Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The investigation of the effect of fatigue's prediction during unilateral upper extremity exercises on upper extremity function, activities of daily living and participation in chronic stroke patients

Protocol summary

Study aim
The effect of fatigue prediction in the form of unilateral upper limb movement exercises on upper limb function, daily activities of life and participation of people with chronic stroke

Design
Randomised control trial with control group, 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: - Having only one experience of stroke, - Having an injury to the middle cerebral artery, -Not having unilateral neglect, -The level of upper extremity function according to Brunstrum ≥3, - level to MMSE ≥21, - Beck Depression Inventory <31, - no history of other neurological or orthopedic conditions. Exclusion criteria: - Noting Have chronic fatigue, Patients who are at an acute stage of stroke, -Noting Have chronic depression

Intervention groups
1) 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 , Participation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140416017301N7**
Registration date: **2019-06-13, 1398/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-13, 1398/03/23**
Update count: **0**

Registration date
2019-06-13, 1398/03/23

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
2019-12-21, 1398/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The investigation of the effect of fatigue's prediction during unilateral upper extremity exercises on upper extremity function, activities of daily living and participation in chronic stroke patients

Public title
The investigation of the effect of fatigue's prediction during unilateral upper extremity exercises on upper extremity function, activities of daily living and participation in chronic stroke patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Occurrence of the first stroke Damage of middle artery cerebral according to physician report in MRI Between 6 months to 5 years interval from onset of stroke Not having unilateral neglect (Star Cancellation Test more than 44) In the terms of brunstroms motor recovery stages, patients should be at least in the 5 stage of arm and 4 in the hand. In the terms of cognitive function to get Mini Mental Status Examination (MMSE) more than 21 In the terms of depression to get Beck Depression Inventory (BDI) under 31 Has not report any other problem like orthopedic, neurological or rheumatology that to be again limitation in upper extermity
Exclusion criteria:
Recurrence of stroke in the implementation of the plan Unwillingness of patients to continue the design process at any time from the stage of work The occurrence of other problems, including orthopedic, rheumatology or neurological affecting the function of upper extremities during the implementation of the plan
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 will be selected from chronic stroke patients referring to rehabilitation centers in Tehran. According to inclusion criteria, the samples will be randomly blocked and assigned in three groups (receiving uni-lateral motor exercises with/ without fatigue's prediction and control group).
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is a simple inaccurate (accessible) type. According to inclusion criteria, the samples will be randomly blocked in three groups (receiving uni-lateral motor exercises with/ without fatigue's prediction and control group). In this way, eligible individuals and volunteers to participate in the study will be placed in the three groups using the bald throwing method
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.1397.653

Health conditions studied

1

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

Primary outcomes

1

Description

Function of Upper Extremity

Timepoint

Before, after and 3 month after intervention

Method of measurement

Box-Block Test (BBT), Purde-Pegboard Test (PPT), Wolf Motor Function Test (WMFT), Fugle-Meyer Upper Extremity Assessment (FMA-UE), Shoulder Position Sense Test (SPST), Elbow Position Sense Test (EPST)

2

Description

Activity of Daily Living (ADL)

Timepoint

before, after and 3 month after intervention

Method of measurement

Shah Barthel Index (Shah BI)

3

Description

Participation

Timepoint

before, after and 3 month after intervention

Method of measurement

Canadian Occupational Performance Measure (COPM)

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 unilateral 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 unilateral 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 rehabilitation clinic, Firoozgar hospital, Shafa-Yahyaian hospital

Full name of responsible person

Akram Azad

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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?

Yes

Title of funding source

Iran University of Medical Sciences

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
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Position
Assistant Professor

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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
Not applicable

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
En Just by giving code

From where data/document is obtainable
Research group

What processes are involved for a request to access data/document
Not decided

Comments