

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Efficacy of occupation-based interventions versus exercise therapy in constraint-induced movement therapy on upper limb function after median and ulnar nerve repair

#### Protocol summary

##### Summary

The aim of the present study is to investigate effects of occupation-based interventions (purposeful and meaningful occupations in real context) compared to exercise therapy on results of CIMT. This study as a prospective, assessor-blind, randomized clinical trial would be performed on 30 patients with median and ulnar nerve injury in 3 groups (CIMT based on occupation-based intervention, CIMT based on exercise therapy, control). In CIMT group based on occupation-based intervention, sensory-motor reeducation is fully based on occupational preferences of own patients (preferred occupations and activities with real stuff and tools provided by patients inside their houses). In CIMT group based on exercise therapy, sensory-motor reeducation is based on present abilities and disabilities according to the usual rehabilitation programs such as repetitive and intensive movement of joints. Outcome measures includes total active motion, box & block test, disabilities of the arm, shoulder, hand questionnaire, self assessment manikin scale, and canadian occupational performance measure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016011710806N4**  
Registration date: **2016-04-22, 1395/02/03**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-04-22, 1395/02/03

##### Registrant information

##### Name

Malahat Akbarfahimi

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 7124

##### Email address

akbarfahimi.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Reserrch Deputy of Iran University of Medical Sciences,  
Thesis of PhD

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2016-06-20, 1395/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of occupation-based interventions versus exercise therapy in constraint-induced movement therapy on upper limb function after median and ulnar nerve repair

##### Public title

Effect of constraint-induced movement therapy on hand function of patients with median and ulnar nerve injury

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: chronic condition (at least 6 months after nerve repair); Non-use learning in injured limb (score less than 2.5 in Motor Activity Log); lack of any non-healed fractures or tendon ruptures; score less than 10 in Beck depression questionnaire; Lack of neurologic disorders related to the central nervous system; Age between 18-55 years Exclusion criteria: any surgery during the study period; complex regional pain syndrome; No participation in more than 2 intervention sessions

#### Age

From **18 years** old to **55 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Iran University of Medical Sciences

##### Street address

Hemmat highway, next to the milad hospital

##### City

Tehran

##### Postal code

#### Approval date

2016-02-16, 1394/11/27

#### Ethics committee reference number

IR.IUMS.REC.13949211525212

## Health conditions studied

### 1

#### Description of health condition studied

Median and Ulnar Nerve Injury

#### ICD-10 code

G56.1 , G5

#### ICD-10 code description

Other lesions of median nerve, Lesion of ulnar nerve

## Primary outcomes

### 1

#### Description

Sensation of fingers

#### Timepoint

before, after, and 1 month afterthe intervention ending

#### Method of measurement

touch perception at volar side of the pulp of index finger (median nerve) and littile finger (ulnar nerve) by semmes-weinstein monofilaments

### 2

#### Description

Occupational performance

#### Timepoint

before, after, and 1 month afterthe intervention ending

#### Method of measurement

patients own score to the performance and satisfaction of performance in preferred occupations in a 0-10 scale in COPM Questionnaire

### 3

#### Description

Disability rate of upper limb

#### Timepoint

before, after, and 1 month afterthe intervention ending

#### Method of measurement

patients own score to 30 questions of DASH questionnaire in a 1-5 likert scale

### 4

#### Description

hand dexterity

#### Timepoint

before, after, and 1 month afterthe intervention ending

#### Method of measurement

number of transfered cubes in one minutes in Box and Block test

## Secondary outcomes

### 1

#### Description

Motivation

#### Timepoint

before, after, and 1 month afterthe intervention ending

#### Method of measurement

This scale is a visual scale. patient chooses one of the pictures that is according to his/her view about Dominancy, Valence, and arousal

## Intervention groups

1

### Description

Occupation-based constraint-induced movement therapy group: immobilization of healthy hand for 6 hours each day 4 weeks. occupation-based interventions for 3 hours a day, 3 days a week, during 4 weeks.

### Category

Rehabilitation

2

### Description

Exercise therapy based constraint-induced movement therapy group: immobilization of healthy hand for 6 hours each day 4 weeks. Exercise-based interventions for 3 hours a day, 3 days a week, during 4 weeks.

### Category

Rehabilitation

3

### Description

control group: 1.5 hours of practice each day by own patient alone in his/her home without therapist for 4 weeks

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Fatemeh Hospital

#### Full name of responsible person

Hamid Reza Rostami

#### Street address

Faculty of Rehabilitation Sciences, Nezam Aly, Shah Nazari Street, Madar Square, Mirdamad blv.

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Research Deputy of Iran University of Medical Sciences

#### Full name of responsible person

seyed Ali Javad Mousavi

#### Street address

Hemat Express Way -near milad hospital-Iran University of Medical University-central block

#### City

Tehran

#### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Research Deputy of Iran University of Medical Sciences

### 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

Iran University of Medical Sciences

#### Full name of responsible person

Malahat Akbarfahimi

#### Position

Assistant Professor, Occupational Therapy Department

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Hamid Reza Rostami  
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PhD student of Occupational therapy  
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**Postal code**  
**Phone**

## 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*