## Trial Description

### Title
Evaluation of a practice team-supported, self-managed exposure training for patients with panic disorder and agoraphobia in primary care

### Trial Acronym
PARADISE (Patient Activation foR Anxiety DISordErs)

### URL of the trial
http://www.jena-paradies.org

### Brief Summary in Lay Language
About 14 percent of Germans suffer from anxiety disorders in which severe anxiety reactions occur, although in fact there is no danger for the individual. Anxiety reactions are generally harmless, but often associated with physical ailments (including heart palpitations, trembling, shortness of breath). For this reason many patients mistakenly believe that they were physically ill. Anxiety disorders can strongly interfere with work life and personal relationships, thereby leading to high emotional distress and considerable costs to society. In a third of cases the anxiety disorder is treated exclusively by the family doctor. Not less than 5 percent of the patients in a German family practice suffer from the specific anxiety disorders "Panic Disorder" and "Agoraphobia". The goal of the "Jena-Paradies"-study is to develop and test practice team-supported training program for these primary care patients. As part of the "Jena-Paradies" training program, patients will firstly learn to understand the anxiety disorder. The family doctor will then provide patients with a number of behavioral therapy-oriented tasks (exercises). These well-proven exercises have already helped many other patients to overcome their anxiety disorder. During the whole treatment patients will be accompanied and supported by the family doctor and by one of his health care assistants. They both form the practice team. A number of well-structured personal appointments and telephone contacts between the patient and the practice team will take place. Additionally patients will receive a self-help manual to support the training program. It is expected that there will be greater decreases in anxiety symptoms when patients are treated by means of the "Jena-Paradies" training program as if they are treated by the family doctor “as usual”. To scientifically test this expectation two groups of participating family practices will be created during the course of the study: One group will treat the patients by means of the "Jena-Paradies" training program and the other will treat them as usual (without using the training program). Within the course of twelve months, all patients will be asked about their health per questionnaire at three timepoints. The two groups will be statistically compared in terms of patient health and treatment costs.

### Brief Summary in Scientific Language
**Background:**
Panic disorder (ICD-10: F41.0) is a widespread anxiety disorder which is
characterized by repeated panic attacks, where strong but harmless physical symptoms occur (like dizziness, chest pain, weakness, tremors, sweating or shortness of breath). Often sufferers do not know what is happening to them during panic attacks, for which reason they erroneously worry about being physically ill or "getting crazy". Above all, they fear that panic attacks are going to occur again. Due to this fear many of them start to avoid certain places or situations where they feel uncomfortable or are afraid to become anxious. This kind of avoidance behavior is called Agoraphobia (ICD-10: F 40.0). Agoraphobia is comorbid to Panic Disorder in 35-65 % of cases. Usually both disorders strongly interfere with work life and personal relationships, thereby leading to high emotional distress and considerable costs to society. At the same time evidence-based, effective treatment options are available.

The “Jena-Paradies”-study is aimed at facilitating the treatment of panic disorder and agoraphobia in primary care as most of the patients are treated by family doctors. The primary treatment of anxiety disorders by means of behaviour-therapy-oriented procedures is recommended by international clinical guidelines (e.g. APA 2009, DGPPN 2000). Additionally, it has been shown that the treatment of chronic diseases can be optimized by methods derived from the Chronic Care Model. In line with this, a practice team-supported, self-managed exposure training for Panic Disorder and Agoraphobia in primary care will be evaluated by the "Jena-Paradies"-study. This training incorporates the recommended behavior therapy-oriented procedures and is carried out in terms of a practice team-based Case Management.

Objectives: Comparing a practice team-supported, self-directed exposure training for panic disorder with/without agoraphobia in ambulant primary care patients to "Usual Care" plus recommended standard in terms of clinical effectiveness and health economic costs.

Methods: This is a prospective, controlled two-armed, multi-centered, cluster-randomized interventional trial. Family practices will be assigned to the study arms following a computer supported randomization. 444 participants (observational units) from 74 family practices (Clusters) shall be included. Recruitment of patients will be carried out by the participating family practices. All participating investigators (general practitioners, GPs) will be trained in evidence based diagnostics and treatment of panic disorder with or without agoraphobia in accordance to recommended standards (DGPPN 2000). In the intervention arm of the study practice teams (i.e. the GP and one of his health care assistants, HCA) will additionally be trained in applying the practice team-supported, self-directed exposure training (i.e. the “Jena-Paradies” training program). The "Jena-Paradies" training program will be carried out in terms of a practice team-based Case Management. It includes the treatment elements counseling, psychoeducation, instructions for confrontation in vivo, and self-help manual. The treatment plan will comprise manualized behavior therapy oriented GP-consultations as well as protocol based HCA-telephone contacts. Anxiety symptoms and treatment progress will be monitored by the HCA using a special monitoring checklist (JA-MoL) during periodical telephone contacts. JA-MoL results will be reported to the GP who will be able to adjust treatment decisions according to them. In the control arm of the study GPs will provide patients with usual care in accordance to recommended standards. Treatment duration will be six months per patient.

Outcomes:
Outcome measurements will be carried out by questionnaires (patient self-report) at measurement points T0 (baseline before treatment start), T1 (26 +/- 4 weeks after baseline), and T2 (52 +/- 4 weeks after baseline). Estimation and significance
testing of the baseline adjusted mean outcome group differences at T1 will be carried out by fitting a mixed linear model. Data of all patients will be analyzed in terms of an Intent-to-Treat analysis. Estimation and significance testing of treatment effects on secondary endpoints will be carried out by fitting mixed linear or generalized mixed linear models as appropriate.

Organizational Data

- DRKS-ID: DRKS00004386
- Date of Registration in DRKS: 2012/09/25
- Date of Registration in Partner Registry or other Primary Registry: 2012/11/07
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: Approved
- (leading) Ethics Committee Nr.: 3484-06/12 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät

Secondary IDs

- Primary Registry-ID: ISRCTN64669297 (Current Controlled Trials)

Health condition or Problem studied

- ICD10: F41.0 - Panic disorder [episodic paroxysmal anxiety]
- ICD10: F40.01 - [generalization F40.0: Agoraphobia]

Interventions/Observational Groups

- Arm 1: Intervention condition: Treatment of patients with a practice team-supported, self-managed exposure program (after training of investigating general practitioners and associated health care assistants in its application). The general practitioner (GP) and the health care assistant (HCA) both form the practice team. The self-managed exposure program includes evidence-based, behavior therapy-oriented procedures (e.g. counseling, psychoeducation, instructions on confrontation in vivo, and self-help manual). It has to be applied in terms of a practice team-based Case Management. The treatment plan comprises three manualized behavior therapy-oriented GP-consultations as well as protocol based HCA-telephone contacts. Anxiety symptoms and treatment progress will be monitored by the HCA using a special checklist (Jena Anxiety Monitoring List, JAMoL) during periodical telephone contacts. JAMoL results will be reported directly to the GP who will be able to adjust treatment decisions according to them.

- Arm 2: Control condition: Treatment of patients with "Usual Care" in accordance with recommended standards (after training of investigators in diagnosis and
Characteristics

- **Study Type:** Intervventional
- **Study Type Non-Interventional:** [---]*
- **Allocation:** Randomized controlled trial
- **Blinding:** [---]*
- **Who is blinded:** [---]*
- **Control:** Active control (effective treatment of control group)
- **Purpose:** Treatment
- **Assignment:** Parallel
- **Phase:** N/A
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels):** N/A

Primary Outcome

Severity of anxiety, measured by the Beck Anxiety Inventory (BAI, sum of scores at measurement point T1 six months after baseline)

Secondary Outcome

- Anxiety-related reduction of mobility (MI); T1/T2
- Number and severity of panic attacks (PAS, Items A1 and A2)
- Depressiveness (PHQ-9); T1/T2
- Health-related quality of life (EQ-5D); T1/T2
- Quality Adjusted Life Years (EQ-5D); T1/T2
- Direct and indirect costs from a societal perspective; T1/T2
- Incremental Cost-Effectiveness Ratio (ICER); T1/T2

T1: 26 weeks after baseline
T2: 52 weeks after baseline

Countries of recruitment

- DE Germany

Locations of Recruitment

- Doctor's Practice Thüringen, Bayern, Hessen, Nordrhein-Westfalen, Berlin, Sachsen, Sachsen-Anhalt

Recruitment
Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

- Panic Disorder with or without Agoraphobia (ICD-10: F.41.0 or F40.01)
- positive screening questionnaires
- sufficient German language skills
- private telephone

Exclusion criteria

- acute suicidality
- acute or chronic psychosis
- drug or alcohol dependence
- severe physical illness
- pregnancy
- current psychotherapeutic treatment of anxiety

Addresses

Primary Sponsor

Universitätsklinikum Jena, Friedrich-Schiller-Universität
Institut für Allgemeinmedizin

Bachstr. 18
D-07743 Jena
Germany

Telephone: ***
Fax: ***
E-mail: 37594251334539725951626a7064696b3163483545416b4f705433754b67544b586733427966674e2f715239525464b472f462f447365786c73564c5266696462 at drks.de
URL: http://www.allgemeinmedizin.uni-jena.de

Contact for Scientific Queries
Contact for Scientific Queries

Universitätsklinikum Jena, Friedrich-Schiller-Universität
Institut für Allgemeinmedizin
*** ***
Bachstr. 18
D-07743 Jena
Germany

Telephone: ***
Fax: ***
E-mail:
426f74455862676e7a534a652b517a62337937776664505a655a6b30594c6f386e566d4874616a754830d at drks.de
URL: http://www.allgemeinmedizin.uni-jena.de

Contact for Public Queries

Universitätsklinikum Jena, Friedrich-Schiller-Universität
Institut für Allgemeinmedizin
*** ***
Bachstr. 18
D-07743 Jena
Germany

Telephone: ***
Fax: ***
E-mail:
49576168784b534b356d514e45616d51426774437474505a655a6b30594c6f38614e566d4874616a754830d at drks.de
URL: http://www.allgemeinmedizin.uni-jena.de

Collaborator, Other Address

Institut für Medizinische Soziologie, Sozialmedizin und Gesundheitsökonomie (IMSG)
Universitätsklinikum Hamburg-Eppendorf
*** ***
Martinistr. 52
D-20246 Hamburg
Germany

Telephone: ***
Fax: ***
E-mail:
63506642627776a46533538556934776542654e59524179335a4930544b6d9692f2b3845462b43655255773d at drks.de
URL: http://secunda.uke.uni-hamburg.de/institute/medizin-soziologie

Sources of Monetary or Material Support

- Public funding institutions financed by tax money/Government funding body
  (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)
**Public funding institutions financed by tax money/Government funding body**

(German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

**Bundesministerium für Bildung und Forschung**

Dienstsitz Berlin

Friedrichstraße 130 B

10117 Berlin

Germany

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: [www.bmbf.de](http://www.bmbf.de)

---

### Status

- **Recruitment Status**: Recruiting complete, follow-up complete
- **Study Closing (LPLV)**: 2016/02/17

### Trial Publications, Results and other documents

- Paper **Study Protocol**
- Further trial documents **Poster des Studienprotokolls**
- Further trial documents **Artikel in "Der Hausarzt" (2012)**
- Further trial documents **Artikel im "Bayerischen Ärzteblatt" (2013)**

---

* 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.

---

Page 7 of 7