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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

Submission date 15/05/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/05/2020	**Overall study status** Completed	
Last Edited 24/04/2025	**Condition category** Other	

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 healty 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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), ref: 2019-03813

Study design
Two-arm parallel group single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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
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SE-58185

Sponsor information

Organisation
Linköping University

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, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

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?
Results article		22/04/2025	24/04/2025	Yes	No
Protocol article		16/07/2021	19/07/2021	Yes	No
Other publications	Secondary analysis	07/03/2025	10/03/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes