ISRCTN16420548 https://doi.org/10.1186/ISRCTN16420548

A digital intervention to support healthy lifestyle behaviours among online help seekers

Submission date	**Recruitment status**	[X] Prospectively registered
25/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2023	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Noncommunicable diseases (NCDs), such as heart disease and cancer, are a major public health concern and cause 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. Thus, it is important to find effective and scalable means of helping individuals to improve their lifestyle behaviours to improve health and well-being.
Recent data indicate that 16% of the adult population of Sweden are risky drinkers, 7% are smokers, 36% have an inadequate level of physical activity, and 51% are overweight or obese. Despite one in three cancer cases being preventable by a healthy lifestyle, these rates have not markedly decreased over the past 15 years, with the exception of smoking. More needs to be done to help individuals change their lifestyle to reduce the incidence of cancer and other NCDs. Also, since unhealthy behaviours interact (e.g. excessive alcohol consumption may lead to weight gain), and risks are multiplicative, it is important to support the change of multiple behaviours.
The main aim of this study is to estimate the effects of the components of a new digital intervention targeting multiple lifestyle behaviours (alcohol, diet, physical activity, and smoking) among people in Sweden who are looking for help online.

Who can participate?
Adults 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 digital intervention on a 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?
May 2020 to March 2024

Who is funding the study?
Swedish Cancer Society (Sweden)

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
20 0883 Pj

Study information

Scientific Title

Multiple lifestyle behaviour digital intervention targeting online help seekers: a randomised factorial trial

Study objectives
The study aims to:
1. Estimate the effects of a novel digital intervention's different components on individual lifestyle behaviours

Primary:
1.1. Weekly alcohol consumption and number of episodes per month of heavy drinking
1.2. Average daily fruit and vegetable consumption
1.3. Weekly moderate to vigorous physical activity
1.4. Four-week point prevalence of smoking

Secondary:
1.5. Health-related quality of life (HRQoL)
1.6. Perceived stress
1.7. Weekly consumption of candy and snacks
1.8. Weekly consumption of sugary drinks
1.9. Body mass index (BMI)
1.10. Number of cigarettes smoked the past week

2. Estimate the degree to which the effects of the components are mediated through perceived 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. Conduct a health economic evaluation of the intervention's components

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 2021-02855

Study design
Double-blind randomized factorial trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Lifestyle behaviour change among adults who are seeking help online and who do not follow national guidelines

Interventions

The digital intervention consists of a set of modules that users access using their mobile phones. 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 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 1, 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 promoting 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 has, 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(s)
1. Alcohol:
1.1. Weekly alcohol consumption, 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,e 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. Weekly consumption of fruit and vegetables, 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
3. Weekly moderate to vigorous physical activity (MVPA), 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), asked as a binary question at baseline, 2- and 4-months post-randomisation

Key secondary outcome(s))
Secondary:
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 2- and 4-months post-randomisation
2. Consumption of sugary drinks, assessed by asking participants how many units (33 cl) of sugary drinks they consumed the past week at 2- and 4-months post-randomisation
3. Body mass index (BMI), measured by asking participants to report their height and weight at 2- and 4-months post-randomisation
4. 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 baseline, 2- and 4-months post-randomisation
5. Perceived stress assessed using the short form perceived stress scale (PSS-4) at baseline, 2- and 4-months post-randomisation
6. Quality of Life (QoL) assessed using PROMIS Global 10 v1.2 at 2-months and 4-months post-randomisation

Mediators:
1. Importance of change, assessed on a scale from 1 to 10 at baseline, 1-, 2- and 4-months post-

randomisation
2. Confidence in one’s ability to change, assessed on a scale from 1 to 10 at baseline, 1-, 2- and 4-months post-randomisation
3. Knowledge of how to change, assessed on a scale from 1 to 10 at baseline, 1-, 2- and 4-months post-randomisation

Completion date
01/03/2024

Eligibility

Key inclusion criteria
Individuals will be included in the trial if they fulfil at least one of five conditions:
1. Weekly alcohol consumption: Consumed 10/15 (female/male) or more standard drinks of alcohol the past week. A standard drink of alcohol in Sweden is defined as 12 g 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 g of fruit and vegetables on average per day the past week
4. Moderate to vigorous physical activity: Spent less than 150 minutes on moderate to vigorous physical activity the past week
5. Smoking: Having smoked at least one cigarette the past week

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
5420

Key exclusion criteria
1. Individuals will be explicitly excluded if they do not fulfil any of the criteria or if they are less than 18 years of age
2. The trial information and intervention will be entirely in Swedish and delivered to participants’ mobile phones, thus not comprehending Swedish well enough to sign up or not having access to a mobile phone will implicitly exclude individuals

Date of first enrolment
31/10/2021

Date of final enrolment
19/10/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Linköpings Universitet
Linköpings Universitet
Linköping
Sweden
S-58183

Sponsor information

Organisation
Linköping University

ROR
https://ror.org/05ynxx418

Funder(s)

Funder type
Charity

Funder Name
Cancerfonden

Alternative Name(s)
Swedish Cancer Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/07/2022	27/07/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes