

# A study to estimate the effects of a novel mHealth intervention that targets multiple lifestyle behaviors (alcohol, diet, physical activity, and smoking) among high school students in Sweden

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| <b>Submission date</b><br>15/05/2020   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>20/05/2020 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>24/04/2025       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data   |

## Plain English summary of protocol

### Background and study aims

Lifestyle factors, e.g. inadequate physical activity, unhealthy diets, smoking and harmful use of alcohol intake are the main causes of diseases such as cancer, respiratory disease and diabetes type II. Unhealthy lifestyle behaviors tend to be established in early childhood and adolescence and track into adulthood.

Over the past ten years, interest has been increased to provide lifestyle interventions and support via mobile phones, so called mHealth. mHealth provides a new potential to achieve changes in multiple lifestyle behaviors

The aim of the current project is to estimate the effect of a novel mHealth intervention that targets multiple lifestyle behaviors, e.g. alcohol, physical activity, nutrition and smoking among high school students in Sweden.

### Who can participate?

High school students who present 'at risk' with respect to at least one of four lifestyles (alcohol, diet, physical activity or smoking)

### What does the study involve?

Participants will be randomly allocated to an intervention or a control group. The intervention group will be given immediate access to the novel intervention, while the control group will be given general health information and be placed on a waiting list.

Students in the intervention condition will be given access to the novel intervention for four months. Students will register their interest by sending a text message to a dedicated telephone number. All students who consent will immediately be asked to complete an online baseline questionnaire, which will also be used to assess eligibility for the trial. The intervention aims to promote physical activity, healthy diet, non-risky drinking of alcohol and smoking cessation during a 16-week period.

What are the possible benefits and risks of participating?

Adverse effects may include an increased risk for eating disorders; however, we find this unlikely since the advice covers healthy foods and physical activity in general and is based on current guidelines for the target group. There are no harmful effects with participation, the study has potential health benefits, the intervention will promote healthy diets, support less alcohol intake and quit or reduce smoking.

Where is the study run from?

Linköping University (Sweden)

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

August 2019 to September 2022

Who is funding the study?

Swedish Research Council for Health, Working Life and Welfare

Who is the main contact?

Ulrika Müssener, [ulrika.mussener@liu.se](mailto:ulrika.mussener@liu.se)

## 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

2018-01410

# Study information

## Scientific Title

Multiple lifestyle mHealth intervention for health behaviour change among high school students in Sweden (LIFE4YOUth): protocol for a randomized controlled trial

## Acronym

LIFE4YOUth

## Study objectives

At-risk high school students who participate in the trial will drink less, eat healthier, increase their physical activity and/or smoke less compared to participants in the control group.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 28/11/2019, Swedish Ethical Review Authority (Etikprövningsnämnden, Box 2110, 57002 Uppsala, S-Sweden; +4610 4750800; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: 2019-03813

## Study design

Two-arm parallel group single-blind randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

School

## Study type(s)

Other

## Participant information sheet

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

## Health condition(s) or problem(s) studied

High school students, at risk with respect to at least one of four lifestyles (alcohol, diet, physical activity or smoking)

## Interventions

Participants will be randomized to an intervention or a control group. All randomization sequences will be computer generated and allocation will be automatically done by a backend system.

The intervention group will be given immediate access to the novel intervention, while the control group will be given general health information and be placed on a waiting list.

Participants randomized to the intervention condition will be given access to the novel intervention for four months. Students will register their interest by sending a text message to a dedicated telephone number (included in all information materials). In response, students will receive a text message with a hyperlink to a web page presenting trial information and asked to leave informed consent. All students who consent will immediately be asked to complete an online baseline questionnaire, which will also be used to assess eligibility for the trial. The intervention aims to promote physical activity, healthy diet, non-risky drinking of alcohol and smoking cessation during a 16-week period.

The content for the m-health intervention will be based on existing evidence-based practice and include key elements from previous text message-based interventions, apps and Internet-based interventions. The intervention will comprise information about health risk of all four unhealthy lifestyle habits, and tips on behavior change strategies. The intervention consists of interactive and personal modules contained within a mobile phone-based instrument panel. Individuals are free to choose which lifestyles they wish to attempt to change. Examples of the evidence-based strategies for behavior change included in the intervention are: distraction techniques to increase resilience for undesired habits, tips to cope with cravings, and how to replace undesired habits. The content is delivered predominately through text but also through short films. In addition, users can opt for additional support via automated SMS-programs available for each health behaviour.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

At baseline and 3 follow-up stages: 1, 2, and 4 months after randomization. All follow-ups will be initiated by sending text messages to participants with hyperlinks to questionnaires.

1. Alcohol: Weekly alcohol consumption; monthly frequency of heavy episodic drinking assessed by asking participants the number of standard units of alcohol they consumed last week.

Frequency of heavy episodic drinking will be assessed by asking participants how many times they have consumed more than four standard units of alcohol on one occasion the past month

2. Diet: Average daily consumption of fruit and vegetables; weekly consumption of sugary drinks assessed by asking two questions regarding how many portions (100g) of fruit and vegetables (respectively) participants consumed on average per day during the past week. Consumption of sugary drinks will be assessed by asking participants how many units of sugary drinks they consumed the past week

3. Physical activity: Weekly moderate to vigorous physical activity assessed by summing responses to two questions regarding the number of minutes spent on physical activity the past week.

4. Smoking: Four week point prevalence of smoking abstinence asked as a binary question. Participants who have smoked any cigarette the past four weeks will be asked for the number of cigarettes smoked the past week

## **Secondary outcome measures**

At baseline and 3 follow-up stages: 1, 2, and 4 months after randomization. All follow-ups will be initiated by sending text messages to participants with hyperlinks to questionnaires.

1. Composite index of alcohol, diet, smoking and physical activity measured as above

2. Body mass index measured by asking participants to report their weight at follow-up

3. Number of cigarettes smoked the past week measured by self-report

## **Overall study start date**

01/08/2019

**Completion date**

07/09/2022

## Eligibility

**Key inclusion criteria**

1. High school students
2. Present at risk with respect to at least one of four lifestyles (alcohol, diet, physical activity or smoking)
3. There will be no age restriction, however, the majority of students attending high school in Sweden are between 16 and 19 years of age

At-risk for each lifestyle is defined as:

- Alcohol: Drinking on average 10 or more standard units of alcohol per week and/or drinking 4 or more standard units of alcohol on a single occasion at least once a month. A standard unit of alcohol is in Sweden defined as 12 grams of pure alcohol
- Diet: Consuming less than 500 grams of fruit and vegetables on average per day and/or drinking on average more than 4 units of sugary drinks per week. One sugary drink unit is defined as approximately 33 cl
- Physical activity: Spending less than 420 minutes on average per week on moderate to vigorous physical activity
- Smoking: Smoking on a daily or weekly basis

**Participant type(s)**

Learner/student

**Age group**

Other

**Sex**

Both

**Target number of participants**

Participating high schools (approximately 300 high schools at which approximately 80,000 students attend) will recruit students to the trial. A total of approximately 1,500 participants, will be randomized into the study; 750 will be allocated to an intervention group and 750 to a control group.

**Total final enrolment**

756

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

07/09/2020

**Date of final enrolment**

06/09/2021

## **Locations**

### **Countries of recruitment**

Sweden

### **Study participating centre**

#### **Linköping University**

Department of Health, Medicine and Caring Sciences

Linköping

Sweden

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## **Sponsor information**

### **Organisation**

Linköping University

### **Sponsor details**

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### **Sponsor type**

University/education

### **Website**

<http://www.liu.se>

### **ROR**

<https://ror.org/05ynxx418>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Forskningsrådet om Hälsa, Arbetsliv och Välfärd

**Alternative Name(s)**

Swedish Research Council for Health, Working Life and Welfare, FORTE

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Sweden

## Results and Publications

**Publication and dissemination plan**

We intend to publish the trial results in a scientific journal. A manuscript will be drafted and submitted during the autumn of 2022. We aim to publish results presenting the effect of an mHealth intervention on physical inactivity, unhealthy diets, smoking and risky drinking of alcohol among high-school students in Sweden.

**Intention to publish date**

01/11/2022

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

| Output type                        | Details            | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|--------------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>   | Secondary analysis | 16/07/2021   | 19/07/2021 | Yes            | No              |
| <a href="#">Other publications</a> |                    | 07/03/2025   | 10/03/2025 | Yes            | No              |
| <a href="#">Results article</a>    |                    | 22/04/2025   | 24/04/2025 | Yes            | No              |