

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Effect of eccentric training on knee muscles torque and functional tests in chronic stroke patients

#### Protocol summary

##### Study aim

The purpose of this study is to investigate the effect of eccentric training on knee muscles torque and functional tests in chronic stroke patients.

##### Design

This study is a randomized clinical trial, with parallel groups, double-blinded with 26 sample size.

##### Settings and conduct

This study will be performed in the Neuromuscular Rehabilitation Research Center in Semnan. Participants in the experimental group will walk on the treadmill with a negative 10% inclination for 30 minutes. Routine physiotherapy only will be performed in the control group. Training will be performed three times in the weeks for four weeks in both groups. Participants and outcome assessor will be blind in this study. Subjects will not be aware of being in which group. The outcome assessor will be the person other than the main investigator to reduce the bias in the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Stroke patients should be in the chronic stage and the spasticity score of plantarflexor muscles should be smaller than 2 in the modified Ashworth scale. Exclusion criteria: Medical condition (apart from the stroke) that impair patients balance

##### Intervention groups

Participants in the experimental group will walk on the treadmill with a negative 10% inclination. Participants in addition to walking on their treadmill, undergo routine physiotherapy (functional electrical stimulation of Quadriceps muscle, balance exercises with tilt board, stretch training of the Gastrocnemius muscle, and training in daily activities). Participants only undergo routine physiotherapy in the control group. Training will be performed three times in the weeks for four weeks in both groups.

##### Main outcome variables

Quadriceps and Hamstrings muscles torque on the affected side

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160424027562N7**

Registration date: **2019-01-06, 1397/10/16**

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

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

##### Registration date

2019-01-06, 1397/10/16

##### Registrant information

##### Name

Roghayeh Mohammadi

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4180

##### Email address

mohammadipt@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-05, 1397/10/15

##### Expected recruitment end date

2019-06-21, 1398/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of eccentric training on knee muscles torque and functional tests in chronic stroke patients

**Public title**

Effect of training in chronic stroke patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All the patients should be more than 6 months poststroke  
The spasticity score of plantarflexor muscles should be smaller than 2 in the modified Ashworth scale  
Stroke patients should be in the chronic stage  
They should be able to walk on treadmill

**Exclusion criteria:**

Medical condition (apart from stroke) that impair patients balance  
Aphasia  
Cognition deficiency

**Age**

From **40 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **26**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be simple and individually. It will be performed by selecting a closed envelope by every patient, enrolling him/her to the experimental or control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, participants and outcome assessor will be blind. Despite explained to patients adequately about the intervention, they will not be aware of being in the intervention or control group. The outcome assessor will be the person other than the main investigator to reduce the bias in the study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

**Street address**

Semnan University of Medical Sciences, Basij Blvd, Semnan

**City**

Semnan

**Province**

Semnan

**Postal code**

3514799442

**Approval date**

2018-12-18, 1397/09/27

**Ethics committee reference number**

IR.SEMUMS.REC.1397.203

**Health conditions studied****1****Description of health condition studied**

Stroke

**ICD-10 code**

I67.9

**ICD-10 code description**

Cerebrovascular disease, unspecified

**Primary outcomes****1****Description**

Quadriceps muscle torque on the affected side

**Timepoint**

Before intervention, and 4 weeks after intervention

**Method of measurement**

Isokinetic System

**2****Description**

Hamsrings muscle torque on the affected side

**Timepoint**

Before intervention, and 4 weeks after intervention

**Method of measurement**

Isokinetic System

**Secondary outcomes****1****Description**

Time of the Timed Up and Go test

**Timepoint**

Before intervention, and 4 weeks after intervention

**Method of measurement**

Chronometer

**2****Description**

Berg Balance Scale

### **Timepoint**

Before intervention, and 4 weeks after intervention

### **Method of measurement**

Questionnaire

## **3**

### **Description**

Functional Reach Test

### **Timepoint**

Before intervention, and 4 weeks after intervention

### **Method of measurement**

Ruler

## **Intervention groups**

### **1**

### **Description**

Intervention group: Participants in the experimental group will walk on the treadmill with a negative 10% inclination for 30 minutes. In the first week, they will walk on the treadmill as fast as 55% of maximum heart rate and also they will walk in the second week with 65% of maximum heart rate and in the third week with 75% and in the fourth week with 85% maximum heart rate. Participants in addition to walking on their treadmill, undergo routine physiotherapy (functional electrical stimulation of Quadriceps muscle for 10 minutes, balance exercises with tilt board, stretch training of the Gastrocnemius muscle for 15 seconds, and training in daily activities). Training will be performed three times in the weeks for four weeks.

### **Category**

Rehabilitation

### **2**

### **Description**

Control group: Participants undergo routine physiotherapy (functional electrical stimulation of Quadriceps muscle for 10 minutes, balance exercises with tilt board, stretch training of the Gastrocnemius muscle for 15 seconds, and training in daily activities). Training will be performed three times in the weeks for four weeks.

### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

### **Recruitment center**

#### **Name of recruitment center**

Neuromuscular Rehabilitation Research Center

#### **Full name of responsible person**

Roghayeh Mohammadi

#### **Street address**

Neuromuscular Rehabilitation Research Center,  
Ghods Blvd, Semnan, Iran

#### **City**

Semnan

### **Province**

Semnan

### **Postal code**

3519698375

### **Phone**

+98 23 3332 8502

### **Email**

mohamadipt@gmail.com

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Semnan University of Medical Sciences

#### **Full name of responsible person**

Dr Parviz Kokhaei

#### **Street address**

Semnan University of Medical Sciences, Basij  
Boulevard, Semnan

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#### **Province**

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#### **Phone**

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#### **Email**

P\_kokha@yahoo.com

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

#### **Full name of responsible person**

Roghayeh Mohammadi

#### **Position**

Assistant Professor

#### **Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Rehabilitation Faculty, Semnan University of Medical Sciences, 5 Kilometer of Damghan Road, Semnan, Iran

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**Postal code**

3513138111

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Roghayeh Mohammadi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Roghayeh Mohammadi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**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**

Not applicable

**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**

Not applicable