

A randomized, prospective, multicenter study of the effective treatments of panic disorder: cognitive behavioral therapy versus antidepressants versus combination therapy

Submission date 19/07/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/07/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/01/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
N/A

Study information

Scientific Title

A randomized, prospective, multicenter study of the effective treatments of panic disorder: cognitive behavioral therapy versus antidepressants versus combination therapy

Acronym

PD-study

Study objectives

In the short-term, the combined treatment is expected to be superior to either mono-treatment. In the long-term, it is expected that cognitive behavioral therapy (CBT) will prove to be more durable and that patients taking selective serotonin reuptake inhibitor (SSRI) will require more mental health care during the one-year follow-up period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

A randomized, prospective, multicenter study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Panic disorder

Interventions

CBT: the CBT protocol is based on the work of Clark and Barlow. Patients in the CBT group received up to 21 CBT sessions each lasting approximately 50 minutes. From session 16 onwards, sessions were scheduled with five-week intermissions. CBT consisted of the following:

1. Interoceptive exposure
2. Cognitive therapy
3. Exposure-in-vivo

SSRI group: patients receiving an SSRI visited their therapist 12 times, with weekly sessions during the first month and the remaining sessions distributed evenly over the treatment period of one year. Each visit lasted approximately 20 minutes. SSRIs used: fluvoxamine, sertraline, citalopram, fluoxetine, and cipramil. Tapering started three months before post-test.

Combination therapy of CBT and SSRI group: patients received both treatments, delivered in a parallel manner by different therapists.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fluvoxamine, sertraline, citalopram, fluoxetine, cipramil

Primary outcome(s)

Short-term:

1. Hamilton anxiety
2. Hamilton depression
3. Frequency of panic attacks
4. Responder status
5. Symptom checklist-90 (SCL-90)
6. Fear questionnaire-subscale
7. Agoraphobia

Long-term:

1. Remitter status
2. Panic coping
3. Quality of life
4. Hamilton anxiety
5. Hamilton depression

Key secondary outcome(s)

1. Treatment satisfaction
2. Locus of control
3. Fear of bodily sensations
4. Anticipation anxiety
5. Negative and positive self statements

Completion date

01/01/2006

Eligibility

Key inclusion criteria

Patients suffering from a primary diagnosis of panic disorder (PD) with or without agoraphobia (AG) (according to Diagnostic and Statistical Manual of mental disorders [DSM-IV] classification) recruited in 11 treatment facilities throughout the Netherlands between 1 April 2001 and 1 October 2003.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Comorbid psychotic disorder
2. Drug dependence
3. Major affective disorder
4. Significant risk of suicidality
5. Pregnancy or lactation
6. Contraindications to either treatment modality

Date of first enrolment

01/01/2001

Date of final enrolment

01/01/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9700 RB

Sponsor information**Organisation**

University Medical Center Groningen (UMCG) (The Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)**Funder type**

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan**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	05/09/2013		Yes	No
Results article	results	01/04/2014		Yes	No