

# Consequences of reducing hypoglycemia-inducing glucose-lowering medication (medication that lowers glucose (sugar) levels in the blood and can cause low blood sugar) in people with type 2 diabetes of 70 years or older

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
02/03/2023	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input checked="" type="checkbox"/> Statistical analysis plan
09/03/2023	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
30/01/2026	Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Older people with type 2 diabetes have a higher risk of health problems like low blood sugar, disability, and death from diabetes medications. In the Netherlands, a study found that many hospital admissions of older people were caused by low blood sugar from insulin or sulfonyl urea drugs. Low blood sugar also increases the risk of falls, fractures, and dementia. Frailty can make diabetes worse and increase the risk of low blood sugar even more. Guidelines suggest being less strict about controlling blood sugar in older people with diabetes, but many doctors still give too much medication. They may not know how to reduce medication safely or worry about the risks of high blood sugar. To make sure it's safe to reduce medication, more research is needed. This study aims to see if reducing medication for older people with diabetes is safe and improves quality of life. It will also look at how to do this in practice and if it saves money.

### Who can participate?

People with type 2 diabetes over 70 years of age who are using insulin or sulfonyl urea derivates and have Hba1c levels below the suggested thresholds of the 2018 Diabetes guideline of the Dutch Society of General Practitioners.

### What does the study involve?

Reducing medication until acceptable levels of Hba1c have been reached. The reduction of the medication and the selection of the threshold is defined in a shared decision making procedure between patient and health care professional. Patients who indicate willingness after a written invitation will be invited to fill in 6-monthly questionnaires during a follow up period of five years (five questionnaires) and might be invited for an interview.

What are the possible benefits and risks of participating?

Possible benefits: reduction of hypoglycemic episodes with negative consequences

Possible risks: increase of hyperglycemic episodes with negative consequences

When is the study starting and how long is it expected to run for?

January 2021 to July 2026

Who is funding the study?

The study is funded by ZonMW, The Netherlands organisation for health research and development.

Who is the main contact?

Prof.dr. P.J.M. Elders, p.elders@amsterdamumc.nl

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Zonmw file number

848018102

## Study information

#### Scientific Title

Consequences of reducing hypoglycemia-inducing glucose-lowering medication in people with type two diabetes: an open cluster controlled intervention study comparing the implementation of a deprescribing program in primary care practises versus usual care

#### Acronym

OMED2

#### Study objectives

Reducing hypoglycemia inducing glucose lowering medication in people of 70 years or older in order to meet the criteria of the 2018 guideline of the Dutch Society of General Practice does not lead to increased registered medical problems by the GP that are -according to a delphi procedure with GP's - related to hyperglycemia or hypoglycemia, reduced quality of life or increased cost.

#### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

The ethics committee of Amsterdam UMC, location VU deemed that the study did not fall under the research with human subjects act (correspondence number 2021.0231) after which the Directory Board of Amsterdam UMC, location VU approved of the study.

**Study design**

Open cluster randomized study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Complications of type 2 diabetes

**Interventions**

The intervention consists of an implementation program aimed at reducing glucose-lowering medications in people of 70 years of age that have too low HbA1c according to the 2018 guideline of the Dutch Society of General Practitioners and are treated with potentially hypoglycaemia-inducing glucose-lowering medication. The study compares the intervention to usual care.

The implementation program consists of digital training sessions, a digital algorithm to select the potential patients for the program, supporting practice visits by specially trained medical students or research assistants and an expert panel consisting of a GP expert in Diabetes, a pharmacist, a diabetologist and a geriatrician.

The control practices receive an implementation program in which the prescription of SGLT2 inhibitors or GLP1 agonist is stimulated in patients younger than 70 years with manifest diabetes complications.

Before practices receive the training program for the study which depends on the intervention allocation, participating practices will be randomly allocated to the intervention, or control condition. Randomisation will be performed by a researcher blinded to characteristics of the practices using a digital tool. Practices starting the monthly training course are stratified by practice size (two strata), to ensure equally sized groups. Patients will be allocated to either one of the treatment conditions, based on the practice where they are listed. Blinding of patients, GPs and practice nurses to treatment allocation is not possible due to the nature of the intervention.

**Intervention Type**

Mixed

**Primary outcome(s)**

Two year follow up count of all ICPC coded reasons of encounter registered in the routine care electronical register of the GP practice that are potentially related to hypoglycemia selected in a Delphi procedure by three GP's.

**Key secondary outcome(s)**

1. Two year follow up count of all ICPC coded reasons of encounter selected in a Delphi procedure by three GP's registered in the routine care electronic register of the GP practice that are potentially related to hyperglycemia .
2. Two year follow up count of all ICPC coded reasons of encounter selected in a Delphi procedure by three GP's registered in the routine care electronic register of the GP practice that are potentially related to either hyperglycemia or hypoglycemia.
3. Quality of life, measured every six months using the EQ5D-5L and EQ5D-VAS as indicated by patients agreeing to fill in 6-monthly questionnaires.
4. Blood pressure measurements and laboratory measurements registered in the routine care electronic digital file of the GP: Hba1c, fasting plasma glucose measurements.
5. Number of medication prescriptions registered in the EMR
6. Hospital admissions, visits to emergency departments (hospital or primary care) and nursing home admissions as indicated by patients agreeing to fill in 6-monthly questionnaires.
7. Health care and patient cost including medical prescription data will be analyzed from the societal perspective based on 6 monthly patient questionnaires.
8. Cognitive evaluation using the Minicog questionnaire if deemed necessary by the health care professionals and registered in the medical file.
9. Process analysis: for the purpose of studying the implementation, we shall study an extraction of the EMR of the patients who were selected for DDP in the intervention study. As part of the analysis all free text in the GP file will be extracted and after erasing all potential identifying information, will be studied as well. Using the administrative labels regarding inclusion and participation in the DDP, we will be able to deduce the aspects that caused enrollment or exclusion in the DDP intervention and how it was performed and which medical interventions (medication changes, lab measurements) were done. We shall also organize interviews with GP's, PN's. A random number of 20 study participants will be approached for an interview during the study to study whether we might improve the program (training, materials) further.

**Completion date**

01/07/2026

## **Eligibility**

**Key inclusion criteria**

1. Age 70 years or older
2. Having type 2 diabetes
3. Using insulin or sulfonyl urea derivative drugs
4. Recent Hba1c below 54 mmol/ mol or if deemed fragile by the GP practice below 58mmol/mol

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Lower age limit**

70 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

Previously having indicated to be not willing to participate in studies using routine care electronic data

**Date of first enrolment**

13/03/2023

**Date of final enrolment**

13/03/2024

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**Amsterdam UMC, Department of General Practice**

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## 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

**IPD sharing plan summary**  
Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		25/07/2024	29/07/2024	Yes	No
<a href="#">Statistical Analysis Plan</a>		30/01/2026	30/01/2026	No	No