

# Prevention Of WEight Regain in diabetes type 2 (POWER).

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21737

### Source

NTR

### Brief title

POWER

### Health condition

Diabetes type 2  
Obesity/overweight

Diabetes type 2  
Obesitas/overgewicht

## Sponsors and support

**Primary sponsor:** Erasmus Medical Centre Rotterdam

**Source(s) of monetary or material Support:** Erasmus MC commissie Zorgonderzoek

## Intervention

## Outcome measures

### Primary outcome

The primary endpoint with respect to the efficacy of CPI, is the between-group difference in

weight change (kg) measured as weight after 2 years follow-up minus weight at week 12 (directly after intervention).

## **Secondary outcome**

1. Anthropometric measurements: BMI, waist-hip-ratio, belly circumference, body composition (%fat and lean body mass);
2. Cardiovascular risk profile: HbA1c, HOMA241, blood pressure, lipids profile;
3. Glycaemic control: insulin, glucose;
4. Psychological measurements: EuroQol, HADS, VOEG-13, CIS, RSE;
5. Lifestyle: SQUASH, EDE-Q;
6. Cost effectiveness: SRS, TIC-P.

## **Study description**

### **Background summary**

In this randomized controlled trial we investigate the effectiveness of adding a Combined Psychological Intervention to a very low calorie diet, as compared to usual care, in maintaining weight loss and improving glycaemic, cardiovascular and psychological parameters in patients with type 2 diabetes and overweight.

### **Study objective**

Adding a Combined Psychological Intervention to a very low calorie diet is more effective than a very low calorie diet followed by usual care in maintaining weight loss and improving glycaemic control, cardiovascular risk score, psychological variables and quality of life in patients with diabetes type 2.

### **Study design**

Outcome measurements at baseline, week 23 (after intervention), 1 year, 1,5 years and 2 years.

### **Intervention**

1. Very low calorie diet + usual care;

2. very low calorie diet + usual care + Combined Psychological Intervention (CPI).

The first 8 weeks, a very low calorie diet will be given, consisting of 750 calories a day. After these 8 weeks, the diet will become less low, building up to 1300 calories a day in 2x 8 weeks.

After the first 8 weeks, randomisation will take place. Only participants who lost more than 5% of their body weight will be randomised.

CPI: An integrated multimodel group treatment, consists of cognitive restructuring, Problem Solving Therapy and Proactive Coping. During the first 10 weeks there will be a weekly session of 1,5 hours. After those 10 weeks, the session will become less frequent. A total of 17 sessions is planned.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

1. Diagnosed diabetes mellitus type 2;
2. Age 18-70 years;
3. BMI 27 kg/m<sup>2</sup> or more.

## Exclusion criteria

1. Pregnancy or lactation during the study;
2. Inadequate expression of the Dutch language (spoken and written);
3. Inability to lose 5% or more of the bodyweight during the first 8 weeks of VLCD;
4. Severe psychiatric problems;
5. Significant cardiac arrhythmias, unstable angina, decompensated congestive heart failure, major organ system failure, untreated hypothyroidism and/or myocardial infarction, end-stage renal disease, cerebrovascular accident or major surgery in the last 3 months;
6. Absence on > 8 sessions CPI.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-03-2010
Enrollment:	250
Type:	Actual

## Ethics review

Positive opinion	
Date:	30-03-2010

Application type:

First submission

## 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
NTR-new	NL2140
NTR-old	NTR2264
Other	Erasmus Medical Ethical Comittee : MEC-2009-143
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A