Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Study of the effect of prediction of fatigue in formation Bilateral Upper Extremity Training on the function of upper extremity, activity of daily living and participation in chronic stroke patients

Protocol summary

Study aim
Prediction of fatigue in Bilateral Upper Extremity Training on the function of upper extremity, activity of daily living and participation in chronic stroke patients

Design
Randomised control trial, double blind

Settings and conduct
This is a randomized clinical trial study.sampling from neurology outpatient clinics is conducted. Then the eligible participant fill out form of willingness, they will randomly be assigned to groups (intervention, control).This is a double blind study.The examiner and all of the participant are blind

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Having only one experience of stroke 2- Having an injury to the middle cerebral artery 3-Not having unilateral neglect 4-The level of upper extremity function according to Brunstrum ≥3 5- level to MMSE ≥21 6- Beck Depression Inventory <31 7- no history of other neurological or orthopedic conditions Exclusion criteria: 1- Noting Have chronic fatigue 2. Patients who are at an acute stage of stroke 3. Noting Have chronic depression.

Intervention groups
The control group): for an hour and a half of rehabilitation treatment routine includes stretching exercises, range of motion, activities of daily living, as well as exercises in the brunstrum approach and the PNF, 2) intervention group no prediction of fatigue: in this group of patients to the routine exercises for 30 minutes Routine occupational therapy treatment and bilateral upper extremity exercises an hour doing on the fly each time that the patient will feel tired to change exercise type.3) intervention group with the prediction of fatigue: in this group of patients to the routine occupational therapy exercises for 30 minutes and one hour bilateral upper extremity exercises with the use of kinect

Main outcome variables
Function of upper extremity, Activity of daily living,.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140416017301N6**
Registration date: **2019-04-20, 1398/01/31**
Registration timing: **prospective**

Last update: **2019-04-20, 1398/01/31**
Update count: **0**

Registration date
2019-04-20, 1398/01/31

Registrant information

Name
Akram Azad

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-11-21, 1398/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of prediction of fatigue in formation Bilateral Upper Extremity Training on the function of upper extremity, activity of daily living and participation in chronic stroke patients

Public title
The effect of prediction of fatigue in formation motor training on the function of upper extremity, activity of daily living and participation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
En Major inclusion criteria:1- Having only one experience of stroke (at least 6 months-5years ago) 2- Having an injury to the middle cerebral artery 3-Not having unilateral neglect 4-The level of upper extremity function according to Brunstrum ≥3 5-Ability of cognitive level according to MMSE ≥21 6- Diagnosis of depression according to Beck Depression Inventory <31 7- no history of other neurological or orthopedic conditions
Exclusion criteria:
1-Patients with stroke have chronic fatigue 2. Patients who are at an acute stage of stroke 3. Stroke patients who have symptoms of chronic depression.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **20**
Samples were selected from among people with chronic stroke referring to rehabilitation centers in Tehran. After selecting samples according to entry criteria, the samples were randomly blocked and placed in three groups receiving two-way motor exercises with fatigue prediction and control group
Randomization (investigator's opinion)
Randomized
Randomization description
The type of study in this study is an experimental and randomized clinical trial. In the first instance, the samples are selected according to the criteria of entry and then randomly blocked in the three groups receiving upper extremity training with prediction of fatigue and without fatigue prediction and control group And each group will be evaluated in terms of upper limb function and participation in everyday activities before and after exercises.
Blinding (investigator's opinion)
Double blinded
Blinding description
The examiner is blind and all of the participant are blind too.
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
School of Rehabilition,Shahnazari Ave., Moder Square,. Mirdamad Blvd
City
Tehran
Province
Tehran
Postal code
1545913187
Approval date
2018-09-17, 1397/06/26
Ethics committee reference number
IR.IUMS.REC.1397.317

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
164
ICD-10 code description
Stroke, not specified as hemorrhage or infarction

Primary outcomes

1

Description
Function of upper extremity
Timepoint
Before, after and 3 month after intervention
Method of measurement
Box-Block Test, Purde-Peg Board Test, wolf motor function test, Fugle meyer upper extremity assesment, Shouder Position Sense Test, Elbow Position Sense Test

2

Description
Activity of daily living
Timepoint
Before, after and 3 month after intervention
Method of measurement
Shah Barthel Index

3

Description
Participation
Timepoint
Before, after and 3 month after intervention
Method of measurement
Canadian Occupational Performance Measure

Secondary outcomes

empty

Intervention groups

1

Description
intervention group no prediction of fatigue: in this group of patients to the routine exercises for 30 minutes Routine occupational therapy treatment and bilateral upper extremity exercises an hour doing on the fly each time that the patient will feel tired to change exercise type.
Category
Rehabilitation

2

Description
Intervention group: intervention group with the prediction of fatigue: in this group of patients to the routine occupational therapy exercises for 30 minutes and one hour bilateral upper extremity exercises with the use of kinect
Category
Rehabilitation

3

Description
The control group: for an hour and a half of rehabilitation treatment routine includes stretching exercises, range of motion , activities of daily living , as well as exercises in the brunstrum approach and the PNF
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
School of rehabiltion clinic, Firoozgar hospital, Shafa-Yahyaian hospital
Full name of responsible person
Akram Azad
Street address
Shahnazari Ave., Moder Square,. Mirdamad Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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School of Rehabilitation, Shahnazari St., Mirdamad Blv., Tehran, Iran
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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-Chancellor of Research
Proportion provided by this source
30
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
Akram Azad
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Occupational Therapy
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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
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
Title and more details about the data/document
Give code to each participant
When the data will become available and for how long
At least one year after the completion of the design and publication of the related article
To whom data/document is available
Research group
Under which criteria data/document could be used
Just by giving code
From where data/document is obtainable
Rehabilitation Center
What processes are involved for a request to access data/document
Not decided
Comments