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# 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

**Registration date**
21/02/2007

**Overall study status**
Completed

**Last Edited**
22/10/2021

**Condition category**
Mental and Behavioural Disorders

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Not Specified

### 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)

### 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

## 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? |
|---|---|---|---|---|---|
| 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 |
| Protocol article | protocol | 01/11/2009 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |