

Prevention of panic disorder: a randomised clinical trial adjoining cost-effectiveness study

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2005	Overall study status Completed	☐ Protocol
Last Edited 06/04/2010	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ 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
63-438

Study information

Scientific Title

Study objectives

Panic disorder is a severe and persistent mental disorder, associated with a high degree of subjective distress, occupational and social disability. In the Netherlands, each year 242,000 people aged 18 to 65 years suffer from panic disorder. A promising intervention aimed at preventing panic disorder and reducing panic symptoms, is the Dutch cognitive-behavioural group course "No Panic". In this trial, respondents are randomly assigned to the group course "No Panic" or to the waiting-list condition, in which the course will be offered later. Data will be collected prior to the intervention, after the intervention and after six months. We predict that the experimental condition would show superior effects in lowering the incidence of panic disorder, reducing panic symptoms, improving quality of life and reducing economic costs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group, multicentre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Panic disorder, mental disorders

Interventions

Experimental condition:

The preventive group course "No Panic". This intervention is based on cognitive-behavioural therapy proved to be effective for patients with a full-blown panic disorder. The course consists of eight sessions of two hours each (session one to six are weekly, session seven to eight are two-weekly).

Control condition:

Waiting-list condition. Respondents assigned to this condition receive the course after the experimental group.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Incidence of DSM-IV panic disorder

Key secondary outcome(s)

1. Panic symptoms
2. Quality of life
3. Economic costs

Completion date

01/07/2007

Eligibility

Key inclusion criteria

1. Aged 18 to 65
2. Subclinical panic disorder (symptoms), with or without symptoms of agoraphobia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Score of 13 or higher on the Panic Disorder Severity Scale (PDSS)
2. Diagnostic and Statistical Manual of Mental Disorders - fourth edition (DSM-IV) diagnosis of panic disorder
3. Comorbid severe depressive disorder (DSM-IV)
4. Comorbid other mental or social problems that deserve priority
5. Language or learning difficulties
6. Not be able to function in a group
7. Insufficient intellectual capabilities to follow the course
8. Cardiological treatment

Date of first enrolment

01/09/2005

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

Netherlands

Study participating centre
Trimbos Institute/Netherlands Institute of Mental Health and Addiction
Utrecht
Netherlands
3500 AS

Sponsor information

Organisation
Trimbos Institute (Netherlands)

ROR
<https://ror.org/02amggm23>

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (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	24/04/2009		Yes	No
Results article	results	01/04/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes