Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A randomized controlled trial to compare the effect of bi-manual activities with and without motivational strategies on participation, motor control and sensory-motor skills of upper extremity in subjects with Parkinson´s disease

Protocol summary

Study aim

The aim of this study is to compare the effect of bi-manual activities with and without motivational strategies on participation, motor control and sensory-motor skills of upper extremity in subjects with Parkinson´s disease.

Design

This study is a double-blinded controlled randomized trial with parallel groups. Forty-five patients with Parkinson's disease will participate in this study and they will be randomly assigned to three groups: control group, bi-manual activities with motivational strategies group and bi-manual activities without motivational strategies group. Randomization will be performed by the person who is not involved in the study using random numbers table.

Settings and conduct

This study will be performed in Djavad Mowafaghian of Neuro-Rehabilitation Research Center. Control group receives conventional rehabilitation. Bi-manual activities groups receive 24 sessions of intervention in the form of bi-manual activities (3 sessions/week, 90 min/session) with or without motivational strategies in addition to conventional rehabilitation. Assessors and patients are blinded to the groups allocation.

Participants/Inclusion and exclusion criteria

In this clinical trial study, 45 patients with idiopathic Parkinson's disease will participate. The main inclusion criteria include having Parkinson's disease according to the neurologist diagnosis, having the disease's progression level of 1 to 3 according to Hoehn and Yahr Scale, and an acceptable level of cognitive function. Subjects are excluded in the case of co-morbid other neurological diseases and orthopedic disorders; or having Juvenile Parkinsonism.

Intervention groups

Control group; Bi-manual activities with motivational strategies group; Bi-manual activities without motivational strategies group

Main outcome variables

Participation; Motor control and sensory-motor skills of upper extremity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140304016830N12**
Registration date: **2020-05-27, 1399/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-27, 1399/03/07**
Update count: **0**

Registration date

2020-05-27, 1399/03/07

Registrant information

Name

Ghorban Taghizadeh

Name of organization / entity

School of Rehabilitation Sciences, Iran University of Medical

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7124

Email address

taghizadeh.gh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-11-06, 1398/08/15
Expected recruitment end date
2020-07-05, 1399/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized controlled trial to compare the effect of bi-manual activities with and without motivational strategies on participation, motor control and sensory-motor skills of upper extremity in subjects with Parkinson´s disease

Public title
The effect of occupational therapy interventions on participation, motor control and sensory-motor skills of upper extremity in subjects with Parkinson's disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having Parkinson's disease according to neurologist diagnosis (based on UK brain Bank criteria for the diagnosis of idiopathic Parkinson's disease) Having the disease's progression level of 1 to 3 according to Hoehn and Yahr Scale Having an acceptable level of cognitive function (i.e. score equal to or greater than 24 on the Persian version of Mini Mental State Examination and score greater than 24 on the Persian version of Montreal cognitive assessment questionnaire) Having at least a fifth grade education Ability to perform uni-manual and bi-manual motor tasks Feeling the need or desire to participate in occupations selected for the intervention (bi-manual occupations in the form of activities of daily living, instrumental activities of daily living and playing)
Exclusion criteria:
Co-morbid other neurological diseases, orthopedic disorders (such as low back pain and arthritis), diabetes or addiction according to the report of the patient, or patient's family or physician Having pathological dementia according to the neurologist diagnosis Having Juvenile Parkinsonism
Age
From **35 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients who are included in the study will randomly allocated to one of the following three groups: the control group (A) or bi-manual activities with motivational strategies group (B) or bi-manual activities without motivational strategies group (C). Randomization method is simple randomization and randomization unit is individual. Randomization and creating a random sequence will be done using a web-based randomization system (https://www.graphpad.com/quickcalcs/randMenu/). Group allocation concealment will be done using sequentially numbered sealed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Evaluation of the primary and secondary outcomes is performed by experienced individuals who are blind of the groups allocation. To keep assessors blinded, participants and therapists were instructed not to reveal received intervention or participants' study experiences to the assessors. Patients are also blind on the groups allocation. To keep patients blind, interventions and evaluation sessions for different groups will be arranged so that participants in different groups will not encounter each other.
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
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2019-10-30, 1398/08/08
Ethics committee reference number
IR.IUMS.REC.1398.794

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

Motor control of upper extremity

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Motion analysis system

2

Description

Sensory-motor skills of upper extremity

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Wrist position sense test, Hand active sensation test, Box & Block Test, Grip Dynamo-meter test, Purdue Pegboard Test, Nine Hole Peg Test, Coin Rotation Test

3

Description

Participation

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Canadian occupational performance measure, Meaningful Activity Participation Assessment Questionnaire

Secondary outcomes

1

Description

Cognitive function

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Clock Drawing Test, Parkinson's Disease-Cognitive Rating Scale, Trail Making Test, Stroop Test, Quick Dementia Rating Scale, Digit Symbol Test, Benton test

2

Description

Quality of life

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Parkinson's Disease Questionnaire (PDQ-39), 36-Item Short Form Health Survey (SF-36)

Intervention groups

1

Description

Control group: receives conventional rehabilitation (including exercises for upper and lower limb stretching, range of motion and activities of daily living).

Category

Rehabilitation

2

Description

First intervention group: Bi-manual activities with motivational strategies group that receives 24 sessions of intervention (8 weeks, 3 sessions per week, 90 minutes per session) in the form of bi-manual activities including activities of daily living, instrumental activities of daily living and playing in addition to the conventional rehabilitation. In this group, different motivational strategies (such as affirming the patient to facilitate a sense of usefulness, helping to gain a sense of fun by facilitating the likelihood of success, giving appropriate positive feedback to increase patient's awareness of his/her abilities to perform the activity, showing positive changes in patient's performance during intervention sessions and explain the importance of the activity to the individual and how it affects his/her daily life) will be used to enhance an individual's level of motivation during the intervention.

Category

Rehabilitation

3

Description

Second intervention group: Bi-manual activities without motivational strategies group that receives 24 sessions of intervention (8 weeks, 3 sessions per week, 90 minutes per session) in the form of bi-manual activities including activities of daily living, instrumental activities of daily living and playing in addition to the conventional rehabilitation. In this group, motivational strategies (such as affirming the patient to facilitate a sense of usefulness, helping to gain a sense of fun by facilitating the likelihood of success, giving appropriate positive feedback to increase patient's awareness of his/her abilities to perform the activity, showing positive changes in patient's performance during intervention sessions and explain the importance of the activity to the individual and how it affects his/her daily life) will not be used.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Rehabilitation centers and hospitals in Tehran

Full name of responsible person
Ghorban Taghizadeh

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 2222 7124

Email
taghizadeh.gh@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Vice Chancellor for research of Iran University of Medical Sciences, Dr. Seyed Abbas Motevalian

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 2503

Email
motevalian.a@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
Ghorban Taghizadeh

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 2222 7124

Email
taghizadeh.gh@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Ghorban Taghizadeh

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 2222 7124

Email
taghizadeh.gh@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ghorban Taghizadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 2222 7124

Email

taghizadeh.gh@iums.ac.ir

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After the completion of this study, a manuscript regarding the documentation and the results of the study will be prepared and published. If more details are needed, individuals can send their request by email to the person responsible for scientific accountability.

When the data will become available and for how long

One year after publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use of the documentation is permitted upon written permission.

From where data/document is obtainable

Ghorban Taghizadeh Adsress: Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran، Tel: 00982122227124، E-mail: taghizadeh.gh@iums.ac.ir

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

Just sending a request by email and mentioning the explanation about the cause of the need for documentation is enough.

Comments