# The OPTIMAAL study: Shared decision making between patients and GPs in the treatment of type 2 diabetes in primary care.

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Objective: this study aims to investigate whether SDM may increase the amount of T2DM patients who reach the individualised T2DM treatment targets (blood pressure, total cholesterol, HbA1C, weight and smoking status).

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

## Summary

### ID

NL-OMON37364

**Source**
ToetsingOnline

**Brief title**
OPTIMAAL: shared decision making in type 2 diabetes in primary care

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
adult onset diabetes, type 2 diabetes mellitus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Innovatiefonds van zorgverzekeraar Nuts-OHRA

## Intervention

**Keyword:** General practice, OPTIMAAL, Shared Decision Making, Type 2 Diabetes Mellitus

## Outcome measures

### Primary outcome

The percentage of patients that achieve all individualised treatment targets

form the SDM group compared with the control group.

### Secondary outcome

- Blood pressure, total cholesterol, HbA1C, smoking habits and weight;

- Satisfaction with the diabetes treatment, quality of life and well-being,

health outcome and functional health, coping style;

- Level of SDM knowledge/attitude of the GPs in the intervention group;

- What are the indepent predictors of the patients who achieve the treatment

targets?

- Can we indentify the patients in the SDM group who show better results

compared to others?

# Study description

### Background summary

Over the past decades, the importance of self-management in the treatment of type 2 diabetes (T2DM) has increased considerably. As a consequence, an increasing amount of responsibility shifts towards the patients. Unfortunately, although numerous patients are willing to take this responsibility, only few receive it. An adaptation of attitude from the health care provider (HCP) is essential to increase T2DM patients' responsibility. We believe that shared decision making (SDM) covers a potential solution where both parties reach a

decision together. As only 20% of the T2DM patients reach all T2DM treatment goals we hypothesise that SDM can improve this percentage by increasing patient involvement in treatment decisions.
The SDM is especially important if there is more than one possible treatment option, and these options are equally suitable in treating the condition. This is the case in T2DM, because the ADDITION trail (METC prtocol number 01/292) showed that neither treatment according to national guidelines, nor more intensive treatment according to ADDITION guidelines has a proven superior effect. This is the reason that we want to recruite the former ADDITION patients, and offer them choice between two evidence based treatment options. The studied intervention (shared decision making) will also be applicable for all the other patients in the general practice. This means that not only the former ADDITIONpatients will be eligible for participation, but other T2DM patients as well, with comparable patient characteristics.

## Study objective

Objective: this study aims to investigate whether SDM may increase the amount of T2DM patients who reach the individualised T2DM treatment targets (blood pressure, total cholesterol, HbA1C, weight and smoking status).

## Study design

Cluster-randomised controlled trial, with randomisation at practice level (and not single patient randomisation).

## Intervention

In the intervention group (with the SDM approach) patient and GP use a decision aid to discuss the pros and cons of two evidence based treatment possibilities: treatment according to the Dutch College of General Practitioners (NHG) guideline, versus the intensive ADDITION guideline. The patient then shared his preferences for treatment and responsibility, and informs the GP about his lifestyle habits and other relevant issues for the decision. Next patient and GP together choose one of these treatments, based on the facts and preferences. Next they arrange the five treatment goals (blood pressure, total cholesterol, HbA1C, weight and smoking status) in orde of priority. Subsequent treatment will take place according to these OPTIMAAL priorities. The priorities will be evaluated every 12 months.

## Study burden and risks

Burdens of this study could be the questionnaires that will be have to be filled out by the patients (completion will take approximately 20-30 minutes). We acknowledge the time burden this may impose on the patient. We expect SDM itself to be without direct risk for the patient. We judge the time burden to

be in proportion with the study duration of three years, because all other appointments will be integrated in usual care visits. Expected benefits are increased responsibility of patients in their disease decisions, which may lead to an increased involvement, satisfaction and empowerment of the patient, and the possible benefits for the diabetes care in the Netherlands.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

Former participant in the ADDITION-Netherlands RCT;
informed consent
OR:
Similar patients with T2DM, age between 60 and 80 years, diabetes duration of 8 to 15 year, who are not detected by screening;

Informed consent

### Exclusion criteria

A history of alcoholism, drug abuse, psychosis, personality disorder or another emotional, psychological or intellectual problem that is likely to invalidate informed consent, or limit the ability of the individual to comply with the protocol requirements;
A limited life expectancy.

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Health services research

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-03-2012 |
| Enrollment: | 250 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 07-02-2012 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 19-06-2012 |
| Application type: | Amendment |

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

# 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 | NL39039.041.11 |