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Jena-Paradise ...defy anxiety to live free! [Jena-Paradies ...der Angst entgegen, freier leben!]

Submission date
14/09/2012

Recruitment status
No longer recruiting

Registration date
07/11/2012

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Panic disorder is a common anxiety disorder. Symptoms include dizziness, chest pain, weakness, tremors, sweating or shortness of breath. Those affected often do not know what is happening to them during panic attacks and they may worry about being physically ill or "going crazy". They also fear that a panic attack is going to occur again, so many start to avoid certain places or situations where they feel uncomfortable or are afraid they may become anxious. This avoidance behaviour is called "agoraphobia". Agoraphobia and panic disorder can strongly interfere with work life and personal relationships, and lead to high emotional distress and considerable costs to society. The 'Jena-Paradies' study is aimed at improving the treatment of panic disorder and agoraphobia by family doctors at local surgeries, where most patients are treated by family doctors. The 'Jena-Paradies' study is aimed at developing and testing a practice team-supported training program for these patients. The main goals of this training program are to reduce the symptoms of anxiety and to improve quality of life.

Who can participate?
Adult patients of both sexes who suffer from panic disorder with or without agoraphobia and who are willing to participate voluntarily.

What does the study involve?
All participating family doctors are trained to give the standard treatment for panic disorder with or without agoraphobia. Training sessions take place at the Institute of General Practice and Family Medicine (Jena University Hospital). Trained family doctors are asked to find eligible patients from their practices by using questionnaires. Two groups of family practices are then created. One group treats patients as usual (providing 'usual care' which meets current recommended standards). The other group has additional training sessions in applying the 'Jena-Paradies' program. During the training sessions, the family doctor is trained, as well as a healthcare assistant from their practice, which forms the 'practice team', and they together provide the 'Jena-Paradies' training program. Patients in this group receive a self-help manual which contains information about anxiety disorders and treatment. The patient takes part in to face anxiety-provoking activities and situations via exercises given to them by the doctor. These exercises enable patients to overcome their anxiety or fear in small steps. The healthcare assistant provides patients with sustainable support during the course of the whole treatment

and makes periodic telephone calls to the patients. During these calls, the healthcare assistant asks certain questions to monitor anxiety symptoms and treatment progress. The answers are reported to the doctor, so that he can quickly react to treat the patient if necessary (for example, make another appointment with the patient). This also allows the safety of the patient to be monitored, and enhances the quality of treatment. The training program takes six months for every patient to complete, but patients are required to participate for 12 months as they are asked to complete study-related questionnaires at three time points within these 12 months.

What are the possible benefits and risks of participating?
Participants with anxiety disorders will hopefully experience less symptoms. There are no known risks associated with taking part in this study. However, the training program requires patients to take an active role during treatment. For instance they are asked to read the self-help manual, to focus anxiety provoking situations, and to complete certain exercises to overcome their anxiety.

Where is the study run from?
Institute of General Practice and Family Medicine at Jena University Hospital (Germany)

When is the study starting and how long is it expected to run for?
October 2012 to June 2016

Who is funding the study?
Federal Ministry of Education and Research (BMBF) (Germany)

Who is the main contact?
Prof. Jochen Gensichen
Jena-Paradies@med.uni-jena.de

Study website
http://www.jena-paradies.org

Contact information

Type(s)
Scientific

Contact name
Prof Jochen Gensichen

Contact details
Institute of General Practice and Family Medicine
Jena University Hospital
Friedrich Schiller University
Bachstr. 18
Jena
Germany
D-07743
+49 (0)3641 9395800
jochen.gensichen@med.uni-jena.de

Type(s)

Scientific

Contact name
Mr Thomas S Hiller

Contact details
Institute of General Practice and Family Medicine
Jena University Hospital, Friedrich-Schiller-University
Bachstr. 18
Jena
Germany
D-07743
+49 (0)3641 9395816
Thomas.Hiller@med.uni-jena.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DRKS00004386

Study information

Scientific Title
Evaluation of a practice team-supported, self-managed exposure training for patients with panic disorder and agoraphobia in primary care [Jena-PARADISE (Patient Activation foR Anxiety DISordErs)]

Acronym
Jena-PARADISE

Study objectives
A practice team-supported, self-managed exposure training for patients with panic disorder with or without agoraphobia in primary care yields significantly greater reductions in anxiety symptoms than 'usual care' plus recommended standard after six months of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Jena University Hospital Ethics Committee, ref: 3484-063/12

Study design
Prospective controlled two-armed multi-centered cluster-randomized interventional trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
http://www.jena-paradies.org

Health condition(s) or problem(s) studied
Panic disorder and panic disorder with agoraphobia

Interventions
Clusters (family practices) will be assigned to the study arms following a computer supported randomization. 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 (APA 2009, DGPPN 2000, NICE 2011).

Only in the intervention arm of the study practice teams (i.e. in each case the GP and one of the health care assistants from his practice, HCA) will additionally be trained in applying the practice team-supported, self-directed exposure training (i.e. the Jena-PARADISE training program). The practice team-supported, self-directed exposure training will be carried out in terms of a Case Management. It will include 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.

In both arms of the study 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)

Intervention Type
Behavioural

Primary outcome measure
Severity of anxiety, measured by the Beck Anxiety Inventory (BAI) sum of scores at measurement point T1 6 months after baseline

Secondary outcome measures

Current secondary outcome measures as of 04/02/2014:
1. Anxiety-related reduction of mobility (MI); T1/T2
2. Number and severity of panic attacks (PAS, Items A1 and A2)
3. Depressiveness (PHQ-9); T1/T2
4. Health-related quality of life (EQ-5D); T1/T2
5. Quality Adjusted Life Years (EQ-5D); T1/T2
6. Direct and indirect costs from a societal perspective; T1/T2
7. Incremental Cost-Effectiveness Ratio (ICER); T1/T2

Previous secondary outcome measures:
1. Anxiety-related reduction of mobility (MI); T1/T2
2. Anxiety-related cognitions (ACQ); T1/T2
3. Anxiety sensitivity (ASI-3); T1/T2
4. Anxiety severity and psychosocial impairments (Brief OASIS); T1/T2
5. Number and severity of panic attacks (PAS, Items A1 and A2)
6. Depressiveness (PHQ-9); T1/T2
7. Patient activation (PAM); T1/T2
8. Health-related quality of life (EQ-5D); T1/T2
9. Quality Adjusted Life Years (EQ-5D); T1/T2
10. Direct and indirect costs from a societal perspective; T1/T2
11. Incremental Cost-Effectiveness Ratio (ICER); T1/T2

Overall study start date
01/10/2012

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Adults (> 18 years)
2. Panic disorder with or without agoraphobia (ICD-10: F.41.0 or F40.01)
3. Positive screening questionnaires
4. Sufficient German language skills
5. Private telephone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

444 participants (observational units) from 74 family practices (study centers/clusters)

Key exclusion criteria
1. Acute suicidality
2. Acute or chronic psychosis
3. Drug or alcohol dependence
4. Severe physical illness
5. Pregnancy
6. Current psychotherapeutic treatment of anxiety

Date of first enrolment
01/10/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
Institute of General Practice and Family Medicine
Jena University Hospital
Friedrich-Schiller-University
Bachstr. 18
Jena
Germany
D-07743

Study participating centre
76 German general practices
Germany
-

Sponsor information

Organisation
Jena University Hospital (Germany)

Sponsor details
Institute of General Practice and Family Medicine
Jena University Hospital

Friedrich Schiller University
Bachstr. 18
Jena
Germany
D-07743
+49 (0)3641 9395800
allgemeinmedizin@med.uni-jena.de

Sponsor type
University/education

Website
http://www.allgemeinmedizin.uni-jena.de

ROR
https://ror.org/035rzkx15

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/04/2014		Yes	No
Results article	cost-effectiveness results	01/04/2020	26/10/2020	Yes	No