Body awareness training in the treatment of wearing-off related anxiety in patients with Parkinson's disease: Results from a pilot randomized controlled trial

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ABSTRACT

Background: In Parkinson’s disease (PD) patients, fluctuations in symptoms commonly occur after many years of dopamine replacement therapy. The so-called wearing-off phenomenon exists of both motor and non-motor symptoms, such as rigidity and anxiety. Current treatment options are limited and an integrated approach is needed to address the complex interactions between motor and non-motor symptoms. Since wearing-off is eventually inevitable, treatment needs to focus on coping, acceptance and self-efficacy. We developed the body awareness training, named BEWARE, combining physical therapy with acceptance and commitment therapy to help PD patients deal better with wearing-off related anxiety (WRA).

Methods: This was an investigator-blinded randomized controlled trial. Forty PD patients with WRA were randomly assigned to the BEWARE or to the treatment as usual (TAU) condition. Assessments were performed prior to and immediately after the treatment period, and at 3-months follow up. The primary outcome was self-efficacy, secondary outcomes focused on mobility, daily functioning, anxiety, depression and quality of life.

Results: There was no significant improvement in self-efficacy in the BEWARE treatment condition when compared to TAU. However, standing balance and emotional wellbeing showed a significant improvement, and feelings of stigmatization showed a trend-significant decrease in the BEWARE condition.

Conclusions: We consider the BEWARE training to be a promising therapeutic approach to address WRA. Improvement points from the participants included 1) less frequent but longer therapy sessions; 2) active involvement of caregivers; and 3) the development of a supportive workbook. The optimized treatment protocol needs further evaluation in a phase III RCT.

Trial registration: ClinicalTrials.gov identifier: NCT02054845
1. Introduction

The typical motor symptoms in Parkinson’s disease (PD) include tremor, rigidity, slowness of movement, postural instability, and freezing. Besides these symptoms, PD is accompanied by non-motor symptoms, such as autonomic failure, fatigue, pain, cognitive rigidity, depression and anxiety. Non-motor symptoms often have a higher impact on patients’ quality of life than motor symptoms [1]. First line treatment for PD symptoms is dopamine replacement therapy (DRT), e.g., levodopa [2]. In reaction to chronic DRT, PD patients eventually develop response fluctuations, including wearing-off. During wearing-off, both motor and non-motor symptoms can occur and/or become more prominent. Wearing-off is common already at the early stages of PD and is underestimated by routine neurological clinical evaluation. The number of wearing-off symptoms, both motor and non-motor, increases along with disease duration and has a negative impact on quality of life [3].

In PD, motor and non-motor symptoms have reciprocal influences [4]. About 75% of patients with motor fluctuations experience fluctuations in mood and/or anxiety in parallel [5], and anxiety is more common in patients that experience motor fluctuations compared to those who do not [6]. Anxiety associated with wearing-off, referred to as wearing-off related anxiety (WRA), is characterized not only by subjective feelings of anxiety but also by physical complaints, such as sweating, abdominal distress and shortness of breath. According to Rutten et al. [7], anxiety symptoms in PD show significant overlap with both autonomic and motor symptoms, which makes it difficult to disentangle them.

The high impact of the physical symptoms accompanying WRA on daily life functioning is often incongruent with the actual severity of the motor symptoms of wearing-off. This suggests heightened body awareness in these patients. Body awareness involves an attentional focus on and awareness of internal bodily sensations [8]. An abnormal increase in body awareness can be maladaptive [8] and is common in anxiety disorders [9]. Normalizing body awareness may therefore help patients to cope with WRA.

A first therapeutic approach to treat WRA is optimization of DRT [10], since the anxiety symptoms experienced by PD patients are sometimes responsive to dopaminergic medication [11–13]. As the disease progresses, this becomes insufficient and is complicated by response fluctuations and increased occurrence of dyskinesias that become unpredictable in nature [14]. Such random fluctuations are difficult to treat with pharmacotherapeutic approaches since they are not directly related to a low level of dopamine [14]. In addition, treating anxiety symptoms with pharmaceutics, such as psychotropic medication, might interfere with DRT and result in increased tremor or rigidity, which is undesirable.

Non-pharmacological approaches to treat wearing-off include exercise programs and physical therapy. These have been shown to improve motor problems, daily functioning and quality of life in PD patients [15–18]. While effective in improving mobility-related problems, current physical rehabilitation approaches typically do not offer tools to address the (interaction with) non-motor symptoms, such as WRA.

Cognitive Behavior Therapy (CBT), mindfulness and Acceptance & Commitment-based therapies (ACT) are effective in reducing anxiety symptoms, distress and avoidance behavior and enhancing quality of life in patients with anxiety disorders and PD [19–23]. Therefore, tools from CBT and ACT might also be useful in the treatment of the debilitating effects of WRA in PD. However, the classical approach aims to reduce symptoms, whereas the inevitability of motor and non-motor fluctuations in PD demands a coping strategy on dealing with these fluctuations. In addition, cognitive rigidity becomes more prominent with disease progression and complicates a monodisciplinary cognitive treatment approach.

To address both the physical and the mental aspects of PD, Wahbeh et al. [24] reviewed mind-body interventions in the treatment of PD and showed that participating in tai chi classes improved the patients’ physical condition. Landsman-Dijkstra and colleagues [25] tested a highly structured and standardized 3-day body-awareness program in 14 participants who suffered from chronic non-specific psychosomatic symptoms. After the intervention body awareness, self-efficacy and quality of life had significantly improved. The main limitation of this study, apart from the small sample size, was the lack of a control group. In summary, mind-body interventions seem promising for the treatment of WRA in PD patients, but the therapeutic efficacy has yet not been investigated.

We therefore developed an integrated body awareness training combining ACT with physical therapy for patients with PD, named BEWARE. We investigated the feasibility and the efficacy of this group intervention using a pilot randomized controlled study, with conventional group physical therapy as active control condition.

2. Methods

For a detailed description of the methodology, including the intervention protocol, we refer to the article of Ghielen et al. [26].

2.1. Study design

We conducted an investigator-blind randomized controlled trial. Forty PD patients with WRA were randomly allocated to either the BEWARE training (4 groups of 4–6 patients) or to the treatment as usual (TAU) receiving group physical therapy (4 groups of 4–6 patients). Block-randomization with 2 blocks of 4 was done using concealed opaque envelopes and conducted by an independent investigator. Assessments were conducted prior to the intervention (baseline), directly after the six-week intervention (post-treatment) and at 18 weeks follow-up (3 months after completing the intervention). A blinded investigator, who was not involved in the intervention and/or randomization, performed all assessments.

2.2. Patients

Forty participants were recruited from the outpatient clinic of the VU University medical center and through the Dutch Parkinson patient association (see Fig. 1 for the flow chart according to the CONSORT-statement [27]). Inclusion criteria were: 1) a diagnosis of idiopathic PD according to the UK PD Brain Bank criteria [28]; 2) the presence of one

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**Fig. 1. Study flowchart.**
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