BEWARE:
Body awareness training for wearing-off related distress in Parkinson patients

Gepubliceerd: 10-09-2018 Laatst bijgewerkt: 15-05-2024

beware-treatment is more effective than usual care

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

Samenvatting

ID

NL-OMON25333

Bron
NTR

Verkorte titel
BEWARE

Aandoening

parkinson's disease

Ondersteuning

Primaire sponsor: VUmc
Overige ondersteuning: Hersenstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Valued living (Chronic Illness Acceptance Questionnaire – CIAQ

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Wearing-off (the re-emergence of Parkinson's disease (PD) symptoms when the medication effect wears off) is considered to be one of the most debilitating symptoms of the disease and is expressed by interacting motor and non-motor symptoms that have reciprocal influences. This results in physical and psychological distress interfering with daily life functioning and social interaction. On-off fluctuations (including wearing-off) are eventually inescapable with prolonged use of dopamine replacement therapy (e.g. levodopa) which is considered the first-line treatment in PD. Current treatment options of wearing-off related distress are monodisciplinary and unsatisfactory.

Objective: The current study aims to investigate the effect of a multidisciplinary group intervention, as compared to usual care, on the awareness and modulation of wearing-off related distress to improve coping, mobility, mood, and quality of life.

Study design: Multicentre, observer blinded, randomized controlled clinical trial.

Study population: Ninety-two PD patients who experience wearing-off symptoms with psychological distress.

Intervention: Patients with PD are randomly allocated to one of two treatment arms (n= 46 each). Per centre approximately six groups of 5/6 patients (three for each arm) will be included. One group receives the experimental group 'body awareness therapy', while the other group receives regular group physiotherapy (treatment as usual). Both interventions will take 10 weeks with weekly sessions of 1,5 hour. Homework assignments will be implemented through an online workbook.
Main study parameters/endpoints: Primary outcome is the Chronic Illness Acceptance Questionnaire (CIAQ). Secondary outcome measures focus on motor and non-motor symptoms of PD, quality of life, anxiety, depression, and mobility. All outcomes will be assessed at pre- and post-treatment, and 12 weeks follow-up.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All participants will receive, and may benefit from, treatment for their wearing-off symptoms; half of them in conventional TAU and half of them the experimental BEWARE treatment. On three time points, extra time will be asked of the patients to assess the primary and secondary outcome measurements (approximately 45 minutes at home and 60 minutes on site).

Doel van het onderzoek

beware-treatment is more effective than usual care

Onderzoeksopzet

0, 10 and 22 weeks

Onderzoeksproduct en/of interventie

Body awareness training

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Diagnosis according to the Movement Disorder Society Clinical Diagnostic Criteria for Parkinson's disease (Postuma et al., 2015);

2) Hoehn and Yahr disease stages 2 - 4;

3) Experiencing wearing-off, as measured by the Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale part IV (motor complications, including wearing-off);

4) Experiencing psychological distress (defined by clinical evaluation concerning avoidance and safety behaviour, anxiety symptoms (as is also assessed with the Parkinson Anxiety Scale), and restrictions in daily life due to wearing-off);

5) Stable and optimal anti-Parkinson and/or psychopharmacological medication regimen, including Deep Brain Stimulation and pump-delivered therapy, for at least six weeks prior to study participation;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Unable to attend at least eight group treatment sessions (including the first and last session);

2) Currently receiving an active form of psychological treatment or physical therapy within six weeks prior to study participation. Supportive physical therapy and supportive conversations with a psychologist are allowed to be continued, as long as this is routinely incorporated for at least six weeks prior to study participation;

3) Cognitive impairment (Montreal Cognitive Assessment (MoCA) score < 24);

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	92
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50397
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7398
NTR-old	NTR7606
CCMO	NL64732.029.18
OMON	NL-OMON50397

Resultaten