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

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Adding a Combined Psychological Intervention to a very low calorie diet is more effective then a very low calorie diet followed by usual care in maintaining weight loss and improving glycaemic control, cardiovascular risk score, psychological...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21737

Bron
NTR

Verkorte titel
POWER

Aandoening

Diabetes type 2
Obesity/overweight

Diabetes type 2
Obesitas/overgewicht

Ondersteuning

Primaire sponsor: Erasmus Medical Centre Rotterdam
Overige ondersteuning: Erasmus MC commissie Zorgonderzoek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

In this randomized controlled trial we investigate the effectiviness 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.

Doel van het onderzoek

Adding a Combined Psychological Intervention to a very low calorie diet is more effective then 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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Kirsten Berk
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7040115

Wetenschappelijk

Kirsten Berk
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7040115

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosed diabetes mellitus type 2;

2. Age 18-70 years;

3. BMI 27 kg/m2 or more.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	24-03-2010
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2140
NTR-old	NTR2264
Ander register	Erasmus Medical Ethical Comittee : MEC-2009-143
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A