

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 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  $\geq 3$ , - level to MMSE  $\geq 21$ , - 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)

##### Phone

+98 21 2226 2450

##### Email address

azad.a@iums.ac.ir

##### 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 extremity

**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 Rehabilitation, 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

##### Street address

Shahnazari Ave., Moder Square, Mirdamad Blvd

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##### Province

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##### Postal code

1545913187

##### Phone

+98 21 2222 8051

##### Email

azad.a@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Akram Azad

##### Street address

School of Rehabilitation, Shahnazari St., Mirdamad Blv., Tehran, Iran

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##### Postal code

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##### Email

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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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**Contact**

**Name of organization / entity**

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**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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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**