



Trial Description

Title

Aggressive behavior and its association with the effectiveness of outpatients psychotherapy

Trial Acronym

ATAV

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to investigate the relationship between (auto)aggressive behavior and the success of psychotherapeutic treatment. Both the association between the symptom severity and the aggressive behavior at the beginning of the therapy as well as the change of the aggressive behavior in the course of the therapy are of interest. Also, it will be examined whether the aggressive behavioral tendencies influence the success of treatment and the rate of premature treatment discontinuation. For this purpose, the symptom severity and the aggressive tendencies will be examined using psychometric questionnaires both at the beginning of an outpatient psychotherapeutic treatment and after the course of twelve psychotherapeutic treatment sessions.

Brief Summary in Scientific Language

Patients with mental disorders show an increased rate of (auto)aggressive behavior compared to healthy individuals. For example, this is for patients with posttraumatic stress disorder and also for patients with major depression the case. In the context of this investigation, it will be examined whether these aggressive behavioral tendencies influence the symptom severity and the success of a psychotherapeutic treatment. For this purpose, both the mental stress and the aggressive behavioral tendencies, are examined at the beginning and after the course of twelve psychotherapeutic sessions.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data



- DRKS-ID: **DRKS00014005**
- Date of Registration in DRKS: **2018/02/13**
- 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.: **18-01 , Ethikkommission der Fakultät für Empirische Humanwissenschaften und Wirtschaftswissenschaft der Universität des Saarlandes**

Secondary IDs

Health condition or Problem studied

- ICD10: **F30-F39 - Mood [affective] disorders**
- ICD10: **F40-F48 - Neurotic, stress-related and somatoform disorders**
- ICD10: **F50-F59 - Behavioural syndromes associated with physiological disturbances and physical factors**

Interventions/Observational Groups

- Arm 1: **In this study, the symptom severity and the (auto)aggressive behaviors of patients undergoing outpatient psychotherapeutic treatment will be analyzed before and during the treatment. All patients over the age of eighteen, regardless of sex or other socio-demographic data, will be included in the survey. Before the beginning of the therapy, the structured clinical interview for DSM-IV is performed to confirm the diagnosis. At the beginning of psychotherapy and after the twelfth therapeutic session, the symptom severity will be measured using the BSI, the BDI-II and a newly developed aggression questionnaire, the "Testinventar zu autoaggressivem und fremdaggressivem Verhalten".**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
-



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Blinding: [---]*

Who is blinded: [---]*

Control: **Uncontrolled/Single arm**

Purpose: **Prognosis**

Assignment: **Single (group)**

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

Primary Outcome

The relation between the severity of the mental symptoms and the aggressive behavioral tendencies, the predictability of the treatment success via the aggressive behavioral tendencies and the predictability of the rate of premature treatment discontinuation via aggressive behavioral tendencies will be examined via psychometric questionnaires. The symptom severity will be recorded at the beginning of the psychotherapy and after the course of twelve psychotherapeutic sessions using the Beck Depression Inventory - Revision and the Brief Symptom Checklist. The detection of aggressive tendencies is carried out using pilot version of the "Testinventar zu autoaggressivem und fremdaggressivem Verhalten". Parallel to this study there will be a second examination to examine the psychometric properties of the "Testinventar zu autoaggressivem und fremdaggressivem Verhalten", with the purpose to select the final items of this inventory. Finally the data evaluation will be only based on this final itemlist. The relationships between the symptom severity and the therapeutic success with the aggressive behavioral tendencies will be analyzed both over all patients together and selective for different categories of disorders, e.g., anxiety disorders and mood disorders.. The diagnosis is recorded before the start of the psychotherapy using the Structured Clinical Interview for DSM-IV. Based on this interview, a diagnosis is given according to DSM 5 and ICD-10.

Secondary Outcome

Recording the differences in the extent of aggressive tendencies depending on the diagnosis. Diagnosis is recorded using the Structured Clinical Interview for DSM-IV. Based on this interview, a diagnosis is given according to DSM 5 and ICD-10.

Countries of recruitment

- DE **Germany**



Locations of Recruitment

- other **Universitätsambulanz der Universität des Saarlandes, Saarbrücken**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/02/19**
- Target Sample Size: **220**
- 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

Beginning of an outpatient psychotherapy at the Center for Behavior Therapy of the Saarland University or at the "Weiterbildungsinstitut für Psychotherapie Saarbrücken". The patient is suffering from a mental disorder according to DSM 5 or ICD-10. The minimum age is 18. Good knowledge of German.

Exclusion criteria

Schizophrenic psychosis

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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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.*