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# Can lifestyle guidance reduce the risk of diabetes and cardiovascular diseases?

**Submission date**
04/03/2025

**Recruitment status**
Recruiting

**Registration date**
13/03/2025

**Overall study status**
Ongoing

**Last Edited**
01/10/2025

**Condition category**
Nutritional, Metabolic, Endocrine

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

**Plain English summary of protocol**
Background and study aims
HALT2Diabetes is a program, implemented by the Diabetes Liga in Flanders (Belgium), which screens individuals for increased risk of developing type 2 diabetes and cardiovascular (heart) diseases and provides lifestyle guidance for those identified with high-risk factors. The program seeks to reduce the risk and prevent the onset of these conditions. This study aims to evaluate the effectiveness of the lifestyle guidance sessions within the ongoing HALT2Diabetes program.

Who can participate?
Adults at high risk of developing type 2 diabetes can take part in this study. Eligible participants have a FINDRISC score of 12 or higher or have been assessed by a GP, have a GP referral for lifestyle guidance sessions, live in or near a participating primary care region, and can provide written informed consent. To fully benefit from the program, participants should be able to take part in lifestyle guidance sessions and have sufficient knowledge of Dutch to follow the sessions.

What does the study involve?
Participants will take part in six group sessions spread over 6 months. These sessions are led by a trained dietitian and focus on healthy eating (practical tips, meal planning), getting more exercise (integrating physical activity into daily life) and sustainable behavioural changes (dealing with challenges, setting goals).
During the first group session, the researchers will ask participants to complete a questionnaire to identify their baseline data. For some participants, there will also be a small blood draw using a Tasso device to measure their HbA1c (blood sugar) and cholesterol levels, and blood pressure will be measured. Both activities are done under the supervision of a trained nurse. During group sessions 5 and 6, measurements will be taken again during or after the group sessions. Finally, about 6 and 12 months after group session 6, the researchers again ask each participant to complete a questionnaire and invite some participants to have a blood draw. Both the questionnaire and blood draw can be done independently at home.
During the introductory and follow-up measurements, the researchers will ask participants to complete questionnaires about (1) nutrition and exercise habits, (2) knowledge about diabetes and health, and (3) motivations and challenges with behavioural changes.

What are the possible benefits and risks of participating?
This study has several benefits for participants. It will help them better understand their health and make informed choices. A dietitian will provide practical advice to develop healthy habits that fit into everyday life. By taking part, they will also contribute to important research on preventing diabetes, which could help others in the future.
However, the study requires some time investment over 18 months. Some measurements, such as blood draws, may cause mild discomfort. Additionally, participants may face risks related to psychological stress, particularly if they feel judged based on their health behaviors or encounter challenges in adhering to recommended lifestyle changes. The process of monitoring biochemical and physical measures, such as weight and blood tests, could cause anxiety, even though these procedures are minimally invasive. Moreover, participants may experience frustration or disengagement if they do not perceive immediate improvements in their health outcomes. To address these risks, the study will emphasize the creation of a supportive and non-judgmental environment during lifestyle guidance sessions. Dietitians are trained in motivational interviewing techniques, enabling them to provide personalized guidance that respects individual needs and challenges. Participants will be reassured of the study's goal to provide constructive support rather than criticism. Clear communication of realistic expectations will help participants stay engaged and motivated. Complaints related to the HALT2Diabetes project can be submitted through various channels such as a dedicated email address or satisfaction surveys.

Where is the study run from?
Diabetes Liga Flanders and the University of Antwerp (Belgium)

When is the study starting and how long is it expected to run for?
July 2024 to August 2027

Who is funding the study?
This study is part of JACARDI - Joint Action on Cardiovascular Disease and Diabetes, which has received funding from the EU4Health Programme 2021-2027 under Grant Agreement 101126953

Who is the main contact?
William Leysen, william.leysen@diabetes.be

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# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**ClinicalTrials.gov (NCT)**
Nil known

**Protocol serial number**
Nil known

# Study information

**Scientific Title**
HALT2DIABETES-JACARDI: evaluating the effectiveness of lifestyle guidance sessions in individuals at increased risk of type 2 diabetes and cardiovascular diseases

**Acronym**
HALT2DIABETES-JACARDI

**Study objectives**
The primary hypothesis is that the HALT2DIABETES lifestyle intervention, specifically its lifestyle guidance sessions, will result in significant changes in health outcomes and healthy lifestyle behavior in participants. The aim of this study is to implement and evaluate the effectiveness of lifestyle guidance sessions within the HALT2DIABETES program.

Objective 1:
To evaluate the effectiveness of the lifestyle guidance sessions within the HALT2DIABETES program on health outcomes, by assessing the differences before and after the intervention for all participants of the sessions, in: (primary outcomes) weight, waist circumference, HbA1c; (secondary outcomes) blood pressure, BMI, cholesterol.

Objective 2:
To evaluate the effectiveness of the lifestyle guidance sessions within the HALT2DIABETES program on behavioral outcomes, by assessing the differences before and after the intervention for all participants of the sessions, in: (primary outcome) dietary habits; (secondary outcome) tobacco use, physical activity, health literacy, diabetes-related knowledge.

Objective 3:
To explore differences in the effectiveness of the lifestyle guidance sessions within the HALT2DIABETES program on behavioral outcomes between relevant subgroups of participants, based on sociodemographic background, health literacy and diabetes-related knowledge.

Objective 4:
To evaluate the reach and the diversity within reach of the HALT2DIABETES program, by assessing the risk profile data from the risk assessment tool and comparing them with the risk profile data of the intervention program participants, as well as by assessing the sociodemographic characteristics of the program participants.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 17/02/2025, Ethisch Comité van het Universitair Ziekenhuis Antwerpen (ethics committee of Antwerp University Hospital ) (Drie Eikenstraat 655, Edegem, 2650, Belgium; +32 (0)3 821 38 97; ethisch.comite@uza.be), ref: BUN B3002025000014

## Study design
Pre-post study design with a single study arm

## Primary study design
Interventional

## Study type(s)
Prevention, Screening

## Health condition(s) or problem(s) studied
Type 2 diabetes and cardiovascular diseases

## Interventions
The HALT2DIABETES intervention encompasses six face-to-face lifestyle guidance group sessions (3-15 participants) led by a trained dietitian. The sessions focus on promoting healthier eating habits, increasing physical exercise and healthy behavior modifications. The session content is oriented towards daily living and tailored to individuals with high-risk profiles. Techniques such as nudging, engaging communication, and retrieved from self-determination theory are applied to foster sustainable behavior change.

A vast majority of study participants are recruited through an online risk assessment tool developed in Dutch (Gezondheidskompas, available at https://www.gezondheidskompas.be/), which serves as the entry point to the HALT2Diabetes program. It is freely accessible and optimized for different devices. The risk assessment tool includes questions to calculate a FINDRISC score (age, BMI, waist circumference, daily physical activity, the daily consumption of vegetables, fruits, and berries, a history of regular use of blood pressure medication, a history of elevated blood glucose and family history of diabetes). Additionally, it gathers information on gender, smoking habits, postal code, family history of CVDs and personal history of diabetes and CVDs. Finally, the users are asked how they learned about Gezondheidskompas. All information collected through the risk assessment tool is stored at an aggregate level, precluding the individual identification of users by observers. All users receive a personalized lifestyle report, while those with a FINDRISC score of 12 or higher are provided with the recommendation to

evaluate their personal risk assessment with a GP in their primary care region. A unique code enables a GP to access the risk assessment results anytime or users may opt to forward the results directly to a GP via the online tool. Individuals identified as high risk can only participate in the intervention after being referred by a GP to lifestyle guidance sessions organized in the primary care regions included in the study. An alternative route to the study is the completion of the risk assessment by a GP or another health professional, together with a patient either online or by means of a paper-and-pencil version before referring to the intervention. In addition, GPs may refer individuals to the intervention based on other parameters besides FINDRISC, such as a history of gestational diabetes or stress hyperglycemia.

The study will be carried out in 30 primary care regions that are part of the HALT2Diabetes program implemented by the Diabetes Liga. At the start, two to five new primary care regions will be introduced to the program, leading to a total of 32-35 regions in Flanders included in the study. In each primary care region individuals can enroll in the intervention and opt into the study. The lifestyle guidance sessions are conducted face-to-face at central locations in the participating primary care regions. All study participants will be examined on multiple occasions (between the start of the intervention and 18 months later). The study focuses on individual changes in behavioral and health outcomes over time.

Each participant will be involved in the study for a total of 18 months, with the intervention occurring during the first 6 months. The study design includes five measurement points over time: t0 at baseline (start of the first session), t1 after three months (end of the fifth session), t2 after 6 months (end of the sixth [follow-up] session), t3 after 12 months and t4 after 18 months. Each measurement point involves repeated data collection (e.g. biochemical measures). At t0, single-time surveyed information (e.g. sociodemographic characteristics at baseline) is gathered as well.

## Intervention Type
Behavioural

## Primary outcome(s)
1. Weight is measured using a self-reported questionnaire at baseline, month 3, month 6, month 12, and month 18
2. Waist circumference is measured using a self-reported questionnaire at baseline, month 3, month 6, month 12, and month 18
3. HbA1c is measured using a Tasso device at baseline, month 3, month 6, month 12, and month 18
4. Dietary habits are measured using a 16-item Food Intake Questionnaire (D2D-FIQ) at baseline, month 3, month 6, month 12, and month 18

## Key secondary outcome(s))
1. BMI is measured using a self-reported questionnaire at baseline, month 3, month 6, month 12, and month 18
2. Blood pressure is measured using an electronic sphygmomanometer at baseline, month 3, and month 6
3. Cholesterol is measured using a Tasso device at baseline, month 3, month 6, month 12, and month 18
4. Physical activity is measured using the WHO STEPS questionnaire at baseline, month 3, month 6, month 12, and month 18
5. Tobacco use is measured using the WHO STEPS questionnaire at baseline, month 3, month 6, month 12, and month 18

6. Diabetes-related knowledge is measured using the Diabetes Knowledge Questionnaire Revised (DKQ-R) at baseline, month 6, month 12
7. Health literacy is measured using the European Health Literacy Survey Questionnaire (HLS-EU-Q6) at baseline, month 6, month 12

### Completion date
31/08/2027

## Eligibility

### Key inclusion criteria
In order to be eligible, study participants must:
1. Be at a high risk of developing type 2 diabetes (FINDRISC score ≥ 12 or by assessment of a GP)
2. Receive a GP referral to lifestyle guidance sessions
3. Live in or close to a participating primary care region being part of the study
4. Be willing and able to provide written informed consent

### Participant type(s)
Other

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. A previous diagnosis of diabetes or (a) CVD(s) (excluding hypertension)
2. Physical or psychological disabilities preventing the participation in a lifestyle guidance program
3. Insufficient knowledge of Dutch to follow the lifestyle guidance sessions

### Date of first enrolment
15/04/2025

### Date of final enrolment
31/08/2027

## Locations

### Countries of recruitment
Belgium

### Study participating centre

**Diabetes Liga**
Ottergemsesteenweg 456
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# Sponsor information

**Organisation**
University of Antwerp

**ROR**
https://ror.org/008x57b05

# Funder(s)

**Funder type**
Government

**Funder Name**
EU4Health Programme 2021-2027

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be made available upon reasonable request and are available from the principal investigator (Prof. Dr. Josefien Van Olmen; josefien.vanolmen@uantwerpen.be). Researchers will need to sign a Data Sharing Agreement to protect the integrity and confidentiality of the requested data. Any shared data will be further minimized and anonymized as possible for the requested purpose.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 30/09/2025 | 01/10/2025 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |