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Stepped care for panic disorder [Stepped care voor paniekstoornis]

Submission date	Recruitment status	[ ] Prospectively registered
04/09/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/11/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims:
Panic disorder is a severe mental disease where patients experience (unexpected) frightful panic attacks. Most patients try to avoid these attacks by developing avoidance behaviour, e.g. they avoid crowded places. Panic disorder is also a burden for society as medical and social costs are high. Panic disorder treatment guidelines suggest cognitive behaviour therapy (CBT) or treatment with drugs, although CBT has known, longer lasting effects. Normally, CBT takes 10-12 weekly sessions, but CBT is not always easy available and waiting lists are long. Therefore, shorter and cheaper programs, such as guided self-help or internet based treatments have been tested and been successful in the treatment of panic disorder.
This study's goal is to examine whether a short program of guided self-help for panic disorder is beneficial, and only followed by more intensive treatment when necessary

Who can participate?
Patients with a panic disorder with or without agoraphobia. Either men or women, aged between 18-70 years.

What does the study involve?
130 patients (across different treatment centres) will be randomly allocated to one of two treatment conditions:
1. A brief CBT intervention (guided self-help) of 10 weeks followed by CBT (13 sessions) only when necessary
2. Treatment as usual according to the (NICE) guidelines

What are the possible benefits and risks of participating?
There are no negative risks known, since both treatment conditions are well studied and proven to be effective in the treatment for panic disorder. Benefits from enrolling in the study are the monitoring of symptoms and the adjustment of the therapy when necessary. A possible disadvantage is the extra time it may cost to fill in the extra questionnaires.

Where is the study run from?
Overwaal Nijmegen/Lent (part of ProPersona), The Netherlands (Lead Centre)
Hendriks & Roosenboom, private practice Arnhem, The Netherlands

Presenz (part of GgzIngeest), Amsterdam, The Netherlands
HSK Nijmegen en Den Bosch, The Netherlands

When is the study starting and how long is it expected to run for?
The study started in March 2009 and recruitment ended in March 2012. The last follow ups are expected at the end of 2012.

Who is funding the study?
ZONMW, The Netherlands.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
100003034

Study information

Scientific Title
Panic disorder intervention for panic disorder with or without agoraphobia [Stepped care interventie voor patienten met paniekstoornis met en zonder agorafobie]

Study objectives

1. Guided self help is an effective first step in the treatment of panic disorder, compared with treatment as usual.
2. In the second step of the stepped care intervention, manualised CBT, panic disorder symptoms will be faster in remission as compared to the treatment as usual.
3. Symptom severity, duration of panic disorder, comorbidity on axis I and II will not predict treatment results of guided self help.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dutch Medical and Ethical Commission, Nijmegen, The Netherlands, 30 September 2008 ref: NL20312 09108

Study design
Randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet [Dutch]

Health condition(s) or problem(s) studied
Mental health, anxiety disorders, panic disorder, treatment studies

Interventions
This study consists of 2 conditions:
1. A first step of guided selfhelp, only when necessary followed by manualised CBT for panic disorder
2. Treatment as usual according to the NICE guidelines

Cognitive behaviour therapy, guided self help, psychopharmacology (in treatment as usual).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Panic and Agoraphobia Scale (PAS, Bandelow, 1999)
2. Outcome Questionnaire (OQ-45, Lambert and Burlingname, 2001)

Secondary outcome measures
1. Agoraphobic Cognition Questionnaire (ACQ, Chambless et al., 1984)
2. Mobility Inventory (MI, Chambless, et al., 1984)
3. Body Sensations Questionnaire (BSQ, Chambless, et al., 1984)

Overall study start date
15/03/2009

Completion date
01/12/2012

Eligibility

Key inclusion criteria
1. Participants have a present, primary diagnosis of panic disorder according to the DSM IV
2. Age between 18-70
3. Patiens give their informed consent
4. Patients are able to read and write the Dutch language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
130

Total final enrolment
128

Key exclusion criteria
1. A present diagnosis of schizophrenia or another psychotic disorder, according to the DSM-IV
2. Mental retardation, or another organic mental disorder
3. Suicidal ideation

4. Addiction to or abuse of drugs and/or alcohol
5. Another ongoing treatment for panic disorder (allthough the use of an SSRI or benzodiazepines is allowed in the treatment as usual condition)

Date of first enrolment
15/03/2009

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Pro Persona
Lent
Netherlands
6663 CB

Sponsor information

Organisation
ZonMw (Netherlands)

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Postbus 93 245
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw (Netherlands) ref: 100003034

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

Funder Name
ProPersona (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
23/07/2020

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		13/08/2020	18/11/2021	Yes	No