Cognitive Behavioural Therapy for anxiety disorders in patients with Parkinson*s disease: a Randomized, Controlled Trial of the clinical effectiveness and changes in cerebral connectivity

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

Summary

ID

NL-OMON46897

Source
ToetsingOnline

Brief title
Cognitive behavioural therapy for anxiety disorders in PD

Condition

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

Synonym
anxiety disorders

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Michael J. Fox foundation for Parkinson's Research

Intervention

Keyword: anxiety disorders, Cognitive behavioural therapy, Parkinson's disease, Randomized controlled trial

Outcome measures

Primary outcome

The primary outcome measure is the difference in change in anxiety score between baseline and post-treatment as measured with the Hamilton Anxiety Rating Scale (HARS) between the intervention- and control group.

Secondary outcome

- Differences in changes between the intervention- and control group in cerebral connectivity between limbic and frontal cortices before and after treatment, as measured with resting state BOLD fMRI and DTI.

- Long term clinical effectiveness of the CBT module, measured by the change in HARS score after 3 months (between group) and 6 months (within group) follow-up in the intervention- and control group.

- The difference between the intervention- and control group in generic health-related quality of life (EQ-5D-5L and PDQ8) and well-being (ICECAP-O) before and after treatment.

- The cost-effectiveness of CBT as treatment for anxiety in PD patients as

measured by the Resource Use Questionnaire.

Study description

Background summary

Anxiety disorders occur in up to 35% of patients with Parkinson*s disease (PD) and have a negative effect on several motor symptoms and quality of life. So far, there is no treatment, neither pharmacological nor psychotherapeutic, that intends to specifically reduce anxiety symptoms in PD. Cognitive Behavioural Therapy (CBT) is an effective treatment for anxiety disorders in patients without PD. In PD, CBT is an effective treatment for depression and for impulse control disorders (ICD), compared to PD patients who only receive clinical monitoring. In addition, recent neuroimaging studies have demonstrated the therapeutic effects of CBT on functional neural activity.

Study objective

The present study aims to study the clinical effectiveness of a CBT module for anxiety in PD. This module is based on existing modules for anxiety disorders in non-PD patients, and on modules for depression and impulse control disorders in PD patients. In addition, we aim to get more insight into biological dysfunction associated with anxiety in PD, as well as alterations in brain structure, brain function and cerebral connectivity due to CBT in order to unravel the biological correlates of successful treatment. Effective CBT treatment of anxiety will provide patients with behavioural and anxiety management techniques that can give lasting benefits, not only on anxiety symptoms, but potentially also on motor symptoms.

Study design

This study involves a Randomized Controlled Trial (RCT) with PD patients recruited in two centres in Europe (Maastricht Universitair Medical Centre (Netherlands) en Lille 2 Medical university (France) who will be randomized to CBT plus clinical monitoring or clinical monitoring only. All participants will undergo baseline clinical assessment (including MRI scan), post-treatment clinical assessment (including MRI scan), 3 months follow-up clinical assessment and a 6 months follow-up clinical assessment (only for patients randomized to CBT plus clinical monitoring). Patients who receive clinical monitoring only will be given the option to receive CBT 3 months after the baseline assessment.

Intervention

Patients who will receive CBT plus clinical monitoring (intervention group) will receive weekly individual sessions, tailored to the preferences and needs of each patient. In each session, a registered psychologist will address specified aspects of (coping with) anxiety and related concerns. Several topics of anxiety will be integrated with a specific focus on behaviour and thoughts associated with anxiety. Patients assigned to clinical monitoring only (control group) will receive general education material on coping anxiety symptoms, not specific for PD.

Study burden and risks

To our knowledge, there are no major risks associated with participating in the CBT intervention. We do not expect the content of the modules to be too confronting or emotionally stressful to cause any psychological harm to the participants, because the sessions will be tailored to the needs and concerns of participants and the content of the modules is based on the needs of the target population and the knowledge of PD experts. However, we acknowledge that participating in the CBT intervention can be time-consuming and demanding for participants. However, the current CBT module can provide them with behavioural and anxiety management techniques that can be used to achieve longer-term benefits and therewith reducing the risk of relapse.
Moreover, there is a low risk for undergoing MRI.

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

* Idiopathic PD according to the Queens Square Brain Bank diagnostic criteria
* Presence of clinically relevant anxiety symptoms
* Using a stable dose of levodopa or other antiparkinsonian medication for at least one month
* No other current psychological treatment for anxiety; pharmacotherapy (e.g., SSRIs) is allowed if a stable dose is used at least 2 months prior to participation and the patient still meets inclusion criteria. During the trial the dosage should not be changed. Medication use and mental health care will be tracked throughout the study.
* Age between 35 and 80 years
* Signed informed consent

Exclusion criteria

* Parkinsonian syndromes or neurodegenerative disorders other than PD
* Dementia or severe cognitive decline
* Major depressive disorder (MDD) as defined by the criteria of a DSM-V diagnosis for MDD
* Abuse of alcohol, drugs or benzodiazepines.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-08-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT02648737
CCMO	NL56176.068.16