The HEADS-Up Trial: Sleeping in a head-up tilt position to treat orthostatic hypotension, supine hypertension and nocturia in Parkinson's disease

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To assess the efficacy and tolerability of HUTS with different angles, leading to optimal implementation strategies of HUTS to alleviate the impact of orthostatic hypotension and supine hypertension in PD

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

Summary

ID

NL-OMON51733

Source
ToetsingOnline

Brief title
HEADs UP

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Michael J Fox Foundation

Intervention

Keyword: Non-pharmacological intervention, Orthostatic hypotension, Parkinson's disease, Supine hypertension

Outcome measures

Primary outcome

Overnight blood pressure (BP) from 24-hour ABPM between patients and controls

Secondary outcome

Secondary endpoints include: daily supine blood pressure, orthostatic blood

pressure, orthostatic tolerance (complaints of orthostatic hypotension),

nocturia, PD motor- and non-motor symptoms, physical activity during the day,

falls and subjective comfort of HUTS.

Study description

Background summary

Othostatic dysfunction is common, disabling and often underrecognized in Parkinson*s disease (PD). Orthostatic hypotension affects up to a third of patients with PD. About half of them also exhibit supine hypertension. In current clinical practice, both are undertreated. Importantly, the common co-occurrence of orthostatic hypotension and supine hypertension complicates pharmacological treatment, as improvement of one can be accomplished only at the expense of the other. Sleeping in a head-up tilt position (HUTS) is the only known intervention that could improve both. The concept of HUTS is based on several small-scale observational studies and expert opinion. HUTS has been proposed as a first-choice treatment for orthostatic hypotension for over three decades. However, it is often not advised to patients in daily practice because of a lack of evidence on its* effectiveness, tolerability and on how to implement it. Moreover, when it is recommended, most physicians prescribe low tilt angles which presumably have no effect on symptoms.

Study objective

To assess the efficacy and tolerability of HUTS with different angles, leading to optimal implementation strategies of HUTS to alleviate the impact of orthostatic hypotension and supine hypertension in PD

Study design

Double-blind multicenter placebo controlled intervention study (phase II)

Intervention

All participants will sleep in whole-body head-up tilt (HUTS) in three angles for two weeks (6°, 12° and 18° for the intervention group; 1°, 6° and 12° for control groups). The 1° condition in the control group is considered the control intervention. and each angle is preceded by a week ofof the HUTS sleeping position is The intervention period is preceded by a week of horizontal sleeping used for baseline measurements in both groups. The materials used to tilt the bed are personalized to the specific situation of the patient (i.e. double or single matrass) and the patient is guided by a home visit and (bi)weekly video visits by the researcher. When necesary, additional home visits are scheduled. When an increased angle is no longer tolerable, the patient is asked to return to the former angle according to the study protocol..

Study burden and risks

The burden of participating in this study consists of 2 in-clinic visits (at the start and end of study) and several home-based measurements (during 7 weeks of participation), in addition to the intervention itself. The in-clinic meetings involve questionnaires, a tilt-table-test (1st visit only), a standing blood pressure test (1st visit only), a timed up and go test and questions on barriers and facilitators of HUTS (last visit only). Every in-clinic visit will take approximately 120 minutes. During the study period of 7 weeks, several home-based blood pressure measurements will be done: 1) 24-hour ABPM 4 times, 2) standing blood pressure test 4 times (guided), 3) daily supine blood pressure in the morning. In addition, participants are asked to wear an activity tracker continuously for 7 weeks and complete a questionnaire every week. Finally, will ask participants to use an urinal during the nights and note the total urine production. The procedures alltogether can be a burden for patients, which we will try to minimize by giving good and clear instructions and by keeping in close contact with the participants throughout the study. Possible risks involve a skin rash due to the straps of the blood pressure device or activity tracker. In case this occurs participants are asked to immediately remove the strap. Risks of falling due to light-headedness during the blood pressure standing test will be minimized by guidance (video call) and participants are advised to sit down in case symptoms occur. Finally, the participants may experience difficulties getting out of bed due to increased

height of the bed when sleeping in head-up tilt. To prevent falls we will provide a firm raised platform beside the bed and we will inform participants extensively about this potential risk and provide advices to minimize it. .

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Orthostatic hypotension defined as a systolic BP decrease of >=20 mmHg, or a diastolic decrease of >=10 mmHg, within 3 min after changing from a supine to standing position OR mean standing BP of <=75 mmHg (marker for symptomatic orthostatic hypotension). In patients with supine hypertension, a decrease in systolic BP of >= 30 mmHg is required.

2. Orthostatic intolerance: direct complants (dizziness, tunnel- or blurry vision etc.) and/or inirect signs (falls or freezing episodes that relate to postual challenge)
3. Supine hypertension defined as a systolic BP of >=140 mmHg, and/or diastolic of >=90 mmHg, after 5 min of supine rest.
4. Idiopathic PD.
5. Ability to walk (with or without a walking aid).
6. Stable medication regimens for orthostatic hypotension and supine hypertension.

Exclusion criteria

Cognitively unable to follow instructions or to fill out questionnaires as judged by the researcher

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2023
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-05-2023
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
CCMO	NL80610.091.22