Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A randomized controlled trial to compare the effect of competitive and noncompetitive exercises (playful ball exercises) with nonlinear pedagogy method on functional balance and mobility, eye movements and activity level of trunk muscles in patients with Parkinson's disease

Protocol summary

Study aim

The aim of this study is to compare the effect of competitive and noncompetitive exercises (playful ball exercises) with nonlinear pedagogy method on functional balance and mobility, postural control, eye movements and activity level of trunk and ankle muscles 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: a group receiving playful ball exercises in a competitive non-linear pedagogy method, a group receiving playful ball exercises in a noncompetitive non-linear pedagogy method and control group. Randomization will be performed by the person who is not involved in the study using sequentially numbered sealed envelopes.

Settings and conduct

This study will be performed in Djavad Mowafaghian Research Centre of Intelligent Neuro-Rehabilitation Technologies. 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. To induce competition in competitive group, exercises are associated with scoring while there is not any scoring in non-competitive group. Assessment of primary and secondary outcomes is performed by individuals who are blinded to the groups allocation before and after receiving playful ball exercises and 8 weeks after receiving these exercises in the intervention groups and before and after conventional rehabilitation and 8 weeks after conventional rehabilitation in the control group.

Participants/Inclusion and exclusion criteria

In this clinical trial study, 48 patients with idiopathic Parkinson's disease will participate. The main inclusion criteria include having Parkinson's disease according to the neurologist diagnosis, age between 35 to 70 years, 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 of equal or greater than 24 on the Mini Mental State Examination. Subjects are excluded in the case of co-morbid other neurological diseases, orthopedic disorders, diabetes or addiction; having pathologic dementia or Juvenile Parkinsonism.

Intervention groups

Control group; Group receiving playful ball exercises in a competitive non-linear pedagogy method; Group receiving playful ball exercises in a noncompetitive non-linear pedagogy method

Main outcome variables

Functional balance and mobility; Eye movements; Trunk muscle activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140304016830N8**
Registration date: **2018-01-23, 1396/11/03**
Registration timing: **prospective**

Last update: **2018-01-23, 1396/11/03**
Update count: **0**

Registration date

2018-01-23, 1396/11/03

Registrant information

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Ghorban Taghizadeh
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-07, 1397/01/18
Expected recruitment end date
2018-08-21, 1397/05/30
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 noncompetitive exercises (playful ball exercises) with nonlinear pedagogy method on functional balance and mobility, eye movements and activity level of trunk muscles in patients with Parkinson's disease

Public title
The effect of rehabilitation exercises on balance, eye movements and muscle activity level in patients 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 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 Examinatio Having at least a fifth grade education Having the ability to walk at least 10 meters independently and without assistive device Age between 35 to 70 years
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 pathologic dementia according to the neurologist diagnosis Having Juvenile Parkinsonism
Age
From **35 years** old to **70 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
Randomization will be performed by the person who is not involved in the study using sequentially numbered sealed envelopes.
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
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
2017-12-08, 1396/09/17
Ethics committee reference number
IR.IUMS.REC 1396.9511355009

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
Functional balance and mobility
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Fuctional reach test, Berg Balance Scale Questionnaire, Timed Up & Go Test, Six Minute Walk Test, Gait speed

2

Description
Eye movements
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Eye tracking system

3

Description
Trunk muscle activity
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Electromyography

Secondary outcomes

1

Description
Postural control
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Force plate (postural sway parameters)

2

Description
Ankle muscle activity
Timepoint
Before and after intervention and 8 weeks after intervention
Method of measurement
Electromyography

Intervention groups

1

Description
First intervention group: Group receiving playful ball exercises in a competitive non-linear pedagogy method that receives 24 sessions of playful ball exercises in the form of volleyball in a competitive non-linear way (8 weeks, 3 sessions per week, 90 minutes per session) in addition to the conventional rehabilitation.
Category
Rehabilitation

2

Description
Second intervention group: Group receiving playful ball exercises in a noncompetitive non-linear pedagogy method that receives 24 sessions of playful ball exercises in the form of volleyball in a noncompetitive non-linear way (8 weeks, 3 sessions per week, 90 minutes per session) in addition to the conventional rehabilitation.
Category
Rehabilitation

3

Description
Control group: receives conventional rehabilitation.
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
Dr. Seyed Kazem Malakouti
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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
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
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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