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

Submission date
12/09/2005

Recruitment status
No longer recruiting

Registration date
12/09/2005

Overall study status
Completed

Last Edited
06/04/2010

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http:\www.cursusgeenpaniek.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 peope 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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
Incidence of DSM-IV panic disorder

Secondary outcome measures
1. Panic symptoms
2. Quality of life
3. Economic costs

Overall study start date
01/09/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
286

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)

Sponsor details
Da Costakade 45
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Sponsor type
Research organisation

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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