

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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
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Full name of responsible person
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<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

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Physiotherapy department, Paramedical sciences
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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