

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

<b>Submission date</b> 21/03/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/01/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**Contact name**  
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## Additional identifiers

**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)

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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?
<a href="#">Protocol article</a>		09/01/2025	20/01/2025	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes