

# Is metabolic regulation of diabetes type 2 patients starting with insulin therapy improved by self-management training? An investigation into decreasing psychological barriers and exploration of ethnic barriers.

Published: 20-03-2007

Last updated: 08-05-2024

The objectives of the present study are twofold: 1 screening patients with diabetes type 2 for psychological risk factors and 2 studying the effect of a self-management training on metabolic regulation in patients starting with insulin therapy

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

## Summary

### ID

NL-OMON30627

### Source

ToetsingOnline

### Brief title

Self management of diabetes type 2 patients

### Condition

- Diabetic complications

### Synonym

diabetes

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** diabetes type 2, group therapy, intercultural medicine, self-management

## Outcome measures

### Primary outcome

Primary outcome is HbA1c level. Secundaire medical outcome measures are systolic blood pressure and cholesterol levels.

### Secondary outcome

Secondary outcome is the effect of the training on self-efficacy and self-management behavior. Furthermore, possible ethnic differences in the effectiveness of the intervention are explored.

## Study description

### Background summary

The prevalence of diabetes type 2 is estimated to be 5,1%, and increasing. Life style and increasing life expectancy can explain this increase. The risk of a cardiovasculair indident is about twice to four times higher and 70 to 80% of the patients die from such an incident. Furthermore, depression is prevalent in about 10 to 15 % of the patients, together with eating disorders and other psychological problems. Severe complications occur in diabetic patients, such as amputations, blindness and renal failure. The incidence of these complations can be reduced by about 50% when metabolic regulation is good and when cardiovasculair risk factors are decreased. Succesful treatment of diabetes is largely dependent on the patient himself. Only 7% of the patients are capable of adequate self-management and in 25% of the patients metabolic regulation is inadequate.

Meta-analysis showed that psychological interventions can improve metabolic regulation and reduce psychological problems. The effect size was large enough to decrease the risk of microvascular complications. Few studies have addressed patients with poor psychological functioning. Furthermore, psychological problems may form a barrier to successful treatment of diabetes. Little research is carried out into the relation of ethnicity and self-management.

### **Study objective**

The objectives of the present study are twofold:

- 1 screening patients with diabetes type 2 for psychological risk factors and
- 2 studying the effect of a self-management training on metabolic regulation in patients starting with insulin therapy

### **Study design**

The study is a randomised controlled study, comparing the effect of the self-management training to a waitinglist control group receiving standard medical care.

### **Intervention**

The intervention consists of 10 weekly sessions of 2 hours in groups of 8 to 10 patients. Ingredients of the training are cognitive restructuring and behavioral techniques. Individual goals will be formulated for each patient, to improve self-management of each patient. Attention will be paid to eating and exercising, controlling glucose levels and self-care.

### **Study burden and risks**

The burden for the participants is the time that the intervention takes. Whenever psychological stress is too much increased by the intervention, individual counseling will be provided.

## **Contacts**

### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040  
3000 CA Rotterdam  
NL

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040  
3000 CA Rotterdam  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

patients starting with insuline therapy

sufficient understanding of Dutch language

elevated scores on the SCL-90, but below the psychiatric range

### Exclusion criteria

diagnosed psychiatric disorders

insufficient understanding of Dutch

no elevated scores on SCL-90

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

**Primary purpose:** Treatment

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-08-2007  
Enrollment: 100  
Type: Actual

## Ethics review

Approved WMO  
Date: 20-03-2007  
Application type: First submission  
Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL14800.078.07