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

Trial Description

Title

Using virtual reality to reduce cognitive biases in psychosis

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Cognitive distortions are associated with the formation and maintenance of delusions. Studies show that correcting cognitive distortions (e.g. jumping to conclusions bias) may also reduce psychotic symptoms. The aim of this study is to investigate whether the correction of overconfidence in false memories via a virtual reality intervention leads to an improvement of delusional ideation in people with a psychosis.

Brief Summary in Scientific Language

Cognitive distortions are associated with the formation and maintenance of delusions. Studies show that correcting cognitive distortions (e.g. jumping to conclusions bias) may also reduce psychotic symptoms. The aim of this study is to investigate whether the correction of overconfidence in false memories via a virtual reality intervention leads to an improvement of delusional ideation in people with a psychosis. A randomised, controlled design was used. The participants complete four different virtual scenarios. Afterwards they are asked for previously shown persons and objects. The intervention group receives feedback on errors in the recognition task to correct possible overconfidence in false memories. The control group receives no feedback. The goal is to decrease overconfidence in false memories by providing corrective experiences and consequently reduce delusional ideation.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013947**
- Date of Registration in DRKS: **2018/06/25**
- 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.: **SM 112015 , Deutsche Gesellschaft für Psychologie**

Secondary IDs

Health condition or Problem studied

- ICD10: **F20 - Schizophrenia**
- Free text: **Psychosis**

Interventions/Observational Groups

- Arm 1: **Feedback group (participants receive immediate feedback for errors in a recognition task).**
  The participants undergo four different virtual scenarios. Afterwards, they are asked for previously shown persons and objects. The intervention group receives feedback on errors in the recognition task to correct possible overconfidence in false memories.
- Arm 2: **No feedback group (participants do not receive feedback for errors).**
  The participants undergo four different virtual scenarios. Afterwards, they are asked for previously shown persons and objects. The control group receives no feedback on their performance (e.g. errors) in the recognition task.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **assessor**

Control: **Control group receives no treatment**

Purpose: **Treatment**

Assignment: **Parallel**

- Phase: **II-III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Reduction of psychotic symptoms, measured with:

Four weeks after baseline:
Positive and Negative Syndrome Scale (PANSS),
Psychotic Symptom Rating Scales (PSYRATS)

Immediatly after the VR (virtual reality) Intervention:
Paranoia Checklist,
Community Assessment of Psychic Experiences

Secondary Outcome

Feasibility and accaptence of the virtual reality and head-mounted display, measured immediatly after the VR intervention:
Simulation Sickness Questionnaire

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Asklepios Klinik Nord-Wandsbek , Hamburg**

Recruitment

- Planned/Actual: **Actual**

Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2016/02/08**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **55 Years**

Additional Inclusion Criteria

- current or past psychotic episode (verified via the MINI)
- informed consent

Exclusion criteria

- history of seizures or epilepsy
- other neurologic disorders

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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.*