New treatment for fear of the future in MS patients

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28790

Source
Nationaal Trial Register

Health condition

Multiple Sclerosis / Multiple Sclerose
future anxiety

Sponsors and support

Primary sponsor: Medical Center ETZ
Source(s) of monetary or material Support: fund initiator

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Other parameters:

- Penn State Worry Questionnaire (PSWQ) scores. The PSWQ is a diagnostic indicator of excessiveness and uncontrollability of worry in non-clinical populations and patient samples (van der Heiden, Muris et al. 2010). Although there is not a norm group specific for MS patients, the PSWQ is used to examine worry in MS (Thornton, Tedman et al. 2006).

ƒ{ Scores on Quality of Life questionnaire: World Health Organisation Quality of Life (WHOQOL-bref). WHOQOL-bref is a solid, cross-cultural valid assessment of Quality of Life, reflected in four domains; physical, psychological, social and environment (Skevington et al., 2004). Although there is not a norm group specific for MS patients, the WHOQoL was been used to examine quality of life in MS (Phillips, Saldias et al. 2009, Wynia, Middel et al. 2009).

Study description

Background summary

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).

Study 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

T0 (premeting, pre treatment)

T1 (nameting, post treatment)

T2 (follow-up 3 maanden)

Intervention

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

group B (control group): supportive listening

Contacts

Public
ETZ medische psychologie

O.C. Wallis
Hilvarenbeekse Weg 60

Tilburg 5022 GC

The Netherlands
013-5392872
Scientific
ETZ medische psychologie

O.C. Wallis
Hilvarenbeekse Weg 60

Tilburg 5022 GC
The Netherlands
013-5392872

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2016
Enrollment:	52
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45157
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results

-