Trial Description

Title

Short-term, long-term and cost-effectiveness of treating depression and anxiety disorders in children and adolescents – a randomized controlled trial.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The current study will evaluate and compare the effectiveness of cognitive-behavioral and psychodynamic therapy. Therefore 420 children and adolescents (ages 8-16 years) with depression and/or anxiety disorder will be randomly assigned to a treatment or a control condition. The intervention´s short-term effectiveness and sustainability as well as cost-effectiveness will be examined over a 5 year period for each participant.

Brief Summary in Scientific Language

This study aims to optimize patient-centered care and to ensure scientific and legal approval of cognitive-behavioral and psychodynamic therapy for children and adolescents in the German health-care system. This prospective, randomized and controlled trial compares psychodynamic and cognitive behavioral therapy for children and adolescents with depression and anxiety disorder.

Number of diagnoses or fulfilled diagnostic criteria - diagnosed by a trained psychologist who is blind for treatment condition as well as rated by patients and parents - will be the primary outcome. Secondary outcomes are patients´ and parents´ subjective burden caused by the child's symptoms, patients´ quality of life, individual and family functioning and treatments´ cost effectiveness.

Patients are recruited in child and adolescent psychiatries in Hamburg.

After gathering informed consent from parents and patients, the latter will be randomly assigned to either psychodynamic therpy or CBT. Both interventions are based on manuals.
Data will be collected annually over a period of five years starting at the beginning of treatment. This allows examination of varying treatment intervals as well as long-term and cost-effectiveness ot the interventions.

To analyze data, comparisons of means will be performed. Groupwise analyses of interaction will be performed for inferential testing of differences in subgroups. Differences in therapy effects will be inferentially analyzed by multifactor analysis of covariance, analysis of variance or logistic regression. Interaction effects and predicting variables are of special interest.

In a Subsample of 32 depressive adolescents (ages 13-16) patients expectations before and experiences whilst therapy will be analyzed by a mixed-methods-approach.

Organizational Data

- DRKS-ID: **DRKS00012823**
- Date of Registration in DRKS: **2017/09/27**
- 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.: **PV5560 , Ethik-Kommission der Ärztekammer Hamburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1202-1831**

Health condition or Problem studied

- ICD10: **F30-F39 - Mood [affective] disorders**
- ICD10: **F40 - Phobic anxiety disorders**
- ICD10: **F41 - Other anxiety disorders**
- ICD10: **F42 - Obsessive-compulsive disorder**
- Free text: **Depression and/or anxiety disorder**

Interventions/Observational Groups

- Arm 1: **outpatient psychodynamic psychothrapy in single patient setting, therapy frequnency and duration depend on indication**
- Arm 2: **oupatient cognitive behavioral therapy in single patient setting, therapy frequnency and duration depend on indication**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
-

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **assessor**

- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Number of psychiatric diagnoses respectively number of diagnostic criteria will be assessed by Kiddie-SADS interview (Delmo et al., 2001). The Kiddie-SADS interview will be conducted by a trained rater external to the project before treatment henceforth annually over a 5 year period for each child.

Secondary Outcome

Children´s depressive symptomatology will be assessed by children´s (aged 10 years and older) and parents´ rating of the german version of the "Children´s depression inventory" (Depressionsinventar für Kinder und Jugendliche (DIKJ; Stiensmeier-Pelster, Schürmann, & Duda, 2000) before therapy starts and henceforth annually over a five year period.
Children´s anxiety symptomatology will be assessed by children´s (aged 10 years and older) and parents´ rating of the german version of the "Screen for child anxiety related emotional disorders" (Scared; Birmaher, Khetarpal, Cully, Brent, & McCanzie, 1995) before therapy starts and henceforth annually over a five year period.
Cildren´s psychiatric disorders will further be assessed by parents´ rating of the german version of the "Child behavior checklist" (CBCL; Achenbach, 1991) before therapy starts and henceforth annually over a five year period.
Cildren´s psychiatric disorders will further be assessed by children´s (aged 10 years and older) rating of the german version of the "Youth self report" (YSR; Achenbach, 1991) before therapy starts and henceforth annually over a five year period.
Children´s structural functioning will be assessed by self-report (children and adolescents aged 10 years and older) using the german structure questionnaire for the "Operationalized psychodynamic diagnostic for children and adolescents" (OPD-KJ2-SF, Schrobildgen et al., 2017) before therapy starts and henceforth annually over a five year period.
Children´s health related quality of life will be assessed by children´s (aged 10 years and older) and parents´ rating of the german version of the Kidscreen (Ravens-Sieberer & the European KIDSCREEN group, 2006) before therapy starts and henceforth annually over a five year period.
Children´s global impairment will be assessed by a trained rater external to the project using the german "Skala zur Gesamtbeurteilung von Kindern und

Jugendlichen" (SGKJ; Steinhausen, 1985) before therapy starts and henceforth annually over a five year period.
Families´ relational functioning will be rated by a trained rater external to the project using the german version of the "Global assessment of relational functioning scale" (GARF; Saß, Wittchen, & Zaudig, 1996) before therapy starts and henceforth annually over a five year period.
Children´s global functioning will be rated by a trained rater external to the project using the german version of the "Global assessment functioning scale" (GAF; American Psychiatric Association, 2000) before therapy starts and henceforth annually over a five year period.
Health economics will be assessed by a trained rater external to the project using the german version of the "Children and adolescent mental health services receipt inventory" (CAMHSRI-EU; Kilian et al., 2009) before therapy starts and henceforth annually over a five year period.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Kinder- und Jugendpsychiatrie des Universitätsklinikums Hamburg-Eppendorf, Stationen, Ambulanzen, Tagesklinik, Hamburg**
- University Medical Center **Ambulantes Versorgungszentrum des Universitätsklinikums Hamburg-Eppendorf, Hamburg**
- Medical Center **Kinder- und Jugendpsychiatrische Klinik Wilhelmsstift, Hamburg**
- Medical Center **Kinder- und Jugendpsychiatrische Klinik Harburg, Hamburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/07/26**
- Target Sample Size: **420**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **6 Years**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

diagnosis of a depressive disorder (ICD-10; F30-F39) or an anxiety disorder (ICD-10; F40-F42)
informed consent (patients and parents)

Exclusion criteria

psychotic disorders, eating disorders, substance use related disorders (except caffeine and nicotine), autism spectrum disorders, mutism,
personality disorders
neurologic disorders
severe mental retardation (filling out questionnaires and interview are not feasible)
low command of the german language

Addresses

■ **Primary Sponsor**

Universitätsklinikum Hamburg-Eppendorf
Ms. Prof. Dr. Silke Wiegand-Grefe
Martinistraße 52
20246 Hamburg
Germany

Telephone: **040 - 741053603**
Fax: **040 - 741055105**
E-mail: **s.wiegand-grefe at uke.de**
URL: **www.uke.de**

■ **Contact for Scientific Queries**

Universitätsklinikum Hamburg-Grefe
Ms. Prof. Dr. Silke Wiegand-Grefe
Martinistr. 52
20246 Hamburg
Germany

Telephone: **040 - 741053603**
Fax: **040 - 741055105**
E-mail: **s.wiegand-grefe**
URL: **www.uke.de**

■ **Contact for Public Queries**

Universitätsklinikum Hamburg-Eppendorf
Ms. Prof. Dr. Silke Wiegand-Grefe
Martinistraße 52
20246 Hamburg
Germany

Telephone: **040 - 741053603**

Contact for Public Queries

Universitätsklinikum Hamburg-Eppendorf
Ms. Prof. Dr. Silke Wiegand-Grefe
Martinistraße 52
20246 Hamburg
Germany

Telephone: **040 - 741053603**
Fax: **040 - 741055105**
E-mail: **s.wiegand-grefe at uke.de**
URL: **www.uke.de**

Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

Vereinigung Analytischer Kinder- und Jugendlichen-Psychotherapeuten in Deutschland e.V (VAKJP)
Kurfürstendamm 72
10709 Berlin
Germany

Telephone: **030 - 32 79 62 60**
Fax: **030 - 32 79 62 66**
E-mail: **geschaeftsstelle at VAKJP.de**
URL: **http://www.vakjp.de/**

Status

- Recruitment Status: **Recruiting ongoing**
- 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.*