Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A randomized controlled trial to comparative study of the effect of single and dual cognitive task-oriented balance exercises on postural control and functional balance in subjects with chronic stroke

Protocol summary

Study aim

The aim of this study is to comparative study of the effect of single and dual cognitive task-oriented balance exercises on postural control, functional balance and mobility and cognitive function in subjects with chronic stroke.

Design

This study is a controlled randomized trial with parallel groups and blinded outcome assessment. Fifty-four chronic stroke survivors will participate in this study and they will be randomly assigned to three groups: control group, single task-oriented balance exercises group and cognitive dual task-oriented balance exercises 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. Single and cognitive dual task-oriented balance exercises groups receive 24 sessions of task-oriented balance exercises (8 weeks, 3 sessions per week, 60 to 90 minutes per session) in addition to conventional rehabilitation. In single task-oriented balance exercises group, the attention of patient will be focused on maintaining his/her balance while in the cognitive dual task-oriented balance exercises group, the attention of patient will be focused on maintaining his/her balance while in the cognitive dual task-oriented balance exercises group, the attention of patient will be focused concurrently on maintaining balance and performing cognitive tasks. Assessment of the primary and secondary outcomes is performed by individuals who are blinded to the groups allocation before and after receiving task-oriented balance 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

The main inclusion criteria include having the first experience of stroke; Having the ability to perform the most difficult condition of laboratory test (quiet standing on foam surface with closed eyes while performing cognitive task); Having an acceptable level of cognitive function, i.e. score equal to or greater than 23 on the Mini Mental State Examination. Subjects are excluded in the case of having unilateral visuospatial neglect and co-morbid other neurological diseases, orthopedic disorders, diabetes or addiction.

Intervention groups

Control group; Single task-oriented balance exercise; Cognitive dual task-oriented balance exercise

Main outcome variables

Functional balance; Postural control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140304016830N9**
Registration date: **2018-02-25, 1396/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-25, 1396/12/06**
Update count: **0**

Registration date

2018-02-25, 1396/12/06

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
2018-02-04, 1396/11/15

Expected recruitment end date
2018-06-21, 1397/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A randomized controlled trial to comparative study of the effect of single and dual cognitive task-oriented balance exercises on postural control and functional balance in subjects with chronic stroke

Public title
Effect of task-oriented balance exercises on balance of patients with chronic stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having the first experience of stroke Passing 6-24 months since stroke Having an ability to walk at least 10 meters without assistive devices Having the ability to perform the most difficult condition of laboratory test (quiet standing on foam surface with closed eyes while performing cognitive task) Having an acceptable level of cognitive function, i.e. score equal to or greater than 23 on the Mini Mental State Examination

Exclusion criteria:
Having unilateral visuospatial neglect (i.e., obtaining score less than 44 at star cancellation test) Co-morbid other neurological diseases Having orthopedic disorders (such as low back pain, arthritis and flat foot) Having diabetes according to the report of patient, or the patient's family or physician Having addiction according to the report of patient, or the patient's family or physician

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed by the person who is not involved in the study using sequentially numberd 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
۱۴۴۹۶۱۴۵۳۵

Approval date
2017-12-08, 1396/09/17

Ethics committee reference number
IR.IUMS.REC 1396.30275

Health conditions studied

1

Description of health condition studied
stroke

ICD-10 code
I64

ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Functional balance

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Berg Balance Scale Questionnaire, Tinetti Balance test

2

Description

Postural control

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Force plate (postural sway parameters)

Secondary outcomes

1

Description

Functional mobility

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Single and dual Timed Up & Go Test, Dynamic gait index Questionnaire

2

Description

Cognitive function

Timepoint

Before and after intervention and 8 weeks after intervention

Method of measurement

Wechsler memory scale

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: Ṡingle task-oriented balance exercises group that receives 24 sessions of single task-oriented balance exercises (8 weeks, 3 sessions per week, 60 to 90 minutes per session) in addition to the conventional rehabilitation. Single task-oriented balance exercises include three types of standing, transferring and walking activities which performed based on two principals of difficulty level of motor task and individual safety.

Category

Rehabilitation

3

Description

Second Intervention group: cognitive dual task-oriented balance exercises group that receives 24 sessions of cognitive dual task-oriented balance exercises (8 weeks, 3 sessions per week, 60 to 90 minutes per session) in addition to the conventional rehabilitation. In this group, task-oriented balance exercises (including three types of standing, transferring and walking activities based on two principals of difficulty level of motor task and individual safety) are performed simultaneously with cognitive tasks (e.g., backward counting, saying the days of the week and the months of the year in reverse order, etc.).

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 Kazem Malakouti

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code
1449614535
Phone
+98 21 8670 2503
Email
research@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

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