ISRCTN10030245 https://doi.org/10.1186/ISRCTN10030245

A supportive plan for people with type 2 diabetes who do not achieve their treatment goals

Submission date
29/09/2020

Recruitment status
Recruiting

Registration date
01/10/2020

Overall study status
Ongoing

Last Edited
04/12/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] 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
Type 2 diabetes is a common condition where the level of sugar in the blood is too high. There is a need for strategies regarding the treatment and support for patients with type 2 diabetes who don’t reach their treatment goals. One of these strategies can be individual care-planning. There is some evidence that patient-centered care-planning can affect blood sugar and self-management ability. These effects are more visible if the individual care planning is integrated into routine care and if the patient receives a written care plan. There are only a few studies where a specific well-described written care plan is examined in a group of patients with type 2 diabetes. Two such studies have demonstrated some evidence for improved clinical outcomes such as blood sugar levels. The aim of this study is to find out whether a written individual care plan for persons with type 2 diabetes and inadequate self-management capability can affect blood sugar levels, the experience of living with diabetes and the support from the diabetes care as well as the patient's health-related quality of life.

Who can participate?
Patients with type 2 diabetes who have high blood sugar levels and have had diabetes for more than 5 years

What does the study involve?
All participants will receive usual care and those randomly allocated to the intervention group will receive the individual care plan. Blood sugar levels (HbA1c), blood pressure, lipids, health-related quality of life and the participant’s experience of living with diabetes and the experience of support from healthcare are assessed.

What are the possible benefits and risks of participating?
The study is not associated with any known increased risks. The questionnaires are well-known and widely used. All data will be stored in a digital form in encrypted files or in a locked cabinet. All personal data will be managed in accordance with the General Data Protection Regulation (GDPR).

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

When is the study starting and how long is it expected to run for?
April 2020 to December 2026

Who is funding the study?
1. Region of Uppsala research and development funds (Sweden)
2. The Family Ernfors fund (Sweden)

Who is the main contact?
Jessica Rosman
jessica.rosman@medsci.uu.se

Contact information

Type(s)
Public

Contact name
Mrs Jessica Rosman

Contact details
Medicinska vetenskaper, ingång 40
5 tr Akademiska sjukhuset
Uppsala Universitet
Uppsala
Sweden
75185
+46 (0)704568377
jessica.rosman@medsci.uu.se

Type(s)
Scientific

Contact name
Mrs Jessica Rosman

Contact details
Medicinska vetenskaper, ingång 40
5 tr Akademiska sjukhuset
Uppsala Universitet
Uppsala
Sweden
75185
+46 (0)704568377
jessica.rosman@medsci.uu.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Individual goal-based plan based on nursing theory for adults with type 2 diabetes and self-care deficits: a randomised controlled trial

Study objectives
A written individual care plan can affect glycemic control, the experience of living with diabetes and the support from the diabetes care as well as the patient's quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2020, The Ethical Review Authority in Uppsala, Sweden (Etikprövningsmyndigheten, Uppsala, Sverige; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: 2020-03421

Study design
Multi-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Type 2 diabetes with inadequate self-management

Interventions

Patients will be asked about participation in connection with their annual check-up at the primary care diabetes nurse. Several primary care units in the Region of Uppsala will be participating in recruiting patients. Approximately 20 study participants will be asked to take part in the qualitative interview study. Both patients for whom the intervention has had a good and effect on glycemic control and patients for whom there was no effect will be included.

Randomization
Included patients will be randomized to either the control or intervention group. Randomization lists will be generated using IBM SPSS Statistics 26.0 software. A person who is not involved in the study will prepare and seal opaque envelopes marked and numbered from 1 to 110. The envelopes will contain a card regarding the group allocation and, for the intervention group, a copy of the written individual care-plan. The envelopes will be opened when a patient is included in the study, and the patient's serial number and social security number will then be sent to the responsible study nurse.

Intervention
During the routine appointment, participants in the intervention group will be offered to create their personal goals using the written individual care-plan. This is done in collaboration with the diabetes nurse. The care plan is intended to support the patients to establish relevant and feasible goals regarding their diabetes self-management. The care-plan is designed according to the principles of person-centered care.

The patients get an opportunity to reflect on the following topics:
1. What is important to me regarding my diabetes care?
2. What is my personal treatment goal and when do I want it to be achieved?
3. What am I doing right now or what do I plan to do to achieve my goal?
4. How do I want the primary care center to help me achieve my goal?

The nurse encourages the participant to write down their individual reflections and goals regarding their self-management on the care plan. The participant's current and target measurements regarding HbA1c, LDL, blood pressure, and other individual target measurements are filled out. The care plan also includes an explanatory scale of the relationship between blood glucose and HbA1c.

Patients then get a copy of the care plan and a customized follow-up plan is set up. The follow-up is individualized based on the participant's individually set self-management goals. The goals and follow-up plan is documented in the patient chart.

On the back of the care plan, there is brief information about the support and care offered at the primary care center regarding type 2 diabetes. There is also short information about pharmaceutical treatment regarding diabetes, blood pressure, and lipids.

In addition to the care plan, both intervention and control group participants receive usual care.

Intervention Type

Behavioural

Primary outcome measure

HbA1c measured using capillary electrophoresis in mmol/mol at baseline, 6 and 12 months. Data will be collected from the National Diabetes Registry.

Secondary outcome measures
1. Blood pressure measured manually at baseline, 6 and 12 months. Data will be collected from the National Diabetes Registry
2. LDL, HDL and triglycerides measured in mmol/L at baseline, 6 and 12 months. Data will be collected from the National Diabetes Registry
3. Health-related quality of life measured with RAND-36 at baseline, 6 and 12 months
4. Change in the experience of living with diabetes and of the support from the diabetes care measured with “The Diabetes Questionnaire” at baseline, 6 and 12 months. Data will be collected from the National Diabetes Registry

Overall study start date
21/04/2020

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. HbA1c ≥58 mmol/mol
2. Diabetes duration ≥5 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
110 participants

Key exclusion criteria
1. Cognitive impairment
2. Inability to read and understand the Swedish language and to autonomously fill out current questionnaires due to physical impairment

Date of first enrolment
02/09/2021

Date of final enrolment
24/12/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Region of Uppsala, Primary Care
Dragarbrunnsgatan 46
Uppsala
Sweden
75320

Sponsor information

Organisation
Uppsala University

Sponsor details
Medicinska vetenskaper, ingång 40
5 tr Akademiska sjukhuset
Uppsala
Sweden
79185
+46 (0)18 471 00 00
registrator@uu.se

Sponsor type
University/education

Website
https://www.uu.se/en/

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Charity

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
Region Uppsala

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The researchers intend to publish a study-protocol as soon as possible.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of informed consent from the participants to share material outside the research group. In addition, the researchers do not have ethical approval for sharing data material outside the research group

IPD sharing plan summary
Not expected to be made available