PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Neuronal olfactory-emotional interaction in depression

Trial Acronym

OLSA

URL of the trial

[---]*

Brief Summary in Lay Language

**The present study focuses on the impact of olfactory stimulation on salience processing in people with major depressive disorder. Salience processing refers to the "relevance" of surrounding Stimuli. A warm, freshly brewed cup of coffee for example would certainly attract several people early in the morning.
Prior studies have shown, that this salience processing is impaired in major depressed patients. Especially when it comes to the presentation of positive stimuli, such as smiling facial expressions. Brain structures involved in salience processing are also involved in olfactory Information processing. Therefore we hypothesize, that olfactory stimulation can influence salience processing.**

**The present study will include two groups, the control group (helathy controls) and the study group (major depressed patients).
During the experimental set up, consisting of three trials, participants are asked to react to smiling facial expressions via button pressing. In one of the trials participants will perceive a lilac odor presentation.**

Brief Summary in Scientific Language

Major depressed (MD) patients present structurally and functionally altered salience processing regions. These affected brain areas receive intense input from the olfactory bulb and the primary olfactory cortex. We therefore aim to modify the salience activity in MD patients by olfactory stimulation.

The study subjects will participate in an event-related fmri design consisting of an emotional oddball paradigm with infrequent positive facial expressions embedded in frequent neutral facial expressions. The experiment will consist of three trials: 1) a blank trial with facial expressions only, 2) facial expressions presented in the same paradigm as in the blank trial, this time accompanied by olfactory stimulation and 3) a control condition based on mechanical trigeminal Stimulation. The mechanical Stimulation will be done by an air flow on the forehead.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00016497**
- Date of Registration in DRKS: **2019/03/14**
- 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.: **EK404102017 , Ethikkommission der Medizinischen Fakultät der Technischen Universität Dresden**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32.2 - Severe depressive episode without psychotic symptoms**
- ICD10: **F32.1 - Moderate depressive episode**

Interventions/Observational Groups

- Arm 1: **Healthy controls (validated by the application of PHQ and BDI)**
  Controls were recruited by public announcement in the technical University, the smell and taste Center and the Intranet of the University Hospital Dresden.
  The study participants are invited for one appointement where they go through the following steps:
  - Filling in of questionnaires on an iPad (approx. 30 min)
  - fMRI measurements (structural T1, Bulbvolume measurement, functional EPI) (approx. 45 min)
  - olfactory testing (olfactory threshold, olfactory identification) approx. 20 min

- Arm 2: **Patients (F32.1/F32.2, SCID) were recruited in the University Hospital and affiliated therapists.**
  The study participants are invited for one appointement where they go through the following steps:
  - Filling in of questionnaires on an ipad (approx. 30 min)
  - MRI measurements (structural T1, Bulbvolume measurement, EPI) (approx. 45

min)
- olfactory testing (olfactory threshold, olfactory identification) (approx. 20 minutes)

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Difference in olfactory function in the peripheral vs the central dimension (olfactory identification vs olfactory threshold), changes in oddball - reaction times during the three different trials, changes of BOLD Signal according to the different trials (1) visual Stimulation only 2) visual and olfactory Stimulation 3) visual and mechanical trigeminal Stimulation).

(The exact duration is described in Arm 1 and Arm 2 above).

Secondary Outcome

Evaluation of olfactory function in group comparison (control vs study group), evaluation of changes of BOLD Signal and oddball reaction times according to the different trials in group comparison, relation of anhedonic symptomatology and related questionnaire data to olfactory function and BOLD Signal in group comparison.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Universitätsklinikum, Dresden**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/08/17**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

For the Patient sample: a diagnosed Major Depression (SCID)

Exclusion criteria

Exclusion criteria are 1) patients with a history of schizophrenia and/or bipolar disorder 2) history of severe head injury; 3) dependence on alcohol or other substances; 4) concurrent neurological or otorhinolaryngical illness; 5) anosmia; 6) contraindication for MRI.

Addresses

- **Primary Sponsor**

  Klinik für Psychotherapie und Psychosomatik, Uniklinikum Carl Gustav Carus Dresden
  Ms. Jun.-Prof.Dr.habil. Ilona Croy
  Fetscherstraße 74
  01307 Dresden
  Germany

  Telephone: **0351 458 3502**
  Fax: **[---]***
  E-mail: **ilona.croy at ukdd.de**
  URL: **https://www.uniklinikum-dresden.de/de/das-klinikum/kliniken-polikliniken-institute/pso/forschung-und-lehre/forschung-1/biomarker**
- **Contact for Scientific Queries**

  Forschergruppe Neuromarker, Klinik für Psychotherapie und Psychosomatik,Uniklinikum Carl Gustav Carus Dresden
  Ms. Jun.-Prof.Dr.habil. Ilona Croy

Contact for Scientific Queries

Forschergruppe Neuromarker, Klinik für Psychotherapie und Psychosomatik,Uniklinikum Carl Gustav Carus Dresden
Ms. Jun.-Prof.Dr.habil. Ilona Croy
Fetscherstraße 74
01307 Dresden
Germany

Telephone: **0351 458 3502**
Fax: **[---]***
E-mail: **ilona.croy at ukdd.de**
URL: **https://www.uniklinikum-dresden.de/de/das-klinikum/kliniken-polikliniken-institute/pso/forschung-und-lehre/forschung-1/biomarker**

- **Contact for Public Queries**

Forschergruppe Neuromarker, Klinik für Psychotherapie und Psychosomatik,Uniklinikum Carl Gustav Carus Dresden
Ms. Carina Köppel
Fetscherstraße 74
01307 Dresden
Germany

Telephone: **0351 458 19793**
Fax: **[---]***
E-mail: **carina.koeppel at ukdd.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

Promotionsprogramm der Medizinischen Fakultät, TU Dresden, welches finanziell von der Dr. Georg E. und Marianne Kosing-Stiftung unterstützt wird
Fetscherstraße 74
01307 Dresden
Germany

Telephone: **+49 351 458-4770**
Fax: **[---]***
E-mail: **med-dezernentin at mailbox.tu-dresden.de**
URL: **[---]***

Status

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

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethical_approval_EK404102017_OLSA_study**
- Further trial documents **ethik_amendement_OLSA**

** 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.*