Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

"Comparison of the effect of action observation therapy and mirror therapy on upper extremity functions in patients with stroke"

Protocol summary

Study aim
Comparison of the effect of action observation therapy and mirror therapy on upper extremity functions in patients with stroke

Design
Randomized clinical trial with control group, single blind, in each group n=11

Settings and conduct
This study will be performed in occupational therapy clinic of SBMU School of Rehabilitation Sciences. Subjects will be selected from stroke patients and randomly allocated in 3 groups. They do not inform from each other intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: A diagnosis of hemiplegia due to stroke; 6 months to 5 years of stroke; Stage 3, 4, 5 and 6 Brunnstrom in proximal and distal of upper extremity; Obtaining at least 18 score from the Mini-Mental Status Examination; Voluntary consent to participate in the study; Age range 30-70 years Exclusion criteria: Visual or perceptual impairments such as hemineglect; Presence any neurological and orthopedic disease in upper extremity; Receiving simultaneously another services

Intervention groups
Intervention group -Mirror therapy: performs 30 minutes per day, 3 days per week, for a total of 4 weeks. Patient will perform the functional tasks with nonparetic upper extremity in front of mirror. Intervention group -action observation therapy: performs 30 minutes per day, 3 days per week, for a total of 4 weeks. Patients perform motor tasks after viewing them in the video. Control group: Conventional intervention includes upper extremity range of motion exercises, Bobath and PNF Techniques and strength training will perform for 45 minutes per day, 3 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: **IRCT20180815040804N1**
Registration date: **2018-10-26, 1397/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-26, 1397/08/04**
Update count: **0**

Registration date
2018-10-26, 1397/08/04

Registrant information

Name
Elnaz Fadaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7756 1721

Email address
fadaei_elnaz@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

"Comparison of the effect of action observation therapy and mirror therapy on upper extremity functions in patients with stroke"

Public title
"The action observation therapy and mirror therapy on treatment of upper limb stroke patients"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A diagnosis of hemiplegia due to stroke 6 months to 5 years of stroke Stage3, 4, 5 and 6 Brunnstrom in proximal and distal of upper extremities Obtaining at least 18 score from the Mini-Mental Status Examination Voluntary consent to participate in the study Age range 30-70 years
Exclusion criteria:
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **33**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomized
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants do not inform about interventions present to each other.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2018-01-21, 1396/11/01
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.985

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 function based on Box and Block Test and Fugl-Meyer Assessment"
Timepoint
"Measurement by Box and Block Test: Before intervention and end of sessions 3, 6, 9 and 12. Measurement by Fugl-Meyer Assessment: Before and after intervention"
Method of measurement
"Box and Block Test, Fugl-Meyer Assessment"

Secondary outcomes

1

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

Intervention groups

1

Description
Intervention group 1: Patients in the mirror group will receive mirror therapy for 30 minutes per session, 3 sessions per week, for 4 weeks in addition to the intervention of the control group. In this intervention, the patient sit on a chair in front of a table and a mirror dimensions 50*62 cm will be placed on the desk, parallel with the midline of the body and between the paretic and nonparetic upper extremity. Patients will be asked to gaze at the nonparetic upper extremity reflected in the mirror. The activities of the mirror therapy group includes: Range of motion exercises such as elbow

flexion.extension, forearm supination.pronation , wrist and fingers flexion.extension, fisting and releasing, reaching and upper extremity functional tasks. The exercises will be presented proportionally to each person's ability of the upper extremity. The patients will be asked to repeat each movement 30 times per set for three sets, with 1-minute break between sets. During intervention participants will be encouraged to actively move their hands and simultaneously move their nonparetic side reflected in the mirror. If patients unable to move their paretic upper extremity the therapist will help them.

Category

Rehabilitation

2

Description

Intervention group 2: Patients in the action observation therapy group will receive action observation therapy for 30 minutes per session, 3 sessions per week, for 4 weeks in addition to the intervention of the control group. In this intervention, the patient sit on a chair in front of the laptop. In the action observation group, patients will see the activities through the video and then perform the observed movements with both upper extremities simultaneously. Each functional task is divided into three motor actions. After observing a motor action for 2 minutes, patients will be asked to perform the observed motor action for 3 minutes. This step will be repeated three times, with 1-minute break between times. Then the patients will observe the functional task as a whole motor action for 2 minutes and then perform whole task for 3 minutes. This step will also be repeated three times. The activities of the action observation therapy group will include the range of motion exercises such as elbow flexion.extension, forearm supination.pronation, wrist and fingers flexion.extension, fisting and releasing, reaching and upper extremity functional tasks. The exercises will be presented proportionally to each person's ability of the upper extremity. If patients unable to move their paretic upper extremity the therapist will help them.

Category

Rehabilitation

3

Description

Control group: Conventional intervention includes upper extremity range of motion exercises, Bobath and PNF Techniques and strength training. Conventional intervention will apply for 45 minutes per session, 3 sessions per week, for 4 weeks. The control group will receive upper extremity exercises for 45 minutes without watching video or performing activities in front of the mirror.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Occupational therapy clinic of SBMU School of Rehabilitation Sciences

Full name of responsible person

Minoo Kalantari

Street address

SBMU School of Rehabilitation Sciences, Damavand St, Across from Bu Ali Hospital, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

دکتر افشین زرقی

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Elnaz Fadaei

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

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Assistant professor

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Person responsible for updating data

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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 Mino Kalantari, Assistant professor of SBMU School of Rehabilitation Sciences Address: SBMU School of Rehabilitation Sciences, Damavand St, Across from Bu Ali Hospital, Tehran, Iran Email: mn_kalantari@yahoo.com Zip Code: 1616913111 Tel: 00982177548496

What processes are involved for a request to access data/document
Email to: mn_kalantari@yahoo.com

Comments