

Improving cognitive behavioural therapy for panic by identifying the active ingredients and understanding the mechanisms of action: a multicentre study

Submission date 15/12/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/10/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.panik-netz.de>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

040203-17

Study information

Scientific Title

Improving cognitive behavioural therapy for panic by identifying the active ingredients and understanding the mechanisms of action: a multicentre study

Study objectives

Cognitive Behavioural Therapy (CBT) is effective in the psychological treatment of Panic Disorder (PD) and Agoraphobia (AG). However, CBT refers to a heterogeneous group of interventions, including psychoeducation, cognitive restructuring and exposure. The main active ingredients of CBT for panic disorder are yet not determined. Although exposure components appear essential to effective treatment of PD/AG, the debate related to the duration and format of exposure persist.

The current study compares two formats of a manualised CBT for panic disorder that differ only in the implementation of exposure therapy:

1. CbT refers to an exposure homework (only) condition; the therapist only assigns exposure.
2. cBT refers to exposure that is therapist-guided; the therapist will accompany the patients in the exposure situation.

Hypotheses are:

1. Both Cognitive Behavioural Therapy (CBT) groups will be significantly superior to the wait-list control group in all primary outcome measures.
2. The in-vivo-cBT" group will be significantly better than the only-CbT group at post-treatment and at follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Ethics Committee of the Medical Faculty, Technical University Dresden on the 1st December 2006 (ref: EK 164082006).

Study design

Randomised clinical trial, intervention study with two active arms and a wait-list control group

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

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

Panic disorder with and without agoraphobia

Interventions

Two treatment conditions are compared, both of them state-of-the-art-CBT:

Condition A: CBT for panic disorder with therapist-guided in-vivo exposure exercises (in-vivo cBT-group)

Condition B: CBT for panic disorder with exposure elements as an homework assignment, only (only-CbT group)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Number of panic attacks/month
2. Aggregated Panic Disorder Scale and Mobility Inventory (PDS-MI) score (panic severity plus avoidance)
3. Hamilton Anxiety Rating Scale

Secondary outcome measures

1. Depressive symptoms
2. Anticipatory anxiety in dark room-challenge and time in darkroom
3. Psychophysiological parameters
4. Neuroimaging parameters
5. Ecological Momentary Assessment (EMA) parameters

Overall study start date

01/05/2007

Completion date

01/02/2008

Eligibility

Key inclusion criteria

1. Outpatients
2. 18 to 65 years old
3. Meet current Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV)

criteria of panic disorder with/without agoraphobia

4. Hamilton Anxiety Scale (HAMA) score more than or equal to 18 and a Clinical Global Impressions scale (CGI) score more than or equal to four

5. Able to attend clinic on his/her own or accompanied by significant others

6. Informed consent to participate and follow study procedures

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

450 (375 completers)

Key exclusion criteria

1. DSM-IV Axis I diagnoses of any psychotic disorder, bipolar disorder, current alcohol or drug dependence and Axis II of borderline personality disorder
2. DSM-IV Axis I disorders (other than panic disorder and agoraphobia) currently treated either by medications or non-pharmacological intervention
3. Acute suicidality (Composite International Diagnostic Interview [CIDI] scale 2+)
4. General medical contraindications

Date of first enrolment

01/05/2007

Date of final enrolment

01/02/2008

Locations**Countries of recruitment**

Germany

Study participating centre

Technische Universität Dresden

Dresden

Germany

01187

Sponsor information

Organisation

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

Sponsor details

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Sponsor type

Government

Website

<http://www.bmbf.de/en/index.php>

ROR

<https://ror.org/04pz7b180>

Funder(s)**Funder type**

Government

Funder Name

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany) (ref: 01GV0615)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/11/2009		Yes	No
Results article	results	01/06/2011		Yes	No
Results article	additional results regarding the impact of depression on CBT	01/06/2012		Yes	No
Results article	results	01/01/2013		Yes	No
Results article	results	01/01/2020	09/03/2021	Yes	No
Results article		12/04/2021	14/04/2021	Yes	No
Results article		16/09/2020	22/10/2021	Yes	No