

The clinical effectiveness of EMDR second-step intervention for non-responders to CBT for Panic Disorder with or without Agoraphobia: an uncontrolled pilot study.

Gepubliceerd: 11-03-2019 Laatste bijgewerkt: 18-08-2022

The aim of this study is to critically examine the effect of EMDR added as a second step intervention to CBT in patients with PD.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26887

Bron

Nationaal Trial Register

Verkorte titel

TBA

Aandoening

Panic disorder

Ondersteuning

Primaire sponsor: HSK, University of Utrecht

Overige ondersteuning: HSK, University of Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure will be severity of PD at follow up, measured with the Agoraphobic Cognitions Questionnaire (ACQ, Dutch version) and the Body Sensations Questionnaire (BSQ, Dutch version).

Toelichting onderzoek

Achtergrond van het onderzoek

An estimated 2-3% of the general population suffers from a panic disorder (PD). A PD is characterized by recurrent, unexpected panic attacks followed fear of physical sensations, catastrophic interpretations of these sensations, and avoidance behavior because of the concern about their possible reappearance (American Psychiatric Association, 2013). Nowadays, cognitive behavioral therapy (CBT) is considered to be the most effective intervention for patients with a panic disorder with or without agoraphobia. Response rates range from 38% to 90%, so a substantial part of patients do not respond to CBT. Unfortunately, there is little information which psychological treatment is needed if this CBT is not resulting in a clinical relevant symptom reduction during treatment. In the current guidelines (Van Balkom et al., 2013), no clear suggestions are made which available treatment options there are when a patient does not respond to CBT. Eye Movement Desensitization and Reprocessing (EMDR) is a treatment method for patients who suffer from past traumatic experiences . It can be argued that EMDR can be helpful in the treatment of PD because: 1) panic attacks can be experienced as life threatening and therefore traumatic; 2) panic memories specific to PD resemble traumatic memories seen in posttraumatic stress disorder and 3) PD can develop after one or more distressing life events. The evidence for EMDR as first choice treatment for PD is scarce but EMDR as second step intervention might be effective for people suffering from PD and who do not respond to CBT as first step treatment. This study examines EMDR as second step intervention for patients who do not respond to CBT. The aim of this naturalistic uncontrolled pilot study treatment project is to generate knowledge about the incremental effect of EMDR, for patients who do not respond significantly to an outpatient CBT for panic disorder.

Doel van het onderzoek

The aim of this study is to critically examine the effect of EMDR added as a second step intervention to CBT in patients with PD.

Onderzoeksopzet

Using a multiple baseline single case series design, 15 patients with panic disorder first enter a baseline phase (CBT treatment according to treatment guidelines), followed by a 4 weeks phase wherein no treatment is given (control phase). Hereafter patients start the active treatment phase (6 sessions EMDR), followed by a 12 weeks follow up. Panic disorder severity is weekly assessed using the ?? (primary outcome measure) from start baseline to end of follow up phase. Secondary outcome measures (ACQ; BSQ; OCI-R, SQ-48) are completed at start baseline, after treatment, and after 3 months FU. Finally, actual drop-out is monitored.

Onderzoeksproduct en/of interventie

Step 1: CBT

Step 2: EMDR

Contactpersonen

Publiek

HSK

Maarten Merckx

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Wetenschappelijk

HSK

Maarten Merckx

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. a PD (with or without agoraphobia) as main classification according to DSM-5 based on the SCID-5-S (APA, 2017)
2. age above 18 years
3. sufficient mastery of Dutch to complete the questionnaires
4. less than 33.33 % symptom reduction after nine treatment sessions of CBT
5. stable medication use (type and dosage) for at least four weeks and willingness of both

patient and treating physician/psychiatrist to keep it stable during the study period
6. use of anxiolytic medication is allowed, even reduction in intake this medication to engage better in treatment attending any other psychological treatment during the study is not allowed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. very severe depression (QIDS-C $\geq$ 20)
2. acute suicidality
3. current Post Traumatic Stress Disorder (DSM-5)
4. severe alcohol or substance dependence (DSM-5)
5. lifetime psychotic disorder (DSM-5).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	08-04-2019
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

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	NL7591
Ander register	HSK/UU : FETC18-043

Resultaten