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Extending health examination and lifestyle health dialogue in primary care with a digital multiple health behaviour change intervention

Submission date	**Recruitment status**	[X] Prospectively registered
09/01/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
11/01/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/01/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Behavioural risk factors, such as harmful alcohol consumption, unhealthy diets, insufficient physical activity, and smoking, contribute to about a third of global disability-adjusted life years and are leading causes of non-communicable diseases (NCDs), including heart disease, lung disease, cancer and diabetes. The World Health Organization has determined that reducing the prevalence of behavioural risk factors should be a priority in many societies to reduce the incidence of NCDs and disability-adjusted life years. It is therefore important to establish effective and scalable means of helping individuals to improve their health behaviours.

Who can participate?
Patients aged 40, 50 and 60 years old who participated in a face-to-face health dialogue at participating primary healthcare units

What does the study involve?
Participants are randomly allocated to either immediate or delayed access to a digital behaviour change intervention. The intervention lasts for 4 months. Questionnaires are sent to all participants throughout the 6-month trial period.

What are the possible benefits and risks of participating?
Improving one's health behaviours prevents disease, and access to the digital intervention is hoped to help individuals change their behaviour. The main risk is that the intervention does not have the desired effects, and can therefore be demotivating for those who were hoping to get help.

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

When is the study starting and how long is it expected to run for?
January 2021 to March 2026

Who is funding the study?
1. The Swedish Cancer Society (Sweden)
2. The Swedish Research Council for Health, Working Life and Welfare (Sweden)

Who is the main contact?
Dr Marcus Bendtsen
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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
1.0

Study information

Scientific Title
A randomized controlled trial of a digital multiple health behaviour change intervention extending health examination and lifestyle health dialogue among primary care patients

Acronym
Coach-PV

Study objectives

A digital multiple health intervention improves health behaviours (alcohol, physical activity, diet, and smoking) when used as an extension to face-to-face health promotion within primary care, in comparison with no extended intervention.

The primary objectives of the study are to:
1. Estimate the effects of a digital multiple health intervention on individual health behaviours:
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
2. Estimate the degree to which the effects of the intervention are mediated through perceived importance, confidence, and know-how.
3. Evaluate the cost versus consequences of extending face-to-face health promotion within primary with a digital health intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2022, the Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46 (0)104750800; registrator@etikprovning.se), ref: 2022-04776-01

Study design
Parallel-group single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Improved health behaviours in primary health care patients

Interventions
Randomisation will be fully automated and computerised. Block randomisation will be used to allocate participants to the two conditions (random block sizes of 2 and 4). Neither research personnel nor participants will be able to influence allocation.

Participants are randomly allocated to either immediate or delayed access to a digital behaviour change intervention. The intervention lasts for 4 months. Questionnaires are sent to all participants throughout the 6-month trial period.

The digital intervention, which is called Coach Primary Care, is accessed using a mobile phone. The intervention is designed around social cognitive theories of behaviour change, with a focus on modifying environment, intention, and skills. The intervention’s components 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. The intervention materials can be accessed at participants’ discretion over a 4-month period, and each Sunday afternoon participants will receive a text message with a link and a reminder to access the intervention materials.

Intervention Type
Behavioural

Primary outcome(s)
All outcomes are measured using questionnaires at 2, 4, and 6 months post-randomization:
1. Alcohol: Weekly alcohol consumption will be assessed by asking participants the number of standard drinks of alcohol they consumed last week (short-term recall method). The frequency of heavy episodic drinking will be assessed by asking participants how many times they have consumed 4/5 (female/male) or more standard drinks of alcohol on one occasion in the past month.
2. Diet: Average daily consumption of fruit and vegetables will be measured utilising a questionnaire based on the previously published questionnaire by the National Board of Health and Welfare in Sweden, and was further modified to also include portion sizes. The consumption of fruit and vegetables will be measured using two questions concerning the number of portions (100 g) of fruit and vegetables (respectively) the participants ate on average per day during the past week.
3. Physical activity: Weekly moderate to vigorous physical activity (MVPA) will be estimated by summing responses to two questions regarding the number of minutes spent on moderate and vigorous physical activity, respectively, during the past week.
4. Smoking: Four-week point prevalence of smoking abstinence (number of cigarettes in the past 4 weeks) will be asked as a binary question.

Key secondary outcome(s))
All secondary outcomes are measured using questionnaires at 2, 4, and 6 months post-randomization:
1. Perceived stress assessed using the short form perceived stress scale (PSS-4)
2. Weekly consumption of sugary drinks measured by a question regarding the number of units (33 cl) of sugary drinks participants consumed the past week
3. Weekly consumption of candy and snacks measured using a single question regarding number of servings consumed last week
4. Body mass index (BMI) measured by asking participants to report their weight and height
5. Weekly number of cigarettes smoked: Participants who have smoked any cigarette the past four weeks will be asked for the number of cigarettes smoked in the past week
6. Quality of life (QoL) measured using PROMIS Global 10

Completion date
01/03/2026

Eligibility

Key inclusion criteria
Individuals aged 40, 50 and 60 years old, living in the county of Östergötland (in the south-east part of Sweden) will be invited to a health dialogue with a healthcare professional at their primary healthcare clinic. Participants will be recruited from approximately 30 primary healthcare clinics. After completing the health dialogue, all individuals will be given brief verbal information about the Coach Primary Care study. 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 is in Sweden 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 in the past month
3. Fruit and vegetables: Consumed less than 500 grams 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 in the past week

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. 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
20/01/2023

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University
Linköping University
Linköping
Sweden
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

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

Data will be made available to researchers upon reasonable request, after approval of a research proposal and signing of data transfer agreements, from Marcus Bendtsen (marcus.bendtsen@liu.se), including responses to questionnaires (anonymized) from 2026 onwards. Consent is obtained from all participants. Any request for data must first have been approved by The Swedish Ethical Review Authority.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			13/01/2023	No	No
Statistical Analysis Plan			13/01/2023	No	No