HIIT-the track: High Intensity Interval cycle-ergometer exercise Training in people with Parkinson*s Disease

Published: 18-06-2020
Last updated: 08-04-2024

1) to study the effects of 4 weeks of HIIT compared to 4 weeks of CAE on motor and non-motor aspects of PD; 2) to investigate the association between blood biomarkers for neuroplasticity / neurodegeneration and motor and non-motor performance for...

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

Summary

ID

NL-OMON49269

Source
ToetsingOnline

Brief title
HIIT-Parkinson

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognition, High Intensity Interval Training, Mobility, Mood, Parkinson, Rehabilitation

Outcome measures

Primary outcome

Outcome measures include disease status (UPDRS)

Secondary outcome

blood biomarkers for plasticity (BDNF and Neurofilament Nfl), and measures for

walking and balance, as well as cognition, mood and biorhythm (sleeping

problems).

Study description

Background summary

People with Parkinson's disease (PD) experience not only motor problems (e.g. with posture, walking and balance) but also non-motor problems (e.g. with regard to cognition, mood, biorhythm, fatigue etc.) that seriously hinder their daily functioning. Current pharmacological treatments are insufficient to adequately improve these problems. Therefore, alternative rehabilitation treatments are needed, which preferably also have a disease-modifying effect on both motor and non-motor symptoms and promote neuroplasticity.
Intensive physical training appears to be very promising for promoting neuroplasticity in people with PD. In particular biomarkers for neuroplasticity such as Brain-derived neurotrophic factor (BDNF, decrease) and neurodegeneration (including neurofilament NfL, increase) are abnormal in people with PD. BDNF has shown to respond well to intensive physical training, for NfL this has not yet been properly investigated. With highly intensive physical training, walking, balance, cognition and mood can improve. However, the optimal type of physical training to achieve these neuroplastic effects is unknown. High Intensity Interval Training (HIIT) appears to be a superior training strategy over traditional moderate "continuous aerobic exercise" (CAE) in terms of physical and neurotrophic effects, with significantly less total training time and burden. Although promising, this training strategy has not yet been well studied in people with PD.

Study objective

1) to study the effects of 4 weeks of HIIT compared to 4 weeks of CAE on motor and non-motor aspects of PD; 2) to investigate the association between blood biomarkers for neuroplasticity / neurodegeneration and motor and non-motor performance for both exercise strategies.

Study design

Single Subject Research Design (SSRD) with alternating treatment setup (ABACA) and frequent repeated measurements. Here a single participant receives different interventions (B / C) interspersed with baseline periods (A, i.e. ABACA or ACABA) and frequent repeated measurements are done over time to quantify the within-subject, individual response patterns with sufficient power for data analysis.
Data analysis: Individual recovery curves are analyzed with visual inspection of between and within phase change, spread and trend. In addition, Pearson correlation coefficients will be calculated for the relationship between motor and non-motor outcomes and neuroplasticity / neurodegeneration markers. We expect that HIIT as compared to CAE will be superior in inducing neuroplasticity related, disease modifying effects.

Intervention

Participants will perform alternate (scheme will be ABACA or ACABA) schedules of 30 minute sessions of B (HIIT) or 50 minute sessions of C (CAE 3x / week for 4 weeks) separated by baseline (A) periods of 8 weeks for a total duration of 28 weeks.

Study burden and risks

All participants will receive, and may benefit from, the training interventions as all participants receive both types of interventions. They will need to come to the VUmc outpatient clinic for training 3x/week during the 4 week intervention periods. Assessment time will be combined with training times as much as possible. During A phases, on multiple time points, extra time will be asked of the patients for home based short answer questions on a smartphone and outpatient visits to assess other outcome parameters.

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 of PD according to brain bank criteria, 2) Hoehn-Yahr stage I (n<=2 patients) and III (n<=2 patients), 3) sufficient cognition to comprehend training instruction (Moca score >21) and 4) able to provide written informed consent.

Exclusion criteria

1) history of neurologic deficits other than PD, 2) severe fluctuating responses to medication, 3) psychiatric, musculoskeletal, cardiac or metabolic disorders prohibiting participation in intensive exercise training.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	4
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-06-2020
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL73033.029.20