

# The social phobia psychotherapy research network

<b>Submission date</b> 22/06/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/08/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

**Scientific Title**  
The social phobia psychotherapy research network

**Acronym**  
SOPHO-NET

**Study objectives**

Differential efficacy of short-term psychodynamic psychotherapy (STPP) and cognitive-behavioral therapy (CBT) in social phobia therapy - named hypothesis A1

The first add-on study (named C1) of this multicentre trial will be studying genetic polymorphisms in patients with social phobia who are treated with STPP and CBT.

The second add-on study (named C2) of this multicentre trial will be studying the neural functional and structural changes in patients with social phobia who are treated with STPP and CBT.

The third add-on study (named C3) of this multicentre trial will be studying the attachment characteristics as differential predictors of treatment outcome in 128 patients with social phobia who are treated with STPP and CBT.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee of the Medical Faculty of the University of Goettingen, 06/12/2006

### **Study design**

Randomized controlled multicenter trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Social phobia (social anxiety disorder)

### **Interventions**

Manualized short-term psychodynamic psychotherapy (STPP) versus manualized cognitive-behavioral therapy (CBT)

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

For A1, primary outcome is no diagnosis of SP according to the SCID-I DSM-IV and the Liebowitz Social Anxiety Scale

For C1, the primary outcome will be, that the psychotherapy outcome is associated with genetic variation in the serotonin transporter (SERT) gene (directed: L12 higher pre-post difference in the Liebowitz Social Anxiety Scale [LSAS])

For C2, primary outcomes will include normalisation of neural structural and functional abnormalities after successful treatment

For C3, primary outcomes will be whether patients reveal a secure organized attachment; representation will reach a better outcome than those with insecure features and/or disorganized states of mind

### **Key secondary outcome(s)**

For A1, secondary outcomes will include:

1. Social anxiety (Social Phobia and Anxiety Inventory [SPAI])
2. Depression (Beck Depression Inventory [BDI])
3. Interpersonal problems (IIP)
4. Self-image
5. Quality of life or social functioning (short-form-12 questionnaire [SF-12])
6. Costs and utilities of the treatments

For C1, the secondary outcome will be, that the severity of social phobia is linked with genetic variation in SERT gene (directed: S10 higher LSAS at baseline)

For C2 secondary outcome will include specificity of neural structural and functional abnormalities in social phobia

For C3, secondary outcome will include whether a self-reported attachment will significantly change after successful therapy indicating increased security. This will be tested by using the Experiences in Close Relationships-Revised (ECR-R) instrument within the entire sample (n = 512)

### **Completion date**

01/10/2009

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of social phobia (SP) according to the Structured Interview for Diagnostic and Statistical Manual of Mental Disorders - fourth edition [SCID-I DSM-IV]) and primary diagnosis of social phobia according to the Liebowitz Social Anxiety Scale >302
2. Aged 18 to 59 versus 60 to 70 years
4. Participants must be made up of 60% women; 40% men

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Psychotic disorder
2. Risk of self-harm
3. Acute substance related disorder
4. Personality disorders except for cluster C
5. Organic mental disorder
6. Severe medical conditions
7. Concurrent psychotherapeutic or psychopharmacological treatment

### **Date of first enrolment**

01/10/2006

### **Date of final enrolment**

01/10/2009

## **Locations**

### **Countries of recruitment**

Germany

### **Study participating centre**

von Sieboldstrasse 5

Goettingen

Germany

37075

## **Sponsor information**

### **Organisation**

Ministry for Development and Research (Bundesministerium für Bildung und Forschung [BMBF])  
(Germany)

### **ROR**

<https://ror.org/04pz7b180>

## **Funder(s)**

### **Funder type**

Government

**Funder Name**

Bundesministerium für Bildung und Forschung

**Alternative Name(s)**

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Germany

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	23/12/2013		Yes	No
<a href="#">Results article</a>	results	19/01/2016		Yes	No