

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

<b>Submission date</b> 12/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/04/2010	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr G Willemse

**Contact details**  
Trimbos Institute/Netherlands Institute of Mental Health and Addiction  
P.O. Box 725  
Utrecht  
Netherlands  
3500 AS  
+31 (0)30 297 1100  
gwillemse@trimbos.nl

## 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

**Study design**

Randomised, active controlled, parallel group, multicentre trial

**Primary study design**

Interventional

**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?
<a href="#">Results article</a>	results	24/04/2009		Yes	No
<a href="#">Results article</a>	results	01/04/2010		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes