

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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

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2

Recruitment center

Name of recruitment center

Biomechanic research center of rehabilitation science school

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Fatemeh Shamsi

Position

Phd student

Latest degree

Master

Other areas of specialty/work

Neuroscience

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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