

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of exercise therapy on the balance of patients after the acute phase of stroke through Telerehabilitation

#### Protocol summary

##### Study aim

The effect of exercise therapy on the balance of patients after the acute phase of stroke through remote rehabilitation with a group of patients receiving rehabilitation treatment without the therapist's supervision; Be compared.

##### Design

This study is a randomized clinical trial with parallel groups; The study population was 30 patients referred to Firoozgar and rasoul akram Physical Medicine and Rehabilitation Clinic.

##### Settings and conduct

30 patients referred to the physical medicine and rehabilitation wards of Rasoul Akram and Firoozgar hospitals who have passed the acute phase after stroke and are eligible for the study are randomly divided into two groups of 15 patients. And in a group of patients in the first session of the visit receive a training pamphlet of exercise exercises. Patient evaluation is done at the beginning of the study and at the end of the intervention and after one month and three months after the end of the sessions.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ischemic or hemorrhagic stroke who have hemiplegia and at least one month has passed since the stroke. Balance and gait of the injured patient and exclusion criteria: bilateral paralysis; Imbalance due to injury to the cerebellum or brainstem; Proprioception impairment of vestibular dysfunction; Neurological diseases other than stroke such as neuropathy and any underlying disease that prevents activity

##### Intervention groups

In the experimental group: they receive an educational video of sports exercises through a virtual communication network and then perform the exercises under the therapist's supervision via video call. Control group: Patients in the first session of the visit received a training pamphlet of sports exercises and they are asked

to do the exercises at home.

##### Main outcome variables

Berg Balance Scale-time up and go-falls efficacy scale

#### General information

##### Reason for update

I made a mistake in entering the start date of sampling. I want to replace it and confirm the actual sampling date.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201204049596N1**

Registration date: **2020-12-25, 1399/10/05**

Registration timing: **prospective**

Last update: **2022-06-05, 1401/03/15**

Update count: **1**

##### Registration date

2020-12-25, 1399/10/05

##### Registrant information

###### Name

Arezoo Attari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8893 3835

###### Email address

attari.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-04, 1399/10/15

##### Expected recruitment end date

2022-02-28, 1400/12/09

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of exercise therapy on the balance of patients after the acute phase of stroke through Telerehabilitation

**Public title**  
The effect of exercise therapy on the balance of patients after the acute phase of stroke through Telerehabilitation

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with ischemic or hemorrhagic stroke who have hemiplegia. Evidence of brain damage by MRI or CTscan At least one month has passed since the stroke. Ability to execute a 3-step command Impaired balance and gait of the patient Be able to walk with or without support: and be in FAC II - IV. High-speed Internet access and telephony programs The presence of a knowledgeable family member next to the patient in all exercise sessions and distance conversation  
**Exclusion criteria:**  
Bilateral paralysis Injury to the cerebellum or brain stem Proprioception injury Unilateral hemianopsy / forgetfulness or any other visual impairment Vestibular dysfunction Neurological diseases other than stroke such as neuropathy Severe postural instability Orthopedic problems Significant cognitive problems Perceptual aphasia Underlying diseases that prevent exercise, such as cardiovascular disease

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization method: block Randomization unit: individual Randomization tool: Random number table

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**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 Medicine, Iran University of Medical Sciences, Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614555

##### Approval date

2020-10-23, 1399/08/02

##### Ethics committee reference number

IR.IUMS.FMD.REC.1399.434

## Health conditions studied

### 1

#### Description of health condition studied

Ataxia following cerebral infarction

#### ICD-10 code

I69.393

#### ICD-10 code description

Ataxia following cerebral infarction

## Primary outcomes

### 1

#### Description

BERG balance scale

#### Timepoint

Before the intervention - after the end of the intervention  
- one month and three months after the end of the sessions

#### Method of measurement

BERG balance scale questionnaire

### 2

#### Description

Timed up and Go test

#### Timepoint

Before the intervention - after the end of the intervention  
- one month and three months after the end of the sessions

#### Method of measurement

Stopwatch

### 3

#### Description

Fall efficiency scale

#### Timepoint

Before the intervention - after the end of the intervention  
- one month and three months after the end of the sessions

#### **Method of measurement**

Persian questionnaire of falling efficiency scale

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: The educational video of the exercise program for the patient is sent in the first absentee communication and through the virtual network. It should be used in the treatment sessions. And the therapist ensures the proper implementation of exercise programs.

##### **Category**

Rehabilitation

#### **2**

##### **Description**

Control group: In the first session of the visit, an educational pamphlet is provided to the patient and the patient is taught how to perform the exercises correctly in the same session. The patient is asked to perform the exercises according to the above program.

##### **Category**

Rehabilitation

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Department of Physical Medicine and Rehabilitation,  
Firoozgar hospital, Tehran

###### **Full name of responsible person**

Ghulam Reza Raisi

###### **Street address**

Firoozgar Hospital, Be Afarin Street, Vali Asr Square.

###### **City**

Tehran

###### **Province**

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###### **Postal code**

1593749999

###### **Phone**

+98 21 8214 1229

###### **Email**

attari.a@iums.ac.ir

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Iran University of Medical Sciences

###### **Full name of responsible person**

Dr. Seyed Abbas Motavlian

###### **Street address**

5th floor, Headquarters, Iran University of Medical Sciences, Shahid Hemmat Highway

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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**

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**

##### **Contact**

###### **Name of organization / entity**

Iran University of Medical Sciences

###### **Full name of responsible person**

Simin Sajjadi

###### **Position**

Assistant Professor

###### **Latest degree**

Specialist

###### **Other areas of specialty/work**

Physical Medicine

###### **Street address**

Department of Physical Medicine and Rehabilitation,  
Firoozgar Hospital, Vali Asr Square

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###### **Province**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Full name of responsible person**  
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**Latest degree**  
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**Street address**  
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**City**  
Tehran

**Province**  
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**Email**  
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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

All the patients data can potentially be shared with privacy in regard to patients name

### When the data will become available and for how long

Access period starts 6 months after the results are published

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

The use of documents is allowed only by mentioning the source

### From where data/document is obtainable

Simin Sajjadi -Department of Physical Medicine and Rehabilitation, Firuzgar Hospital, Valiasr Square  
attari.a@iums.ac.ir -00982182141229

### What processes are involved for a request to access data/document

First, the identity of the person is verified, then the data is provided to the person

### Comments