

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effectiveness of eccentric training on hand tremor in parkinsonian patients with control group

Protocol summary

Study aim

To evaluate the efficacy of 18 sessions of arm and forearm eccentric training on hand tremor in patients with Parkinson's disease

Design

parallel clinical trial with control group and random allocation of the patients to control and intervention group and blinded analysis of the outcomes.

Settings and conduct

This study will recruit patients with Parkinson's disease who visit neurology clinic in Firoozgar and Rasoul Akram hospitals in Tehran. Eccentric exercise sessions will be completed in occupational therapy part of Firoozgar hospital with occupational therapist assistance and surveillance. Tremor will be quantified by Seismometer application (validated by laboratory accelerometers) and Sony experia Z1 smartphone. Tremor data will be extracted as excell file and analyzed by MatLab software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Parkinson's disease whose diagnosis has been confirmed by neurologist Visible hand tremor. Being capable of performing upper limb eccentric exercise Exclusion criteria: Diagnosis of Parkinson like diseases with hand tremor Cardiovascular, neurological, orthopedic and psychological disabilities in performing eccentric exercise of upper limbs Concurrent other movement abnormalities in upper limbs like chorea or spasticity

Intervention groups

patients in intervention group will go under 18 sessions of bilateral arm and forearm eccentric training with moderate intensity and with assistance of occupational therapist. sessions will be three days a week in 6 weeks. patients in control group will not receive any intervention. they will be asked to keep their usual level of physical activity for 6 weeks.

Main outcome variables

Resting hand tremor ; postural hand tremor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180221038819N1**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

Registration date

2018-04-21, 1397/02/01

Registrant information

Name

Mona Kadkhodaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 1021

Email address

mk.sbm@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of eccentric training on hand tremor in parkinsonian patients with control group

Public title

The effect of eccentric training on hand tremor in parkinson's disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Parkinson's disease whose diagnosis has been confirmed by neurologist Visible hand tremor Being capable of upper limb eccentric exercise

Exclusion criteria:

Diagnosis of Parkinson like diseases capable of manifesting with hand tremor Cardiovascular, neurological, orthopedic and psychological disabilities in operating eccentric exercise of upper limbs Concurrent other movement symptoms in upper limbs like chorea or spasticity

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block. Subjects are assigned to blocks, based on stage of disease.(Hoehn and Yahr staging) Then, within each block, subjects are randomly assigned to intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Main building, Iran University of Medical Sciences, Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-11-06, 1396/08/15

Ethics committee reference number

IR.IUMS.FMD.REC 1395.28471

Health conditions studied

1

Description of health condition studied

Parkinson's disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Resting hand tremor amplitude

Timepoint

before intervention and after 18 sessions of eccentric exercise

Method of measurement

Seismometer 6th application in Sony experia Z1 smartphone

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: this group will undergo 18 sessions of eccentric exercise with moderate intensity of forearm flexors and extensors and arm flexors group of muscles in 30-40 minutes in each session. Exercise sessions will be assisted by trained occupational therapist as 3 sessions in week. Concentric phase of each exercise will be performed by occupational therapist and only the eccentric phase will be done by patient. As the sessions progress, according to patient ability, the weights will be heavier with maintaining moderate intensity.

Category

Rehabilitation

2

Description

Control group: This group will receive no intervention. Control group will be asked to maintain their usual level of activity for six weeks.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoul Akram hospital

Full name of responsible person

Hassan Amiri

Street address

Niayesh Ave., Sattar khan Town.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2190

Email

hrmc@iums.ac.ir

Web page address

http://hrmc.iums.ac.ir

2**Recruitment center****Name of recruitment center**

Firoozgar hospital

Full name of responsible person

Farhad Zamani

Street address

Beh afarin Ave., Karimkhan Ave., Valieasr Square.

City

Tehran

Province

Tehran

Postal code

1593747811

Phone

+98 21 8214 1600

Fax

+98 21 8894 2622

Email

h_firoozgar@yahoo.com

Web page address

http://firoozgar.iums.ac.ir/

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyyed Kazem Malakouti

Street address

By Milad Tower, Hemmat Highway,

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research@iums.ac.ir

Web page address

http://res.iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mona Kadkhodaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

No. 1, Parvaneh Dead end, Chizari Ave., Ehteshamieh Town,

City

Tehran

Province

Tehran

Postal code

1945616571

Phone

+98 21 2259 3044

Email

mk.sbmua@yahoo.com

Person responsible for scientific inquiries**Contact**

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mona Kadkhodaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

No. 1, Parvaneh Dead end, Chizari Ave., Ehteshamieh

Town,

City

Tehran

Province

Tehran

Postal code

1945616571

Phone

+98 21 2259 3044

Email

mk.sbmuh@yahoo.com

Email

mk.sbmuh@yahoo.com

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

Yes - There is a plan to make this available

Title and more details about the data/document

Almost all deidentified data of participants like demographic data (age, sex,...) , disease related data (stage, type,...) and finally samples of unanalysed data adapted from participants tremor; can be shared.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Deidentified IPD and other documents will only be available for people working in academic institutes.

Under which criteria data/document could be used

Any scientific analysis on shared data is allowed but the main researcher must be informed about the results obtained from data analysis before publication. After sending requesting email to main researcher, giving information about the reason of request, being assured about scientific position of requester in universities or scientific institutes and passing 6 months from publication; data will be shared.

From where data/document is obtainable

main researcher : Mona Kadkhodaie sending request via email: mk.sbmuh@yahoo.com

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

after receiving data sharing request, the request will be checked by all researchers of the article and if the reasons of requesting are convincing, data will be sent via email in maximum 2 weeks.

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

Iran University of Medical Sciences

Full name of responsible person

Mona Kadkhodaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

No. 1, Parvaneh Dead end, Chizari Ave., Ehteshamieh

Town,

City

Tehran

Province

Tehran

Postal code

1945616571

Phone

+98 21 2259 3044