

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Brunstrom 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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##### Email address

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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](http://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

**City**

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**Province**

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**Postal code**

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**

Shohreh Noorizadeh Dehkordi

**Street address**

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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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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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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