The role of inFLAmation in brain and behavIouR in overweight and obesity: the FLAIR-o study.

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Primary Objectives: • To study the association between inflammation and food-related effort-based decision making in brain and behaviour in obese participants, taking into account possible other influencing factors in a causal discovery model....

Ethical review	Approved WMO
Status	Completed
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON54343

Source
ToetsingOnline

Brief title
FLAIR-o

Condition

- Appetite and general nutritional disorders

Synonym
obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: European Research Council

Intervention

Keyword: fMRI, inflammation, motivation, obesity

Outcome measures

Primary outcome

The main outcomes are brain activity and behavioural weightings of effort and reward valuation, measured by functional MRI and by a behavioural effort-based decision-making task.

Secondary outcome

Secondary outcomes are effort- and reward-related food intake in the lab, anhedonia, reward anticipation, and active behaviour in daily life, measured by Experience Sampling Method and qualitative interviews.

Study description

Background summary

Obesity is a major health problem worldwide and is characterized by increases in low-grade, systemic inflammation, caused by an immune response in visceral adipose tissue. Approximately 40-60% of the individuals with a BMI > 30 kg/m2 have this increased inflammatory state.
Outside the field of obesity, increases in inflammation have been related to loss of motivation and effortful behaviour (anhedonia). In several neuropsychiatric disorders, such as depression and schizophrenia, the level of low-grade inflammation has even been linked to symptom severity.
In obesity, functional MRI studies additionally show altered activation in the striatum, a brain area related to motivational behaviour, but the direction and size of this effect is highly related to the individual and the situation.
Here, we hypothesize that low-grade inflammation is predicting/causing altered brain responses in the striatum and effortless behaviour, resulting in more 'fast food' choices in obesity.

Study objective

Primary Objectives:

• To study the association between inflammation and food-related effort-based decision making in brain and behaviour in obese participants, taking into account possible other influencing factors in a causal discovery model.

Secondary Objective:
• To study whether the two primary objectives translate to more ecologically valid measures/settings.

Study design

The study has an observational cross-sectional design.

Intervention

During the intervention period of 12 weeks, participants included in the trial will receive 1 tablet of 0.5mg colchicine or placebo per day.

Study burden and risks

Participants will come to the lab at least one time for ±4.5 hours. During the visit, participants will perform a behavioural task in the MRI scanner, do a food intake test, fill out questionnaires, a blood sample will be taken and anthropometric measurements will be done. In the week after the visit, participants will fill out 10 short questionnaires per day on their phone for 10-14 consecutive days.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

General inclusion criteria:
• BMI >= 30 kg/m2
• Female sex
• Age: 18-59 years

Exclusion criteria

• Presence of acute infection, indicated by high-sensitive C-reactive protein (hsCRP) > 10.0 mg/L for BMI between 30-31 kg/m2 and hsCRP > 22.1 mg/L for BMI > 31 kg/m2 at day of testing*.
In case of a hsCRP level above these thresholds, the measurement is repeated at least 4 weeks after the first measurement, for this second measurement the thresholds for exclusion are: hsCRP > 19.7 for BMI between 30-31 kg/m2 and hsCRP > 27.8 for BMI > 31 kg/m2.
• Diagnosed with Diabetes Mellitus type I or II
• Having been vaccinated in the 4 weeks preceding the first test session
• Having had an infection characterized by a fever, or diagnosed by a medical physician in the 4 weeks preceding the first test session
• Gained or lost >2 points in BMI (kg/m2) over the last 6 months
• Followed an energy restricting diet during the last 2 months
• Having had bariatric surgery in the past 5 years
• Habitual smoking, i.e. one or more cigarettes per day
• Current or history of alcohol and/or drugs abuse (i.e. >14 units per week)
• Pregnant, lactating or wishing to become pregnant in the period between the screening and until 3 months after the last study visit (self-reported)
• (History of) clinically significant psychiatric or neurological disorder
• (History of) clinically significant metabolic, cardiovascular, renal, endocrinological, autoimmune or chronic inflammatory disease

• General medical conditions, such as sensorimotor handicaps, deafness, blindness or colorblindness, as judged by the investigator
• Regular use of anti-inflammatory, anti-diabetic, weight-loss, and psychoactive medication
• Contraindications for fMRI

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-04-2022
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-08-2022
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL77503.091.21