

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Investigating the effectiveness of biofeedback exercise on reducing hand tremors in Parkinson's patients

Protocol summary

Study aim

Investigating the effectiveness of biofeedback exercise on reducing hand tremors in Parkinson's patients

Design

A clinical trial with two parallel groups (intervention group and sham) with triple blind strains on 18 patients

Settings and conduct

Parkinson's patients are treated for 10 sessions at the neurologist's office. According to their nature, the intended messages are checked before the session, during the test and after the session.

Participants/Inclusion and exclusion criteria

Conditions for entering the study: 1) Diagnosis of Parkinson's disease based on UPDRS criteria 2) Presence of resting tremor in at least one hand 3) Absence of mood disorders (depression or anxiety disorder)

Informed consent 4) Consent to participate in the study. Conditions for not entering the study: 1) Severe disability that prevents the patient from cooperating in the trial 2) Symptoms of neuropathy and other neurological disorders affecting feedback

Intervention groups

The intervention group performs 10 sessions of biofeedback exercises to control hand tremors at rest. The Sham group tries to control their hand tremors in 10 sessions by using the device in off mode

Main outcome variables

In this study, tremor measurement based on UPDRS and accelerometer data are measured as the main outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230226057541N1**

Registration date: **2023-10-17, 1402/07/25**

Registration timing: **prospective**

Last update: **2023-10-17, 1402/07/25**

Update count: **0**

Registration date

2023-10-17, 1402/07/25

Registrant information

Name

Sajedeh Movahedian Far

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of biofeedback exercise on reducing hand tremors in Parkinson's patients

Public title

Investigating the effectiveness of biofeedback on reducing hand tremors in Parkinson's patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Parkinson's disease based on UPDRS criteria
rest tremor in at least one hand
Absence of mood disorders (depression or anxiety disorder)
Informed consent

Exclusion criteria:

Severe disability that prevents the patient from cooperating in the trial
Symptoms of neuropathy and other neurological disorders affecting feedback

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

Cluster randomization using Excel software; to assign the participants to each of the intervention and sham groups, we use the rand and rank functions in Excel software. By using these functions, half of the participating population is selected for the intervention group and the other half is assigned to the sham group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The clinical trial will be done in a triple-blind way. 1- The person who divides the patient into two groups is one of those interventions that does not identify the patients. The list of patients is divided into two intervention and sham groups by random selection in Excel. 2- It is clear whether they are in the intervention or sham group. 3- All the recorded data are analyzed, and it is determined whether it belongs to the intervention or sham group. Patients are divided into two groups by random selection of Excel software, and each person is assigned a code, and data analysis is performed for each code, and the analyst is completely blinded to the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoreshi Building, Daneshgah Street

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Approval date

2023-07-18, 1402/04/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.235

Health conditions studied

1

Description of health condition studied

Parkinson

ICD-10 code

G520

ICD-10 code description

Parkinson disease

Primary outcomes

1

Description

Postural tremor of hands

Timepoint

Before starting interventions, after completing interventions, follow-up session

Method of measurement

Based on movement disorder society-sponsored revision of the unified Parkinson's disease rating scale (MDS-UPDRS)

2

Description

Kinetic tremor of hands

Timepoint

Before starting interventions, after completing interventions, follow-up session

Method of measurement

Based on movement disorder society-sponsored revision of the unified Parkinson's disease rating scale (MDS-UPDRS)

3

Description

Rest tremor amplitude

Timepoint

Before starting interventions, after completing interventions, follow-up session

Method of measurement

Based on movement disorder society-sponsored revision of the unified Parkinson's disease rating scale (MDS-

UPDRS)

4

Description

Constancy of rest tremor

Timepoint

Before starting interventions, after completing interventions, follow-up session

Method of measurement

Based on movement disorder society-sponsored revision of the unified Parkinson's disease rating scale (MDS-UPDRS)

5

Description

Characteristics of hand tremor accelerometer

Timepoint

During training with the device

Method of measurement

Using an accelerometer

Secondary outcomes

1

Description

Quality of life scale in Parkinson's disease PDQ-39

Timepoint

Before starting interventions, after completing interventions, follow-up session

Method of measurement

Quality of life in Parkinson's disease PDQ-39 Questionnaire

Intervention groups

1

Description

Intervention group: 10 sessions of biofeedback training to control hand tremors

Category

Rehabilitation

2

Description

Control group: trying to control the hand tremor, by holding the device in turned-off mode in 10 sessions

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Ali Shoaibi's office

Full name of responsible person

Sajedeh Movahedian Far

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Mashhad University of Medical Sciences

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

Islamic Azad University

Full name of responsible person

Hamidreza Kobravi

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available