Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 recieve 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 recieve 14 task oriented activity and 7 Bobath training. Each execise depending on the conditions will repeat 10-20 times and will take 2-5 minutes. Required equipment consisit 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 recieve 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
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Sponsors / Funding sources

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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

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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