

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 Rehabilitation,Shahnazari Ave., Moder Square,. Mirdamad Blvd

City

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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 rehabilitation clinic, Firoozgar hospital, Shafa-Yahyaian hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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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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