Trial Description

Title

Transfer of manualized Short Term Psychodynamic Psychotherapy (STPP based on SET) for Social Phobia into clinical practice

Trial Acronym

SOPHO-NET D2

URL of the trial

http://www.sopho-net.de/

Brief Summary in Lay Language

The aim of our study is to examine the effects of an additional training in a manualized Short Term Psychodynamic Psychotherapy (STPP) procedure on outcome in routine psychotherapy for Social Phobia.
The efficacy of this STPP for Social Phobia has been evaluated in a controlled clinical trial. It is important to investigate, whether new methods can be transferred from controlled trials into the less structured setting of routine clinical care, and whether the health care system benefits from such developments.
Therapists will be randomly assigned to either a training group in which the treatment approach will be delivered or a treatment as usual group (standard treatment). The inclusion of 105 patients suffering from social anxiety is intended.
The treatment is designed for a time limited approach with 25 + 5 individual sessions of STPP over 6 month (STPP of 25 sessions as reimbursed by German health insurance).
Before treatment starts, patients complaints and life situation will be assessed in detail by interview and standardized questionnaires. Diagnostic interviews will be conducted by the trial sites. Patients will be assessed by questionnaires 8 and 15 weeks after treatment start, directly at, as well as 6 month after end of treatment. After 25 session of treatment and twelve months after end of treatment, patients are invited for detailed assessment.
The research questions are:
(1) How can manualized STPP for Social Phobia be implemented into routine outpatient care?
(2) Will the new methods lead to an improvement of treatment courses and outcomes?
(3) Will treatment effects reached in routine psychotherapeutic treatments be comparable to those of the controlled, strictly manualized treatment of the main study?

Brief Summary in Scientific Language

There has been a lack of studies on the transfer of manualized treatments to routine psychodynamic practice. Our study is the first one to examine the effects of additional training in a manualized Short Term Psychodynamic Psychotherapy (STPP based on Supportive Expressive Therapy, SET) procedure on outcome in routine psychotherapy for Social Phobia. As an extension to the large multi-site RCT (N=512) in which Cognitive-Behavioral Therapy (CBT) and STPP for Social

Phobia have been evaluated, we will investigate how the treatment can be transferred from controlled trials into the less structured setting of routine clinical care, and whether the health care system benefits from such developments. This question represents Phase IV of psychotherapy research. It combines the benefits of randomized controlled trials (efficacy studies) and naturalistic studies (effectiveness research). Private practitioners will be randomized to one of two treatment conditions (training in manualized STPP vs. treatment as usual without a specific training). We plan to enrol 105 patients (84 completers). The study is genuinely designed to promote faster and more widespread dissemination of effective interventions. The research questions are: (1) How can manualized STPP for Social Phobia be implemented into routine outpatient care? (2) Will the new methods lead to an improvement of treatment courses and outcomes? (3) Will treatment effects reached in routine psychotherapeutic treatments be comparable to those of the controlled, strictly manualized treatment of the main study?

Organizational Data

- DRKS-ID: **DRKS00000570**
- Date of Registration in DRKS: **2011/03/03**
- 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.: **837.249.10 (7258) , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- ICD10: **F40.1 - Social phobias**

Interventions/Observational Groups

- Arm 1: **manualized Short Term Psychodynamic Psychotherapy (STPP based on Supportive Expressive Therapy, SET)**
- Arm 2: **routine psychodynamic treatment ("treatment as usual" without a specific training)**

Characteristics

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

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- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Health economics**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Primary endpoint: assessment after 25 sessions;
Primary outcome measure: Liebowitz Social Anxiety Scale (LSAS) <= 30 (remission).

Secondary Outcome

Secondary endpoint: post-treatment;
Secondary outcome measures: another scale for the assessment of Social Phobia (SPAI) and analyses of variance for continuous measures (e.g. BDI, CGI); intent-to-treat (LOCF) and completer analyses.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/04/26**
- Target Sample Size: **105**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

1. Diagnosis of Social Phobia (SCID-I) and Liebowitz Social Anxiety Scale > 30;
2. primary diagnosis of Social Phobia (ADIS-IV)

Exclusion criteria

1. Psychotic disorder;
2. Risk of self-harm;
3. Acute substance related disorder;
4. Personality disorders except for cluster C (SCID-II);
5. Organic mental disorder;
6. Severe medical conditions;
7. ongoing psychotherapy or initiation/ dose increase of psychopharmacological treatment

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/06/09**

Trial Publications, Results and other documents

- Paper **Veröffentlichung des Studienprotokolls / Publication of trial protocol**
- Paper **Veröffentlichung der Studienergebnisse / Publication of trial results**

** 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.*