Is the success of protein diets related to predisposition of overweight and sensitivity for food-reward?

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To asses whether the success of protein diets is related to predisposition of overweight and sensitivity for food-reward

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON34707

Source
ToetsingOnline

Brief title
Diet, predisposition and reward

Condition

- Appetite and general nutritional disorders

Synonym
obesity and overweight

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Top Institute of Food and Nutrition

Intervention

Keyword: Brain plasticity of reward, polymorphisms, weight maintenance

Outcome measures

Primary outcome

1. Differences in brain plasticity of reward

2. 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

To asses whether the success of protein diets is related to predisposition of

overweight and sensitivity for food-reward

Study design

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 sagital 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.

Intervention

Weight loss using a commercial available meal substitute: modifast.
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

Study burden and risks

This research is neither beneficial nor harmful to the subjects. fMRI is a non-invasive standard brain-imaging method without any significant risks (See chapter K4A for standardized and approved methods for conducting fMRI experiments involving human subjects). It is a technique that utilizes magnetic fields and low energy radio frequencies to visualize brain structures and brain function. During screening subjects with metallic fragments in their body will be excluded from the study since the fMRI magnet exerts a force on ferromagnetic objects. The blood sampling in this study does not include any other risks for the subjects, apart from its usual risk of minor bruising.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for the whole study are being healthy (no medication use except contraception), both genders, age between 18-55 years (over the age of 55 basal metabolic rate is diminished because of loss of muscle mass, which has an influence on weight loss), BMI over 25 kg/m2 (Following a long intervention on a restrictive protein diet would not be advisable with a BMI under 25), non-smoker (smoking affects appetite and reward) and weight loss during the weight loss phase of at least 0.5 kilo every week.
For the subjects that are included for the fMRI extra inclusion criteria are as follows: not having any metallic fragments in the body, being right-handed. Because of the different brain laterality in left- and right-handed subjects we chose to include only right-handed subjects. Hence the results can be compared between the subjects.

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), smoking, pregnancy, breast feeding, menopause, diabetes, claustrophobia, depression, hypertension, kidney dysfunctions, other serious disorders (for

example epilepsy, arrhythmia, parkinsonism, insomnia) and less then 0.5 kilo weight loss in one week during the weight loss phase. For the subjects that are included for the fMRI extra exclusion criteria are as follows: having metallic fagments in the body, being left-handed.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25100
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL30898.068.09
Other	TC = 2174
OMON	NL-OMON25100