

Efficacy of manualized short-term psychodynamic therapy for separation anxiety disorder, generalized anxiety disorder and social anxiety disorder in children

Submission date 05/11/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/11/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/11/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Children often have anxiety disorders. They are usually treated by psychodynamic therapies in Germany. There are not a lot of studies evaluating whether this type of treatment works for children. This is the aim of this study.

Who can participate?

Children between 7 and 13 diagnosed with anxiety disorder, generalized anxiety disorder, or social anxiety disorder.

What does the study involve?

After initial assessment, participants are randomly allocated to one of two groups: a short-term psychotherapy group (intervention) or a waiting list group (control). Participants that are allocated to the waiting list group will receive the treatment after the waiting period has elapsed.

What are the possible benefits and risks of participating?

We expect that the intervention will reduce anxiety symptoms. If symptoms of anxiety increase for participants in the waiting list group, they will start treatment immediately. There are no further risks.

Where is the study run from?

The lead center is Clinic of Psychosomatic Medicine and Psychotherapy, University of Goettingen, Germany. Other centres include the International Psychoanalytic University IPU Berlin, Germany and the Heidelberg University Hospital, General Psychiatry, University of Heidelberg, Germany.

When is the study starting and how long is it expected to run for?

November 2014 to November 2018.

Who is funding the study?

Vereinigung Analytischer Kinder-und Jugendlichenpsychotherapeuten in Deutschland e.V.
VAKJP

Stiftung zur Foerderung der universitaeren Psychoanalyse

Foerderverein für analytische Kinder- und Jugendpsychotherapie e.V. Krefeld

Who is the main contact?

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Study website

<http://www.ask-studie.de>

Contact information

Type(s)

Scientific

Contact name

Dr Simone Salzer

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Efficacy of manualized short-term psychodynamic therapy for separation anxiety disorder, generalized anxiety disorder and social anxiety disorder in children: a randomized controlled multicenter trial

Acronym

ASK-Studie

Study objectives

Manualized psychodynamic therapy is more effective in reducing symptoms of separation anxiety disorder/generalized anxiety disorder/social anxiety disorder than waiting list control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical Faculty of the University of Goettingen, 01/08/2014

Study design

Randomized controlled multicenter trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Anxiety disorders in children (separation anxiety disorder, generalized anxiety disorder, social anxiety disorder)

Interventions

Manualized psychodynamic short-term psychotherapy versus waiting list condition (16 weeks)

Intervention Type

Behavioural

Primary outcome measure

Response defined as at least 30% reduction of ADIS-C/P-IV CSR ratings for the primary diagnosis or ADIS-C/P CSR ≤ 3 rating for the primary diagnosis (ADIS-C/P) (Silverman & Albano, 2008) by trained experts unaware of group assignment. Primary outcomes are measured at baseline, after 2, 4, 8, 12 and 16 months (and additionally after 20 months for patients from the waiting list).

Secondary outcome measures

1. Rates of remission
2. CGI
3. TAI-R-K or SPAIK or PSWQ-K (dependent on primary diagnosis)
4. SCARED
5. SDQ
6. DIKJ
7. Familienboegen
8. FTB

9. EQ-5D-Y for children

Secondary outcomes are measured at baseline, after 2, 4, 8, 12 and 16 months (and additionally after 20 months for patients from the waiting list).

Overall study start date

10/11/2014

Completion date

10/11/2018

Eligibility

Key inclusion criteria

1. Primary diagnosis of separation anxiety disorder, generalized anxiety disorder or social anxiety disorder according to DSM-IV/-5
2. Aged 7 to 13 years old

Participant type(s)

Patient

Age group

Child

Lower age limit

7 Years

Upper age limit

13 Years

Sex

Both

Target number of participants

174

Key exclusion criteria

1. Psychotic disorders
2. Substance-related disorders
3. Organic mental disorders
4. Severe medical conditions
5. IQ 80

6. Post-traumatic stress disorder (PTSD)
7. Severe attention deficit hyperactivity disorder (ADHD)
8. Suicidal ideation
9. Concurrent psychotherapeutic or psychopharmacological treatment

Date of first enrolment

24/11/2014

Date of final enrolment

10/11/2018

Locations

Countries of recruitment

Germany

Study participating centre

Clinic of Psychosomatic Medicine and Psychotherapy

Goettingen

Germany

37075

Study participating centre

International Psychoanalytic University (IPU)

Berlin

Germany

Study participating centre

Heidelberg University Hospital, General Psychiatry, University of Heidelberg

Heidelberg

Germany

Sponsor information

Organisation

University Medical Center Goettingen (Germany)

Sponsor details

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Sponsor type

University/education

Website

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ROR

<https://ror.org/021ft0n22>

Funder(s)

Funder type

Research organisation

Funder Name

Vereinigung Analytischer Kinder-und Jugendlichenpsychotherapeuten in Deutschland e.V.
VAKJP (Germany)

Funder Name

Stiftung zur Foerderung der universitaeren Psychoanalyse (Germany)

Funder Name

Foerderverein für analytische Kinder- und Jugendpsychotherapie e.V. Krefeld (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