

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The effect of action observation training on kinetic and kinematic parameters of gait and quantitative electroencephalography (qEEG) patterns of chronic stroke patients with hemiparetic gait

#### Protocol summary

##### Study aim

Evaluation of the effect of action observation on kinetic and kinematic parameters of gait using a gait analysis system and QEEG-based cortical brain activity in patients with chronic stroke

##### Design

30 patients with chronic stroke will be randomly allocated to the experimental and sham control groups using opaque envelopes randomization method. Each group will receive intervention three times a week for four weeks.

##### Settings and conduct

Gait analysis will be done in the biomechanics center of rehabilitation school and QEEG acquisition, physical training, and action observation training will be done in the neuroscience laboratory of Advanced Medical Sciences and Technologies of Shiraz University of Medical Sciences. The patients, the assessors, and the therapist would be blinded.

##### Participants/Inclusion and exclusion criteria

Patients with unilateral stroke who have hemiparetic gait will be recruited in the study. The patients must be able to walk at least 10 meters independently. Both right-handed males and females will be included. In case of the presence of any other disorders including visual impairment, orthopedic, or other neurological disorders or depression they will be excluded.

##### Intervention groups

The experimental group will watch a video depicting actions commonly used for improvement of walking ability of patients with stroke and subsequently will practice the same actions with the help of an experienced therapist. The control group will watch a video depicting landscapes and after that will practice the same actions done by the experimental group.

##### Main outcome variables

Gait parameters, including spatiotemporal parameters,

joint angles and moments and also connectivity map of cortical motor areas and inter-hemispheric asymmetry of different brain frequency bands would be recorded.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181014041333N1**

Registration date: **2020-09-01, 1399/06/11**

Registration timing: **retrospective**

Last update: **2020-09-01, 1399/06/11**

Update count: **0**

##### Registration date

2020-09-01, 1399/06/11

##### Registrant information

##### Name

Fatemeh Shamsi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5262 2836

##### Email address

f.shamsi86@yahoo.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-10-23, 1397/08/01

##### Expected recruitment end date

2019-10-23, 1398/08/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of action observation training on kinetic and kinematic parameters of gait and quantitative electroencephalography (qEEG) patterns of chronic stroke patients with hemiparetic gait

**Public title**

Action observation training for the improvement of walking ability in patients with chronic stroke

**Purpose**

Treatment

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

Chronic stroke > 6 months after onset In the territory of the middle cerebral artery (MCA) Hemiparetic gait First stroke experience Unilateral lesion Walking at least 10 meter independently mRS : 2-3 Ashworth Scale :1,2 Right/ left hemiparesis Right-handed Literate enough to cooperate with the therapist Residence in Shiraz

**Exclusion criteria:**

Any other neurological disorder rather than stroke or any orthopedic disorder Visual field impairment Hemineglect Depression Cognitive disorder /<24 on MMSE The history of Botox injection The history of tendon lengthening surgery The history of seizure

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done using opaque envelopes. In this method, clinicians are given randomly generated treatment allocations within sealed opaque envelopes. Once a patient has consented to enter a trial an envelope is opened and the patient is then offered the allocated treatment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, physical therapist and assessors will be blinded in this study by recruiting a person to assess the outcomes and a different one to provide physical training and another person for implementation action observation training

**Placebo**

Used

**Assignment**

Other

**Other design features**

A randomized controlled trial

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz university of medical sciences

**Street address**

Zand street

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2018-09-30, 1397/07/08

**Ethics committee reference number**

IR.SUMS.REC.1397.564

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

Chronic stroke resulting in hemiparetic gait

**ICD-10 code**

164

**ICD-10 code description**

Stroke, not specified as haemorrhage or infarction

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

Kinetic and kinematic parameters of gait

**Timepoint**

Before intervention and after a 4-week intervention

**Method of measurement**

gait analyzing system

**2****Description**

Delta-alpha ratio

**Timepoint**

Before intervention and after a 4-week intervention

**Method of measurement**

Quantitative Electroencephalography

## Secondary outcomes

### 1

#### Description

Balance

#### Timepoint

Before intervention and after a 4-week intervention

#### Method of measurement

Berg Balance Scale

## Intervention groups

### 1

#### Description

Intervention group: the group that watches videos depicting actions commonly used for the improvement of walking ability of patients with hemiparesis

#### Category

Rehabilitation

### 2

#### Description

Control group: the group that watches videos depicting landscapes without any moving content

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neuroscience Laboratory of Advanced Medical Sciences and Technology

##### Full name of responsible person

Dr. Mohammad Nami

##### Street address

Ghasrodasht

##### City

Shiraz

##### Province

Fars

##### Postal code

7194684560

##### Phone

+98 71 3230 5471

##### Email

pajouhesh\_novin@sums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Biomechanic research center of rehabilitation science school

##### Full name of responsible person

Dr. Mohammad Taghi Karimi

##### Street address

Chamran avenue, Abiverdi 1

##### City

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##### Province

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##### Phone

+98 71 3627 1552

##### Email

MT\_Karimi@Sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Younes Ghasemi

##### Street address

Zand street

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##### Province

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##### Postal code

14336-71348

##### Phone

+98 71 3235 7282

##### Email

vcrdep@sums.ac.ir

#### 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

Fatemeh Shamsi

##### Position

Phd student

##### Latest degree

Master

**Other areas of specialty/work**

Neuroscience

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Ghasrodasht street, School of Advanced Medical Sciences and Technology

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**Person responsible for scientific inquiries**

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**Full name of responsible person**

Fatemeh Shamsi

**Position**

Phd. Candidate

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

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Fatemeh Shamsi

**Position**

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**Latest degree**

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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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

All collected deidentified data for the primary outcome measures can be shared

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

The documents/data files will become available at least 3 months after the article is published and it will be available for at least 6 months

**To whom data/document is available**

The deidentified IPD and any additional supporting information/documents will be available only for people working in academic institutions

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

People must let the researcher know what they want to do for this data and get permission for any use

**From where data/document is obtainable**

The applicant can get these documents or data files by sending an email to the corresponding author of the related article. the email address will be available in the published article

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

The applicant must give the corresponding author the reason for which he/she needs the data and the corresponding author will let other authors know about the request and will send the data to the applicant if all authors agree with this work. it may take at least two weeks

**Comments**