Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 commitee 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 Labratory of Advanced Medical Sciences and Technology
Full name of responsible person
Dr. Mohammad Nami
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Ghasrodasht
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7194684560
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+98 71 3230 5471
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2

Recruitment center
Name of recruitment center
Biomechanic research center of rehabilitation science school
Full name of responsible person
Dr. Mohammad Taghi Karimi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
Street address
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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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Person responsible for scientific inquiries

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Position
Phd. Candidate

Latest degree
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Other areas of specialty/work
Neuroscience

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Person responsible for updating data

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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