Onderzoek naar voeding en de hersenen

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We hypothesize that: 1) Post-ingestion nutrient signals trigger striatal dopamine release, which may be disturbed (decreased) in obese individuals and thereby contribute to pathological feeding behavior. 2) Post-ingestion nutrient signals affect...

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

Samenvatting

ID

NL-OMON28668

Bron
Nationaal Trial Register

Verkorte titel
SPIN trial

Aandoening

Obesity
Gut-brain-axis

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Amsterdam
Overige ondersteuning: Academic Medical Center (AMC), Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The effect of intragastric infusion of nutrients on:
- Brain activity assessed as the induced change in fMRI signal and resting state brain connectivity measured with fMRI.

- Striatal dopamine response, measured as the change in D2/D3R binding potential of IBZM assessed by SPECT.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The worldwide obesity epidemic is a major health burden. Obesity is caused by disturbed feeding behaviour, leading to overconsumption of high-calorie and highly palatable food. Feeding behaviour is regulated by a complex interplay of the homeostatic and hedonic systems, and influenced by peripheral inputs. Recent evidence suggests that ingested nutrients trigger gut-to-brain signals that stimulate central (brain) dopamine release. Changes in post-ingestion nutrient signals may be involved in the development of the pathological (habitual/compulsive) feeding behaviour in obese humans. However, the mechanism of nutrient-triggered dopamine release and its potential role in obesity remain to be elucidated. Gaining more insight in post-ingestion nutrient signalling is necessary to develop new therapeutic options to restore disturbed feeding behaviour in obesity.

Objective: To study the effects of post-ingestion nutrients on brain activity and brain dopaminergic responses in lean subjects, and in obese subjects before and after diet-induced weight loss.

Study design: Single-blind randomized cross-over study

Study population: Lean (BMI 20-25 kg/m2) and obese (BMI >30 kg/m2) men and (postmenopausal) women aged 50-75 years (n = 30 per group)

Main study parameters/endpoints:

Differences in brain fMRI signal and differences in striatal dopamine release (measured as D2/3 receptor binding potential (D2/3R-BP) in response to intragastric infusion of fat and glucose, between lean and obese subjects (before and after diet-induced weight loss). Correlations between gut-derived hormones and measured brain responses.

Doel van het onderzoek

We hypothesize that:

1) Post-ingestion nutrient signals trigger striatal dopamine release, which may be disturbed (decreased) in obese individuals and thereby contribute to pathological feeding behavior.

2) Post-ingestion nutrient signals affect brain activity in brain regions involved in the regulation of food intake/feeding behavior and this effect will differ between lean and obese individuals: we expect obese individuals to show reduced post-ingestion nutrient signal-

induced inhibition of brain activity in regions involved in homeostatic control of food intake, and reduced activation of brain areas involved in reward.

3) Diet-induced weight loss will change (increase) the dopaminergic response in the striatum to post-ingestion nutrient signals.

4) Diet-induced weight loss will improve the brain activity response to post-ingestion nutrient signals in obesity.

5) The effects of post-ingestion nutrient signals will depend on the type of macronutrient

Onderzoeksopzet

Lean individuals:

- 1 Training session

- 3 fMRI sessions (water, glucose, lipid; random order)

- 2 SPECT sessions (one with glucose, one with intralipid; random order)

Obese individuals:

- Baseline: 1 training session, 3 fMRI sessions, 1 SPECT session (either with intralipid or glucose)

- During the diet: several visits to assess progress of weight loss

- Following the 3 month hypocaloric diet: 3 fMRI sessions, 1 SPECT session (intralipid or glucose)

Onderzoeksproduct en/of interventie

Intra-gastric infusion of:

- 250 ml water

- 250 ml intralipid 20%

- 250 ml glucose 50%

Hypocaloric diet intervention: 3 months, aim to lose 10% of total bodyweight.

Contactpersonen

Publiek

K.A. van Galen
[default]
The Netherlands
020-56663507

Wetenschappelijk

K.A. van Galen
[default]
The Netherlands
020-56663507

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Ability to provide informed consent;

- Age: 50-70 years

- Females: postmenopausal (history, amenorrhoea, elevated FSH)

- BMI: 20-25kg/m2 for lean subjects, >30kg/m2 for obese subjects

- For obese subjects: insulin resistance, defined as fasting insulin >74 pmol/l

- Stable weight (i.e. <10% change) for 3 months prior to study inclusion

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Use of any medication except for those related to treatment of components of the metabolic syndrome (not including insulin, oral glucose lowering drugs, alpha- and beta-blockers)

- Any actual medical condition except for treated hypothyroidism and the metabolic

syndrome

- History of any psychiatric disorder, neurological disorders, eating disorders (anorexia, binge eating, bulimia), alcohol abuse or upper gastrointestinal tract surgery/abnormalities.

- Shift work

- Intensive sports (>3/week)

- Restrained eaters

- Smoking

- XTC, cannabis, amphetamine or cocaine abuse

- Alcohol abuse (>3 units/day)

- Occupational radiation exposure

- Contraindication for MRI

- Lactose/gluten intolerance

- Soya oil, egg or peanut allergy

- Childhood onset of obesity (<4 years)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	13-12-2017
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50660
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6864
NTR-old	NTR7042
CCMO	NL61132.018.17
OMON	NL-OMON50660

Resultaten