Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Empowering Parkinson's patients with vibrational Coordinated Reset method

Protocol summary

Study aim
The goal of this study is to empower Parkinson's disease by reducing the motor and non-motor symptoms of the disease, affecting brain connections, and strengthening the brain's dopaminergic pathways.

Design
The clinical trial is without a control group and patients are divided into two groups in a single-blinded manner (patients are unaware of the type of glove) using the randn command of the Matlab software, and 3 of them start the intervention with the original glove and the other 3 with the dummy glove. After one month, the gloves are changed between the patients.

Settings and conduct
EEG data collection from patients is done in the brain mapping laboratory and UPDRSIII score is taken at Hazrat Rasool Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: While taking the medication, have been diagnosed with typical Parkinson's disease according to Hoehn and Yahr stage 2 to 4 criteria - Inclusion criteria: Cannot have dopamine dis regulation syndrome or other neurological diseases such as major depression, dementia, attention deficit disorder, psychosis or essential tremor. Patients cannot have severe sensory abnormalities of the fingertips such as vibratory urticaria. Patients who are pregnant, breastfeeding or trying to become pregnant during the study period are excluded from the study. Patients must not have a history of multiple sclerosis (MS), Alzheimer's, hip fracture, total knee or hip replacement surgery, Huntington's disease and a history of stroke.

Intervention groups
The number of participants is 6. The intervention is such that from the beginning of the study, patients undergo a medical examination and visit with a neurologist for 1 month, and in the following month,

Main outcome variables
Effect on motor neuron plasticity; reduction of neuronal synchronization; reduction of Parkinson's disease symptoms; improvement of the patient's quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250922067329N1**
Registration date: **2025-10-21, 1404/07/29**
Registration timing: **prospective**

Last update: **2025-10-21, 1404/07/29**
Update count: **0**

Registration date
2025-10-21, 1404/07/29

Registrant information

Name
Aboozar Moradi
Name of organization / entity
The University of Tehran
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2025-11-22, 1404/09/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Empowering Parkinson's patients with vibrational Coordinated Reset method

Public title

Studying the effect of vibrating gloves on reducing symptoms of Parkinson's disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients participating in this trial are between 45 and 85 years old. While taking the medication, Parkinson's disease was diagnosed with Hoehn and Yahr stage 2 to 4 criteria. Patients must communicate clearly with staff and speak Persian.

Exclusion criteria:

Patients cannot have dopamine dis regulation syndrome or the presence of other neurological diseases such as major depression, dementia, attention deficit disorder, psychosis, or essential tremor. Patients cannot have a history of epilepsy, traumatic brain injury, or brain surgery. Patients cannot have severe sensory abnormalities of the fingertips, such as vibratory urticaria. They were excluded from the study if they were currently using psychotropic or narcotic medications or taking medications that affect brain function that would alter recorded EEG activity (such as anticonvulsant, ADHD, depression, or anxiety medications). Patients who are pregnant, lactating, or trying to become pregnant during the study period will be excluded from the study. Also, according to the selected TUG task, patients should not have a history of multiple sclerosis (MS), Alzheimer's, hip fracture, total knee or hip replacement surgery, Huntington's disease, and a history of stroke.

Age

From **45 years** old to **85 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **6**

More than 1 sample in each individual

Number of samples in each individual: **9**

For each individual, an electroencephalography sample is taken with a 32 channel Nautilus helmet, the description of which is included in the message to the referee, for 9 sessions, and we use the Matlab software to analyze it.

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Two gloves, one as a dummy glove with no effect and one as a real glove that affects the disease, are randomly provided to patients. During the study, two gloves are used for each patient, one of which is a sham, and the patient and the clinical caregiver do not know whether the dummy glove or the real glove was received first.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of Medical Sciences

Street address

Department of Research and Technology Central Headquarters Building Iran University of Medical Sciences Adjacent to Milad Tower,Hemmat Highway Tehran,Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2025-09-03, 1404/06/12

Ethics committee reference number

IR.IUMS.REC.1404.569

Health conditions studied

1

Description of health condition studied

Idiopathic Parkinson’s

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

EEG connectivity

Timepoint

We have an EEG data acquisition as initial data from the patient, 14 days later the glove is delivered and data is

collected on the same day, the next day-15th day data is collected to examine the short-term effect, then 2 weeks later, 14 days after delivery, we will have another data collection session, and finally 30 days after delivery, we will have another session. Then the Sham glove will be delivered and 3 data collection sessions will be taken in the first month, the middle of the month, and the end of the month, which will ultimately have 8 data collection sessions.

Method of measurement

EEG data acquisition is performed with the help of a portable device at the National Brain Mapping Laboratory. For each patient, two weeks before the start of the study, a 10-minute EEG is taken during a standard cognitive TUG task with a vibrating glove.Then, after two weeks, data collection is repeated. First, 10 minutes without stimulation are taken before data collection, and then the glove is worn by the patient and 10 minutes of EEG data collection is performed with the vibrating glove stimulation during the TUG task. Then, data is collected from the patient again for 10 minutes without gloves during the TUG task. This will be a data collection session.The next day, data collection is also collected in the same way. Then the glove will be provided to the patient. Then, 2 weeks after the glove is delivered, we will have an EEG data collection session on the same day. Finally, we will have a data collection session 2 weeks later. In this way, in the first month, we will have 4 half-hour EEG data collection sessions from the patient. Then, we perform the same procedure in the second month with the Sham glove, which will be a total of 9 sessions in 2 months and 2 weeks, collecting data from the patient.

2

Description

UPDRS-III

Timepoint

Before each EEG session, the patient's ,UPDRS-III is taken once, for a total of 8 times.

Method of measurement

This variable is taken by a neurologist - the project consultant - from patients in the neurology clinic of Hazrat Rasool Akram Hospital.

3

Description

PDQ-39 Questionnaire

Timepoint

Each time the UPDRS-III is taken from patients, the questionnaire will be filled out once. In total, we will have 7 questionnaires from patients.

Method of measurement

The patient sits next to the researcher and answers the questions, which the researcher records on a response sheet. This is a standardized form validated by Oxford University.

Secondary outcomes

1

Description

Comparison of EEG connectivity before and after using with gloves

Timepoint

Once the data is collected, a meaningful comparison analysis is performed.

Method of measurement

By comparing the brain connectivity matrix before and after the intervention, connectivity should be reduced on average.

2

Description

Comparison of UPDRS-III score before and after intervention with effect size criterion and t-test statistical test

Timepoint

Once after data collection, every 7 data collection times are examined with the pre-intervention state for these statistical criteria.

Method of measurement

The UPDRS-III score before and after the intervention is examined using t-test and Anova-test statistical tests to determine the effect size of the intervention.

3

Description

Comparison of PDQ-39 scores before and after intervention using t-test and Anova-test statistical tests.

Timepoint

Once after data collection, every 7 data collection times are examined with the pre-intervention state for these statistical criteria.

Method of measurement

The PDQ-39 score before and after the intervention is examined using t-test and Anova-test statistical tests to determine the effect size of the intervention.

Intervention groups

1

Description

Intervention group: A group of 3 patients who have been provided with the original gloves.Then, after a month of using the original glove, they receive the sham glove.We do not have a control group.

Category

Rehabilitation

2

Description

Intervention group: A group of 3 patients who are given sham gloves. Then after a month of using the sham gloves, they receive the original gloves. We do not have a control group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasul Akram educational, research and treatment complex

Full name of responsible person
Dr. Mohammad Rouhani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Manouchehr (Hadi) Moradi Sabzevar

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
The University of Tehran

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
The University of Tehran

Full name of responsible person
Aboozar Moradi

Position
PhD Candidate

Latest degree
Master

Other areas of specialty/work
Medical Engineering

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Age, gender, and duration of Parkinson's disease will be included in a table in articles submitted to reputable international journals. The study protocol, statistical analysis plan, informed consent form, clinical study report, and codes used in the MATLAB environment will also be included in the article.

When the data will become available and for how long
After the articles are published, research information in most articles will be made available to experts and researchers. Approximately 9 months after the research

To whom data/document is available
The general public, researchers, and patients can use its information.

Under which criteria data/document could be used
This research data can be used without preconditions for continued research in this field and for the use of researchers and physicians.

From where data/document is obtainable
They can obtain the necessary information on the official website of the published articles.

What processes are involved for a request to access data/document
Go to the article publishing website and download it or email the research manager and receive the required information.

Comments