

# The effectiveness of an intervention, including a very low calorie diet, cognitive behavioural therapy and maintenance contract, regarding weight and weight regain, diabetes management, cardiovascular risk, depression and quality of life in overweight patients with type 2 diabetes mellitus, after 2 year follow-up.

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In this RCT we combine cognitive behavioural therapy (CBT) with a maintenance contract and a specific diet (very low calorie diet), to obtain and maintain favourable effects on weight and risk profile over the long term.

<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-OMON39024

### Source

ToetsingOnline

### Brief title

Prevention Of WEight Regain in diabetes type 2 (POWER)

## Condition

- Diabetic complications
- Diabetic complications
- Lifestyle issues

### Synonym

diabetes, Overweight

### 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:** Cardiovascular risk, Cognitive behavioural treatment, Diabetes mellitus type 2, Obesity

## Outcome measures

### Primary outcome

Primary outcome measures are weight (kg) and weight regain.

### Secondary outcome

Other outcome measures are Body Mass Index ( $BMI = \text{weight (kg)} / \text{length (m)}^2$ ),

HbA1c (%), waist circumference (cm), systolic blood pressure (mmHg), lipid

levels (LDL, HDL, TG (mmol/l) en chol/HDL), antidiabetic agents en doses,

cardiovascular risk (UKPDS), lifestyle and quality of life (EuroQol). A small

amount of hair will be collected at 3 timepoints during the study to measure

hair cortisol. Psychosocial parameters like depression, self-esteem, relational

functioning and fear for negative appearance evaluation are studied, as

secondary outcome as well as determinant for weight loss.

In this unique population we want to collect DNA-material to study the genetic

factors associated with succeeding of the intervention.

Last but not least we want to conduct an analysis of the cost effectiveness of the intervention as compared to usual care.

## Study description

### Background summary

Obesity is thought to be of major pathogenetic importance in type 2 diabetic patients and can contribute to poor glycemic control and increase the risk for cardiovascular disease. It is estimated that over 80% of patients with diabetes type 2 is overweight (BMI>25 kg/m<sup>2</sup>). To achieve a more favourable risk profile, changes in diet and lifestyle are needed. However, current treatment programs for obese DM type 2 patients are not effective over the long term.

### Study objective

In this RCT we combine cognitive behavioural therapy (CBT) with a maintenance contract and a specific diet (very low calorie diet), to obtain and maintain favourable effects on weight and risk profile over the long term.

### Study design

This study is a randomised parallel group intervention study, with varying block size.

### Intervention

Participants all start with a very low calorie diet and will be included in the study by obtaining 5% weight loss, after which they will be randomly assigned to the 2 research groups. After finishing the 3-months diet period, the control group will receive the normal treatment. During the very low calorie diet, the intervention group starts with cognitive behavioural group therapy for 10 weeks. Subsequently, the intervention group will receive 7 evaluation group meetings till the end of the study (2 years).

### Study burden and risks

There are minimal risks associated with participation in this study. However, the metabolic benefits outweigh the investment of time and possible adverse effects.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Diabetes mellitus type 2

Overweight: Body Mass Index (BMI) > 25 kg/m<sup>2</sup>

Age >18 years

### Exclusion criteria

Pregnancy/lactation

Inadequate knowledge of the Dutch language/Inability to fill in questionnaires

Inability to lose 5% of body weight during very low calorie diet

Severe psychiatric problems

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	300
Type:	Actual

## Ethics review

Approved WMO	
Date:	29-06-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	13-12-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	26-04-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	19-11-2013
Application type:	Amendment
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	NL26508.078.09
Other	NTC2264