Managing the mental state to tackle anxiety-related freezing of gait in people with Parkinson*s disease: a randomized controlled intervention trial

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

Summary

ID

NL-OMON56264

Source
ToetsingOnline

Brief title
TACKLING-FOG

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Jacques and Gloria Gossweiler Foundation

Intervention

Keyword: anxiety, freezing of gait, parkinson's disease, randomized controlled trial

Outcome measures

Primary outcome

The primary outcome measure is the subjective impact of anxiety and stress on FOG, as measured with a 7-point Likert scale.

Secondary outcome

Secondary outcomes involve the perceived levels of anxiety, and the percentage of time frozen during a home-based gait task within a participant self-selected FOG *hotspot* in the home setting and during a standardized FOG-provoking gait protocol, which includes rapid 360 degrees turning in both directions, navigating a narrow passage, and performing a cognitive (serial subtraction) dual-task to assess freezing severity. Participants will also fill in several questionnaires. Additionally, upon completion of all other measures, we will perform in-depth interviews and perform a thematic analysis on these data to evaluate patients* interpretations of the intervention material, ways in which they feel it relates/related to them, and the degree to which it was (not) effective.

Study description

Background summary

Freezing of Gait (FOG) is a common and disabling symptom in people with Parkinson*s Disease (PD), characterized by paroxysmal episodes where there is

an inability to step effectively, despite attempting to do so. Treatment consists of complementary pharmacological and non-pharmacological treatment options which unfortunately only partially alleviate FOG. Anxiety has been found to contribute to the occurrence and exacerbation of FOG, which often manifests itself in situations where people with FOG anticipate not being in control of their movements. People with FOG are often aware of the feelings and situations that elicit FOG episodes, but they rarely actively employ strategies targeting their mental state to improve FOG. With the exception of general interventions including mindfulness, yoga and meditation, tailored strategies to ameliorate anxiety-related FOG have never been evaluated in a systematic manner.

Study objective

In this project we aim to evaluate whether a non-pharmacological and tailored intervention targeting anxiety- and stress-related FOG in people with PD is effective to reduce the impact of anxiety and stress on FOG. Specifically, we aim to study: (1) the effect of four sessions of a *managing the mental state* intervention in people with disabling and anxiety-related FOG; and (2) the key determinants of the effectiveness of the intervention to reduce the impact of anxiety and stress on FOG.

Study design

This study is a randomized controlled trial (RCT). The intervention group will receive the intervention immediately after randomization while a (waitlist) control group receives the same intervention thereafter.

Intervention

The intervention consists of four sessions of a *managing the mental state* intervention, of which the first and second session will take place in the home-setting of the patient; the two remaining sessions will take place remotely. The sessions include psychoeducation on what anxiety is and how stress and anxiety can influence FOG, identifying how people are allocating attention and engage in specific thought-processes (e.g. worrisome thoughts) during walking, and educating patients about *managing the mental state* compensation strategies that involve ways to reduce anxiety or stress and will be specifically tailored to the individual patient.

Study burden and risks

Benefit: We expect responders to benefit from the intervention by reducing anxiety- and stress-related FOG.
Burden: The risk associated with participation will be negligible.

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

-Men/women of age > 18 years with idiopathic Parkinson*s disease, as diagnosed by the UK Brain Bank Criteria.
-Presence of daily FOG (as objectified with the new-freezing of gait questionnaire), that is related to anxiety (positive answer to the question: Does FOG occur -or get worse- when you are anxious or stressed?).
-Written informed consent.

Exclusion criteria

-Any comorbidity (i.e. neurological, orthopedic) that significantly impacts gait.

-Severe cognitive impairment hampering the ability to comply to the study protocol.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-03-2024
Enrollment:	46
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	20-12-2023
Application type:	First submission
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
CCMO	NL85217.091.23