ISRCTN80046034 https://doi.org/10.1186/ISRCTN80046034

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

Study website
http://www.panik-netz.de

Contact information

Type(s)
Scientific

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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