

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of hip joint mobilization with movement on muscle activity pattern, postural control and static and dynamic balance in patients with chronic stroke: Randomized clinical trial

#### Protocol summary

##### Study aim

-Determining the pattern of muscle activity, postural stability, dynamic and functional balance before, after and two weeks after treatment in each group and between groups

##### Design

This clinical trial contains: a control group, parallel group trial, double blinded, pilot study, permuted block randomization with a block size of 4

##### Settings and conduct

After screening, the patients with hemiplegia following stroke will sign the informed consent. The patients will be randomly allocated to the experimental (hip joint mobilization with movement) and the control group (conventional physiotherapy). Assessments and statistical analysis will be performed by blinded physiotherapist and statistician, respectively.

##### Participants/Inclusion and exclusion criteria

-Hemiplegia secondary to stroke; -stroke onset >6 months; -The ability to stand and walk independently; Exclusion criteria: -Any orthopedic and neurological disease affecting balance control; -Contraindications for hip joint mobilization and superficial electromyography;

##### Intervention groups

Intervention group: hip joint mobilization with movement in addition to the conventional physiotherapy Control group: conventional physiotherapy

##### Main outcome variables

Postural stability; dynamic balance; functional balance and muscle activity pattern

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200613047759N1**

Registration date: **2020-08-02, 1399/05/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-08-02, 1399/05/12**

Update count: **0**

##### Registration date

2020-08-02, 1399/05/12

##### Registrant information

###### Name

soudeh arabzadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3627 1552

###### Email address

s\_arabzadeh@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2021-06-22, 1400/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of hip joint mobilization with movement on muscle activity pattern, postural control and static and dynamic balance in patients with chronic stroke: Randomized clinical trial

## Public title

The effect of hip joint mobilization with movement on muscle activity, and balance in patients with chronic stroke

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

-The presence of hemiplegia secondary to stroke -History of stroke onset >6 months and a maximum of 1 year prior to the study -The ability to stand and walk independently without the use of assist-devices -Mini-Mental State Examination score of >24 -Within stages 2-4 of Brunnstrom -The age range of 35-65 years old -The ability to follow verbal commands

### Exclusion criteria:

-Any orthopedic disease affecting balance control -Any neurological condition affecting balance control -Taking any medication that causes peripheral neuropathy -Have a visual impairment -Have a hearing impairment -Have a history of spinal disorders affecting gait and lower limb function -There is a cerebellar stroke at the same time - Contraindications for hip joint mobilization - Contraindications on the use of superficial electromyography

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Permuted block randomization with a block size of 4 will be done with statistical software.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients are unaware of whether they are in the control or experimental group. Also all outcome will be measured and analyzed by an experienced physical therapist and statistician, who was blinded to the grouping. Also, in order to blind the participants, the treatment of each group will be done on different days of the week.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Second Floor, No. 18, Niloufar Alley, Hasht Behesht Sharghi St.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8157686811

#### Approval date

2020-06-09, 1399/03/20

#### Ethics committee reference number

IR.SUMS.REHAB.REC.1399.019

## Health conditions studied

### 1

#### Description of health condition studied

Chronic stroke

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Postural stability

#### Timepoint

1 day before intervention, 1 day after intervention and 14 days after intervention

#### Method of measurement

Biodex balance system

### 2

#### Description

Dynamic balance

#### Timepoint

1 day before intervention, 1 day after intervention and 14 days after

#### Method of measurement

Time Up and Go test

### 3

#### Description

Functional balance

#### Timepoint

1 day before intervention, 1 day after intervention and 14 days after

**Method of measurement**

Berg Balance Scale

**Secondary outcomes**

**1**

**Description**

Muscle activity pattern

**Timepoint**

1 day before intervention, 1 day after intervention and 14 days after intervention

**Method of measurement**

Surface electromyography

**Intervention groups**

**1**

**Description**

Experimental group: hip joint mobilization with movement technique for three times per week for 4 weeks, a grade III glide will be sustained for 10 seconds and relaxed for 5 seconds over 3 sets of 6 repetitions with a 1- minute rest between sets after receiving 30 minutes of conventional physiotherapy

**Category**

Rehabilitation

**2**

**Description**

Control group: 30 minutes of conventional physical therapy, 3 times a week for 4 weeks as follows: the first 10 minutes of the active and passive range of motion exercises for the lower limb of the affected side; the next 10 min for Weigh Bearing training during sitting and standing; and the final 10 min for walking.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Clinic of School of Rehabilitation Sciences

**Full name of responsible person**

Mohsen Razeghi

**Street address**

Clinic of Shiraz Faculty of Rehabilitation Sciences  
Clinic, Abiverdi 1 Alley, Chamran Blvd.

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Rehab@Sums.ac.ir

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Yunes Ghasemi

**Street address**

Deputy of Research and Technology, 7th Floor,  
Central Building of Shiraz University of Medical  
Sciences, Zand St.

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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**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Soudeh Arabzadeh

**Position**

PhD candidate in physiotherapy

**Latest degree**

Master  
**Other areas of specialty/work**  
Physiotherapy  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Soudeh Arabzadeh  
**Position**  
PhD candidate in Physiotherapy  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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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

Yes - There is a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

After coordination with the Research Ethics Committee for approval of the ethics committee, participants data file will be provided in complete secrecy and for research purposes only.

### When the data will become available and for how long

After acceptance of the article by the journal

### To whom data/document is available

In addition to the principal researcher and the supervisor of the project, upon request, access to information can be reviewed by the Ethics Committee.

### Under which criteria data/document could be used

Preferably it is only used for the subject of my research, but if research is to be done in order to use the statistical population, the main project executor and the student's main collaborator will make a decision with the permission of the ethics committee.

### From where data/document is obtainable

Executors of the project can first be referred to through Dr. Fahimeh Kamali Sarvestani (09177110341), secondly through Dr. Mohsen Razaghi (09173130718) and the main colleague and student collaborator Ms Soudeh Arabzadeh (09369332615).

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

6 months after the article was published, referring the request to the executor of the project, in addition, an official letter from the ethics committee will be commented on in order to obtain a license, and if the ethics committee approves, emphasizing the confidentiality of the information, the requested information will be provided to the applicant.

### Comments