

Diet, predisposition and reward.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25100

Source

NTR

Brief title

Diet, predisposition and reward

Health condition

overweight
obesity
weight maintenance
polymorphisms
Brain plasticity of reward

overgewicht
obesitas
gewichtsbehoud
polymorfismen
hersenplasticiteit van beloning

Sponsors and support

Primary sponsor: Maastricht university

Postbus 616

6200 MD Maastricht

Source(s) of monetary or material Support: Top institute of food and nutrition

Nieuwe Kanaal 9a

6709 PA Wageningen

The Netherlands

Intervention

Outcome measures

Primary outcome

1. Differences in success between the diets (anthropometry measurements);
2. Differences in brain plasticity of reward;
3. Differences in the FTO and TaqIA genes.

Secondary outcome

Measurements of hunger suppression using visual analogue scales and ghreline determination.

Study description

Background summary

Overweight is a major health problem with serious co morbidities. Weight loss is usually achieved more readily than weight maintenance after body weight loss. Conditions for weight maintenance after weight loss are (a) sustained satiety despite negative energy balance, (b) sustained basal energy expenditure despite body weight loss, due to (c) sparing of fat-free mass, which is the main determinant of basal energy expenditure. Diets with a relatively high-protein content act on these metabolic targets (4). Increasing the relative protein content reduces food intake under ad libitum conditions, resulting in immediate body weight loss. In the long term, body weight reaches a new value at a significantly lower level. Thus, an increase in the relative protein content of the diet, irrespective of protein type, reduces the risk of a positive energy balance and the development of overweight. Increasing protein intake also increases the chance of maintenance of body weight after weight loss induced by an energy-restricted diet.

So the most successful diets are those with a relatively high-protein content. But compliance remains an issue with all diets. In the first place it will be assessed whether predisposition for overweight affects compliance and success; second, whether sensitivity for food-reward affects compliance and success.

Study objective

Overweight is a major health problem with serious co morbidities. Weight loss is usually achieved more readily than weight maintenance after body weight loss. Conditions for weight maintenance after weight loss are (a) sustained satiety despite negative energy balance, (b)

sustained basal energy expenditure despite body weight loss, due to (c) sparing of fat-free mass, which is the main determinant of basal energy expenditure. Diets with a relatively high-protein content act on these metabolic targets (4). Increasing the relative protein content reduces food intake under ad libitum conditions, resulting in immediate body weight loss. In the long term, body weight reaches a new value at a significantly lower level. Thus, an increase in the relative protein content of the diet, irrespective of protein type, reduces the risk of a positive energy balance and the development of overweight. Increasing protein intake also increases the chance of maintenance of body weight after weight loss induced by an energy-restricted diet.

So the most successful diets are those with a relatively high-protein content. But compliance remains an issue with all diets. In the first place it will be assessed whether predisposition for overweight affects compliance and success; second, whether sensitivity for food-reward affects compliance and success.

Study design

1. Baseline (before weight loss);
2. After 6 months of weight loss;
3. After 3 months of weight maintenance.

Intervention

The study has a double blind parallel 2-arm design, with 2 conditions (diets). There are 2 different diets: one that is relatively high in protein and one with normal protein content. The subjects ($n=300$, $BMI>25$, age 18-55) first have a three-month period of weight loss during which they are on the same weight loss diet consisting of the commercially available meal substitute: modifast. This is followed by a six-month period of weight maintenance during which the subjects are randomized in 2 diet groups. Of the 300 subjects that complete the weight loss and weight maintenance, the polymorphisms of the TaqIA gene and the FTO gene are determined together with anthropometry measurements (body weight, body composition, waist-hip ratio and sagittal diameter); of these 300, 88 will be assessed in the fMRI to investigate the brain areas involved in plasticity of reward with respect to food.

In total there are three measurement moments: before the weight loss, before the weight maintenance and after the weight maintenance at which anthropometry measurements are taken and the fMRI investigations are conducted. Compliance is determined by magnitude of weight loss.

Thus:

1. Weight loss using a commercial available meal substitute: modifast;
2. Weight maintenance during which the subjects are assigned to 1 of 2 diets: a relatively

high protein diet and a diet with normal protein content.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for the whole study are being healthy (no medication use except contraception), both genders, age between 18-55 years, BMI over 25 kg/m², non-smoker.

For the subjects that are included for the fMRI extra inclusion criteria are as follows: not having any metals in the body, being right-handed.

Exclusion criteria

Exclusion criteria are: use of medication (except contraception), extensive alcohol consumption (more than 10 consumptions per week), instable weight (changed more than 5 kilo over the last year), pregnancy, depression, hypertension, kidney dysfunctions and other serious disorders (for example epilepsy, arrhythmia, parkinsonism, insomnia).

For the subjects that are included for the fMRI extra exclusion criteria are as follows: having metals in the body, being left-handed and claustrophobia.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2010
Enrollment:	300
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 34707
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2057
NTR-old	NTR2174

Register

CCMO

ISRCTN

OMON

ID

NL30898.068.09

ISRCTN wordt niet meer aangevraagd.

NL-OMON34707

Study results

Summary results

N/A