Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical Evaluation of Vibrotactile Coordinated Reset Stimulation in Motor and Non-motor Symptoms of Parkinson’s Disease: A Double-Blind, Placebo-Controlled Trial

Protocol summary

Study aim

To determine the efficacy, safety, and durability of vibrotactile coordinated reset stimulation (vCRS) on motor and non-motor symptoms of Parkinson's disease; to assess scores of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS); to investigate brain oscillations via electroencephalography (EEG), quality of life via the 39-item Parkinson's Disease Questionnaire (PDQ-39), and sleep via the Parkinson's Disease Sleep Scale-Revised (PDSS-2); and to analyze acoustic indices and medication dosage between the two intervention and placebo.

Design

A randomized, controlled, parallel-group, double-blind, sham-controlled clinical trial of twenty-nine patients per group, with a twelve-week intervention period, and followed for twelve weeks

Settings and conduct

This double-blind study in a neurology clinic involves twelve weeks of intervention (two daily 2-hour vibratory stimulation sessions with a 1-hour rest interval). With patients and assessors blinded, evaluations include regular clinical scales and EEG.

Participants/Inclusion and exclusion criteria

inculsion: Age 45-80; Idiopathic PD (H&Y 2-4); MDS-UPDRS-III at least 20; stable medication. Exclusion: Dementia , history of brain surgery, seizures, or injury; finger sensory/skin disorders; pregnancy; concurrent clinical trial participation.

Intervention groups

Active vCRS gloves , twice daily, 2 hours/session for 12 weeks, including thumb stimulation. Control: Identical sham gloves providing random vibration (placebo) following the same temporal protocol and clinical monitoring to ensure blinding.

Main outcome variables

Change in MDS-UPDRS Part III and Part IV scores from baseline to week 12; Changes in beta-band oscillations and phase-amplitude coupling in EEG data; Quality of life indices based on the PDQ-39 questionnaire; Occurrence of adverse events and device tolerability reported by patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260511069343N1**
Registration date: **2026-06-06, 1405/03/16**
Registration timing: **prospective**

Last update: **2026-06-06, 1405/03/16**
Update count: **0**

Registration date

2026-06-06, 1405/03/16

Registrant information

Name
Amiratabak Poureh
Name of organization / entity
Najafabad University of Medical Sciences
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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Evaluation of Vibrotactile Coordinated Reset Stimulation in Motor and Non-motor Symptoms of Parkinson’s Disease: A Double-Blind, Placebo-Controlled Trial

Public title

Investigating the effectiveness of a vibrating glove in improving symptoms and quality of life in Parkinson's patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants aged between 45 and 80 years Clinical diagnosis of idiopathic Parkinson's disease based on international criteria. Being in stages II to IV of the Hoehn and Yahr scale. Presence of moderate to severe tremor, rigidity, or bradykinesia. Minimum score of 20 in the Movement Disorder Society - Unified Parkinson’s Disease Rating Scale part III (MDS-UPDRS III). At least 30% motor improvement in response to dopaminergic medication Maintenance of a stable dopaminergic medication regimen for at least three months prior to enrollment

Exclusion criteria:

A Mini-Mental State Examination (MMSE) score < 24 or a diagnosis of dementia Significant psychiatric or neurological disorders, history of traumatic brain injury, seizures, or past brain surgery Presence of severe comorbidities or systemic diseases. Abnormalities in vibration sensation or skin disorders at the fingertips. Recent Deep Brain Stimulation (DBS) or other neurosurgical interventions within the past three months. Pregnancy, breastfeeding, or planning to become pregnant Participation in any other clinical trial within the past 30 days.

Age

From **45 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are assigned to the intervention and control groups using Stratified Randomization. Initially, patients are categorized into separate strata based on key variables, including disease severity (Hoehn & Yahr stage) and gender. Subsequently, within each stratum, group allocation is performed using random permuted blocks of variable sizes by an independent individual. This methodology ensures an appropriate balance between the groups and minimizes the potential for bias stemming from baseline confounding factors

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is conducted in a double-blind manner. Participants are blinded using a placebo device that is physically identical to the active vCRS device but delivers no effective vibration. The Principal Investigator and Clinical Caregivers are blinded as an independent technician configures the device modes. Outcome Assessors performing clinical evaluations (e.g., MDS-UPDRS) are blinded to group assignments and have no access to the randomization list. Data Analysts will process the data using coded group labels (Group A/B) to remain blinded until the completion of the primary analysis.

Placebo

Used

Assignment

Parallel

Other design features

This study is the first clinical trial of vibrotactile coordinated reset stimulation (vCRS) in Iran, utilizing an innovative stimulation protocol. A unique feature of this design is the inclusion of the thumb in the stimulation process to enhance the engagement of sensorimotor pathways. Furthermore, unlike many similar studies, this project employs advanced neurophysiological assessments, namely electroencephalography (EEG), in addition to clinical indices, to investigate changes in beta-band power and phase-amplitude coupling, thereby objectively monitoring the neural desynchronization process. Additionally, the twelve-week follow-up period after intervention cessation allows for the evaluation of the induced neuroplasticity capacity.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Research Ethics Committee of the "Alzahra Research Centers"

Street address

Vice-Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City

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Province

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Postal code

81746-73461

Approval date

2026-04-29, 1405/02/09

Ethics committee reference number

IR.ARI.MUI.REC.1405.047

Health conditions studied

1

Description of health condition studied

Idiopathic Parkinson's Disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Movement Disorder Society-Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score to assess motor function.

Timepoint

Measurements at baseline (before intervention), weeks 3, 6, 9, and 12 after the start of the intervention, and a final follow-up at week 24 (12 weeks post-intervention)

Method of measurement

Completion of the standardized assessment form by a neurologist based on Part III of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale.

2

Description

Movement Disorder Society-Unified Parkinson's Disease Rating Scale Part IV (MDS-UPDRS IV) score to assess motor complications of therapy.

Timepoint

Measurements at baseline (before intervention); weeks 3, 6, 9, and 12 after the start of the intervention; and a final follow-up at week 24 (12 weeks post-intervention).

Method of measurement

Movement Disorder Society-Unified Parkinson's Disease Rating Scale, Part IV: Motor Complications

Secondary outcomes

1

Description

Changes in beta-band oscillatory power and phase-amplitude coupling in brain electrical signals.

Timepoint

Baseline (before intervention) and week 12 (end of intervention).

Method of measurement

Recording brain signals using Electroencephalography

2

Description

Total score of health-related quality of life in patients with Parkinson's disease.

Timepoint

Baseline, week 6, week 12, and week 24 (follow-up).

Method of measurement

Using the Parkinson's Disease Questionnaire-39.

3

Description

Incidence of potential adverse events and device tolerability index by participants.

Timepoint

Continuously during the 12-week intervention and final assessment at week 24.

Method of measurement

Patient self-report checklist and clinical examination by a neurologist.

4

Description

Non-motor experiences of daily living score in patients with Parkinson's disease.

Timepoint

Baseline, week 12, and week 24 (follow-up).

Method of measurement

Part One of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale.

Intervention groups

1

Description

Intervention group: Intervention group: Application of Vibrotactile Coordinated Reset Stimulation (Model: Neuroset PD-Basic V3). The device delivers 250 Hz vibratory pulses in a quasi-random 3:2 (on: off) burst pattern to the fingertips. Stimulation intensity is calibrated to each patient's sensory threshold. The intervention lasts for 12 weeks, 5 days per week, consisting of two 2-hour sessions per day with a 1-hour rest interval, conducted in a

Category

Treatment - Devices

2

Description

Control group: Application of a sham device (placebo) with identical appearance, weight, and user interface. Instead of organized stimulation, the device delivers non-therapeutic random vibrations lacking the coordinated reset pattern. The temporal protocol is identical to the intervention group (12 weeks, 5 days per week, two 2-hour sessions per day with a 1-hour rest interval) to maintain study blinding.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra University Hospital

Full name of responsible person
Dr Mohammad Saadatnia

Street address
Al-Zahra Research Institute Complex, Al-Zahra University Hospital, Sofheh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr Gholamreza Asgari

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
20

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

2

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr Gholamreza Asgari

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Vice-Chancellery for Research and Technology, Building No. 4, Isfahan University of Medical Sciences, Hezar Jerib Ave, Isfahan, Iran

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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
Private Benefactor

Proportion provided by this source
80

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Saadatnia

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
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Medical Intern
Latest degree
A Level or less
Other areas of specialty/work
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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
No - There is not 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
Yes - There is a plan to make this available
Title and more details about the data/document
In this study, individual participant data,including baseline demographic characteristics (excluding names, national ID numbers, or contact information), pre- and post-intervention scores on the MDS-UPDRS (both motor and non-motor sections), primary outcome measures, and secondary outcomes—will be fully available for potential sharing upon study completion and full de-identification of the individuals. This sharing will strictly encompass structured numerical and methodological data; identity-bearing documents or formal consent forms will not be disclosed to maintain patient confidentiality.
When the data will become available and for how long
Starting date of availability: 6 months following the publication of the primary manuscript in a peer-reviewed journal. Duration of availability: The de-identified data will remain accessible for 3 years (36 months) from the starting date of availability.
To whom data/document is available
Eligible Requesters: The de-identified individual participant data and study documents will be accessible exclusively to qualified researchers, academicians, and students affiliated with accredited academic institutions, universities, and formal research centers. Restrictions: Data access is strictly limited to non-commercial, scientific, and educational research purposes. Requesters from commercial industries, private pharmaceutical companies, or medical device corporations are not eligible to access the data independently, unless through an approved collaborative research agreement with the principal investigator and the sponsoring institution.
Under which criteria data/document could be used
Conditions for Data Use & Allowed Analyses: 1. The shared de-identified data are strictly limited to secondary statistical analysis, clinical methodological evaluations, and purely educational purposes. 2. Any attempt to re-identify the study participants or link the data to other medical records is strictly prohibited. 3. Utilizing the study protocols, data dictionary, or analysis codes for

commercial purposes, reverse engineering of the vibrotactile stimulation system, or copying the device technology is forbidden. 4. Any resulting publications or scientific presentations must properly cite the primary manuscript of this trial and acknowledge the Isfahan Neurosciences Research Center. Requirements and Mechanism for Access: Eligible requesters must submit the following documents to the Principal Investigator (Dr. Mohammad Saadatnia): 1. A formal, institutionally approved research proposal outlining the specific aims of the secondary analysis. 2. An official endorsement letter signed by the Vice-Chancellor for Research or the Dean of the applicant's affiliated university/institution. 3. A signed Data Sharing Agreement (DSA) executed by the primary requesting investigator, committing to all privacy and non-commercial terms.

From where data/document is obtainable

Eligible requesters must submit their formal request along with the required documents (the approved research proposal and an institutional endorsement letter from the originating university) via email to the Principal Investigator: - Principal Investigator Email (Dr. Mohammad Saadatnia): mosaadatnia@yahoo.com - Co-Investigator Email (For faster follow-ups): amiratabakpr@gmail.com

What processes are involved for a request to access data/document

Step 1 (Initial Screening & Document Verification - 2-3 weeks): Upon receiving the requester's email containing the research proposal and institutional letter, the co-investigator will verify the completeness of the documents and forward them to the Principal Investigator (Dr. Mohammad Saadatnia) for formal scientific review. Step 2 (Approval & DSA Execution - 2 weeks): If the scientific and methodological objectives are approved by the research team, the official Data Sharing Agreement (DSA) will be sent to the requester to be signed and stamped by their originating institution. Step 3 (Data Compilation & Delivery - 2 weeks): Following the receipt of the fully executed DSA, the de-identified clinical dataset and related methodological documents will be compiled and securely transferred to the requester via a secure link. Estimated Total Timeline: The entire process, from the initial submission to the final delivery of the data files, is estimated to take between 6 to 8 weeks (approximately 2 months). This timeline ensures meticulous compliance with participant privacy and data security protocols.

Comments