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Behavioural medicine for lower-educated patients with type 2 diabetes: the effectiveness and implementation of a tailored intervention in primary care

Submission date
21/03/2022

Recruitment status
No longer recruiting

Registration date
29/03/2022

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
This study is focused on behavioural medicine for lower educated type 2 diabetes patients. This study aims to test the effectiveness of a behavioural programme in lower educated type 2 diabetes patients in primary care.

Who can participate?
Eligible participants are between 35 and 70 years old and should be diagnosed at least one year with type 2 diabetes.

What does the study involve?
Patients in the intervention group will receive the behavioural programme 'Powerful together with diabetes' for 27 weeks in weekly group sessions, patients in the control group receive standard care. The 'Powerful together with diabetes' programme aims to support and empower patients to improve their diabetes self-management such as control of blood sugar levels (glycaemic control) and medication adherence. Improvement in glycaemic control will be compared across the intervention and control groups using data from routinely collected blood samples. Participants will also complete questionnaires on their quality of life throughout the study.

What are the possible benefits and risks of participating?
The benefits of participating are that patients' glycaemic control is improved and improvement of their medication adherence and quality of life.

Where is the study run from?
Amsterdam UMC, location AMC (Netherlands)

When is the study starting and how long is it expected to run for?
From February 2021 to October 2025

Who is funding the study?
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Who is the main contact?
Bedra Horreh
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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
555003202

Study information

Scientific Title
The DISC-2 (Diabetes in Social Context) study: an effectiveness-implementation hybrid evaluation of a group-based self-management intervention for lower educated T2DM patients

Acronym
DISC-2

Study objectives
Glycaemic control is improved in patients receiving the behavioural programme 'Powerful together with diabetes' as compared to patients not receiving the programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/02/2022, Medical Ethics Committee of the Academic Medical Center (AMC), (Meibergdreef 9, 1105 AZ, Amsterdam; +310205667389; mecamc@amsterdamumc.nl), ref: 2021_222 - NL79337.018.21

Study design
Single center interventional quasi-experimental non-randomized trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Current interventions as of 16/10/2024:

Patients in GP practices receive in the intervention group the 'Powerful together with diabetes' program in 27 weekly group sessions. Patients in the control group receive standard care.

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Previous interventions:

Patients in GP practices receive in the intervention group the 'Powerful together with diabetes' program for 1 year in weekly group sessions. Patients in the control group receive standard care.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 16/10/2024:

HbA1c levels are retrieved from GP registries through a database owned by a GP collective at baseline, 12, and 24 months

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Previous primary outcome measure:

HbA1c levels are retrieved from GP registries through a database owned by a GP collective at baseline, 6, 12, and 24 months

Key secondary outcome(s))
Current secondary outcome measures as of 16/10/2024:

1. Prescribed diabetes type 2 medication is retrieved from GP registries from a database owned by a GP collective at baseline, 12, and 24 months
2. Use of primary and specialist care is retrieved from GP registries from a database owned by a GP collective at baseline, 12, and 24 months
3. Quality of life is measured through a questionnaire at baseline, 6, 12, and 24 months (in the intervention group only)

Previous secondary outcome measures:

1. Prescribed diabetes type 2 medication is retrieved from GP registries from a database owned by a GP collective at baseline, 6, 12, and 24 months
2. Use of primary and specialist care is retrieved from GP registries from a database owned by a GP collective at baseline, 6, 12, and 24 months
3. Quality of life is measured through a questionnaire at baseline, 6, 12, and 24 months (in the intervention group only)

Completion date
15/10/2024

Eligibility

Key inclusion criteria
1. At least one year since diagnosed with type 2 diabetes
2. Aged >35 and <70 years
3. Current diabetes self-management education is insufficient

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
70 years

Sex
All

Key exclusion criteria

1. Objection against participation from the GP
2. A psychiatric disorder which hampers participation
3. Being unable to come to the intervention location independently
4. Planning to stay abroad for a longer time during the intervention period

Date of first enrolment
14/02/2022

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC, location AMC
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Amsterdam University Medical Centers

ROR
https://ror.org/05grdyy37

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Bedra Horreh (b.horreh@amsterdamumc.nl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/01/2025	20/01/2025	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