Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Efficacy of Occupation-Based and Exercise-Based Interventions on Performance Components and Areas of Occupation in Subjects with Chronic Stroke (Clinical Trial)

Protocol summary

Study aim

1. Comparison of the efficacy of occupation-based, exercise-based intervention and traditional interventions on parameters of motor control strategies of upper limb in reach and grasp in people with chronic stroke 2. Comparison of the efficacy of occupation-based, exercise-based intervention and traditional interventions on cognitive function, upper limb function, balance and functional mobility in people with chronic stroke 3. Comparison of the efficacy of occupation-based, exercise-based intervention and traditional interventions on participation in occupational areas in people with chronic stroke

Design

45 chronic stroke patients who have the eligibility criteria will be included in the study and will be randomly assigned to one of the three groups of occupation-based intervention, exercise-based intervention or control group. The sample size is 15 people per group.

Settings and conduct

In this randomized clinical trial, eligible patients will be recruited and randomly assigned to one of three groups. Interventions will be provided for 3 months in all groups. Interventions and assessmwnts will conduct mainly in school of rehabilitation and Dr. Movafaghiyan research center. The assessment of primary and secondary outcomes will be done by a researcher who is not aware of the patients' assignment.

Participants/Inclusion and exclusion criteria

We will recruit chronic stroke patients who experience the first stroke and have no history of other neurological disorders and depression before stroke onset. Patients who experience another stroke and patients with inappropriate collaboration will be excluded.

Intervention groups

In occupation based group, “cognitive orientation to daily occupational performance” will be used. This is a client-centered problem-solving protocol which focuses directly on improving performance in everyday life activity rather than treating the underlying impairments. Intervention in the exercise based group will be a structured exercise protocol including the range of motion and strengthening exercises, balance and endurance training and functional use of the upper extremity. Participants in the routine occupational therapy group will receive traditional occupational therapy including neurodevelopmental methods, stretching and strengthening programs, positioning, training of balance and fine motor skills and functional exercises.

Main outcome variables

1. Participation in occupational areas 2.Performance components including upper limb function, balance and functional mobility and cognition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023277N2**
Registration date: **2017-12-16, 1396/09/25**
Registration timing: **prospective**

Last update: **2017-12-16, 1396/09/25**
Update count: **0**

Registration date

2017-12-16, 1396/09/25

Registrant information

Name

Laleh Lajevardi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8051

Email address
lajevardi.l@iums.ac.ir

Recruitment status
Recruitment complete
Funding source
Vice Chancellor for Research, Iran University of Medical Sciences

Expected recruitment start date
2017-12-22, 1396/10/01
Expected recruitment end date
2018-11-22, 1397/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy of Occupation-Based and Exercise-Based Interventions on Performance Components and Areas of Occupation in Subjects with Chronic Stroke (Clinical Trial)

Public title
The Efficacy of Occupation-Based and Exercise-Based Interventions in Stroke Subjects
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Stroke survivors who are experiencing first occurrence of stroke. Are 24 to 80 years old. Are in chronic phase of stroke (6 months to 5 years). Acquire a score equitable or higher than 24 in Mini-Mental State Exam. Have no history of other neurological disabilities. Have the ability to grasp and release a block of Box and Bloc Test. Are able to walk at least 3 meter with or without assistive devices. Understand the global strategy of the occupation-based intervention (Cognitive Orientation to Daily Occupational Performance). Have no history of depressin before stroke onset.
Exclusion criteria:
Patients who experience two or more stroke.
Age
From **24 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
According to "Table of Random Numbers" participants will be randomly assigned to three groups of occupation-based intervention, exercise-based intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is an assessor blind study in which interventions in each group will be delivered by a therapist and outcome measurements will be conducted by another researcher who is not aware of participant's assignment.
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
School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
15459-13487
Approval date
2017-12-08, 1396/09/17
Ethics committee reference number
IR.IUMS.REC.1396.9221525203

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
Participation in Occupational Areas
Timepoint
Pre-test, 12 Sessions after onset of intervention, Post-test and Follow up
Method of measurement

Canadian Occupational Performance Measure, Goal Attainment Scale, Stroke Impact Scale, Community Integration Questionaire, Barthel and Katz Index, Lawton Instrumental Activity of Daily Living Scale

2

Description
Upper Extremity Function
Timepoint
Pre-test, 12 Sessions after onset of intervention, Post-test and Follow up
Method of measurement
Fugl-Meyer assessment, Motor Activity Log, Wolf Motor Function, Box and Block Test

3

Description
Functional Mobility and Balance
Timepoint
Pre-test, 12 Sessions after onset of intervention, Post-test and Follow up
Method of measurement
Timed Up and Go, Dynamic Gait Index, Functional Reach Test and Timed 10 Meter Walk Test

4

Description
Cognitive Function
Timepoint
Pre-test, 12 Sessions after onset of intervention, Post-test and Follow up
Method of measurement
Stroop Test, Wisconsin Card Sorting Test, Trail Making and Digit Span Subtest of Wechsler Memory Scale

Secondary outcomes

1

Description
Parameters of Motor Control Strategies of Upper Limb in Reach and Grasp of a subject on Single and Dual Tasks
Timepoint
Pre-test and Post-test
Method of measurement
Clinical and Laboratory Aseessment of Single and Dual Task

Intervention groups

1

Description
Intervention Group1: In occupation based group, “cognitive orientation to daily occupational performance” will be used. This is a client-centered problem-solving protocol which focuses directly on improving performance in everyday life activity rather tha
Category
Rehabilitation

2

Description
Intervention Group2: Intervention in exercise-based group will be a structured exercise protocol including the range of motion and strengthening exercises, balance and endurance training and functional use of the upper extremity.
Category
Rehabilitation

3

Description
Control Group: Participants in this group, will receive traditional occupational therapy including neurodevelopmental methods, stretching and strengthening programs, positioning, training of balance and fine motor skills and functional exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Javad Mowafaghian Research Center
Full name of responsible person
Ghorban Taghizade
Street address
No. 11, Khark Street, Enghelab Street, Tehran
City
Tehran
Province
Tehran
Postal code
11339-13813
Phone
+98 21 6671 6100
Email
Gh_taghizade@yahoo.com

2

Recruitment center
Name of recruitment center
School of Rehabilitation, Iran University of Medical Sciences
Full name of responsible person
Laleh Lajevardi
Street address
School of RehabilitationShahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
15459-13487

Phone
+98 21 2222 2059
Email
Lajevardi.l@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mojtaba Kamyab
Street address
School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
15459-13487
Phone
+98 21 2222 8051
Email
Lajevardi.l@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
Laleh Lajevardi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Occupational Therapy
Street address
School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
15459-13487
Phone
+98 21 2222 8051
Fax
Email
lajevardi.l@iums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Ghorban Taghizade
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
15459-13487
Phone
+98 21 2222 8051
Fax
Email
gh_taghizade@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Laleh Lajevardi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Occupational Therapy
Street address
School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran
City
Tehran
Province

Tehran

Postal code

15459-13487

Phone

+98 21 2222 8051

Fax

Email

lajevardi.l@iums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the primary and secondary outcome measures

When the data will become available and for how long

After publishing the articles

To whom data/document is available

Researchers intending to research in this field.

Under which criteria data/document could be used

-Obtaining written permission from the research team -Mention the source of information

From where data/document is obtainable

-Mahnaz Hejazi Shirmard: School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran. Email Adress: M.hejazishirmard@yahoo.com -Dr. Laleh Lajevardi: School of Rehabilitation, Shahid Shahnazari Street, Madar Square, Mirdamad Blvd, Tehran. Email Adress: Lajevardi.l@iums.ac.ir

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

After sending the email to the researcher and requesting the document, the researcher will request the opinion of other members of the research team regarding the provision of this information and, if the members agree, the documents will be sent as soon as possible but sending the documents requires the acceptance of the criteria mentioned above.

Comments