Towards a more custom tailored treatment of obesity: Subtyping the motivation to overeat.

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We hypothesize that motivational and behavioral characteristics of eating behavior, in addition to genetic and environmental factors play a major role in the development of obesity. We aim to identify obesity subtypes based on these factors.

Ethische beoordeling Niet van toepassing **Status** Werving nog niet gestart

Type aandoening -

Onderzoekstype Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21495

Bron

NTR

Aandoening

obesity

Ondersteuning

Primaire sponsor: Alan Turing Institute Almere

Louis Armstrongweg 84

1311RL Almere

Overige ondersteuning: The research is financed by the investigator.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The classification of the obese into three personality subtypes, assessment of the

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motivational behavior and the role of genetic and biochemical variations. The design of the study is cross-sectional and aimed to clarify which parameters and interactions are most important in obesity. Causal relationships of the most important parameters will need to be investigated in future studies.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Many obese individuals have tried to lose weight, however, few succeed in long-term maintenance of weight loss and weight is often regained after initial loss. It is clear that inducing a negative energy balance to produce weight loss is the key, but it is difficult to predict which obesity treatment or combination of treatment strategies are most likely to be successful in obese individuals or subgroups.

Objective:

We hypothesize that motivational and behavioral characteristics of eating behavior, in addition to genetic and environmental factors play a major role in the development of obesity. We aim to identify obesity subtypes based on these factors. Study design: Observational with invasive measurements.

Study population:

Obese subjects from the obesity clinic at MC Zuiderzee, 18 - 70 yr old, both male and female.

Main study parameters/endpoints:

The classification of the obese into three subtypes for their motivation to overeat, and the role of genetic and biochemical variations. We expect to identify: 1) reward-prone/hedonic eaters, 2) Reward-deficient eaters, 3) Stress-activated eaters. After initial data analysis using conventional statistics, antropometric, psychological, biochemical and genetic data will be entered in a unique heterogeneous multi-agent system, developed and available at ATIA, allowing the identification of unexpected nonlinear correlations between parameters, providing information on previously unknown interactions, which will provide further insight in the development of obesity in our study participants.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The proposed studies are largely observational, therefore the risks associated with participation are low. Blood will be drawn on one occasion. Neuropsychological testing will also be done on one single occasion, and will take approx.. 2h. In consultation with the participants, we aim to combine the blood drawing and neuropsychological testing in one visit to MC Zuiderzee. Anthropometric data are collected routinely as part of the medical treatment protocol in these participants, so collection of these data do not form any additional burden for our study participants. Saliva sampling and D2O measurements can be performed at home, and saliva and urine samples collected at home will be returned to the investigators by mail. Participants will be notified of the study results, which will provide them with more insight in their motivation to overeat, and which will contribute to the development of subtype specific treatment protocols for obesity.

Doel van het onderzoek

We hypothesize that motivational and behavioral characteristics of eating behavior, in addition to genetic and environmental factors play a major role in the development of obesity. We aim to identify obesity subtypes based on these factors.

Onderzoeksopzet

This study will be cross-sectional.

Blood will be drawn for biochemical and genetic evaluation and neuropsychological evaluation will be performed using validated questionnaires and computer tasks. This will take approximately 2h. Participants will be asked to perform two take home tasks, a body composition assessment using double labeled water and a saliva cortisol awakening response test, which they will return by mail. Data on the medical history and physical examination will be obtained from the medical record, so that this will form no additional burden for the participants.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1. Subjects must be between 18≤ age ≤70 years;
- 2. BMI≥35;
- 3. Subjects must be able to read and understand Dutch language and instructions;
- 4. Subjects must have ample sight and hearing, or corrected sight and hearing to a level that this does not interfere with the neuropsychological testing;
- 5. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Any of the following is regarded as a criterion for exclusion from the study:

- 1. Pregnancy;
- 2. Use of psychoactive medication (ATC groups N03 through N07), or medication with
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significant psychoactive side-effects, currently or during the past 3 months, including, but not restricted to antidepressants, psychostimulants and antipsychotics;

- 3. Use of medication with significant effects on body weight, currently or during the past 3 months, with the exception of drugs used for treatment of comorbidities of obesity, such as for type 2 diabetes, in case of the use of metformin, sulfonylureum derivatives, thiazolidinediones, DPP4 inhibitors, GLP1 analogues, or meglitinides);
- 4. Significant use of illicit psychoactive substances, currently or during the past 3 months as reported by the participant;
- 5. Abuse of or dependence on legal psychoactive substances (alcohol, nicotine, cannabis), currently or during the past 3 months. Smoking is associated with altered performance on two subscales of the BIS BAS questionnaire (Voigt et al, 2009). In addition, smoking has clear effects on energy expenditure. This is expected to generalize to other substances and neuropsychological tests;
- 6. Use of any psychoactive substance (excluding nicotine and caffeine) on the testing day;
- 7. A significant change (quitting attempt or starting) in the use of legal psychoactive drugs in the past three months;
- 8. Known underlying clinically relevant endocrine disease, or mobility impairments underlying the development of obesity, e.g.
- A. Thyroid disease;
- B. Cushing's disease;
- C. Parkinson's disease;
- D. Being bound to a wheelchair (with the exception of being bound to a wheelchair as a result of obesity).
- 9. Color blindness, since this interferes with the interpretation of the instructions and stimuli for the neuropsychological tasks;
- 10. Inability to comprehend the questionnaires or follow the instructions sufficiently in the opinion of the supervising doctor or investigator (at any time during the test visit).

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel: Parallel

Toewijzing: N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-03-2012

Aantal proefpersonen: 400

Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33182

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register ID

NTR-new NL3117 NTR-old NTR3267

CCMO NL28955.068.09

Register ID

ISRCTN wordt niet meer aangevraagd.

OMON NL-OMON33182

Resultaten

Samenvatting resultaten

N/A