

## Trial Description

### Title

**Multi-Center Effectiveness Study of Inpatient Psychosomatic-Psychotherapeutic Treatment in German University Hospitals**

### Trial Acronym

**MEPP Study**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**This study evaluates the effectiveness of inpatient and day-/night-care treatment of people with psychic and psychosomatic disorders. Treatment are delivered at 19 German university clinics of psychosomatics and psychotherapy for ca. 8-12 weeks. A sample of about 2,000 patients will be assessed before and after treatment as well as one year after treatment. Outcome criteria are symptoms of disease, problems in everyday life, and mental health care utilization.**

### Brief Summary in Scientific Language

**The efficacy of psychotherapy for a wide range of psychic and psychosomatic disorders is indisputable and well-validated. However, most efficacy studies have been undertaken in highly selected patients and an outpatient setting. Data of the effectiveness of inpatient treatment are comparably sparse and from smaller studies. This multicenter cohort study aims to assess the effectiveness of inpatient and day-/nightcare treatment in 19 German university clinics of psychosomatic medicine and psychotherapy in a large sample of about 2,000 patients. After informed consent has been obtained from the patients, assessments are performed at the beginning and end of the treatment as well as a one-year follow-up. Assessments employ questionnaires focusing symptom load, social functioning, and mental health care service use. Baseline diagnoses are made by standardized structured interviews.**

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

**No**

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00016412**
- Date of Registration in DRKS: **2018/12/20**
- 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.: **18-6388 , Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum**

## Secondary IDs

## Health condition or Problem studied

- Free text: **All disorders that are being treated at the clinics for psychosomatic medicine and psychotherapy (primarily ICD-10: F3, F4, F5, F6).**
- ICD10: **F30-F39 - Mood [affective] disorders**
- ICD10: **F40 - Phobic anxiety disorders**
- ICD10: **F50-F59 - Behavioural syndromes associated with physiological disturbances and physical factors**
- ICD10: **F60-F69 - Disorders of adult personality and behaviour**

## Interventions/Observational Groups

- Arm 1: **Inpatient or day-/nightcare treatment for ca. 8-12 weeks in university clinics of psychosomatic medicine and psychotherapy. These treatments combine different compounds, e.g., individual psychotherapy, group psychotherapy, non-verbal psychotherapeutic therapies.**

## Characteristics

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

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Single arm study**

Blinding: [---]\*

Who is blinded: [---]\*

Control: **Uncontrolled/Single arm**

Purpose: **Treatment**

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

### Primary Outcome

**Symptom load (anxiety, depression, somatic symptoms) as assessed by th PHQ-D at the end of the treatment and one-year follow-up.**

### Secondary Outcome

**Social functioning (WHODAS 2.0), personality structure (OPD-SF), mental health care service utilization (modified version of the CSSRI) at the end of the treatment and one-year follow-up.**

### Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Medizinische Klinik mit Schwerpunkt Psychosomatik , Berlin**
- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Klinik für Psychosomatische Medizin & Psychotherapie, Bochum</style>
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, Bonn**
- University Medical Center **Klinik für Psychotherapie und Psychosomatik , Dresden**
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, Düsseldorf**
- University Medical Center **Psychosomatische und Psychotherapeutische Abteilung, Erlangen**
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, Essen**
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, Freiburg im Breisgau**
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie , Göttingen**
- University Medical Center **Klinik für Psychosomatik und Psychotherapie, Hannover**
- University Medical Center **Klinik für Allgemeine Innere Medizin und Psychosomatik, Heidelberg**
- University Medical Center **Klinik für Psychosomatik und Psychotherapie, Köln**
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, Mainz**
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, München**
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, Nürnberg**
- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, Ulm**
- University Medical Center **Klinik für Psychosomatik und Psychotherapie, Gießen/Marburg**
- University Medical Center **Klinik für Psychosomatik und Psychotherapeutische Medizin, Rostock**
- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Klinik für Psychosomatische Medizin & Psychotherapie, Tübingen</style>

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/03/01**
- Target Sample Size: **2000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

## Additional Inclusion Criteria

**Age  $\geq$  18 years, sufficient knowledge of German language, admission for inpatient or day-/nightcare treatment in clinic for psychosomatics and psychotherapy**

## Exclusion criteria

**Acute psychotic disorder, brain organic disease, substance dependency with current substance use and intoxication**

## Addresses

### ■ Primary Sponsor

**Klinik für Psychosomatische Medizin und Psychotherapie Ruhr Universität  
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## Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]\*
- Reason, if Reason for Recruiting Stop "Other": [---]\*
- Study Closing (LPLV): [---]\*
- Number of Participants in Germany after Recruiting complete: **2094**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **2094**

## 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.