Trial Description

Title

Short-term psychodynamic therapy of obsessive-compulsive disorder

Trial Acronym

STPP-OCD

URL of the trial

[---]*

Brief Summary in Lay Language

In the planned study we will test the efficacy of manual-guided short-term psychodynamic psychotherapy (STPP) in patients with the diagnosis of an obsessive compulsive disorder (OCD).

The active treatment condition (STPP) will be compared against a waiting list control condition. There will be two participating sites with study centers in Giessen/Göttingen (Clinic of Psychosomatics and Psychotherapy) and Frankfurt (Sigmund-Freud-Institute).

We plan to randomly assign 2x33 patients to the study conditions. Patients between 18 and 65 years of age with the primary diagnosis of an obsessive-compulsive disorder (OCD) will be included. Concomitant comorbid disorders are allowed provided that OCD is the most severe diagnosis.

The following exclusion criteria will be applied: psychotic disorders, acute substance-related disorders, organic mental disorders, somatic disorders not compatible with psychotherapy, Cluster A and B personality disorders, patients with acute risk of self-harm or suicide, concurrent psychotherapy or psychopharmacotherapy.

Primary outcome measure will be the Yale-Brown Obsessive Compulsive Scale (Y-BOCS). Additionally, several secondary outcomes will be investigated, among them anxiety, depression, interpersonal problems, obsessive beliefs and stress-cortisol. It will also be examined how different mediators influence outcome: the therapeutic relationship (alliance), changes in central psychodynamic conflicts associated with symptoms of obsessive-compulsive disorder, attachment and mentalizing. Furthermore we will investigate if and how traumatic childhood experiences effect outcome (mediator of outcome).

Therapy will be manual-guided following published manuals. Assessments will be performed at baseline (prior to therapy), immediately after therapy as well as 6 and 12 months after therapy. Assessments will be carried out by trained raters unaware of patient assignment to groups (observer-blind outcome assessment).
The study will be set up as a randomized-controlled trial testing the efficacy of manual-guided short-term psychodynamic psychotherapy (STPP). The active treatment condition will be compared against a waiting list control condition. There will be two participating sites with study centers in Giessen/Göttingen (Clinic of Psychosomatics and Psychotherapy) and Frankfurt (Sigmund-Freud-Institute).

It is planned to randomize 2x33 patients, which allows detection of a medium to large effect size (d=0.7) with a power of 0.80. Patients with the primary diagnosis of obsessive-compulsive disorder (ICD-10 F42, DSM-5 300.3) will be included. 18-65 years of age. Comorbid disorders are permitted provided that OCD is the most severe (primary) diagnosis. The following exclusion criteria will be applied: psychotic disorders, acute substance-related disorders, organic mental disorders, somatic disorders not compatible with psychotherapy, Cluster A and B personality disorders, patients with acute risk of self-harm or suicide, concurrent psychotherapy or psychopharmacotherapy.

Primary outcome measure: Yale-Brown Obsessive Compulsive Scale (Y-BOCS). Secondary outcomes measures: Response (Y-BOCS), remission (Y-BOCS), Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Inventory of Interpersonal Problems (IIP), Obsessive Beliefs Questionnaire (OBQ), Stress-Cortisol (hair sample).

Mediators: Helping Alliance Questionnaire (HAQ), Core Conflictual Relationship Theme (CCRT), attachment (Experiences in Close Relationships Questionnaire-Revised, ECR-RD), mentalization (Mentalization Questionnaire, MZQ).

Moderators: Childhood Trauma Questionnaire (CTQ).

Therapy will be manual-guided, following published treatment manuals.

Assessments will be made pre and post therapy as well as 6 and 12 months after therapy. Assessments will be performed by masked and trained raters.

Organizational Data

- DRKS-ID: DRKS00011256
- Date of Registration in DRKS: 2017/02/14
- 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.: 126/16, Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen

Secondary IDs

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Health condition or Problem studied

- ICD10: F42 - Obsessive-compulsive disorder

Interventions/Observational Groups

- Arm 1: Manualized short-term psychodynamic therapy (STPP) specifically tailored to OCD, up to 24 sessions (1 session lasts 50 minutes), frequency: 1 session/week (total duration: 6 months). The treatment manual has been published, including details of the procedures (Leichsenring & Steinert, 2016; Leichsenring & Steinert, in press).


- Arm 2: waiting list, six months

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Randomized controlled trial
- Blinding: [---]*
- Who is blinded: assessor, data analyst
- Control: Control group receives no treatment
- Purpose: Treatment
- Assignment: Parallel
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

Y-BOCS, assessed blinded evaluators, assessed immediately after end of therapy. Further assessments will be carried out before therapy and 6 and 12 months after end of therapy.

Secondary Outcome

All assessments will be carried out before therapy, after end of therapy, 6 and 12 months after end of therapy.
Secondary outcomes Response (Y-BOCS), Remission (Y-BOCS), Beck Depression Inventory (BDI), Inventory of Interpersonal Problems (IIP), Beck Anxiety Inventory (BAI), Obsessive Beliefs Questionnaire (OBQ), stress cortisol (hair sample)

Mediators: Helping Alliance Questionnaire (HAQ), Core Confictual Relationship Theme (CCRT), attachment (Experience in Close Relationships-Revised, ECR-RD), mentalization (Mentalization Questionnaire, MZQ)

Moderator: Childhood trauma questionnaire (CTQ)

Countries of recruitment

- DE Germany

Locations of Recruitment

- University Medical Center Psychosomatik und Psychotherapie, Göttingen
- other Sigmund-Freud-Institut, Frankfurt a.M.

Recruitment

- Planned/Actual: Planned
- (Anticipated or Actual) Date of First Enrollment: 2017/06/01
- Target Sample Size: 66
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: 65 Years

Additional Inclusion Criteria

primary diagnosis of obsessive-compulsive disorder (ICD-10 F42, DSM-5 300.3)

Exclusion criteria

psychotic disorders, acute substance-related disorders, organic mental disorders, somatic disorders not compatible with psychotherapy, Cluster A and B personality disorders, patients with acute risk of self-harm or suicide, concurrent psychotherapy or psychopharmacotherapy.
Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ Private sponsorship (foundations, study societies, etc.)

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Status

- Recruitment Status: Recruiting planned
- 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.