# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## "Comparison of the effect of mirror therapy and modified constraint-induced movement therapy on upper extremity motor function in stroke patients"

## Protocol summary

**Study aim**
Comparison of the effect of mirror therapy and modified constraint-induced movement therapy on upper extremity motor function in stroke patients

**Design**
Randomized clinical trial with control group, double blind, in each group n=14

**Settings and conduct**
This study will be performed in SBMU Hospital. Subjects will be selected from stroke patients and randomly allocated in 3 groups. They do not inform from each other intervention and will be assessed by a therapist who do not aware from intervention type.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Inclusion is voluntary; Age 75-18 years; Diagnosis of stroke; brunnstrom stage 4 and above, Enough cognitive ability to understand and carry out verbal and practical orders; Modified Ashworth Scale less than 3; Existence of at least 20 degrees of wrist extension and 10 degree extension of fingers Exclusion criteria: Use of mirror therapy or constraint-induced before intervention; Receiving simultaneously another services; Presence any disease in upper limb; Pain greater than 4 In Visual Analog Scale; Botox injection at least 3 months before the intervention

**Intervention groups**
Intervention group -Modified Constraint-Induced Therapy: intervention performs 1 hour per day, 5 days per week, for a total of 4 weeks. The intervention sessions include performing tasks with upper limb. In addition to occupational therapy sessions the participants will be asked to wear mitts and do functional tasks. Intervention group -Mirror therapy: performs 1 hour per day, 5 days per week, for a total of 4 weeks. After adjusting the mirror, the image reflection of non-affected upper limb will be used in the mirror. Control group: common occupational therapy upper limb interventions that include Bobath, Rood and PNF Techniques will perform for 1 hour per day, 5 days per week, for a total of 4 weeks.

**Main outcome variables**
Upper extremity function

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180526039856N1**
Registration date: **2018-10-10, 1397/07/18**
Registration timing: **prospective**

Last update: **2018-10-10, 1397/07/18**
Update count: **0**

**Registration date**
2018-10-10, 1397/07/18

**Registrant information**

**Name**
Shiva Abedi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 2218 0083

**Email address**
sh.abedi@uswr.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-10-27, 1397/08/05

**Expected recruitment end date**
2019-01-10, 1397/10/20

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
"Comparison of the effect of mirror therapy and modified constraint-induced movement therapy on upper extremity motor function in stroke patients"

**Public title**
"The mirror therapy and modified constraint-induced movement therapy on treatment of upper limb stroke patients"
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Inclusion is voluntary (completed consent form) Age range 75-18 years Ischemic or hemorrhage stroke diagnosed by neurologist Stage 4, 5 and 6 Brunnstrom in proximal and distal of upper extremities Sufficient cognitive ability to understand and execute verbal and practical commands (obtaining at least 22 score from the Mini-Mental Status Examination) Mild spasticity in all involved upper limb joints (Modified Ashworth Scale less than 3) Existence at least 20 degrees wrist extension and 10 degrees extension of the affected fingers
**Exclusion criteria:**
Use of mirror therapy and modified constraint-induced movement therapy before intervention Refer to other clinics and receive other upper limb rehabilitation services Despite previous dementia, difficulty understanding given explanations and execute commands such as Wernicke aphasia, global aphasia, and any impairment of vision and hearing examinations by specialist Presence of musculoskeletal damage, frozen shoulder joint and any other neurological and orthopedic disease based on examination of specialist who leads to motion impairment. Excessive pain in the upper limb ( in this study the score more than 4 in the Visual Analog Scale to be regarded as pain)) Botox injections at least 3 months before the intervention
**Age**
From **18 years** old to **75 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **42**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple randomized with use of random number table.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Participants do not inform about interventions present to each other. Assessor varies with the person who intervenes.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of University of Social Welfare and Rehabilitation Sciences
**Street address**
kodakyar Ave., daneshjo Blvd.,Evin
**City**
Tehran
**Province**
Tehran
**Postal code**
۱۹۸۵۷۱۳۸۳۴
**Approval date**
2018-01-13, 1396/10/23
**Ethics committee reference number**
IR.USWR.REC.1396.284

## Health conditions studied

### 1

**Description of health condition studied**
stroke patients
**ICD-10 code**
VI
**ICD-10 code description**
Diseases of the nervous system

## Primary outcomes

### 1

**Description**
"Upper extremity score based on Fugl-Meyer Assessment "
**Timepoint**
"Before the intervention, after the intervention, one month after the intervention."
**Method of measurement**
"Fugl-Meyer Assessment"

## Secondary outcomes

### 1

**Description**
"functional independence score"
**Timepoint**
Before the intervention, after the intervention, one month after the intervention
**Method of measurement**
"Functional Independence Measure"

### 2

**Description**
"Muscle Tone Score"
**Timepoint**
"Before the intervention, after the intervention, one month after the intervention."
**Method of measurement**
"Modify Ashworth Scale"

## Intervention groups

### 1

**Description**
Intervention group 1: intervention performs 1 hour per day, five days per week, for a total of four weeks. The intervention sessions include performing tasks with upper limb. In addition to occupational therapy sessions the participants in this group will be asked to wear mitts and do functional tasks.
**Category**
Rehabilitation

### 2

**Description**
Intervention group 2: intervention performs 1 hour per day, five days per week, for a total of four weeks. After adjusting the mirror, the image reflection of non-affected upper limb will be used in the mirror so that patient is placed in a sitting position and mirror is placed in front of the non-affected upper limb and patient focuses on the image inside the mirror while practicing.
**Category**
Rehabilitation

### 3

**Description**
Control group: common occupational therapy upper limb interventions that include Bobath, Rood and PNF Techniques will perform for 1 hour per day, five days per week, for a total of four weeks.
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Rofeide Rehabilitation Hospital
**Full name of responsible person**
Shiva Abedi
**Street address**
"Qeytarieh Ave, Soleimani Brothers street, Nemati road
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rofeideh.hospital@uswr.ac.ir
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
University of social welfare and rehabilitation sciences
**Full name of responsible person**
Amir Massoud Arab Loodaricheh
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Koodakyar Ave, Evin, Tehran, Iran
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am.arabloo@uswr.ac.ir
**Web page address**
http://researchdeputy.uswr.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Shiva Abedi

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

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## Person responsible for scientific inquiries

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Nazila Akbarfahimi

**Position**

Assistant professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

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University of social welfare and rehabilitation sciences

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Statistical outcomes include MD, SD

**When the data will become available and for how long**

"From article acceptation"

**To whom data/document is available**

"Practitioners and students"

**Under which criteria data/document could be used**

"Use of data with permission"

**From where data/document is obtainable**

Dr Nazila Akbarfahimi, Assistant professor of University of Social Welfare and Rehabilitation Sciences Address: Kodakyar Ave, Daneshjo Blvd, Evin Email: na.akbarfahimi@uswr.ac.ir Zip Code: 1985713834 Tel: 00982122180063

**What processes are involved for a request to access data/document**

Email to: na.akbarfahimi@uswr.ac.ir

**Comments**