ISRCTN10423173 https://doi.org/10.1186/ISRCTN10423173

Effectiveness of an optimized mobile phone-based life skills training program for addiction prevention among adolescents

Submission date
16/08/2023

Recruitment status
No longer recruiting

Registration date
18/08/2023

Overall study status
Completed

Last Edited
09/04/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The results of an already completed study showed the effectiveness of a mobile phone-based life skills training program for addiction prevention. However, socially stratifying factors like educational level or migration background were associated with lower program use and participation. Taking into account these differences, we subsequently optimized and tailored program elements, particularly for subgroups with low program engagement using qualitative interview data. This study aims to test whether the optimized program version is superior to the original one in terms of effectiveness and program use.

Who can participate?
Secondary and upper secondary school students, typically aged between 14 and 17, who own a mobile phone.

What does the study involve?
Participants will be randomly allocated to either the optimized program version with advanced tailoring or the original version. Both groups will receive mobile phone-based life skills training, where they receive up to 4 weekly individually tailored text messages over 4 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 a friendly competition between users to collect credits.

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

What are the possible benefits and risks of participating?
The possible benefit to participants 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?
April 2022 to April 2025

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

Who is the main contact?
Dr. Severin Haug, severin.haug@isgf.uzh.ch (Switzerland)

Study website
https://www.smartcoach.info/

Contact information

Type(s)
Principal Investigator

Contact name
Dr Severin Haug

ORCID ID
http://orcid.org/0000-0002-6539-5045

Contact details
Konradstrasse 32
Zurich
Switzerland
8005
+41444481174
severin.haug@isgf.uzh.ch

Type(s)
Scientific

Contact name
Dr Severin Haug

Contact details
Konradstrasse 32
Zurich
Switzerland
8005
+41444481174
severin.haug@isgf.uzh.ch

Type(s)
Public

Contact name
Dr Severin Haug

Contact details
Konradstrasse 32
Zurich
Switzerland
8005
+41444481174
severin.haug@isgf.uzh.ch

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
10001C_204412/1

Study information

Scientific Title
Effectiveness of a mobile phone-based life skills training program for addiction prevention among adolescents optimized with regard to social inequalities: a cluster randomized controlled trial

Acronym
SmartCoach

Study objectives
We hypothesize that the optimized program version, including advanced tailoring, will result in increased program effectiveness, indicated by lower substance use at six-month follow up and increased program engagement.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/04/2022, Ethics Committee of the Faculty of Arts and Sciences at the University of Zurich (Andreasstrasse 15, P.O. Box 12, Zurich, 8050, Switzerland; +41 44 635 71 81; chair.ethics.committee@phil.uzh.ch), ref: 22.2.15

Study design
Interventional two-arm single-blind cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Internet/virtual, School, Telephone

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 prevention

Interventions
Participants will be cluster-randomized, using school class as a randomization unit. Due to the heterogeneity of students in the different secondary schools, we will use a separate randomization list for each school (stratified randomization). Furthermore, to approximate the equality of sample sizes in the study groups, we will use block randomization with computer generated randomly permuted blocks of 4 cases.
School classes will be randomized into two groups (1) an intervention group receiving the optimized program version with advanced tailoring or (2) the original program version. Research assistants supervising the baseline and follow-up assessments will be blinded to the group allocation of the participants.
Participants in both intervention groups will receive up to 4 weekly text messages over 4 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 include interactive features to stimulate active program engagement, such as quiz questions, message and picture contests, and integration of a friendly competition with prizes, in which program users collect credits with each interaction.
The optimized program version will include additional tailoring for participants with personal or parental backgrounds from non-German-speaking countries, who will receive shorter video clips. Furthermore, other stressors, including acculturation and quarrel with the family, will be addressed and the weekly text messages are not always sent on Tuesdays but on different days of the week. Finally, the contest's time was extended, and a reminder was integrated into the optimized program version.
There will be a follow-up assessment 6 months after study inclusion, which will include program evaluations as well as questionnaires addressing life skills (stress, social skills) and substance use (alcohol, nicotine, and cannabis use).

Intervention Type
Behavioural

Primary outcome measure

The following primary outcome measures will be assessed at the baseline and at the 6-month follow-up:
1. Alcohol use in the preceding 30 days measured using the Alcohol Use Disorders Identification Test (AUDIT-C)
2. Number of days that nicotine-containing products are smoked in the preceding 30 days measured using a questionnaire
3. Cannabis use days in the preceding 30 days measured using a questionnaire

Secondary outcome measures
The following secondary outcome measures will be assessed at the baseline and at the 6-month follow-up:
1. Perceived stress measured using a single item from the Swiss Juvenir study: “How often have you had the feeling of being overstressed or overwhelmed in the last month?”
2. Interpersonal competencies measured using the brief version of the Interpersonal Competence Questionnaire (ICQ-10)

The following secondary outcome measure concerning program use will be measured from the server protocol:
Total number of interactions with the program (replying to quizzes, retrieving media objects like videos or web links, and participating in self-challenges or contests)

Overall study start date
01/04/2022

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Secondary or upper secondary school student
2. Minimum age of 14 years
3. Possession of a mobile phone

Participant type(s)
Learner/student

Age group
Child

Lower age limit
14 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
860

Total final enrolment
890

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
01/09/2023

Date of final enrolment
01/12/2024

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
+41 44 448 11 60
isgf@isgf.uzh.ch

Sponsor type
Research organisation

Website
http://www.isgf.ch

Funder(s)

Funder type
Research organisation

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
Planned publication in a high-impact peer-reviewed medical or psychological journal

Intention to publish date
30/04/2025

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://www.swissubase.ch/en/. 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