal information
 - 5.4. Emotional support
 - 5.5. Conflict management

Overall study start date

01/09/2018

Completion date

30/09/2022

Eligibility

Key inclusion criteria

1. Secondary school student
2. Minimum age 14
3. Possession of a mobile phone

Participant type(s)

Healthy volunteer

Age group

Other

Sex

Both

Target number of participants

n=656 per study group and a total of n=1312 study participants. Approximately 100 secondary school classes are required to reach this sample size.

Total final enrolment

1473

Key exclusion criteria

N/A

Date of first enrolment

01/01/2019

Date of final enrolment

31/12/2020

Locations**Countries of recruitment**

Switzerland

Study participating centre

Swiss Research Institute for Public Health and Addiction

Konradstrasse 32

Zurich

Switzerland

8005

Sponsor information**Organisation**

Swiss Research Institute for Public Health and Addiction

Sponsor details

Konradstrasse 32

Zurich

Switzerland

8005

Sponsor type

Research organisation

Website

<http://www.isgf.ch>

ROR

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

Funder(s)

Funder type

Not defined

Funder Name

Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Publication and dissemination plan

We intend to publish the study protocol in 2018, the short-term outcomes in 2021, and the main outcomes and moderators of outcome in 2022. All results will be published in high impact peer reviewed medical or psychological journals.

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository (SwissUbase) at <https://doi.org/10.48573/g6hb-qc82>. SWISSUbase is a research data service that provides a technical environment and services for the

management of research projects and the archiving, dissemination, and promotion of research data and metadata. SWISSUbase fulfils the FAIR data principles and is compliant with international data and metadata standards. The data are open access to provide unrestricted access to research results and to promote collective knowledge. The researchers obtained consent from all participants that their data are available anonymously via this publicly available repository. All data for the outcome analyses, syntax and documentation are available via SwissUbase.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2018	04/06/2019	Yes	No
Results article		13/07/2021	14/07/2021	Yes	No
Results article		16/08/2022	22/08/2022	Yes	No
Dataset		14/04/2022	23/08/2022	No	No
Other publications	secondary analysis	19/01/2022	15/08/2024	Yes	No