Functional magnetic resonance imaging of human hypothalamic responses to oral glucose ingestion in subjects with obesity before and after lifestyle intervention.

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The objective of the study is to determine hypothalamic function in response to oral glucose ingestion in subjects with obesity before and after the start of a combined lifestyle intervention (CLI).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49389

Source
ToetsingOnline

Brief title
fMRI of hypothalamic function after lifestyle intervention.

Condition

- Hypothalamus and pituitary gland disorders
- Appetite and general nutritional disorders

Synonym
Obesity, Over weight

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Functional MRI, Hypothalamic function, Lifestyle intervention, Obesity

Outcome measures

Primary outcome

- Hypothalamic activity as measured by BOLD signal intensity of the hypothalamus after ingestion of solution (75 gram in 300ml) in patients with obesity before CLI (baseline)

- Hypothalamic activity as measured by BOLD signal intensity of the hypothalamus after ingestion of solution (75 gram in 300ml) in patients with obesity after CLI (in-tervention effect)

- Differences in BOLD signal intensity before and after a CLI

- Comparison in BOLD signal intensity between patients with obesity, healthy con-trols (data previously collected), and patients with diabetes mellitus type 2 (previ-ously collected).

Secondary outcome

- Resting state whole brain fMRI outcome measures:

- Voxel-based connectivity as measured by Eigen vector centrality mapping of resting FMRI data

- Network connectivity as measured by network Z-scores of functional connec-tivity of resting FMRI data

- Associations between MRI data and questionnaires, anthropometrics,

biochemical and metabolic parameters, immunological parameters and endocrine

parameters collected at the Erasmus MC.

Study description

Background summary

In obesity the homeostatic energy balance is disrupted, which leads to an over storage of energy in the form of excess bodyweight. The brain plays a very important role in regulating homeostasis and energy balance. Various earlier studies have shown an altered function and response of the brains of persons with obesity. We hypothesize that participants with obesity will demonstrate an attenuated hypothalamic response to glucose ingestion and that this response could be improved after an improved diet and weight loss.

Study objective

The objective of the study is to determine hypothalamic function in response to oral glucose ingestion in subjects with obesity before and after the start of a combined lifestyle intervention (CLI).

Study design

Prospective cohort study with baseline measurements and measurements after intervention.

Study burden and risks

The study will consist of two visits to the LUMC (10 weeks between visits). For each visit participants will undergo one MRI scan, the duration of this visit will be 1.5 -2 hours excluding travel time (one hour for the MRI scan plus instructions and preparations).
The potential risks are limited. The risks of MRI are minimal (risk of everyday life), because there are no consequences to the health of the participant. Potential risks from the MRI study include movement of paramagnetic objects in the body. Furthermore, some subjects may feel claustrophobic in the restricted space of the MR scanner.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participants with a Body Mass Index (BMI) > 30 kg/m2 with obesity related comorbidities. Allowed comorbidities are defined as follows:
- Insulin resistance (as defined by the HOMA index based on fasted insulin/glucose)
- Dyslipidaemia
- Hypertension
- Arthrosis
- Sleep apnoea
- Fatty liver disease
- Polycystic Ovary Syndrome (PCOS)

Exclusion criteria

- Does not speak Dutch

- Cognitive impairment (IQ<80)
- Physical impairment that impairs movement therapy.
- Other underlying treatable causes of obesity
- Lack of motivation
- Behavioural problems that impair group therapy.
- Psychopathologies pathology that require other treatment
- Current desire to have children
- Diabetes mellitus type 2

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2019
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	22-08-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	04-02-2021
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL68911.058.19

Study results

Date completed:	07-06-2021
Actual enrolment:	5