

**Trial Description****Title**

**A longitudinal study on the relationship between olfactory performance, mental health, and life satisfaction**

**Trial Acronym**

**LROH**

**URL of the trial**

**[---]\***

**Brief Summary in Lay Language**

**On the current status of the research, a connection between mental disorders and deficits of smell perception is suspected. Both persons with mental disorders have accumulated deficits of the smell perception and persons with primary smell disorders have more psychical disturbances. The direction of the connection is still unclear. It is thus not yet known whether the deficits of smell perception are first present, or the mental disorder first occurs. Using a longitudinal study with a duration of one year the planned research is intended to help clarify this issue. The primary purpose is to evaluate if deficits of olfactory perception can be used to predict the development of mental disorders. For this purpose, the olfactory performance and the symptom load of a healthy, student sample is raised to two measuring points.**

**Brief Summary in Scientific Language**

**Patients with mental disorders often have deficits in olfactory perception. The significance of this connection is still unresolved. On the one hand, these deficits could be a result of mental illness, e.g., by a changed neurotransmitter concentration or deficient attention processes. On the other hand, olfactory deficits could constitute a biomarker of disturbed cerebral cycles or influence the social interaction of the affected persons, which would be a vulnerability factor. For degenerative diseases, e.g. Alzheimer's disease already have positive findings on the predictive value of olfactory perception. The objective of this longitudinal study is to examine the predictive value of the olfactory identification ability for the change of the psychological stress or the occurrence of mental disorders over a period of one year on a student sample.**

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

**[---]\***

**Description IPD sharing plan**

**[---]\***

## Organizational Data

- DRKS-ID: **DRKS00013258**
- Date of Registration in DRKS: **2017/11/21**
- 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.: **[---]\*** , **Ethikkommission der Fakultät für Empirische Humanwissenschaften und Wirtschaftswissenschaft**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F40 - Phobic anxiety disorders**
- ICD10: **F41 - Other anxiety disorders**
- ICD10: **F42 - Obsessive-compulsive disorder**
- ICD10: **F43 - Reaction to severe stress, and adjustment disorders**
- Free text: **healthy subjects**
- Free text: **Alexithymia**

## Interventions/Observational Groups

- Arm 1: **With a distance of one year, students are examined at two measure points. At both measurement points, their olfactory perception is examined using the Sniffin' sticks. Their symptom load, the quality of life as well as the importance of the sense of smell for their daily life are examined using questionnaires. The existence of a mental disorder is also clarified at both measuring times using questionnaires.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**



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Study Type Non-Interventional: **Other**

- Allocation: **Single arm study**
- Blinding: **[---]\***
- Who is blinded: **[---]\***
- Control: **Uncontrolled/Single arm**
- Purpose: **Screening**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Prediction of the development of a mental disorder and the chance of the symptom load and the quality of life between the measurement times using the quality of the olfactory perception at measure point one as a predictor. The measurement of the smelling achievement occurs by means of the Sniffin' Sticks. The life satisfaction, the symptom load and the meaning of the odour sense for the everyday life of the test persons, are raised by means of questionnaires.**

### Secondary Outcome

**Second outcome ist to examine the relationship between the quality of the olfactory perception and the symptom load, the quality of life and the existence of a mental disorder at both measurement times and to test a moderation of these relationships by the importance of the sense of smell for their daily life. The measurement of the smelling achievement occurs by means of the Sniffin' Sticks. The life satisfaction, the symptom load and the meaning of the odour sense for the everyday life of the test persons, are raised by means of questionnaires.**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- other **Universität des Saarlandes, Saarbrücken**

### Recruitment

- Planned/Actual: **Actual**

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- (Anticipated or Actual) Date of First Enrollment: **2017/11/27**
- 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

**Psychology students, not in psychotherapeutic treatment**

#### Exclusion criteria

**drug addiction, alcohol addiction, primary smell disorder, neurological disorder**

#### Addresses

##### ■ Primary Sponsor

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##### ■ 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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E-mail: [---]\*

URL: [---]\*

## 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.*