ISRCTN11231856 https://doi.org/10.1186/ISRCTN11231856

Snack food influence on resting state activity in healthy individuals

Submission date	Recruitment status	[ ] Prospectively registered
16/08/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/08/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/09/2018	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hedonic hyperphagia (overeating for pleasure) is a major cause of obesity. Specific foods such as snack food may cause someone to eat even when they are full. This study looks at how snack foods induce food intake using Magnetic Resonance Imaging (MRI) scans of the brain.

Who can participate?
Men aged between 25-50 years with a body mass index (BMI) of no more than 27kg/m2

What does the study involve?
All participants attend two sessions of brain MRI scans of about 40 minutes in total to see how different foods can affect the brain. These studies are completed within one week. The participants are asked to not eat for at least two hours before the experiment. Participants are scanned after viewing images of potato chips and zucchini. There is then a break of 5 minutes where the participants leave the scanner and are asked to eat either potato chips or sliced zucchini for 2 minutes, followed by another scan.

What are the possible benefits and risks of participating?
The benefit will be to contribute to the research of how diet can influence the brain. This study does not involve any major risks.

Where is the study run from?
Friedrich-Alexander-Universität Erlangen-Nürnberg (Germany)

When is the study starting and how long is it expected to run for?
December 2015 to August 2017

Who is funding the study?
Friedrich-Alexander-Universität Erlangen-Nürnberg (Germany)

Who is the main contact?
Prof. Dr. Andreas Hess

Contact information

Type(s)
Scientific

Contact name
Prof Andreas Hess

Contact details
Fahrstraße 17, 22
Erlangen
Germany
91054

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Faunt1

Study information

Scientific Title
High vs low caloric food modulation of human resting-state functional connectivity in healthy individuals

Study objectives
Resting state networks (RSNs) can individually adapt to experience after short time exposures to a stimulus, and these RSNs are a good indicator for addictive behaviors. The current study hypothesizes that visualization and ingestion of different food types (high-caloric: chips, and low-caloric: zucchini) will elicit distinct changes in the RSNs of healthy individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-Kommission der Medizinischen Fakultät of Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU), 15/09/2015, ref: 220_15B

Study design
Single-center single-blind controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Nutrition

Interventions
Every subject will undergo two different fMRI sessions of ~40 minutes in total. The interval between the two sessions was 3 days. Participants will arrive to the fMRI unit previously knowing what food they will be presented each day.
The subjects will be asked not to eat food for at least two hours before the experiment.
In each session resting state will be measured twice. Each fMRI session will start by acquiring the individual anatomical imaging, followed by the first resting state RS scan, BOLD visual stimulation (presentation of different images of potato chips and zucchini) image presentation: total 196 vol. (time points) = 28 x 7 , 1 block of images contain 7 images, 1 image = 1 vol. = 3 sec). There will then be a pause of 5 minutes, where the participants will exit the scanner and be asked to consume day 1= salted potato chips 528kcal/100g 33% fats 49% carbohydrates, day 3= sliced zucchini 17kcal/100g 3% fats 3.5% carbohydrates ad libitum for 2 minutes, followed by the second resting state RS scan.

Intervention Type
Behavioural

Primary outcome measure
Brain activity measured using fMRI after the visual stimulation and consumption of the different foods

Secondary outcome measures
Correlation of BMI with changes in brain activation measured using fMRI after the visual stimulation and consumption of the different foods

Overall study start date
15/12/2015

Completion date
01/08/2019

Eligibility

Key inclusion criteria

1. Healthy
2. Right handed
3. BMI from 19 to 27
4. Aged 25-50

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Any current or past form neurological/psychiatric diseases
2. BMI outside the range of 19-27
3. Any contradictions to fMRI scanning

Date of first enrolment
15/12/2015

Date of final enrolment
15/12/2016

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinikum Erlangen
Erlangen
Germany
91054

Study participating centre
Friedrich-Alexander-Universität Erlangen-Nürnberg
Erlangen
Germany
91054

Sponsor information

Organisation
Friedrich-Alexander-Universität Erlangen-Nürnberg

Sponsor details
c/o Dr. rer. nat. Esther Schnetz
Schlossplatz 4
Erlangen
Germany
91054

Sponsor type
University/education

ROR
https://ror.org/00f7hpc57

Funder(s)

Funder type
University/education

Funder Name
Friedrich-Alexander-Universität Erlangen-Nürnberg

Alternative Name(s)
FAU Erlangen-Nürnberg, University of Erlangen-Nuremberg, Friedrich Alexander University of Erlangen Nuremberg, FAU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Publication and dissemination plan

Study protocol, statistical analysis plan among other additional information will be available upon request. Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Andreas Hess. Type of data: resting state fMRI. Access criteria: research purposes. Consent from participants was obtained, anonymisation was carried out by a third person not belonging to the study.

IPD sharing plan summary
Available on request