Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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