New treatment for fear of the future in MS patients

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28790

Bron
Nationaal Trial Register

Aandoening

Multiple Sclerosis / Multiple Sclerose
future anxiety

Ondersteuning

Primaire sponsor: Medical Center ETZ
Overige ondersteuning: fund initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary parameter:
Anxiety scores on the hospital anxiety and depression scale (HADS-A).
The HADS questionnaire is specially designed to measure mood disturbance in people with physical illness (Zigmond and Snaith 1983).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Prevalence of anxiety in MS patients is high and anxiety itself can contribute to the overall decrease of Quality of Life (QoL). The anxiety of MS patients seems mostly specifically focused on the future related to their MS. Evidence of applicability of Eye Movement Desensitisation Reprocessing (EMDR) to desensitize a feared 'worst case scenario' in the future (flash forward) is growing. EMDR is a cost-effective psychotherapy, especially due to the short duration of the treatment. However, research is needed to examine the flash forward EMDR procedure as treatment option for feared future events.

Objective:
The objective of this study is to examine whether EMDR with flashforward targets can be effective in reducing anxiety related to the future in MS patients. Specifically, following hypotheses will be examined: EMDR with flashforward target significantly decreases anxiety, and decreases worrying as well as improving QoL more, compared to Supportive Listening.

Our hypothesis is that cognitive status (having cognitive disorders) does not influence the treatment effect of EMDR therapy. And that patients with higher Subjective Unit of Disturbance (SUD) scores and patients with more cognitive avoidance strategies benefit more from EMDR therapy.

Study design:
Controlled intervention study, with randomised controlled design (RCT).

Study population:
MS patients (all types of MS) treated in the MSpoli in Elisabeth Tweesteden Hospital (ETZ), suffering from anxiety (HADS-A >=8), male and female, age 18-80.

Intervention:
Patients will randomly be assigned to getting EMDR treatment (EMDR ff) or supportive listening (SL).

Doel van het onderzoek

The objective of this study is to examine whether EMDR with flashforward targets can be effective in reducing anxiety related to the future in MS patients. Specifically, following hypotheses will be examined: EMDR with flashforward target significantly decreases anxiety, and decreases worrying as well as improving QoL more, compared to Supportive Listening.

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Onderzoeksopzet

T0 (premeting, pre treatment)

T1 (nameting, post treatment)

T2 (follow-up 3 maanden)

Onderzoeksproduct en/of interventie

group A (treatment group): EMDR treatment with flash forward target

group B (control group): supportive listening

Contactpersonen

Publiek

ETZ medische psychologie

O.C. Wallis
Hilvarenbeekse Weg 60

Tilburg 5022 GC
The Netherlands
013-5392872

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

ƒ{ diagnosis Multiple Sclerosis

ƒ{ Dutch speaking

ƒ{ adult (18+)

ƒ{ HADS-A score 8 or higher

ƒ{ anxiety related to the future

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

ƒ{ severe psychiatric comorbidity; i.e. dissociation, high suicide risk

ƒ{ following other psychological treatment at the same time

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2016
Aantal proefpersonen:	52
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45157
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4463
NTR-old	NTR5705
CCMO	NL54423.028.15
OMON	NL-OMON45157

Resultaten

Samenvatting resultaten

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