Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of " constraint induced movement therapy " of lower limb on gait kinematics and functional test of lower limbs in hemiparetic patients

Protocol summary

Study aim
Comparative study of the effect of lower limb constraint induced movement therapy with conventional physical therapy on gait kinematics and functional tests in hemiparetic patients

Design
Randomized comparative study, with experimental and control groups, parallel, single blinded, randomized via block randomization with 15 participants in each group

Settings and conduct
This study was conducted in Qaem hospital in Mashhad. Patients with stroke in experimental group received constraint induced movement therapy via a shoe lift with 6mm thickness in conjunction with conventional physiotherapy. Patients in control group received only conventional physiotherapy. The outcome measures of the study included gait kinematics and functional tests which were recorded before and after intervention in each group and then were compared between the two groups. Persons who were involved in collecting and analyzing of data were blinded to group allocation.

Participants/Inclusion and exclusion criteria
1) Age range of 40-70 years 2) First ever stroke 3) Unilateral hemiparesis 4) Chronic stroke 5) Modified Ashworth Scale < or = 2 6) ability to walk without assistive device 7) weight bearing asymmetry

Intervention groups
Experimental group: constraint induced movement therapy in conjunction with conventional physiotherapy Control group: conventional physiotherapy

Main outcome variables
Weight bearing asymmetry- COP velocity changes- Spatial temporal gait measures- The changes of angular velocity of the lower limb joints during gait- Berg Balance Scale- Timed up and go

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190603043808N1**
Registration date: **2019-07-24, 1398/05/02**
Registration timing: **retrospective**

Last update: **2019-07-24, 1398/05/02**
Update count: **0**

Registration date
2019-07-24, 1398/05/02

Registrant information

Name
Hossein Asghar Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3884 6710

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hosseiniha@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2011-08-19, 1390/05/28

Expected recruitment end date
2012-08-18, 1391/05/28

Actual recruitment start date
2011-08-19, 1390/05/28

Actual recruitment end date
2012-08-18, 1391/05/28

Trial completion date
2012-11-18, 1391/08/28

Scientific title
Effect of " constraint induced movement therapy " of lower limb on gait kinematics and functional test of lower limbs in hemiparetic patients

Public title
Effect of constraint induced movement therapy in hemiparetic patients
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age range of 40-70 First ever stroke Chronic unilateral hemiparesis Modified Ashworth Scale < or = 2 Ability to walk without asisstive device Weight bearing asymmetry
Exclusion criteria:
Bilateral hemiparesis Occiput and limbic system lesions Cognitive impairments Aphasia Any neurologic condition in addition to stroke Any orthopedic condition that could affect walking pattern
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
Personnel who collect and analyse the outcome measures were blinded to study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Vice-Chancellor for research, Ghorashi Building, University street
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Approval date
2011-06-18, 1390/03/28
Ethics committee reference number
98/67031

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I 67.9
ICD-10 code description
Cerebrovascular disease, unspecified syndrome, cerebellar, stroke

Primary outcomes

1

Description
Weight bearing asymmetry index
Timepoint
Before and after intervention
Method of measurement
Force platform

2

Description
Spatio-temporal gait parameters
Timepoint
Before and after intervention
Method of measurement
Video camera

3

Description
COP velocity
Timepoint
Before and after intervention
Method of measurement
Force platform

4

Description
Joints angular velocity
Timepoint
Before and after intervention
Method of measurement
Video camera

5

Description

Berg Balance Scale

Timepoint
Before and after intervention

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Timed up & go

Timepoint
Before and after intervention

Method of measurement
Chronometer

Intervention groups

1

Description
"Experimental group": Patients in Experimental group received lower limbs constraint induce movement therapy (via a 6 mm shoe lift under the non-paretic leg) in conjunction with conventional physiotherapy for 6 weeks."

Category
Rehabilitation

2

Description
"Control group:Patients in Control group only received conventional physiotherapy for 6 weeks."

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Quaem hospital

Full name of responsible person
Hossein Asghar Hosseini

Street address
Rehabilitation ward, Quaem hospital, Ahmadabad Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Vice-Chancellor for research, Gorashi building, University Ave.

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vcresearch@mums.ac.ir

Web page address
http://v-research.mums.ac.ir/

Grant name
Research grant

Grant code / Reference number
511/1278

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Hossein Asghar Hosseini

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Physiotherapy department, Paramedical sciences faculty, University campus, Azadi square

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable