Validation of Tremor Assessment Software and Exploratory Sweat Lactate Analysis in Essential Tremor and Parkinson's Disease

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Primary Objectives: The primary objectives of this study are: To validate the performance of the Steady Hands software as a medical device in assessing hand tremor symptom intensity for Parkinson's Disease (PD) and Essential Tremor (ET) by comparing...

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

Summary

ID

NL-OMON57513

Source Onderzoeksportaal

Brief title

Mobile Tremor Assessment and Exploratory Sweat Lactate Analysis in Essential Tremor and Parkinson's Disease

Condition

• Movement disorders (incl parkinsonism)

Synonym

Parkinson's Disease and Essential Tremor

Research involving

Human

Sponsors and support

Primary sponsor: Van Broekhoven Fysiotherapie **Source(s) of monetary or material Support:** Derde geldstroom (anders, zoals collectebussenfondsen, Europese Unie, vakministeries of bedrijven)

Intervention

- Medical device
- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

The hand tremor intensity assessment (symptom quantification using the stability score) endpoint is agreement between the scores obtained using Steady Hands and those from the conventional tremor rating scales. Performance of Steady Hands in distinguishing between PD and ET, measured against confirmed clinical diagnoses.

Secondary outcome

To identify and characterize associations between sweat lactate values and thresholds measured using the IDRO device and symptoms in PD and ET (not as a medical device).To identify and characterize association between the evolution of sweat lactate values and thresholds over time and the evolution of symptoms in PD and ET over time (not as a medical device).

Study description

Background summary

Hand Tremors

Hand tremors (shaking) can significantly disrupt daily life, causing difficulties with eating, writing, or holding objects. These tremors are common in conditions such as Essential Tremor (ET) and Parkinson's Disease (PD). In ET, the hands shake primarily during movement, whereas tremors in PD usually occur at rest. Measuring and understanding these symptoms is crucial for improving patient care and treatment.

What is Essential Tremor (ET)?

In ET, the hands tremble during movement or while holding a position, often affecting both sides of the body. Diagnosing ET is challenging since there are no specific tests. Doctors rely on medical history, physical examination, and ruling out other causes such as Parkinson's. Assessing the severity of ET is also done using measurement methods that can be subjective and not always reliable.

What is Parkinson's Disease (PD)?

PD is a condition characterized by tremors, stiffness, and slowness of movement. Tremors play a major role in diagnosis and treatment. Doctors use scales such as the MDS-UPDRS to assess the severity of PD symptoms. However, these methods are time-consuming, rely on a physician's assessment, and provide only a snapshot in time. This makes it difficult to accurately track changes in symptoms.

Why new measurement methods are needed

Current ways of measuring tremors and other symptoms have several drawbacks:

- Few doctor visits: Patients often see their doctor only a few times a year, meaning fluctuations in symptoms may go unnoticed.
- Subjective assessment: Many tests depend on how a doctor or patient perceives the symptoms, which can lead to inaccuracies.
- Individual differences: Symptoms such as tremors vary from patient to patient, making personalized treatment essential.
- Limited access to technology: Some tools are expensive or complex, making them inaccessible to everyone.

Smart technology, such as mobile apps and wearable devices, can continuously collect objective data. This offers new possibilities for personalized care.

What is the Steady Hands app?

The Steady Hands app is a simple mobile application used as a medical tool, utilizing smartphone sensors such as motion sensors and the camera. The app accurately measures the severity of tremors and can assist in making the correct diagnosis, for example, distinguishing between ET and PD. This technology is accessible, affordable, and user-friendly.

What is the IDRO device?

The IDRO device is a small wearable sports device that measures lactate in sweat. Lactate is a substance that can provide insights into physical exertion, fatigue, and possibly certain bodily processes in conditions such as PD. Normally, lactate is measured through blood tests, but IDRO can do this non-invasively and continuously. This makes it ideal for individuals who

want more insight into their lactate levels. IDRO only presents lactate values without interpretation.

Study objective

Primary Objectives:

The primary objectives of this study are:

- To validate the performance of the Steady Hands software as a medical device in assessing hand tremor symptom intensity for Parkinson's Disease (PD) and Essential Tremor (ET) by comparing tremor intensity scores derived from Steady Hands to those obtained using conventional tremor rating scales.
- To validate the Steady Hands software's ability to differentiate between PD and ET by comparing the disease classification scores generated by the software with the patients' confirmed clinical diagnoses.

Secondary Objectives:

The secondary objectives of this study are:

- To identify and characterize associations between sweat lactate values and thresholds measured using the IDRO device and symptoms in PD and ET (not as a medical device).
- To identify and characterize association between the evolution of sweat lactate values and thresholds over time and the evolution of symptoms in PD and ET over time (not as a medical device).
- To evaluate the safety of the Steady Hands software for use by ET and PD patients in both home and clinical environments.
- To collect clinical data from ET and PD patients to support the ongoing development and refinement of the symptom assessment algorithms, ensuring enhanced diagnostic and monitoring capabilities.

Study design

Prospective longitudinal cohort study, observational study.

Setting: Participants will be assessed based on predefined eligibility criteria and, if eligible, recruited through two physiotherapy practices in the Netherlands (Van Broekhoven Fysiotherapie) and one rehabilitation hospital in Greece (Apokatastasi Rehabilitation Hospital). The study will involve assessments conducted both in the participants' home environments and at the participating centres.

Duration: The overall study will span one year, with each participant enrolled for a duration of 8 weeks.

Data collection: Data will be gathered from the participants in two channels: during in-clinic sessions and at home.

In-clinic sessions will be held once in a week. Patients will attend the clinical facility for the symptom evaluation using the Steady Hands application, as well as validated, conventional tremor assessment scales:

- MDS-UPDRS part III sec. 3, 14, 15-18 for PD patients (tremor, rigidity and bradykinesia).
- Essential Tremor Rating Assessment Scale (TETRAS), Performance subscale, sec. 4, 6, 7, 8 for the ET patients.

During the first, middle and last weeks of the patient's study cycle (weeks 1, 4 and 8) all 200 participants will also undergo an in-clinic incremental exercise test using the IDRO wearable sweat-lactate sensing device to measure sweat lactate.

In-home measurements consists of performing tremor measurements using the Steady Hands app at least twice a day to assess hand tremor symptoms. Also, it involves filling the MDS-UPDRS part "Patient Questionnaire" once a week via the same mobile application. Patient questionnaire is important for gathering subjective information about the symptoms and daily functioning.

Intervention

Medical device: Steady-Hands Software to measure hand tremor

Sport device: IDRO device prototype to measure sweat lactate

Study burden and risks

This study provides patients and healthcare professionals with objective, frequent monitoring methods devices. Results are expected to inform clinical decision-making and potentially enhance personalized management strategies in these movement disorders after the study period. Both devices are non-invasive and the number of site visits are only once every week without the experience of discomfort for the patients. Once every week the participants will complete a questionnaire and Steady-hands-app measurements will be on daily basis. The most severe documented risk is incorrect tremor assessment, caused by the error in the software's algorithms. It is mitigated by implementing verification methods for the device. All tests are conducted by well-trained individuals in a safe environment, with standard protocols in place to ensure the participants' safety. Both devices (the Steady Hands software and the IDRO device) are non-harmful to the body and non-invasive. The risks are therefore negligible and kept to a minimum.

Contacts

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Trial sites

Trial sites in the Netherlands

Van Broekhoven Fysiotherapie Target size: 30

Listed location countries

Greece, Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Disturbing tremor in one or both hands in the sense of a Parkinson's disease or Essential tremor.
- Diagnosed with probable Parkinson's Disease and/or Essential tremor.
- Age at least 18 years old.
- Willing and able to sign an informed consent form.
- Willing and able to follow instructions and use mobile phone confidently.

Exclusion criteria

- Unwillingness or incapacity to take part in the study.
- Aged less than 18 years old.

- Having tattoos or scar tissue or very sensitive skin at the location where the IDRO device will be attached (subscapular left)
- Inability to perform a cardiovascular incremental exercise test on a stationary bike

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

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NL	
Recruitment status:	Pending
Start date (anticipated):	02-06-2025
Enrollment:	30
Duration:	2 months (per patient)
Туре:	Anticipated
WORLD Recruitment status:	Pending
Start date (anticipated):	02-06-2025
Enrollment:	200
Туре:	Anticipated

Medical products/devices used

Product type:	Medical device
Generic name:	Steady-Hands Software
Registration:	No

IPD sharing statement

Plan to share IPD: Undecided

Plan description N.a.

Ethics review

Approved WMO	
Date:	25-04-2025
Application type:	First submission
Review commission:	METC Brabant

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 Research portal **ID** NL-009314