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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

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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
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes