Binging on processed foods

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29485

Source
NTR

Brief title
BINGE

Health condition

Binge Eating Disorder

Sponsors and support

Primary sponsor: n.a.
Source(s) of monetary or material Support: The study is funded by Nederlandse Wetenschaps Organisatie (NWO) NWA-IDG 2019 grant NWA.1228.192.006

Intervention

Outcome measures

Primary outcome

1. Changes in brain connectivity and activity (BOLD signal), Z-scores for functional connectivity, eigen vector values) after ingestion of different food stimuli within groups
2. Differences in brain connectivity and activity (BOLD signa)l, Z-scores for functional connectivity, eigen vector values) after ingestion of different food stimuli between groups

Secondary outcome

1. Visual Analogue Scale (VAS) scores for the level of hunger, thirst and satiety before and after ingestion of the food stimuli.

Study description

Background summary

Rationale: Processed foods are foods that are produced industrially from substances derived from foods, often with many additives, but with little ‘whole original food’ ingredients. These types of food tend to be high in calories, (saturated) fat, sugar, and salt, while being nutrient-poor compared to unprocessed foods. Not surprisingly, increased consumption of processed foods raises our daily calorie intake, as in addition to the higher calorie content, processed foods are also associated with a relatively short period of satiation, this is seen as an important cause of overweight an obesity. Even though most people are aware that processed foods are unhealthy, over 50% of our modern diet consists of these foods. The importance of the (subconscious) regulatory role of the brain in directing this eating behavior is increasingly recognized.

Objective: The objective of the study is to determine the difference in brain responses after consumption of processed and unprocessed food between healthy lean subjects with a ‘normal’ eating pattern with that of Binge Eating Disorder (BED) patients, who are prone to overeating processed foods. We hypothesize that the brain responds much stronger to processed food in BED, whereas much smaller differences are expected after consuming unprocessed food.

Study design: Cross-over trail study design with two study visits with a patient and a control group.

Study population: The study population will consist of a group of healthy normal weight (BMI 18.5-25) adult female participants from the general population and a group of adult female BED patients with obesity (BMI >30) recruited from the GGZ Rivierduinen Eating Disorders Ursula.

Intervention (if applicable): We will compare the response of the brain to a commercially available candy bar (processed) with a mix of peanuts and dried dates (unprocessed) matched for total calories, carbohydrates, fat, and protein content.

Main study parameters/endpoints: Differences in brain responses between processed and unprocessed food as measured with functional Magnetic resonance imaging (fMRI).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The study will consist of two visits to the LUMC (1-2 weeks between visits). For each visit participants will undergo one MRI scan, the duration of this visit will be 1.5 hour excluding travel time (one hour for the MRI scan plus instructions and preparations and questionnaires). 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. The potential risk of the food intervention are limited as these are commercially available products and participants with food allergies will not be included in the study. The questionnaires used during the study are also of a low burden nature. This study will provide more insight into the underlying subconscious reasons why processed foods are overconsumed or binged on. These insight are of importance for a better understanding, prevention and treatment of obesity in general and Binge Eating Disorder specifically. In light of the minimal risks for the study participants we believe that the further insights gained from the study into the ever growing obesity problem outweigh the very limited potential risks.

Study objective

We hypothesize that especially the reward centres of the brain respond much stronger to processed food in BED, whereas much smaller differences are expected after consuming unprocessed food.

Study design

The study will consist of two time points at least one week apart. Participants will consume one of the two study interventions (processed or unprocessed snack) per visit.

During the first visit (time point 1) baseline characteristics will be measured (weight, height, BMI, fat percentage and waist circumference) and questionnaires for eating behavior and physical activity habits will be taken.

During both visits (time point 1 and 2) functional MRI will be performed to determine changes in brain connectivity and activity in response to the ingestion of the food stimuli as the primary outcome.
During both visits (time point 1 and 2) VAS scores for the level of hunger, thirst and satiety will taken before and after ingestion of the food stimuli as the secondary outcome.

Intervention

We will compare the response of the brain to a commercially available candy bar (processed) with a mix of peanuts and dried dates (unprocessed) matched for total calories, carbohydrates, fat, and protein content.

Contacts

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Eligibility criteria

Inclusion criteria

Control subjects:
• Aged >18
• Female
• BMI >18,5 and <25
BED patients:
• Aged >18
• Female
• A primary diagnosis of BED according to DSM-IV criteria or subthreshold BED (an average of one binge eating episode a week)
• BMI >30

Exclusion criteria

• Age <18
• BMI not >18,5 and <25 for control subjects and BMI <30 for BED patients
• Male sex
• Diabetes
• Any know food allergy or intolerance
• Renal or hepatic disease
• Use of medication known to affect glucose (for example prednisone) or lipid metabolism
• A current history of self-induced vomiting, misuse of laxatives, diuretics, enemas, diet pills or other weight controlling medications, fasting, or excessive exercise within the last 24 weeks;
• A comorbid diagnosis of psychotic disorder, self-damaging behaviors or mental deficiency
• Pregnancy
• Any contra-indication to MRI scanning

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-08-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55035
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8851
CCMO	NL74714.058.20
OMON	NL-OMON55035

Study results