The effect of mindfulness-based cognitive therapy on psychological distress in people with Parkinson*s Disease: clinical effects and cerebral mechanisms.

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Test whether a mindfulness-based cognitive therapy intervention (MBCT) improves psychological distress, clinical symptoms, slows neurodegeneration, and/or enhances neuroplasticity in PD.

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

Summary

ID

NL-OMON51467

Source
ToetsingOnline

Brief title
MIND-PD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO VIDI beurs

Intervention

Keyword: fMRI, Mindfulness, Parkinson's Disease, Psychological stress

Outcome measures

Primary outcome

The primary outcome measure is psychological stress complaints, measured with the validated Hospital Anxiety and Depression Scale (HADS) post-intervention (T1; for the MBCT group immediately post-intervention, for the control group 2-3 months after T0).

Secondary outcome

We will measure inflammatory markers in blood, cortisol levels from hair and saliva, and collect several clinical and MRI measures at baseline (T0), post-intervention (T1) and after a follow-up period of 12 months after baseline (T2).

Study description

Background summary

Parkinson*s disease (PD) patients are very sensitive to the effects of psychological stress. The prevalence of stress-related neuropsychiatric symptoms is high, stress worsens motor symptoms and chronic stress might also accelerate disease progression, as suggested by animal models. Mindfulness-based interventions (MBI) train participants to focus on the present moment without judgement, while allowing experienced difficulties. Previous studies suggest that MBIs can reduce stress and improve depression and anxiety in PD, but many studies have been small-scale or have mixed results. The effects on motor symptoms and underlying cerebral mechanisms remain fully

unclear.

Study objective

Test whether a mindfulness-based cognitive therapy intervention (MBCT) improves psychological distress, clinical symptoms, slows neurodegeneration, and/or enhances neuroplasticity in PD.

Study design

Randomized controlled trial.

Intervention

62 PD patients will receive an 8-week mindfulness-based cognitive therapy (MBCT) program, and 62 PD patients receive treatment as usual (TAU).

Study burden and risks

The load on patients consists mostly of the time spent on the intervention, which will be eight 2-2.5-hour sessions and a 4-hour silence day in the mindfulness group with daily exercises to be performed at home. In addition, there will be three study visits (baseline (T0), post-intervention (T1) and 12 months after baseline (T2)) where clinical, psychological, blood samples and MRI measures will be collected. During these study visits all measurements happen OFF-medication and therefore symptoms might temporarily worsen, which can lead to discomfort. Except for three blood samples that will be taken, all measures (MRI, clinical assessments, questionnaires, cortisol) are non-invasive. Finally, participants are asked to fill out home questionnaires at T0, T1, T2, and in the middle of the follow-up period (6 months after baseline). Mindfulness adherence will be assessed every 2 months (exclusively in the mindfulness group). Participants could directly benefit from the intervention. Participants in the control group are offered the possibility to follow the MBCT course after the study is finished.

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

For patients:
- A diagnosis of idiopathic Parkinson's Disease made by a movement disorders specialist.
- Parkinson disease duration is <=10 years, defined as time since diagnosis made by a neurologist.
- Mild-moderate symptoms of psychological distress (Hospital Anxiety and Depression Scale score >10 points).
- Subject can read and understand the Dutch language.

For healthy controls:
- Subject can read and understand the Dutch language.

Exclusion criteria

For patients:
- Severe neurological or psychiatric co-morbidity (psychosis or suicidality).
- Contraindications for MRI (i.e.: brain surgery in medical history, claustrophobia, an active implant, epilepsy, pregnancy, and/or metal objects in the upper body that are incompatible with MRI).
- Moderate to severe head tremor (to avoid artifacts caused by extensive head motion during scanning).

- Cognitive dysfunction (clinical diagnosis of dementia, or a score of 20 or lower on the MoCA, which will be measured at T0).
- Previous participation in MBSR or MBCT (>4 sessions).

For healthy controls:
- Severe neurological or psychiatric co-morbidity (psychosis or suicidality).
- Contraindications for MRI (i.e.: brain surgery in medical history, claustrophobia, an active implant, epilepsy, pregnancy, and/or metal objects in the upper body that are incompatible with MRI).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2023
Enrollment:	174
Type:	Actual

Ethics review

Approved WMO Date:	04-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-06-2023

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-10-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-10-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-01-2025
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT05779137
CCMO	NL81309.091.22