

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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**

Pich e shemiran- Enghlab st.

City

Tehran

Postal code

1148965141

Phone**Fax****Email**

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,

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

Pich e shemiran- Enghlab st.Tehran

City

Tehran

Postal code

1148965141

Phone

+98 21 7753 6134

Fax**Email**

hadianrs@sina.tums.ac.ir , - k_otadi @ razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Faculty of Rehabilitation, TUMS

Full name of responsible person

Khadije Otadi

Position

Instructor ,Post Graduate Department

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

Pich e shemiran- Enghlab st.

City

Tehran

Postal code**Phone****Fax****Email****Web page address**

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