Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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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Province

Razavi Khorasan

Postal code

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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
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Sponsors / Funding sources

1

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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

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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