

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

comparison of three neurological rehabilitation approaches on the function of upper extremity in chronic post stroke hemiparesis patients

Protocol summary

Study aim

Comparison of three rehabilitation approaches; Task oriented, Brunstrom and Bobath on the upper limb function of the stroke patients.

Design

a double blind clinical trial, with parallel's groups, control groups and randomized.

Settings and conduct

This study will be performed in Neurological Physiotherapy Clinic, School of Rehabilitation Sciences. Participants are randomly divided into three groups. Group 1 will receive a combination of task-oriented training and the Brunstrom, the intervention, Group 2 will received a combination of Task-oriented and Bobath training and control group will received Task-oriented training. The assessment will be carried out by a therapist who is unaware of the groups, additionally participants won't be aware of how groups are allocated.

Participants/Inclusion and exclusion criteria

Individuals will be enrolled in this study if they have first unilateral hemiparesis, age range between 45-70 years, Ability to comprehend simple instructions, having motor recovery of hand Brunnstrom stages equal and above 3. They will be excluded if they have previous contracture of the upper extremity and no sitting balance, Having any neurological diseases like Multiple Sclerosis, Parkinson's and so on.

Intervention groups

Interventions will take a 4-week. At that time, participants will be received 12 sessions for 3 days a week. The intervention group1, will receive 60 minute Task-oriented training and Brunstrom training. The second intervention group will receive 60 minutes of Task-oriented training and Bobath training and control group 60 minutes task-oriented training.

Main outcome variables

Upper limb Motor function which are measured by the "Wolf Motor Function Test" and "Fugle-Meyer test".

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140222016680N6**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-10, 1399/01/22**

Update count: **0**

Registration date

2020-04-10, 1399/01/22

Registrant information

Name

Shohreh Noorizadeh Dehkordi

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of three neurological rehabilitation approaches on the function of upper extremity in chronic post stroke hemiparesis patients

Public title

comparison of three neurological rehabilitation approaches on the function of upper extremity in chronic post stroke hemiparesis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Having first unilateral hemiparesis following stroke. 2. confirming stroke by computerized tomography (CT) or Magnetic Resonance Imaging (MRI). 3. Having a stroke for 2 to 12 months ago. 4. Having age range between 45 to 70. 5. Ability to comprehend simple instructions (Score above 20 base on "Mini-Mental State Examination"). 6. Score above 3 base on hand motor recovery stages of Brunnstrom approach. 7. Spasticity score of the elbow flexors below 2 base on the "Modified Ashworth Scale". 8. Depression score above 8 base on the "Geriatric Depression Scale". 9. During the study, they are not involved in other rehabilitation programs in upper limbs.

Exclusion criteria:

1. Having previous injury, disease, or contracture in the involved upper extremity 2. Having severe shoulder pain. 3. No sitting balance 4. Having any comorbid neurological disease or conditions such as Multiple Sclerosis, Parkinson Disease, Spinal Cord Injury, Traumatic Brain Injuries, Brain Tumor, Epilepsy or Dementia. 5. Having unilateral neglect.

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is an experimental and double-blind clinical trial. After finding patients as cases in hand or simple non probable which have inclusion criteria people as absolute random will be divided into three groups using random sealed envelopes. They will be selected randomly by a person who is unaware of the groups. Random blocks (permuted block randomization) with four blocks will be used for randomization. According to the sample size of 24, six blocks will be generated using the online site (www.sealedenvelope.com). For concealment in the randomization process, unique code will be used on each envelope with the type of training specified inside.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants are blind (each 3 groups will be receive common task oriented exercises). Assessor who evaluates outcome measures is blind to the groups and kind of treatment. Additionally, data analyzer will be unaware of intervention type and assessments.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmmat Expressway, Tehran, Iran

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1449614535

Approval date

2020-02-29, 1398/12/10

Ethics committee reference number

IR.IUMS.REC.1398.1276

Health conditions studied**1****Description of health condition studied**

stroke

ICD-10 code

G81.1

ICD-10 code description

Spastic hemiplegia

Primary outcomes**1****Description**

Motor function in the "Wolf Motor Function Test" and the "Fugl Meyer Assessment"

Timepoint

before intervention, in the middle (6th session) and post intervention (12th session)

Method of measurement

"Wolf Motor Function Test" and "Fugl Meyer Assessment"

Secondary outcomes**1****Description**

" dependency in activity of daily living

Timepoint

before intervention, middle (six sessions post intervention) and post intervention (12th session)

Method of measurement

The "Barthel Index"

2**Description**

Grip Strength in force tester

Timepoint

before intervention, middle (six sessions post intervention) and post intervention (12th session)

Method of measurement

"Force Tester"

Intervention groups**1****Description**

Intervention group1: Participants will receive 30 minute "task oriented training" and 30 minute "Brunstrom training" for 12 sessions (3 session per week). Under supervision of a therapist. patients will receive 14 task oriented activity and 7 Brunstrom training. Each exercise depending on the conditions, will repeat 10- 20 times and will take 2-5 minutes. Required equipment consist of ball, towel, pitcher and mug, shopping bag, button and soda can.

Category

Rehabilitation

2**Description**

Intervention group2: Participants will receive 30 minute "task oriented training" and 30 minute "Bobath training" for 12 sessions (3 session per week). Under supervision of a therapist, patients will receive 14 task oriented activity and 7 Bobath training. Each exercise depending on the conditions will repeat 10-20 times and will take 2-5 minutes. Required equipment consist of ball and mat and bed.

Category

Rehabilitation

3**Description**

Control group: Participants will receive 60 minute "task oriented training" for 12 sessions (3 session per week). Under supervision of a therapist, patients will receive 14

task oriented activity. Each exercise depending on the conditions will repeat 10-20 times and will take 2-5 minutes. Required equipments consist of ball, towel, pitch and mug, shopping bag, button and soda can.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neurological Physiotherapy Clinic, School of Rehabilitation Sciences, Iran University of Medical Sci

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice Cancellor for Research of Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Shohreh Noorizadeh Dehkordi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available