# Diabetes in Social Context Study 2

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON50377

**Source**
ToetsingOnline

**Brief title**
DISC-2 study

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
type 2 diabetes mellitus; sugar diabetes

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC locatie AMC
**Source(s) of monetary or material Support:** ZonMw programma Leefstijlgeneeskunde

### Intervention

**Keyword:** health behavior, lower socio-economic status, self-management program, type 2 diabetes type

## Outcome measures

### Primary outcome

The primary endpoint of the DISC-2 study is a 5% decrease in HbA1c in the intervention group against no decrease in HbA1c in the control group, measured at 12 months after intervention patients started in the PTWD program.

### Secondary outcome

Secondary study outcomes include:

- prescribed T2D medication and use of primary and secondary care

- blood pressure and anthropometrics

- diabetes-related distress, depression and quality of life

- diabetes-related coping behaviors, other health-related behaviors

# Study description

### Background summary

Type 2 diabetes (T2D) is highly prevalent in lower-educated persons. The Powerful Together With Diabetes (PTWD) program is tailored to the specific needs of this target group. Our hypothesis is that participation in the program will improve diabetes self-management behaviours and blood glucose levels in lower-educated T2D patients.

### Study objective

The main study objective is to examine the effect of the PTWD program on glycaemic control of lower-educated participants with T2D. The secondary objectives include the effect on medication use, use of care and T2D self-management behaviours. We also assess conditions for implementation of the PTWD program in the primary care setting.

### Study design

The effect of the program on glycaemic control is evaluated in a

quasi-experimental design, most other outcomes are assessed in observational studies.

### Intervention

On top of usual care, intervention patients participate in the tailored PTWD diabetes self-management program, including trainer-led group meetings for a period of 1.5 years. T2D patients in the control group receive primary care as usual.

### Study burden and risks

The burden of the study relates to the intervention condition only. At four points of time, we measure blood pressure and anthropometrics. Also, a structured interview is held by a trained interviewer (e.g., T2D self-management behaviors). Other data for both intervention and control patients will be collected from the GP information system (HIS) through the Academic Network of General Practice (ANHA). Physical and physiological discomfort associated with participation in the DISC-2 study is expected to be negligible. Participation of lower educated T2D patients is needed because their specific needs are not being adequately addressed by other diabetes self-management programs.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)

### Inclusion criteria

being diagnosed with type 2 diabetes mellitus (T2D) since at least 1 year, aged > 35 and < 70 years, lower educational level (pre-vocational training at the highest), in need of more than standard care to support adequate T2D self-management

### Exclusion criteria

- objection against participation from the general practitioner
- a psychiatric disorder which hampers participation in the self-management program
- being unable to come to the intervention location independently
- planning to stay abroad for a longer time during the intervention period

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Health services research |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2022 |
| Enrollment: | 152 |
| Type: | Anticipated |

## Ethics review

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| Approved WMO Date: | 04-02-2022 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| CCMO | NL79337.018.21 |