PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Efficacy of Child-Centered Cognitive-Behavioral Prevention of Internalizing Disorders and Impact of a Simultaneous Parent Training

Trial Acronym

Psychologische Prävention Internalisierender Störungen

URL of the trial

http://www.uni-marburg.de/ivv/aktuelles/news/angstpraevention

Brief Summary in Lay Language

Anxiety, Depression and somatoform Disorders are very common in child psychopathology. The efficacy of a psychological group program for children aged 8-12 to prevent these disorders and an additional parent training are evaluated.

Brief Summary in Scientific Language

Internalizing disorders represent a large group of psychological disorders among children who are referred to psychological treatment. Anxiety, Depression and somatoform disorders in children and adolescents increase the risk of mental disorders in adulthood. Some english programs have proved the efficacy of CBT-G prevention.This study will test the efficacy of CBT-G in German children. The role of parental involvement is currently subject to scientific discussions. The impact of an additional parent-group training will be investigated.

Organizational Data

- DRKS-ID: **DRKS00000235**
- Date of Registration in DRKS: **2010/01/11**
- Date of Registration in Partner Registry or other Primary Registry: **2007/11/26**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **Studie 04/07 , Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1111-1194**
- Primary Registry-ID: **NCT00564239 (Clinicaltrials.gov)**

Health condition or Problem studied

- ICD10: **F40.1 - Social phobias**
- ICD10: **F41.1 - Generalized anxiety disorder**
- ICD10: **F41.2 - Mixed anxiety and depressive disorder**
- ICD10: **F32.0 - Mild depressive episode**
- ICD10: **F32.1 - Moderate depressive episode**
- ICD10: **F34.1 - Dysthymia**
- ICD10: **F93.0 - Separation anxiety disorder of childhood**
- ICD10: **F93.1 - Phobic anxiety disorder of childhood**

Interventions/Observational Groups

- Arm 1: **Cognitive-behavioral group intervention with parental psychoeducation (active control)**
- Arm 2: **Cognitive-behavioral group intervention plus parent training (intervention group)**
- Arm 3: **Waitlist control**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

youth psychopathology via parent report using the Child Behavior Checklist

(CBCL); Time Frame: 0, 3, 6 and 18 months

Secondary Outcome

Assessment of life quality (ILK), parent and child versions; Time Frame: 0, 3, 6 and 18 months || Youth Anxiety Symptoms by self- and parent report using the Spence Children's Anxiety Scale (SCAS) and the FBB-ANG (parent report on anxiety symptoms), Time Frame: 0, 3, 6 and 18 months || Youth Depression Symptoms by self report using the DIKJ (german depression inventory based on CDI); Time Frame: 0, 3, 6 and 18 months || Youth somatoform symptoms by parent and self report using the GBB-KJ (report of somatic symptoms), Time Frame: 0, 3, 6 and 18 months || Parental Psychopathology via self-report using the Symptom-Checklist (SCL-90-R), german version, Time frame: 0, 3, 6 and 18 months || Youth Intelligence using Culture Fair Intelligence Test (CFT 20-R); Time frame: once at start of intervention

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/07/15**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **8 Years**
- Maximum Age: **12 Years**

Additional Inclusion Criteria

-age 8- 12 years and
-anxiety symptoms and/or
-depressive symptoms and/or
-somatoform symptoms

Exclusion criteria

-psychiatric disorder according to ICD-10 requiring individual psychotherapy
-IQ < 85

Addresses

■ **Primary Sponsor**

Institut für Verhaltenstherapie und Verhaltensmedizin an der Philipps-Universität Marburg
Mr. Prof. Dr. Fritz Mattejat
Hans-Sachs-Str.4-6
35039 Marburg
Germany

Telephone: **06421 5866472**
Fax: **06421 5865667**
E-mail: **mattejat at med.uni-marburg.de**
URL: **http://www.uni-marburg.de/ivv**

■ **Contact for Scientific Queries**

Institut für Verhaltenstherapie und Verhaltensmedizin an der Philipps-Universität Marburg
Mr. Dr. Jan Pauschardt
Hans-Sachs-Str.4-6
35037 Marburg
Germany

Telephone: **06421 5863063**
Fax: **06421 5865667**
E-mail: **pauschar at med.uni-marburg.de**
URL: **http://www.uni-marburg.de/ivv**

■ **Contact for Public Queries**

Institut für Verhaltenstherapie und Verhaltensmedizin an der Philipps Universität Marburg
Mr. Dr. Jan Pauschardt
Hans-Sachs-Str.4-6
35037 Marburg
Germany

Telephone: **06421 5863063**
Fax: **06421 5865667**
E-mail: **pauschar at med.uni-marburg.de**
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Sources of Monetary or Material Support

- **Institutional budget , no external funding (budget of sponsor/PI)**

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an der Philipps-Universität Marburg
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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.*