Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A randomized controlled trial to compare the effect of occupation-based interventions with and without motivational strategies on functional balance, postural control and participation in activities of daily living in people with chronic stroke

Protocol summary

Study aim
The aim of this study is to compare the of occupation-based interventions with and without motivational strategies on postural control and participation in activities of daily living in people with chronic stroke.

Design
This study is a double-blinded controlled randomized trial with parallel groups. Forty-eight chronic stroke survivors will participate in this study and they will be randomly assigned to three groups. Randomization will be performed by the person who is not involved in the study using sealed envelopes method.

Settings and conduct
This study will be performed in Djavad Mowafaghian of Neuro-Rehabilitation Research Center. Control group receives conventional rehabilitation. Occupation-based intervention groups receive 12 sessions interventions (6 weeks, 2 sessions per week, 75 minutes per session) in addition to conventional rehabilitation. In occupation-based interventions with motivational strategies group, different motivational strategies will be used to enhance an individual's level of motivation. Assessors and patients are blinded to the groups allocation.

Participants/Inclusion and exclusion criteria
In this clinical trial study, 48 subjects with chronic stroke will participate. The main inclusion criteria include having the first experience of stroke, passing at least 6 months since stroke, and 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; Occupation-based interventions with motivational strategies group; Occupation-based interventions without motivational strategies group

Main outcome variables
Postural control; functional balance; Participation in activities of daily living

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140304016830N10**
Registration date: **2019-12-07, 1398/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**
Update count: **0**

Registration date
2019-12-07, 1398/09/16

Registrant information

Name
Ghorban Taghizadeh

Name of organization / entity
School of Rehabilitation Sciences, Iran University of Medical

Country
Iran (Islamic Republic of)

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+98 21 2222 7124

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

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 occupation-based interventions with and without motivational strategies on functional balance, postural control and participation in activities of daily living in people with chronic stroke

Public title

The effect of occupational therapy interventions on balance and participation in activities of daily living in people with chronic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having the first experience of stroke Passing at least 6 months since stroke Ability to walk at least 10 meters with or without assistive device Ability to stand for at least 5 minutes on the foam surface Having an acceptable level of cognitive function, i.e. score equal to or greater than 23 on the Persian version of Mini Mental State Examination Feeling the need or desire to participate in occupations selected for the intervention

Exclusion criteria:

Having unilateral visuospatial neglect (i.e., obtaining score less than 44 at star cancellation test) 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 **25 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- 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 sealed envelopes method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Evaluation of the primary and secondary outcomes is performed by experienced individuals who are blind on the groups allocation. Patients are also blind to the type of intervention they receive.

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

2019-02-24, 1397/12/05

Ethics committee reference number

IR.IUMS.REC.1398.002

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

Postural control parameters (including velocity and amplitude of center of pressure sways recorded by force plate)

Timepoint

Before and after intervention and 6 weeks after intervention

Method of measurement

Force plate

2

Description
Functional balance
Timepoint
Before and after intervention and 6 weeks after intervention
Method of measurement
Timed Up and Go test, Berg balance scale

3

Description
Level of participation in activities of daily living
Timepoint
Before and after intervention and 6 weeks after intervention
Method of measurement
Canadian occupational performance measure, Meaningful Activity Participation Assessment Questionnaire

Secondary outcomes

empty

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: Occupation-based interventions with motivational strategies group that receives 12 sessions of intervention including different occupations with emphasize on motor learning approach (6 weeks, 2 sessions per week, 75 minutes per session) in addition to the conventional rehabilitation. In this group, different motivational strategies will be used to enhance an individual's level of motivation during the intervention.
Category
Rehabilitation

3

Description
Second Intervention group: Occupation-based interventions without motivational strategies group that receives 12 sessions of intervention including different occupations with emphasize on motor learning approach (6 weeks, 2 sessions per week, 75 minutes per session) in addition to the conventional rehabilitation. In this group, motivational strategies will not be used during the intervention.
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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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 updating data

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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
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, Tehranو Tel: 00982122227124و 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