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A pilot community outreach intervention with digital health coaching for the prevention of cardiometabolic diseases in socioeconomically disadvantaged neighbourhoods in Uppsala, Sweden

Submission date
26/02/2025

Recruitment status
No longer recruiting

Registration date
05/03/2025

Overall study status
Completed

Last Edited
30/01/2026

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Cardiometabolic diseases (CMDs), including type 2 diabetes (T2D), heart disease and stroke, are major public health concerns, largely influenced by lifestyle factors such as physical inactivity, poor diet and smoking. In Sweden, around half a million people have diabetes, mostly T2D, and many cases go undiagnosed. Cardiovascular disease remains the leading cause of death, with risk factors showing clear social and economic disparities—socioeconomically disadvantaged populations face higher risks.

Swedish healthcare provides treatment and prevention efforts primarily through primary care, with lifestyle modification as a key strategy. However, access to prevention services varies between regions, and few patients receive practical guidance on improving diet and physical activity. Moreover, many individuals struggle to integrate health recommendations into daily life. While national guidelines exist, outreach efforts remain limited. The COVID-19 pandemic further disrupted prevention efforts, making innovative and accessible interventions more urgent.

The PREVENT project builds on findings from previous research, including the SMART2D study, which showed that telehealth coaching and community-based interventions can be effective in supporting sustained healthy and active living. Through co-design workshops and ethnographic studies, we have identified key barriers to physical activity and healthy eating in socioeconomically disadvantaged communities in Uppsala, emphasizing the need for social support and stronger collaboration with local stakeholders including public, private and non-governmental sectors.

The aim of this study is to test the feasibility of a combined telehealth coaching and codesigned community outreach intervention to promote healthy and active living in socioeconomically disadvantaged areas in Uppsala. The goal is to implement and test community support and referral pathways, with the potential to empower individuals and families to sustain healthy and active living while assessing the potential for future scale-up.

Who can participate?
People aged 30-75 years who are at high risk for cardiometabolic diseases, residing in socio-economically disadvantaged neighbourhoods in Uppsala, Sweden

What does the study involve?
All participants will receive the same PREVENT intervention. This will be delivered over 12 months. The first 6-months consist of telehealth coaching sessions (ranging from four to ten sessions based on need). These sessions focus alternately on diet and physical activity. The last 6 months include maintenance sessions with the coach for continued support as needed. Parallelly, community outreach activities such as referrals and inspiration sessions will be offered to all participants. They will be connected and or referred to local community resources for healthy and active living. Further, inspiration sessions will be open for participants and the larger community during the intervention period to provide info on physical activity, diet and prevention of chronic diseases.
Measurements taken during the pilot study will include finger-prick blood tests (lipid and HbA1c), as well as other measures like blood pressure, weight and waist circumference. Participants will fill out questionnaires related to their household, profession, education, overall health, nutrition and physical activity. Further measurements will be collected to assess physical activity over a 7-day period using an accelerometer. Lastly, participants will be asked to use a mobile app to detail their food purchases and food preparation over a 7-day period.

What are the possible benefits and risks of participating?
Participants can gain valuable knowledge about preventing CMDs and other related diseases through healthier eating and physical activity. They will receive support to sustain a healthier and more active life and may be referred for further medical care if needed. Risks are minimal but may include slight discomfort during blood sampling and feeling uneasy during interviews. All data collected will be securely handled to protect privacy.

Where is the study run from?
The Global Health and Migration Unit at the Department of Women's and Children's Health at Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?
March 2024 to June 2026

Who is funding the study?
1. The Swedish Research Council (Sweden)
2. The Swedish Diabetes Foundation (Sweden)
3. Uppsala Diabetes Centre (Sweden)
4. The Familjen Ernfors Foundation (Sweden)
5. The Nils Erik Holmsten Foundation (Sweden)

Who is the main contact?
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Study information

Scientific Title
The PREVENT pilot: Testing the content and processes of a codesigned community outreach and telehealth coaching for the prevention of cardiometabolic diseases in socioeconomically disadvantaged neighbourhoods in Uppsala, Sweden

Acronym
PREVENT

Study objectives
Utilizing findings from the formative research of the PREVENT project, we have conceptualized an interaction between neighbourhood systems (including the health system) and communities for the prevention of cardiometabolic diseases. The approach is to empower individuals at high risk for cardiometabolic diseases (and their families) to engage in and sustain healthy and active living, with a focus on healthy diet and physical activity, through supported self-management. The pilot is designed to evaluate the content, processes and protocols of a telehealth coaching and linked community outreach intervention for the prevention of cardiometabolic diseases.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/08/2024, The Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2024-04379-01

Primary study design
Interventional

Study design
Pilot non-randomized study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Cardiometabolic disease (CMD), defined as an umbrella term for a set of diagnoses that includes diabetes, stroke and ischaemic heart disease, and cardiometabolic syndrome

Interventions
The PREVENT project pilot is designed to evaluate the content, processes and protocols of the telehealth coaching and community outreach.

The framework developed in SMART2D and applicable for the PREVENT intervention is based on the Self-Determination Theory and built on the understanding that self-management behaviors result from a continuous and reciprocal interaction between the individual and his or her proximal environment. This interaction is critical to allow sustained changes in healthy and active living and in turn reductions in biochemical and anthropometric parameters.

The PREVENT intervention will be delivered over 12 months. A minimum of four telehealth coaching sessions will be delivered during an initial six-month period focusing alternately on diet and physical activity topics with three to six maintenance/support sessions over 6 months. The number of coaching sessions and maintenance sessions will be dependent on the individual's sense of coherence score/grouping and their need for individual support. The telehealth coaching will be delivered by trained facilitators using a guide with a focus on Strength-Based Behavioural Coaching and goal setting. The telehealth coaching is connected to a community outreach component through referrals to community resources and inspiration sessions co-organized with stakeholders. The intervention will be delivered in Swedish, English and Arabic.

The Tele-Health Coaching:
Brief motivational coaching for behavior change is based on autonomy support integrated into a strength model and a participatory, appreciative approach, i.e., the aim is to identify existing healthy habits and self-management behaviors and help the individual build further changes onto these strengths. It will be delivered on an individual basis either over a phone call or via video call (i.e. secure Zoom links shared with the participant via WhatsApp or SMS), and each session will last approximately 10-25 minutes. SMS reminders about set goals and next session dates will be sent out to participants in between the telehealth coaching sessions.

Depending on the individual’s sense of coherence level, the support may be adapted to suit their specific needs. For some groups, this may mean that they will receive fewer sessions and can choose which sessions they find relevant and in which order they would like to receive them.

Community Outreach:
Community outreach runs parallel to and is linked to the telehealth coaching in two ways: 1) PREVENT is identifying community resources with the help of local stakeholders including the municipality, which include activities and actors who offer specific activities or support to residents in the neigbourhoods. Participants in the trial will be connected to these resources through referrals, based on their individual needs and interests. Local stakeholders will share and inform about local community resources that relate to healthy and active living; 2) Inspiration sessions that will be open for participants as well as their family, friends and other interested community members will be co-organized with stakeholders over the 12-month intervention period. This will include expert-facilitated and peer-interactive sessions on physical activity, diet, prevention of chronic diseases and local community resources, to name a few.

Maintenance Sessions:
After the telehealth coaching sessions all participants will move into a 6 month-maintenance period, tailored by sense of coherence grouping. During a 6-month period we are expecting that the highest sense of coherence group will have a minimum of 3 maintenance sessions and that the lowest sense of coherence group will have a maximum of 6 sessions. Maintenance sessions will include short follow-ups or text-based support or reminders that will be focused on checking on participants' goals, struggles and triggers associated with staying healthy and active. Participants will also have the added opportunity to reach out to their facilitator/coach in case they need additional support during this period.

Intervention Type
Behavioural

Primary outcome(s)
The primary aim of this pilot is to test the content, processes, tools and protocols of a future intervention trial. The following will be assessed:
1. The number of people recruited from among eligible participants during the recruitment period
2. Attrition rate assessed using the number of participants who consent to participate who remain in the study until the end of follow-up at 12 months
3. The proportion who complete different measures: physical activity, diet measures, Point of Care (the number who complete each of these tools at different timepoints throughout the pilot)

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/05/2025:

1. The individual is at high risk for cardiometabolic diseases based on the Finnish Diabetes Risk Score (FINDRISC) > 12
2. Be residents of the selected suburbs (via postal code) in Uppsala as described above
3. Have either a Swedish personal or coordination number

4. If female: self-reporting gestational diabetes or impaired glucose tolerance during any pregnancy (regardless of the FINDRISC score)

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Previous inclusion criteria:

1. The individual is at high risk for cardiometabolic diseases based on the Finnish Diabetes Risk Score (FINDRISC) > 12 and answered 'negatively' to either of the following behavioural questions:
1.1. Do you usually have daily at least 30 min of physical activity at work and/or during leisure time? (yes, no)
1.2. How often do you eat vegetables, fruit or berries? (every day, not every day)
2. Be residents of the selected suburbs (via postal code) in Uppsala as described above
3. Have either a Swedish personal or coordination number
4. If female: self-reporting gestational diabetes or impaired glucose tolerance during any pregnancy (regardless of the FINDRISC score)

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. If the individual is less than 30 years or older than 75 years old at the time of recruitment
2. Self-reported pregnancy and physical or mental disability that could severely compromise their ability to be physically or cognitively active
3. Self-reported diabetes, stroke or heart disease (primarily ischaemic heart disease and myocardial infarction)
4. If the individual is planning to move out of Uppsala Kommun over the next 18 months from the date of enrollment in the study
5. If the individual has not resided in Uppsala Kommun for at least 3 months prior to enrollment
6. If the individual is involved in other intervention studies related to diet or physical activity and /or specifically for any of the cardiometabolic diseases (diabetes, stroke or heart disease)

Note: Participants will be recruited to ensure a distribution of both gender and sense of coherence.

Date of first enrolment
03/03/2025

Date of final enrolment
03/06/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University
MTC-huset, Department of Women's and Children's Health
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Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Government

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
The Swedish Diabetes Foundation

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Nils Erik Holmsten Foundation

Funder Name
Stiftelsen Familjen Ernfors Fond

Alternative Name(s)
Family Ernfors Foundation, Ernfors Family Foundation

Funding Body Type
Private sector organisation

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

Location
Sweden

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon reasonable request from Meena Daivadanam (meena.daivadanam@uu.se).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes