

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### the effect of Constraint induced (CI)and traditional rehabilitation(TR) on motor activity log(MAL) and wolf motor function test(WMFT )in chronic hemiplegic patientpatient

#### Protocol summary

##### Summary

The aim of this study was to assess the effects of constraint-induced movement therapy (CIT) in comparison with traditional rehabilitation in chronic hemiplegic patients. Inclusion criteria was having at least 20 and 10 degree extension in affected wrist and fingers respectively, having sufficient balance in walking when the less affected arm was immobilized. Exclusion criteria were having serious cognitive problems (aphasia, attention deficits, visual neglect, serious uncontrolled medical problems, limited spasticity and pain, and having motor activity log (MAL) score more than 3) 12 patients (10 male ,2 female were assigned randomly to two groups. The first group received CIT (restraint of the less affected limb combined with intensive training of the affected limb for 2 hours daily, 5 days per week for 3 weeks and restraint of the less affected hand for 5 hours outside of the rehabilitation training). The second group received a traditional intervention without hand restraint for the same duration. Outcome measures were the MAL, Wolf Motor Function Test (WMFT). These tests were done one day before treatment, after 3 weeks in the end of treatment and three months later as follow-up.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138712111719N3**  
Registration date: **2009-09-19, 1388/06/28**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-09-19, 1388/06/28

#### Registrant information

##### Name

khadije Otadi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7753 6134

##### Email address

k\_otadi@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences (TUMS),IRAN

#### Expected recruitment start date

2005-10-30, 1384/08/08

#### Expected recruitment end date

2008-09-30, 1387/07/09

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

the effect of Constraint induced (CI)and traditional rehabilitation(TR) on motor activity log(MAL) and wolf motor function test(WMFT )in chronic hemiplegic patientpatient

#### Public title

The effect of Constraint induced movement and traditional rehabilitation on chronic hemiplegic patient

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Presence of at least 20 and 10 degree extension in affected wrist and each finger respectively, sufficient balance to walk when the less affected arm is immobilized. Exclusion criteria: serious cognitive problems (aphasia, attention deficits, visual neglect, serious uncontrolled medical problems, limited spasticity and pain, and good MAL greater from 3 score

#### **Age**

From **30 years** old to **75 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **12**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Research Center for Medical Ethics

##### **Street address**

No 21, 4th floor, Poorsina St

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2005-10-05, 1384/07/13

#### **Ethics committee reference number**

132/5744

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Other disorders of brain

#### **ICD-10 code**

G93.2

#### **ICD-10 code description**

Benign intracranial hypertension

## **Primary outcomes**

### **1**

#### **Description**

Functional movement

#### **Timepoint**

Before intervention, and after three weeks treatment

#### **Method of measurement**

wolf motor function test

### **2**

#### **Description**

Daily function recovery

#### **Timepoint**

Before intervention, and after three weeks treatment

#### **Method of measurement**

motor activity log

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Constraint induced movement therapy. This method involves motor restriction of the unaffected upper extremity by a resting hand splint and sling and training of the affected extremity, and the patients to repeatedly practice use of the paretic arm for many hours a day for a period of consecutive days.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Traditional hemiplegic rehabilitation

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Outpatient clinic of Rehabilitation Faculty

##### **Full name of responsible person**

Khadije Otadi

##### **Street address**

Pich e shemiran- Enghlab st.

##### **City**

Tehran

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences (Primary sponsor)

**Full name of responsible person**

Dr. Akbar Fotouhi

**Street address**

Keshvarz.BLV,Kods street.central organization of TUMS

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences (Primary sponsor)

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Faculty of Rehabilitation

**Full name of responsible person**

Khadije Otadi

**Position**

MS PT , Post Graduate Department, Instructor

**Other areas of specialty/work****Street address**

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1148965141

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k-otadi@razi.tums.ac.ir

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Faculty of Rehabilitation

**Full name of responsible person**

Dr. Mohammad Reza Hadian and Khadije Otadi

**Position**

Ph.D. Professor, Faculty of Rehabilitation, Imam komeini Hospital-MS PT , Post Graduate Department,

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### Person responsible for updating data

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Faculty of Rehabilitation, TUMS

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Instructor ,Post Graduate Department

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### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*