

# Eindhoven Long-term Diabetes Education Study

Published: 15-01-2014

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To investigate the cost-effectiveness and long-term effects on cardiovascular risk, quality of life and diabetes self-management behavior of the educational program \*Beyond Good Intentions\* in known type 2 diabetes patients.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Diabetic complications
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON44706

### Source

ToetsingOnline

### Brief title

ELDES

### Condition

- Diabetic complications

### Synonym

diabetes, type 2 diabetes mellitus

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** European Foundation for the Study of Diabetes

## Intervention

**Keyword:** Long-term, RCT, self-management, Type 2 diabetes mellitus

## Outcome measures

### Primary outcome

Change in Body Mass Index (BMI;-1 kg/m<sup>2</sup>) between baseline and follow-up (2.5 years after the start of the course) between groups.

### Secondary outcome

Change in other clinical measures (HbA1c, lipid profile and systolic blood pressure), quality of life, diabetes self-management behavior (level of physical activity, dietary intake and medication adherence) and proactive coping between baseline and follow-up will be determined. Cost-effectiveness will be based on total health care resources use during the whole study period. To determine which patient- and disease characteristics are associated with participation to the BGI course, baseline data of participants will be compared to those of patients who were approached but declined to participate.

## Study description

### Background summary

The theory based 12 weeks self-management program \*Beyond Good Intentions\* (BGI) is one of the very few programs that improved cardiovascular risk factors at 9 months follow-up and is cost-effective. Originally it was designed for patients with screen-detected type 2 diabetes, but the program is now implemented on a larger national scale. If long-term effectiveness and a higher cost-effectiveness ratio could be proven, the program will be reimbursed by health insurance companies and implementation across Europe could be encouraged.

### Study objective

To investigate the cost-effectiveness and long-term effects on cardiovascular risk, quality of life and diabetes self-management behavior of the educational program \*Beyond Good Intentions\* in known type 2 diabetes patients.

## **Study design**

A randomized clinical trial with long-term follow-up.

## **Intervention**

Patients in the BGI-group will follow the 12-week course (2 individual sessions, 4 group sessions) and a booster session one year thereafter.

## **Study burden and risks**

Participants are asked to fill in a questionnaire for pre-selection. Selected participants are in addition asked to fill in questionnaires on quality of life, diabetes self-management and proactive coping at baseline and follow-up (2.5 years after start of the course). Depending on regular clinical controls (not older than 4 months) an extra blood sample is taken at one or both measurement occasions. Participants in the BGI-groups receive over a period of 12 weeks two 30-minutes individual sessions and four 2.5-h group sessions. In addition, one booster-session is given 52 weeks after the second individual session.

Many diabetes education programs have been developed, but only two European programs provided long-term results. Until now no European diabetes education program has proven to be both effective and cost-effective after a period of more than two years. Our program is very promising in this respect. By differentiating between patients who will and those who will not benefit from the course we think we can make this course more effective and cost-effective, also on the long-run.

## **Contacts**

### **Public**

Universitair Medisch Centrum Utrecht

Universiteitsweg 100

Utrecht 3584CG

NL

### **Scientific**

Universitair Medisch Centrum Utrecht

Universiteitsweg 100

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Diagnosed with type 2 diabetes mellitus between 3 months \* 5 years;
- Adults, aged \* 75 years.

### Exclusion criteria

- High self-management capability;
- Insufficient cognitive functioning;
- Insufficient understanding of the Dutch language to follow instructions and to complete questionnaires.

## Study design

### Design

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

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-05-2014

Enrollment: 106

Type: Actual

## Ethics review

Approved WMO

Date: 15-01-2014

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 01-09-2014

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 11-08-2015

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 14-06-2016

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 08-02-2017

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**

CCMO

### **ID**

NL46285.041.13