

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 hemianops / 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

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1593749999

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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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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