

Cognitive therapy (CT-A) versus short-term psychodynamic psychotherapy (STPP-A) for social phobia (SP) in adolescents

Submission date 07/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/02/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/02/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

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

Contact information

Type(s)

Scientific

Contact name

Dr Klaus-Thomas Kronmüller

Contact details

Voßstraße 4
Heidelberg
Germany
69115
+49 (0)62 21565938
klaus.kronmueller@med.uni-heidelberg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

01GV0903

Study information

Scientific Title

Cognitive therapy (CT-A) versus short-term psychodynamic psychotherapy (STPP-A) for social phobia (SP) in adolescents: a randomised controlled multicentre study

Acronym

SOPHOYOU

Study objectives

Manualised CT-A and manualised STPP-A are more effective in reducing symptoms of SP than waitlist control condition (WL).

In addition, to identify responder and non-responder profiles of CT-A and STPP-A, moderators of treatment outcome will be examined.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Ethics Committee of the Medical Faculty of the University of Heidelberg on the 10th of May 2010

Study design

Multicentre randomised active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

More information is available at <http://www.sopho-net.de/>

Health condition(s) or problem(s) studied

Social Phobia (Social Anxiety Disorder)

Interventions

The trial compares 25 sessions (within 16 weeks) of manualised cognitive therapy for adolescents (CT-A) and manualised short-term psychodynamic psychotherapy (STPP-A) with a waitlist (WL) control condition of 16 weeks. In the first 8 weeks bi-weekly individual sessions

provide an intensive start. For the remaining 8 weeks CT-A and STPP-A are conducted with 1 weekly session.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS-CA) at post-assessment (and 1 year follow-up)

Secondary outcome measures

1. Diagnosis of SP, evaluated by Kiddie-Schedule for Affective Disorders and Schizophrenia (Kiddie-SADS)
 2. Remission in Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS-CA)
 3. Social Phobia and Anxiety Inventory (SPAI)
 4. Clinical Global Impression and Improvement Scale (CGI)
 5. EuroQuol for Children (EQ-5D)
- Secondary outcomes will be measured at pre and post-assessment and at 1 year follow-up.

Overall study start date

01/01/2010

Completion date

31/12/2012

Eligibility**Key inclusion criteria**

1. Primary diagnosis of Social Phobia according to Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV)
2. Aged 14 to 20 years

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

126

Key exclusion criteria

1. Psychotic disorders
2. Substance related disorders

3. Organic mental disorders
4. Attention Deficit Hyperactivity Disorder (ADHD)
5. Post Traumatic Stress Disorder (PTSD)
6. Suicidal ideation
7. Severe medical conditions
8. Concurrent psychotherapeutic or psychopharmacological treatment
9. IQ <80

Date of first enrolment

01/01/2010

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

Germany

Study participating centre

Voßstraße 4

Heidelberg

Germany

69115

Sponsor information

Organisation

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

Sponsor details

Hannoversche Straße 28-30

Berlin

Germany

10115

+49 (0)18 88570

Detlef.Boecking@dir.de

Sponsor type

Government

Website

<http://www.bmbf.de>

ROR

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

Funder(s)

Funder type

Government

Funder Name

German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration