

Trial Description**Title**

Change in olfactory perception during psychotherapeutic treatment of patients with depressive disorder

Trial Acronym

COPD

URL of the trial

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Brief Summary in Lay Language

Empirical studies show that patients with a depressive disorder have deficits in olfactory perception. However, the meaning of these deficits has not yet been conclusively clarified. The aim of the planned investigation is to check whether the olfactory performance is improved in the course of an improvement of the depressive symptoms, or whether the deficits persist. In addition, it should be checked whether the initial olfactory performance has an influence on the recovery potential of the patients suffering from depressive disorders. For this aim, the olfactory performance of patients with Major Depression will be examined before, during and after a psychotherapeutic treatment.

Brief Summary in Scientific Language

Deficits of olfactory perception are widespread in mental disorders, including depression, posttraumatic stress disorder, and obsessive-compulsive disorder. Especially in depressive disorder, all dimensions of olfactory perception appear to be deficient. However, the findings are heterogeneous, and there are also conflictive findings. It is also not known whether the olfactory deficits are a secondary symptom of depressive disorders, regressing in the course of the recovery from depressive symptoms, or whether the olfactory deficits represent a biological marker of dysfunctional cerebral processing. If the first assumption is true, it is expected that the olfactory performance improves in the course of the psychotherapeutic treatment. If the second assumption is true, it is expected that the severity of the olfactory deficits predicts the change of symptom severity in the course of a psychotherapeutic treatment. The aim of the planned study is to answer these questions and to examine the relationship between olfactory perception depressive symptoms.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00012970**
- Date of Registration in DRKS: **2017/10/24**
- 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.: **16-11 , Ethikkommission der Fakultät für Empirische Humanwissenschaften und Wirtschaftswissenschaft der Universität des Saarlandes**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**

Interventions/Observational Groups

- Arm 1: **The olfactory perception (perception threshold, discrimination, identification) of Patients with depressive disorder will be examined at three time points (before the start of a psychotherapy, after the 12th and after the 24th session). In addition, the symptom severity will be assessed by questionnaires (BDI-II and BSI) and clinical diagnostics are assessed by the SKID.**
- Arm 2: **The olfactory perception and the symptom severity of healthy controls will be assessed at the same time points and by the same measurements as described in Arm 1.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
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Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Examination of the presence of deficits in olfactory perception (perception threshold, discrimination, identification) in patients with depression compared to a healthy control group adjusted for age and sex. The olfactory perception is measured in all dimensions with the Sniffin 'Sticks.

Change of the olfactory perception (perception threshold, discrimination, identification) in the course of the therapy.

Predictability of the change in symptom stress, recorded by the BDI, in the course of the therapy based on the olfactory perception.

Three survey days: 1) before the start of therapy (during or after the probatory sessions), 2) after the 12th therapies session, 3) after the 24th therapies session.

Secondary Outcome

Diagnostic Interview using SKID. Examination of the correlation between olfactory performance and the severity of comorbidities like e.g. anxiety disorders (BSI).

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- other **Universität des Saarlandes, Klinische Psychologie und Psychotherapie, Saarbrücken**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/10/12**
- 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: **no maximum age**

Additional Inclusion Criteria

Patient sample: Depressive disorder as primary diagnosis, participation in cognitive behavioral therapy

Control group: healthy volunteers

Exclusion criteria

Patients: Drug or substance abuse, permanent use of medication (exception: oral contraceptives or occasional use of headache tablets up to one week before the beginning of the study, prescribed psychopharmaceuticals)

Control group: Mental disorder, drug or substance abuse, permanent administration of medications (exception: oral contraceptives or occasional use of headache tablets up to one week before the start of the study)

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries



Contact for Scientific Queries

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Sources of Monetary or Material Support

■ Institutional budget, no external funding (budget of sponsor/PI)

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Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]*

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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.*