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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26056

Bron
NTR

Verkorte titel
PD-study

Aandoening

1. Cognitive-Behavioral therapy (CBT);

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

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

Ondersteuning

Primaire sponsor: This study was initiated by the University Medical Center Groningen (UMCG).

Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development (OG00-029)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2001
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-06-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL626
NTR-old	NTR685
Ander register	: N/A
ISRCTN	ISRCTN8156869

Resultaten

Samenvatting resultaten
Acta Psychiatr Scand. 2008 Apr;117(4):260-70. Epub 2008 Feb 26.