Body awareness training in the trEatment of Wearing-off related Anxiety in patients with paRkinson*s diseasE.

Published: 29-01-2014
Last updated: 23-04-2024

The current proposal aims at investigating the effect of a multidisciplinary non-verbal intervention on the awareness and modulation of WRA to improve self-efficacy, mobility, mood, and quality of life as compared to usual care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON40171

Source
ToetsingOnline

Brief title
BEWARE

Condition

- Movement disorders (incl parkinsonism)
- Anxiety disorders and symptoms

Synonym
anxiety symptoms when medication wears off, Wearing-off related anxiety

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Parkinson Vereniging

Intervention

Keyword: ACT, BEWARE, Parkinson, wearing-off

Outcome measures

Primary outcome

Self-Efficacy, as measured with the 10 item General Self Efficacy Scale.

Secondary outcome

Secondary outcome measures: at the levels Functions, Activities and Participation of the International Classification of Functioning, Disability and Health (ICF).

1. Quality of Life: the Parkinson*s Disease Questionaire-39.

2. Wearing-off Questionnaire 19

3. Beck Anxiety Inventory

4. Beck Depression Inventory

5. Walking speed: 10 meter walk test

6. Balance performance: Timed Single leg stance test

7. ADL independence: the Nottingham Extended ADL index

8. Freezing symptoms: the Freezing of Gait questionnaire

9. Visual-Analogue-Scales to assess the state of the patient before and after every therapy session

Study description

Background summary

Approximately 60% of the patients with Parkinson*s Disease (PD) that receive Levodopa therapy eventually develop response fluctuations in motor symptoms, such as rigidity, freezing and akinesia. Patients experience an *off*-period just before the next dose of dopaminergic medication is needed, called the *wearing-off*-phenomena. Wearing-off is also accompanied by non-motor symptoms such as depression, anxiety, pain and thinking disability. Together, these motor and non-motor symptoms have a major impact on the quality of life of patients and their partner or caregiver.
Patients with wearing-off often experience severe anxiety and panic symptoms that are incongruent with the severity of the motor symptoms during an *off* period. These symptoms include stress, dizziness, pounding/racing of the heart, dyspnoea and hyperventilation. This type of anxiety is called wearing-off related anxiety (WRA) and might be a consequence of the hypersensitivity towards somatic manifestations and effects of a wearing-off period. This bodily misperception can have major consequences for the patient*s feelings and behaviour. The experienced anxiety is often not consciously linked to the wearing-off and is therefore not well recognized by neurologists.
Treatment as usual in response fluctuations is physiotherapy, consisting of physical exercises for mobility problems, freezing, dyskinesias, etc. This kind of training hardly touches upon the mental aspects and the role of anxiety as integral element of the response fluctuations. Cognitive behaviour therapy (CBT, including exposure in vivo) is sometimes used to treat WRA, but seems to have unsatisfactory results since the changed body awareness is not sufficiently addressed. Also, the methods used in cognitive therapies focus on the elimination of WRA which is often not realistic since wearing-off symptoms will remain or even increase during disease progression. As of yet, there are no known alternative intervention options. This study focuses on a new intervention by integrating elements from physiotherapy, mindfulness, CBT (mainly exposure), Acceptance and Commitment Therapy (ACT) and psycho-education.

Study objective

The current proposal aims at investigating the effect of a multidisciplinary non-verbal intervention on the awareness and modulation of WRA to improve self-efficacy, mobility, mood, and quality of life as compared to usual care.

Study design

This is a randomized controlled clinical trial.
Patients with Parkinson*s disease (n=48) that experience wearing-off related anxiety will be randomly allocated to either the BEWARE training group (n=24) or to a control group receiving usual care (n=24) using permuted blocks of 6 with concealed opaque envelopes. Randomization will be performed by an independent person not involved in the study. Both groups will be asked to maintain the regular medication schedule. Assessments will be conducted prior

to intervention, at 6 weeks directly after intervention and at 18 weeks follow up.

Intervention

Patients with PD are randomly allocated into one of two groups (n= 24 each). One group receiviesthe experimental *body-awareness therapy*, while the second group receives regular group-physiotherapy (treatment as usual). The experimental condition addresses elements and techniques from mindfulness training, physical therapy, exposure/flooding therapy and psychoeducation. One home-based therapy session together with a caregiver or partner will also be part of the intervention and will be scheduled between the third and fourth group training session. Also, the patients are given homework assignments to generalize treatment outcomes to their daily lives.

Study burden and risks

The PD patients will receive treatment for their WRA. On three time points, extra time will be asked of the patients to perform the primary and secondary outcome measurements.

Contacts

Public
Vrije Universiteit Medisch Centrum

van der Boechortstraat 7
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit Medisch Centrum

van der Boechortstraat 7
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

idiopathic Parkinson's disease
experiencing wearing-off
BAI-score > 26
written informed consent

Exclusion criteria

MMSE-score < 22
Other neurological, orthopedic, cardiopulmonary problems that may interfere with participation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2014
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	29-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL46282.029.13