

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3729 8358

###### Email address

s.movahedian.91@gmail.com

##### 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**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

##### **Street address**

2th Floor, No. 5, 18th Daneshgah street, Daneshgah Avenue

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## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Mashhad University of Medical Sciences

###### **Full name of responsible person**

Mohsen Tafaghodi

###### **Street address**

Central Building (Ghoreishi) Of Mashhad University of Medical Sciences, Daneshgah Avenue

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vcresraech@mums.ac.ir

##### **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**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Engineering

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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Neurology

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

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**Full name of responsible person**

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**Position**

Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Medical Engineering

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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