BEWARE 2.0: body awareness training for wearing-off related distress in Parkinson's disease patients

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Do patients that receive the BEWARE training have a higher score on the Chronic Illness Acceptance Questionnaire at the end of treatment (and at 3 month follow-up) compared to the treatment as usual (physical therapy only)?

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

Summary

ID

NL-OMON50397

Source
ToetsingOnline

Brief title
BEWARE 2.0

Condition

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

Synonym
Parkinson

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: distress, multidisciplinary, Parkinson, wearing-off

Outcome measures

Primary outcome

Chronic Illness Acceptance Questionnaire, which measures valued living.

Secondary outcome

- Mobility (10 Meter Walk Test, Activity tracker, One Leg Stance Test, and new Freezing of Gait Questionnaire), where the tests will be performed in optimal *on* (from 30 minutes after anti-Parkinson medication intake);

- Activities of daily living (Nottingham Extended Activities of Daily Living Index with domains mobility, kitchen, household, and leisure activities);

- Anxiety and depression using the Parkinson Anxiety Scale and the Beck Depression Inventory;

- Body awareness (Body Awareness Questionnaire);

- Quality of Life (eight-item Parkinson*s Disease Questionnaire);

- Caregiver burden (Caregiver Strain Index);

- Wearing-off symptoms measured with the 10-item Wearing-Off Questionnaire.

Other study parameters:

- Cognition represented by the MoCA score;

- Coping style measured with the Coping Inventory of Stressful Situations (CISS-21);

- Disease severity measured with the Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) part III

(motor examination), IV (motor complications, including wearing-off), and V

(Hoehn & Yahr stage) in optimal *on*;

- Duration of illness (since diagnosis);

- Medication schedule and usage (dopaminergic and psychopharmacological);

- The time spent on homework assignments (available through the online

platform).

Study description

Background summary

About 75% of Parkinson*s disease (PD) patients with motor fluctuations, including wearing-off (the re-emergence of PD symptoms when the medication effect wears off), experience very disabling mood, anxiety and/or cognitive fluctuations in parallel. The wearing-off phenomenon in PD patients is accompanied by both motor and non-motor (autonomic, cognitive and emotional) symptoms, resulting in physical and psychological distress interfering with daily functioning and social interaction. Wearing-off is considered the one of the most troublesome symptoms of PD. The impact of the physical symptoms accompanying wearing-off on daily life functioning is often higher than can be explained from the actual severity of the motor symptoms, resulting in severe wearing-off related distress (WRD) and suggesting a deviating body awareness. The reciprocal interactions between motor, autonomic and psychological features of wearing-off seem to underlie the negative vicious circle that often results. Besides predictable medication-related wearing-off, unpredictability of the reoccurrence of PD symptoms has been described by individuals as a primary concern affecting participation in daily life. Current treatment options are very limited and typically focus on either the physical or psychological aspects of PD fluctuations. Optimizing dopaminergic therapy can improve both types of fluctuations to some extent. However, as the disease progresses these pharmacological options become insufficient and have downsides or side effects (such as the development of dopamine dysregulation syndrome, hallucinations or impulse control disorders). In line with this evidence, the Parkinson Patient Association (Parkinson Vereniging) investigated research priorities in the PD population. Within the non-motor domain, coping was considered most important to study. In addition, it was argued that when one learns to cope with the disease, this reduces distress and avoidance of daily activities. The primary focus of BEWARE is to teach PD patients to cope with the fluctuations of the disease and by this to improve valued living. In an already conducted phase II

pilot randomized controlled trial, it has been shown that PD patients that received the BEWARE training improve in their emotional wellbeing, as well as in their balance and trend-wise in feeling less stigmatized about their disease.

Study objective

Do patients that receive the BEWARE training have a higher score on the Chronic Illness Acceptance Questionnaire at the end of treatment (and at 3 month follow-up) compared to the treatment as usual (physical therapy only)?

Study design

This will be an observer-blinded multicenter randomized controlled trial.

Intervention

The BEWARE training primarily focuses on living a valuable life despite the presence of motor and non-motor wearing-off. This is achieved by combining Acceptance and Commitment Therapy (ACT) with physical therapy. Treatment will be delivered by a team consisting of a psychotherapist trained in ACT and a physical therapist trained in PD treatment guidelines.
The intervention consists of the following elements:
1) Psycho-education about PD and wearing-off, including the motor and non-motor symptoms and their reciprocal interactions. This information will also be delivered to the caregiver/partner of the patients;
2) Explanation on and training of in the concepts of body awareness, self-recognition, cognitive defusion, and valued living. This will be combined with imaginary exposure, in ACT therapy known as FEEL (Feeling Experiences Enriches Living) exercises. The patients will practice with experiencing and daring to allow the feelings that are triggered by the *off* during this imaginary exposure. The patients are gradually encouraged to take part in activities that they previously avoided because of the (anticipation of) wearing-off;
3) Physical exercises that are alternated with the psychological exercises. These exercises include mobility and body awareness strategies to initiate movement when the patient finds him/herself in an *off*, body-scan exercises, moving on rhythms and music helping the patient to consciously experience physical movement and relieve stress after the imaginary exposure.
4) Finally, to generalize the intended treatment effect to daily life functioning, the patients are given homework assignments, including body awareness exercises and planning of value-based committed actions in their daily lives. Help with these assignments will consist of an online, web-based workbook with audio and video instructions. These homework assignments will also encourage the active involvement of the caregiver/partner of the patient and a prolonged retention of the learned skills. The homework assignments shall

be monitored to take the amount of time practicing into account in the analyses. A prolonged retention is also achieved by relapse prevention, which is the focus of the last therapy session.
The BEWARE training will be compared with TAU, e.g. physical therapy focussed on improving mobility related to transfers, posture, balance instability and gait, according to the current European guidelines from the Royal Dutch Physical Therapy Society. Elements 3 & 4 of the BEWARE training will also be implemented in the TAU. However, the homework assignments in the TAU group will solely focus on physical therapy exercises by using the *Parkinson exercise app*, as is in line with European guidelines.

Study burden and risks

Risks are considered negligible.
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. They are asked to maintain their medication schedule, and are expected to do homework assignments.
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).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

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

Exclusion criteria

1) 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;
2) Cognitive impairment (Montreal Cognitive Assessment (MoCA) score < 24).

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:	Recruiting
Start date (anticipated):	17-03-2019
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO Date:	05-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-07-2020
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

ID: 25333
Source: NTR

Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT02054845
CCMO	NL64732.029.18
OMON	NL-OMON25333