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A mobile phone-based intervention to support healthy lifestyle behaviours among Swedish college and university students

Submission date 26/01/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 28/01/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/01/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Noncommunicable diseases (NCDs), such as heart diseases and cancer, constitute a major public health concern by causing 71% of deaths globally each year. The World Health Organization (WHO) has made it clear that the burden of disease that NCDs cause would be greatly reduced if the prevalence of harmful alcohol consumption, unhealthy diets, physical inactivity, and smoking was reduced. Behavioural risk factors, such as an individual's lifestyle, additionally accounted for 36% of all disability-adjusted life years in 2017. Thus, it is important to find effective and scalable means of helping individuals to improve their lifestyle behaviours in order to improve health and well-being.
Surveys conducted by the Public Health Agency of Sweden have found that many individuals engage in multiple unhealthy lifestyle behaviours simultaneously, with only one in two women and one in three men reporting not having any unhealthy lifestyle behaviours. Despite this, the Swedish National Board of Health and Welfare have reported a lack of research regarding multiple lifestyle behaviour change interventions. Since unhealthy behaviours tend to co-occur, not addressing multiple unhealthily lifestyles is potentially a missed opportunity.
The main aim of this study is to estimate the effects of the components of a novel mHealth intervention targeting multiple lifestyle behaviours (alcohol, diet, physical activity, and smoking) among college and university students in Sweden.

Who can participate?
University students in Sweden who have at least one behaviour classified as risky (e.g. heavy drinking, poor diet, low physical activity, smoking)

What does the study involve?
Participation involves answering questionnaires and being given access to a novel mHealth intervention on their mobile phone. Participants are randomly allocated to different combinations of modules. The intervention is 4 months with follow-ups at 2 and 4 months.

What are the possible benefits and risks of participating?
The benefits of participating include access to a new intervention designed to help participants

change their lifestyle behaviour for the better, which will have positive health consequences. Risks include being disappointed or feeling de-motivated if the support given does not suit one's needs.

Where is the study run from?
Linköping University (Sweden)

When is the study starting and how long is it expected to run for?
September 2020 to March 2024

Who is funding the study?
Swedish Research Council for Health, Working Life and Welfare (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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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

Multiple lifestyle behaviour mHealth intervention targeting Swedish college and university students

Acronym
BUDDY

Study objectives
The study aims to:
1. Estimate the effects of a novel mHealth intervention's different components on individual lifestyle behaviours:
1.1. Weekly alcohol consumption and number of episodes per month of heavy drinking
1.2. Weekly consumption of sugary drinks and average daily fruit and vegetable consumption
1.3. Weekly moderate to vigorous physical activity
1.4. Smoking
2. Estimate the degree to which the effects of the components are mediated through importance, confidence, and know-how.
3. Detect interactions among lifestyle behaviour change, e.g. those who stop smoking may also reduce their alcohol consumption, and the degree to which this is moderated by the components of the intervention
4. Investigate the perceived usefulness and general opinion of the support received in contrast to factorial allocation
5. Investigate strategies employed by participants for behaviour change in contrast to factorial allocation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/12/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, FE 111 20, 838 82 Frösön, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: Dnr 2020-05496

Study design
Double-blind randomized factorial trial

Primary study design
Interventional

Secondary study design
Randomized factorial trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Lifestyle behaviour change among university students who do not follow national guidelines

Interventions
The BUDDY multiple lifestyle behaviour intervention is an mHealth intervention which consists of a set of modules which users access using their mobile phone. The modules are intended to be used as a toolbox, allowing users to choose which parts of the intervention to interact with and tailor the support to their needs. Each Sunday afternoon, participants will receive a text message with a link and a reminder to access BUDDY and engage with the intervention materials.

Below the six modules of the intervention are briefly described, which will also represent the factors in the factorial trial. Each participant recruited to the trial will be randomly allocated by block randomisation with random block sizes of 64 and 128 to one of 64 conditions, each condition representing a combination of available/not-available of the modules. The intervention is 4 months with follow-ups at 2 and 4 months.

MODULE 1: SCREENING AND FEEDBACK
The first module consists of screening and feedback. When pressing the link in the weekly text message, participants will be asked to respond to a questionnaire regarding their current lifestyle behaviours, after which they are shown feedback on their current behaviour in contrast to national guidelines. They will subsequently be given access to the rest of the modules appropriate for their randomised allocation. Self-monitoring has been shown to be a potentially effective strategy for reducing excessive alcohol consumption and to promote healthy eating and physical activity.

MODULE 2: GOAL SETTING AND SELF-REGULATION
The second module supports enhanced self-regulatory capacity and skills via goal setting and planning. This includes setting goals for future behaviour (and receiving feedback on previous set goals), preparing for triggers, and accepting ready-made habit challenges. Intervention content designed around goalsetting, action planning, practising behaviour, and habit formation have, amongst other planning-related activities, been shown to be important among effective lifestyle interventions. Participants will be reminded of the goals that they have set, including any habit challenges they have accepted, via text message prompts throughout the week.

MODULE 3: MOTIVATION AND SELF-EFFICACY
The third module aims to increase users' awareness of their own motivation, prompt commitment, and boost motivation and self-efficacy. This is supported via texts, videos and exercises relating to health, economics and motivation awareness. Digital behaviour change interventions have been shown to have the capacity to increase self-efficacy, however, there is a lack of consensus across reviews with regards to which content works to facilitate this increase. The module will also allow participants to sign up for text messages with motivational content sent to them throughout the week. The content of the messages has been derived from previously developed and evaluated interventions.

MODULE 4: SKILLS AND KNOW-HOW
The fourth module aims to increase the user's skills and know-how of how to make lasting behavioural changes. This will include concrete tips on how to initiate and maintain change in everyday life. For instance, participants are given strategies they can employ when going to parties where alcohol is served, or how to introduce vegetables to their breakfast. As with the

third module, participants will be able to sign up for text messages with tips sent to them throughout the week – the content of which has also been derived from previously developed and evaluated interventions.

MODULE 5: MINDFULNESS
The fifth module aims to help participants to build the mental resources needed for behaviour change. A set of mindfulness exercises, including guided meditation, will be available in the module. The exercises are based on previous research, and are believed to be important to improve the mental well-being of those who engage with them.

MODULE 6: SELF-COMPOSED TEXT MESSAGES
The sixth module consists of self-composed text messages sent to participants throughout the week. Participants will be allowed to author up to three messages to themselves and have them sent at specified intervals. For instance, a participant can write a message about their commitment to increase their physical activity and decide to have it sent to them every Monday and Wednesday at 5 pm. This type of activity seems under-studied in the literature more widely, but has shown preliminary interesting results in an ongoing trial.

Intervention Type
Behavioural

Primary outcome measure
1. Alcohol:
1.1. Weekly alcohol consumption will be assessed by asking participants the number of standard drinks of alcohol they consumed last week (short term recall method) at baseline, 2- and 4-months post-randomisation
1.2. Frequency of heavy episodic drinking will be assessed by asking participants how many times they have consumed more than four/five (female/male) standard drinks of alcohol on one occasion the past month at baseline, 2- and 4-months post-randomisation
2. Diet:
2.1. Weekly consumption of fruit and vegetables will be assessed by asking two questions regarding how many portions (100 g) of fruit and vegetables (respectively) participants consumed on average per day during the past week at baseline, 2- and 4-months post-randomisation
2.2. Consumption of sugary drinks will be assessed by asking participants how many units (33 cl) of sugary drinks they consumed the past week at baseline, 2- and 4-months post-randomisation
3. Weekly moderate to vigorous physical activity (MVPA) will be assessed by summing responses to two questions regarding the number of minutes spent on physical activity the past week (moderate and vigorous respectively) at baseline, 2- and 4-months post-randomisation
4. Four-week point prevalence of smoking abstinence (no cigarettes the past week) will be asked as a binary question at baseline, 2- and 4-months post-randomisation

Secondary outcome measures
1. Weekly consumption of candy and snacks, assessed by means of questionnaires published by the National Board of Health and Welfare in Sweden, modified to also include portion sizes at baseline, 2- and 4-months post-randomisation
2. Body mass index (BMI) will be measured by asking participants to report their height and weight at baseline, 2- and 4-months post-randomisation
3. Number of cigarettes smoked the past week: participants who have smoked any cigarette the past 4 weeks will be asked for the number of cigarettes smoked the past week at 2- and 4-months post-randomisation

4. Perceived stress will be assessed using the short form perceived stress scale (PSS-4) at baseline, 2- and 4-months post-randomisation

Overall study start date
01/09/2020

Completion date
01/03/2024

Eligibility

Key inclusion criteria
University students in Sweden will be included in the trial if they fulfil at least one of six conditions, which are connected to the primary outcomes of the trial. The conditions are:
1. Weekly alcohol consumption: consumed 10/15 (female/male) or more standard drinks of alcohol the past week. A standard drink of alcohol is in Sweden defined as 12 grams of pure alcohol
2. Heavy episodic drinking: consumed 4/5 (female/male) or more standard drinks of alcohol on a single occasion at least once the past month
3. Fruit and vegetables: consumed less than 500 grams of fruit and vegetables on average per day the past week
4. Sugary drinks: consumed 3 or more units of sugary drinks the past week. One sugary drink unit is defined as approximately 33 cl
5. Moderate to vigorous physical activity: spent less than 420 minutes on moderate to vigorous physical activity the past week (i.e. approximately 60 minutes per day)
6. Smoking: having smoked at least one cigarette the past week

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A Bayesian group sequential design will be used, thus no fixed target exists. The researchers expect between 1500-2500 participants, but there are target posterior probabilities that will dictate this.

Total final enrolment
1704

Key exclusion criteria
1. Not fulfilling inclusion criteria
2. Less than 18 years of age

Date of first enrolment
28/02/2021

Date of final enrolment
19/10/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Linköpings Universitet
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Sponsor information

Organisation
Linköping University

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Sponsor type
University/education

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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
1. A protocol, including a statistical analysis plan, will be submitted for publication prior to trial commencement.
2. Planned publications in open access peer-reviewed journals.

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available in order to comply with GDPR. Data will be held at Linköping University.

IPD sharing plan summary
Not expected to be made available