A randomized, prospective, multicenter study of the effective treatments of panic disorder: cognitive behavioral versus antidepressants versus a combination therapy.

No registrations found.

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

Summary

ID

NL-OMON26056

Source
NTR

Brief title
PD-study

Health condition

1. Cognitive-Behavioral therapy (CBT);

2. a treatment with a Serotonin Selective Reuptake Inhibitor (SSRI);

3. A combination of both (CBT+SSRI).

Sponsors and support

Primary sponsor: This study was initiated by the University Medical Center Groningen (UMCG).
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development (OG00-029)

Intervention

Outcome measures

Primary outcome

Short-term:

Hamilton Anxiety, Hamilton Depression, Frequency of Panic attacks, Responder status, SCL-90, Fear Questionnaire-subscale Agoraphobia.

Long-term:

remitter status, panic coping, quality of life, Hamilton Anxiety, Hamilton Depression.

Secondary outcome

Treatment Satisfaction, Locus of Control. Fear of Bodily Sensations, Anticipation Anxiety, Negative and Positive Self statements.

Study description

Background summary

PD tends to be a chronic condition associated with substantial reduction in quality of life. Relapse rates are high. For these reasons, attempts to study (long-term) effectiveness of the different treatments for PD, seems in order. In today's clinical practice, PD is mostly treated with some form of either a psychopharmacological (mostly SSRI) treatment or a psychological (mostly CBT)treatment. Besides offering some mono-treatment, a combined treatment seems to be offered regularly as well. Evidence for a short-term benefit of a combined treatment is still scarce however. Further, there are potential long-term disadvantages to a combined treatment. In the present study, one hundred and fifty patients were randomised to receive either CBT, SSRI, or CBT+SSRI. All treatments lasted one year. After nine months, the SSRIs were gradually tapered-off and patients were thus medication-free at post-test. During the second (follow-up) year, participants came to the clinic twice to be interviewed and to fill-in questionnaires. The aim of the present research is twofold. First, we want to study the short- and long-term effectiveness of the different treatment modalities. Second, we want to gain insight into the costs of these treatments and also of the additional treatments that may be warranted during the follow-up period. Results of this study may lead to a future situation in which patients with this disabling disorder will, when they seek help for the first time, be

offered the most effective treatment with the most powerfull long-lasting effect.

Study objective

On short-term, the Combined treatment is expected to be superior to either mono-treatment. On long-term it is expected that CBT will prove to be more durable and that patients in the SSRI will require more mental health care during the one-year follow-up period.

Study design

N/A

Intervention

CBT: The CBT protocol is based on the work of Clark and Barlow. Patients in the CBT group received up to 21 CBT sessions each lasting approximately 50 minutes. From session 16 onwards, sessions were scheduled with 5 week intermissions. CBT consisted of the following: 1. interoceptive exposure, 2. cognitive therapy, and 3. exposure-in-vivo.

SSRI: Patients receiving an SSRI visited their therapist 12 times, with weekly sessions during the first month and the remaining sessions distributed evenly over the treatment period of one year. Each visit lasted approximately 20 minutes. SSRIs: fluvoxamine, sertraline, citalopram, fluoxetine, and cipramil. Tapering started three months before posttest.

CBT+SSRI: Patients received both treatments which were delivered parallel by different therapists.

Contacts

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Eligibility criteria

Inclusion criteria

Patients suffering from a primary diagnosis of PD with or without AG (according to DSM-IV classification) recruited in 11 treatment facilities throug-out the Netherlands between 1 April 2001 and 1 October 2003.

Exclusion criteria

1. Comorbid Psychotic Disorder;

2. Drug dependence;

3. Major affective disorder;

4. Sifnificant risk of suicidality;

5. Pregnancy or lactation;

6. Contra-indications to either treatment modality.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2001
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	09-06-2006
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	NL626
NTR-old	NTR685
Other	: N/A
ISRCTN	ISRCTN8156869

Study results

Summary results

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