

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of Core stability exercises with Otago exercises on balance and quality of life in patients with stroke

#### Protocol summary

##### Study aim

Determining and Comparing the Effect of Central Stability Exercises with Otago Exercises on Balance and Quality of Life in Patients with Stroke

##### Design

Clinical trial with control group, with parallel, blinded, randomized, 69 patients

##### Settings and conduct

By the Ethics Committee on University Research. At the beginning of the study, demographic questionnaires, leaf equilibrium, time-to-go test, and quality of life questionnaire for stroke were completed. Then, after the intervention, leaf balance questionnaire and time-to-go test were completed and the quality of life questionnaire for stroke was completed one month after completion of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age range 40 to 70 years 2. Neurologist diagnoses ischemic stroke 6 months after stroke 4. Patient balance with cut-off score of 32 and below based on leaf balance questionnaire 5. Individual time  $14 \leq$  seconds in the timed take-and-go test 6. Ability to walk independently 7. Having the physical ability to participate in exercise based on the opinion of a specialist 8. No Comorbidities (Heart, Pulmonary and Mental Disorders) 9. Consent to participate in the study and sign the informed consent form 10. Patient's previous non-participation in studies similar to current research Exclusion criteria: 1. Research participants can be excluded from the study under any circumstances.

##### Intervention groups

The three intervention groups consisted of central stabilization exercises, Otago exercises and control groups. In the Central Stability and Otago Exercises group, there are eight sessions of exercise for eight weeks, three times a week, and 5 minutes of cooling off after each session. The control group received no training.

##### Main outcome variables

Balance and quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200107046046N1**

Registration date: **2020-03-21, 1399/01/02**

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

Last update: **2020-03-21, 1399/01/02**

Update count: **0**

##### Registration date

2020-03-21, 1399/01/02

##### Registrant information

##### Name

Fatemeh Pirayesh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3323 4115

##### Email address

fatemeh.pirayesh@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-20, 1399/01/01

##### Expected recruitment end date

2020-05-21, 1399/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effect of Core stability exercises with Otago exercises on balance and quality of life in patients with stroke

### Public title

Comparison of the Effect of Central Stability Exercise and Otago Exercise on Stroke

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Neurologist diagnoses ischemic stroke 6 months after stroke Patient balance with cut-off score of 32 and below based on leaf balance questionnaire Individual time  $14 \leq$  seconds in the timed test of getting up and going Ability to walk independently Having the physical ability to participate in exercise based on the opinion of a specialist No Comorbidities (Heart, Pulmonary and Mental Disorders) Consent to participate in the study and sign the informed consent form No previous patient participation in studies similar to current research Age range 40 to 70 years

#### Exclusion criteria:

Research participants can be excluded from the study at any time.

### Age

From **40 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **69**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Eligible individuals were randomly assigned based on the lottery method in which the number of individuals in each group was placed in a numbered container and randomly selected at the time of referral and divided into 3 groups for exercise. Central stability, auto-training and control will be provided.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

##### Street address

Yasuj, Shahid Motahari Blvd., Yasuj University of Medical Sciences

##### City

Yasuj

##### Province

Kohgiluyeh-va-Boyerahmad

##### Postal code

7591741417

#### Approval date

2020-02-22, 1398/12/03

#### Ethics committee reference number

IR.YUMS.REC. 1398. 162

## Health conditions studied

### 1

#### Description of health condition studied

Patients with stroke

#### ICD-10 code

G46.4

#### ICD-10 code description

Cerebellar stroke syndrome

## Primary outcomes

### 1

#### Description

Balance

#### Timepoint

Balance at baseline (before intervention) and after baseline

#### Method of measurement

Berg balance scale (BBS)

### 2

#### Description

Quality of life

#### Timepoint

Quality of life at baseline (before intervention) and one month after baseline

#### Method of measurement

Stroke Specific Quality Of Life (SSQOL)

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Core stability exercises: Includes Gestures: Camel Cat (lean on your hands and knees on the ground. Rotate your back with your abdominal muscles and pelvis held steady. Then let your waist down as you lift your chest up. And arches), four arms and legs (raising one leg and one arm and one leg), cobra (sleeping on the abdomen and placing your head on your hands and lifting your head upwards and then lowering your chest) Lift up to the hip, lying on the back (raising one leg, raising one foot to the side of the hand and then the opposite hand, raising the pair of legs, raising the pair of legs with two hands and raising the pair of legs). With the ball), hamstring stretches on the chair and on the ground, crunch (flat foot, regular, reverse and ball), bridge (assisted and unassisted) and bridging the Swiss ball They will do three sessions per week for eight weeks and will complete a 5 minute cool down after each session.

### Category

Rehabilitation

## 2

### Description

Intervention group: Otago exercises: Includes gestures: walking forward (with and without support), heel (with and then without support), lateral walking (with and without support), single leg (with and without support) Backing), getting up from the chair (with two hands, one hand, no hands and with the ball), walking backwards (with backing and then unsupported and finally with the ball), heel walking (with backing and then Unsupported and ultimately with the ball), they walk and rotate around, doing three sessions for eight weeks each week, and doing 5 minutes of cooling down after each session.

### Category

Rehabilitation

## 3

### Description

Control group: Non-intervention: This group will not be trained.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Fatemeh Pirayesh

##### Street address

Shahid Beheshti Hospital, Shahid Mohammad Montazeri Street, Yasuj

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyrahmad

##### Postal code

7591794857

##### Phone

+98 74 3322 4721

##### Email

beheshtihospital@yasooj.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Hossein Mari Oryad

##### Street address

Shahid Motahari Blvd, Yasuj University of Medical Sciences

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyrahmad

##### Postal code

7591977833

##### Phone

+98 74 1333 7251

##### Fax

+98 74 3333 7230

##### Email

Oryad.hossein@yums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

##### Full name of responsible person

Fatemeh Pirayesh

##### Position

MSc Student of Internal Surgery Nursing

##### Latest degree

Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Imam Khomeini street  
**City**  
Pataveh  
**Province**  
Kohgilouyeh-va-Boyrahmad  
**Postal code**  
7598119761  
**Phone**  
+98 74 3323 4115  
**Email**  
fatemehpirayesh72@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Pirayesh  
**Position**  
MSc Student of Internal Surgery Nursing  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Imam Khomeini street  
**City**  
Pataveh  
**Province**  
Kohgilouyeh-va-Boyrahmad  
**Postal code**  
7598119761  
**Phone**  
+98 74 3323 4115  
**Email**  
fatemehpirayesh72@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Pirayesh  
**Position**  
MSc Student of Internal Surgery Nursing  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Imam Khomeini street  
**City**  
Pataveh  
**Province**  
Kohgilouyeh-va-Boyrahmad  
**Postal code**  
7598119761  
**Phone**  
+98 74 3323 4115  
**Email**  
fatemehpirayesh72@yahoo.com

## 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

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

### Statistical Analysis Plan

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

### Informed Consent Form

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

### Clinical Study Report

Undecided - It is not yet known if there will be 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

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