

## Trial Description

### Title

**Cerebral energy homeostasis and ingestion at neuronal activation**

### Trial Acronym

**ZEINA**

### URL of the trial

**[---]\***

### Brief Summary in Lay Language

**We investigate brain metabolism in overweight human and explore whether an influence affect the organism. We include 15 healthy obese subjects. Each volunteer receive transcranial direct current stimulations of the brain and placebo-stimulations.**

### Brief Summary in Scientific Language

**Brain energy metabolism and neuropsychological aspects of food intake control with respective behavioural correlates have been suggested to be closely interlinked. This project aims at testing the hypothesis that food intake behaviour, and particularly the preference for palatable high caloric ("comfort") food by its incentive salience, is synchronized by the human brain in dependence of its current energy status.**

### Do you plan to share individual participant data with other researchers?

**[---]\***

### Description IPD sharing plan

**[---]\***

## Organizational Data

- DRKS-ID: **DRKS00008882**
- Date of Registration in DRKS: **2015/07/08**
- Date of Registration in Partner Registry or other Primary Registry: **[---]\***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **15-040 , Ethik-Kommission Universität zu Lübeck**



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Ethics Approval/Approval of the Ethics Committee: **Approved**

**Medizinische Fakultät des Universitätsklinikums Schleswig-Holstein**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1171-8336**

## Health condition or Problem studied

- Free text: **Basic research: food intake and brain metabolism**
- Free text: **healthy participants**

## Interventions/Observational Groups

- Arm 1: **brain-stimulation - direct current, transcraniell, anodal, 20min, 1,5mA, daily for one week**
- Arm 2: **placebo-stimulation**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: **patient/subject**
- Control: **Placebo**
- Purpose: **Basic research/physiological study**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

## **Food intake measured by Buffet-Test on first day of stimulation and after a week stimulation**

### **Secondary Outcome**

**cerebral energy content measured by medical imaging on first day and on last day of stimulation. (before and after stimulation, respectively)**

## **Countries of recruitment**

- **DE Germany**

## **Locations of Recruitment**

- other **Sektion für Psychoneurobiologie, Lübeck**

## **Recruitment**

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/07/15**
- Target Sample Size: **15**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### **Inclusion Criteria**

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **30 Years**

### **Additional Inclusion Criteria**

**BMI: 25-40 kg/m<sup>2</sup>**  
**Body fat percentage: >25 %**

### **Exclusion criteria**

**Smoker**  
**disturbe eating behaviour (tested with FEV)**  
**acute or chronic disease**  
**explicit: diagnosis of migraine or other headache diseases**  
**permanent medication**  
**shiftworker**  
**circadian dysrhythmia**



**competitive sportsman  
diabetics  
mental illness**

## Addresses

### ■ Primary Sponsor

**Sektion für Psychoneurobiologie  
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### ■ Contact for Scientific Queries

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### ■ Contact for Public Queries

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## Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Research (BMBF), etc.)**

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Kennedyallee 40  
53175 Bonn  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **www.dfg.de**

## Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]\*

## Trial Publications, Results and other documents

\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.