# 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)

**Phone**
+98 51 3884 6710

**Email address**
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.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3844 2242

**Fax**

+98 51 3845 3239

**Email**

Hosseiniha@mums.ac.ir

**Web page address**

http://quaem.mums.ac.ir/

## 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.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91388-13944

**Phone**

+98 51 3841 2081

**Fax**

+98 51 3841 3006

**Email**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3884 6710

**Fax**

+98 51 3884 6728

**Email**

Hosseiniha@mums.ac.ir

**Web page address**

http://sps.mums.ac.ir/

## Person responsible for scientific 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.

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**Fax**

+98 51 3884 6728

**Email**

Hosseiniha@mums.ac.ir

**Web page address**

http://sps.mums.ac.ir/

## Person responsible for updating data

**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**

Physical therapy department,Faculty of paramedical Sciences,University campus,Azadi square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3884 6710

**Fax**

+98 51 3884 6728

**Email**

hosseiniha@mums.ac.ir

**Web page address**

http://sps.mums.ac.ir/

## 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