Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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)

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+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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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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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

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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