

# Efficacy of ready4life: a digital addiction prevention program for young people

<b>Submission date</b> 20/10/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/11/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A large proportion of apprentices shows addictive behaviors like cigarette smoking, alcohol-, cannabis- or compulsive internet use. Others do not show these behaviors and develop a low-risk handling of substances due to their resources and life skills. "ready4life" is a mobile phone-based addiction prevention program that takes into account the heterogeneity of adolescent addictive behavior by promoting life skills on the one hand and reducing risk behaviors on the other. The main objective of the planned study is to test "ready4life" among vocational school students in Switzerland within a controlled trial.

### Who can participate?

Vocational school students in Switzerland who own a smartphone

### What does the study involve?

Participants of the intervention group will participate in the digital coaching program "ready4life". Based on their risk and resource profile, they can select two out of 6 program modules on stress, social skills, Internet use, tobacco, cannabis, and alcohol. They receive coaching for a period of four months by a conversational agent (chatbot). This virtual coach motivates the participants to deal sensitively with addictive substances, gives feedback on current use and provides information in weekly dialogues. In a separate chat within the app, the participants can pose personal questions to regional addiction prevention experts.

A total of 1,318 study participants will be recruited within vocational schools. A follow up assessment, focusing on the study participant's addictive behaviors, will be conducted in month 6, i.e., 2 months after the end of the program.

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, stress symptoms and self-efficacy 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 addictive behaviors. 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?

August 2020 to December 2022

Who is funding the study?

Research Fund of the Swiss Lung Association (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

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Efficacy of a digital coaching program for addiction prevention among vocational school students: Study protocol of a cluster-randomised controlled trial

**Acronym**

ready4life

**Study objectives**

The intervention program will be more effective than assessment only, to prevent the onset and escalation of addictive behaviors (at-risk alcohol use, tobacco use, cannabis use, and problematic Internet use) at 6-months follow-up.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 16/10/2020, Ethics Committee of the Faculty of Arts and Sciences at the University of Zurich (Binzmühlestrasse 14, Box 22, CH-8050 Zürich, Switzerland; +41 44 635 74 70; k.oberauer@psychologie.uzh.ch), ref: 20.10.12

**Study design**

Interventional two-arm single-blind cluster-randomized 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**

Prevention of addictive behaviors in students

**Interventions**

Participants will be cluster-randomised, using school class as a randomisation unit. Due to the heterogeneity of students in the different vocational 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 group will participate in the digital prevention program "ready4life". Within this app-based program, an individual profile is generated on the basis of a survey conducted via smartphone. This profile shows areas in which a participant has sufficient

resources and in which there is a need for coaching or counselling. Based on their risk and resource profile, the participants can select two out of the following 6 program modules: stress, social skills, Internet use, tobacco, cannabis, and alcohol. Participants of the intervention group will receive individualised coaching for a period of four months by a conversational agent (chatbot). This virtual coach motivates the participants to deal sensitively with addictive substances, gives feedback on current consumption and provides information in weekly dialogues. In a separate chat within the app, the participants can pose personal questions to regional addiction prevention experts. In order to achieve high engagement rates, interactive elements such as quiz questions, contests, and a playful competition are integrated into ready4life.

Participants in the control group will not participate in the intervention program.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

At baseline- and 6-months follow-up, measured by self-report:

A composite measure for addictive behaviors composed of:

1. At risk-drinking in the preceding 30 days, according to guidelines of the Swiss Federal Office of Public Health
2. 30-days point prevalence for tobacco/e-cigarette smoking
3. 30-days point prevalence for cannabis use
4. Problematic Internet use assessed by the Compulsive Internet Use Scale, CIUS

## **Secondary outcome measures**

At baseline- and 6-months follow-up assessments:

1. General self-efficacy assessed by the Short Scale for Measuring General Self-efficacy Beliefs (ASKU)
2. Stress assessed by a single-item measure of stress symptoms

## **Overall study start date**

01/08/2020

## **Completion date**

31/12/2022

# **Eligibility**

## **Key inclusion criteria**

1. Vocational school student
2. Minimum age 15
3. Possession of a smartphone

## **Participant type(s)**

Healthy volunteer

## **Age group**

Other

**Sex**

Both

**Target number of participants**

n=659 per study group and a total of n=1,318 study participants. Approximately 100 vocational school classes are required to reach this sample size.

**Total final enrolment**

1351

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/06/2021

**Date of final enrolment**

31/05/2022

**Locations****Countries of recruitment**

Switzerland

**Study participating centre**

**Swiss Research Institute for Public Health and Addiction**

Konradstrasse 32

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**Sponsor information****Organisation**

Swiss Research Institute for Public Health and Addiction

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**Sponsor type**

Research organisation

### Website

<https://www.isgf.uzh.ch>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Research Fund of the Swiss Lung Association

## Results and Publications

### Publication and dissemination plan

We intend to publish the study protocol in 2021, the outcomes and moderators of outcome in 2023. All results will be published in high impact peer reviewed medical or psychological journals.

### Intention to publish date

31/03/2023

### Individual participant data (IPD) sharing plan

Data available on request due to restrictions. The datasets generated and analyzed during the current study are not publicly available due to the Swiss data protection law but are available from the corresponding author (severin.haug@isgf.uzh.ch) on reasonable request. Requests will be reviewed for reasonability and compliance with the study purpose and the participants' informed consent.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		14/12/2020	18/08/2021	Yes	No
<a href="#">Results article</a>		25/11/2022	28/11/2022	Yes	No