Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A randomized controlled trial to compare the effect of competitive and non-competitive non linear pedagogy exercises (playful exercises in the form of volleyball) on sensory and motor function of upper extremity and eye movements in people with Parkinson’s disease

Protocol summary

Study aim

The aim of this study is to compare the effect of competitive and noncompetitive exercises with nonlinear pedagogy method on sensory and motor function of upper extremity and eye movements in patients with Parkinson's disease.

Design

This study is a controlled randomized trial with parallel groups and blinded outcome assessment. Forty-eight patients with idiopathic Parkinson's disease will participate in this study and they will be randomly assigned to three groups: competitive playful ball exercises group, noncompetitive playful ball exercises group and control group. Randomization will be conducted by an individual who is not involved in the study using sealed envelopes method.

Settings and conduct

This study will be performed in Djavad Mowafaghian Neuro-Rehabilitation Research Center. Control group receives conventional rehabilitation. Competitive and noncompetitive non-linear pedagogy playful ball exercises groups receive 24 sessions of playful ball exercises in the form of volleyball (8 weeks, 3 sessions per week, 90 minutes per session) in addition to conventional rehabilitation. Assessors are blind on the groups allocation.

Participants/Inclusion and exclusion criteria

The main inclusion criteria are: 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, an acceptable level of cognitive function (i.e. score 24 on the Mini Mental State Examination). Subjects are excluded in the case of co-morbid other neurological diseases or Juvenile Parkinsonism.

Intervention groups

Control group; Competitive playful ball exercises; Noncompetitive playful ball exercises

Main outcome variables

Upper extremity motor function including motor-control related parameters (e.g. peak velocity, movement time, etc) and gross manual dexterity; Eye movements parameters (saccade latency, peak velocity and amplitude)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140304016830N11**
Registration date: **2019-12-08, 1398/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-08, 1398/09/17**
Update count: **0**

Registration date

2019-12-08, 1398/09/17

Registrant information

Name

Ghorban Taghizadeh

Name of organization / entity

School of Rehabilitation Sciences, Iran University of Medical

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-11-06, 1397/08/15
Expected recruitment end date
2020-03-05, 1398/12/15
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 competitive and non-competitive non linear pedagogy exercises (playful exercises in the form of volleyball) on sensory and motor function of upper extremity and eye movements in people with Parkinson’s disease

Public title
The effect of rehabilitation exercises on upper extremity function and eye movements in people with Parkinson's disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 35 to 75 years Having Parkinson's disease according to the neurologist diagnosis (based on UK brain Bank criteria for the diagnosis of idiopathic PD) 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 Mini Mental State Examination Having the ability to walk at least 10 meters independently and without assistive device Having at least a fifth grade education
Exclusion criteria:
Having pathological dementia according to the neurologist diagnosis Having Juvenile Parkinsonism 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
Age
From **35 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients who were included in the study will randomly allocated to one of the following three groups: control group or competitive playful ball exercises group or noncompetitive playful ball exercises group. Randomization will be conducted by an individual who is not involved in the study using sealed envelopes method. A letter indicating the intervention group is placed in a sealed opaque envelope and the envelopes will kept in the randomized order in a container. For each patient, one envelope will be randomly drawn from the container and the intervention group of that patients will be determined based on a letter in the envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
Evaluation of the primary and secondary outcomes is performed by experienced individuals who are blind on the groups allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی ایران
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-10-28, 1397/08/06
Ethics committee reference number
IR.IUMS.REC.1397.562

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 function of upper extremity including motor-control related parameters extracted from recorded data by motion analysis system (e.g. peak velocity, movement time, etc)

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Motion analysis system

2

Description

Motor function of upper extremity including gross manual dexterity

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Box & Block Test

3

Description

Eye movements parameters (including saccade latency, peak velocity and amplitude)

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Eye tracking system

Secondary outcomes

1

Description

Sensory function of upper extremity

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Wrist Position Sense Test, Two Point Discrimination Test, Hand Active Sensation Test

2

Description

Cognitive function

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

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

3

Description

Levels of Activities of Daily Living

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Barthel Index, Lawton Instrumental Activities of Daily Living Scale

4

Description

Motor function of upper extremity including fine manual dexterity

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Purdue Pegboard Test, Nine Hole Peg Test, Coin Rotation Test

5

Description

Hand grip power

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Grip Dynamo-meter test

6

Description

Manual ability level

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

ABILHAND Questionnaire, DASH Questionnaire

Intervention groups

1

Description

Control group: receives conventional rehabilitation.

Category

Rehabilitation

2

Description

First Intervention group: Group receiving competitive playful ball exercises that receives 24 sessions of playful ball exercises in the form of volleyball in a competitive non-linear pedagogy way (8 weeks, 3 sessions per week, 90 minutes per session) in addition to the conventional rehabilitation. To induce competition in competitive group, exercises are associated with scoring.

Category

Rehabilitation

3

Description

Second Intervention group: Group receiving non-competitive playful ball exercises that receives 24

sessions of playful ball exercises in the form of volleyball in a non-competitive non-linear pedagogy way (8 weeks, 3 sessions per week, 90 minutes per session) in addition to the conventional rehabilitation. There is not any scoring during exercises in the non-competitive group.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Rehabilitation centers and hospitals in Tehran

Full name of responsible person
Ghorban Taghizadeh

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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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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

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+98 21 8670 2503

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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

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Person responsible for scientific inquiries

Contact

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Ghorban Taghizadeh

Position
Assistant professor

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Other areas of specialty/work
Neuroscience

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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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

8 months 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