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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON29238

**Source**
Nationaal Trial Register

**Brief title**
N/A

**Health condition**

In the Netherlands, each year 242.000 peope aged 18-65 years suffer from panic disorder. Panic disorder is a severe and persistent mental disorder, associated with a high degree of subjective distress, occupational and social disability. For these reasons, prevention of panic disorder is an important issue.

### Sponsors and support

**Primary sponsor:** Trimbos Institute/Netherlands Instute of Mental Health and Addiction (G. Willemse, F. Smit)
GGNet (P. Meulenbeek)
Vrije Universiteit Amsterdam (P. Cuijpers)
**Source(s) of monetary or material Support:** ZonMw (Healthcare Research Council of the Netherlands)

### Intervention

## Outcome measures

### Primary outcome

Incidence of DSM-IV panic disorder.

### Secondary outcome

1. Panic symptoms;

2. Quality of life;

3. Economic costs.

# Study description

### Background summary

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 peope aged 18-65 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 6 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.

### Study objective

The preventive group course "No Panic" would show superior effects in lowering the incidence of panic disorder, reducing panic symptoms, improving quality of life and reduced economic costs, compared with a waiting-list control group.

### Study design

N/A

### Intervention

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 8 sessions of 2 hours each (session 1-6 are weekly, session 7-8 are 2-weekly).

Control condition: waiting-list condition. Respondents assigned to this condition receive the course after the experimental group.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Persons aged 18-65 with subclinical panic disorder (symptoms), with or without symptoms of agoraphobia.

## Exclusion criteria

1. Score of 13 or higher on the Panic Disorder Severity Scale (PDSS);

2. 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.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-09-2005 |
| Enrollment: | 286 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 01-08-2005 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL67 |
| NTR-old | NTR99 |
| Other | : 63-438 |
| ISRCTN | ISRCTN33407455 |

# Study results

**Summary results**
N/A