Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A Comparative Study of the Effect of Reactive and Proactive Exercises on Balance Performance and Confidence in Balance in Stroke Patients: A Randomized Clinical Trial

Protocol summary

Study aim
Comparative study of the effect of reactive and proactive exercises on balance and confidence in the balance of patients with stroke

Design
In this double-blind trial study, 33 people were randomly assigned to control and experimental groups.

Settings and conduct
This study is performed in the physiotherapy ward of Kashani Hospital in Isfahan on patients with stroke.

Participants/Inclusion and exclusion criteria
Patients (male or female) with the first history of unilateral stroke who do not have other neurological disorders and should be referred by a neurologist.

Intervention groups
All patients receive conventional evidence-based treatment for stroke rehabilitation. The control group performs only conventional therapy and the two intervention groups, depending on the type of group, perform special balance exercises (reactive and proactive) in addition to conventional therapy.

Main outcome variables
Evaluations include assessing the degree of balance and confidence in balance in patients with stroke.The number of patient falls per week is also recorded.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200101045970N1**
Registration date: **2020-08-18, 1399/05/28**
Registration timing: **prospective**

Last update: **2020-08-18, 1399/05/28**
Update count: **0**

Registration date
2020-08-18, 1399/05/28

Registrant information

Name
Ehsan Ghasemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-25, 1399/06/04

Expected recruitment end date
2021-02-22, 1399/12/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Comparative Study of the Effect of Reactive and Proactive Exercises on Balance Performance and Confidence in Balance in Stroke Patients: A Randomized Clinical Trial

Public title
The effect of exercise therapy on balance in patients with stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. A history of the first unilateral stroke proven by a neurologist with CT scan or MRI. 2. At least 6 months have passed since the onset of stroke symptoms. 3. Existence of appropriate cognitive status in order to understand simple verbal commands and follow them) According to the Persian version Mini-mental status examination ≥ 24. 4.Ability to stand and walk independently without an aid 5. Having spasticity in gastrocnemius muscle ≥1 based on Modified Modified Ashworth Scale (MMAS≥1) 6. Having a minimum age of 18 and a maximum of 85 years

Exclusion criteria:

1. The presence of other neurological disorders such as Parkinson's, diabetes,... 2. Existence of severe visual, profound and vestibular disorders 3. Existence of severe orthopedic disorders such as fixed contractures in the lower extremities 4. Severe pain in the lower extremities: According to the VAS scale, pain between 75 and 100 mm 5. Participate in other physiotherapy treatment interventions 6. Taking drugs that affect balance function (tone, sensory system and muscle strength). 7. Having a weight of more than 150 kg and a height of more than 2.1 meters

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, due to the small number of samples, it was done in consultation with a statistician decided to use random blocking method. Blocking is usually done to balance the number of samples assigned to each groups. Statistical specialist using a statistical software of 10 blocks of 3 members according that we had 3 groups, they designed. The person who divides patients according to this table is unaware of groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients are blind to the type of treatment. Also, the evaluator that collects information is blind to the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib St., Isfahan University of Medical Sciences, Faculty of Rehabilitation

City

Isfahan

Province

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Postal code

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Approval date

2020-07-25, 1399/05/04

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.224

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Balance

Timepoint

Before study, after study, two months after study

Method of measurement

Mini BES Test

2

Description

Balance Confidence

Timepoint

Before study, after study, two months after study

Method of measurement

The Activities-specific Balance Confidence (ABC) Scale

Secondary outcomes

1

Description

Functional Mobility

Timepoint

Before study, after study, two months after study

Method of measurement

Timed Up and Go Test

2

Description

Number of falls per week

Timepoint

Before study, after study, two months after study

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Reactive + Conventional

Category

Rehabilitation

2

Description

Intervention group: proactive + Conventional

Category

Rehabilitation

3

Description

Control group: Conventional

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Ehsan Ghasemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ehsan Ghasemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to non-plagiarism

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The study protocol and the informed consent form can be submitted as a proposal. A clinical study report can also be provided upon completion of the work.

When the data will become available and for how long

. The proposal is available in the fall and winter of 1399. Access to clinical results is also possible in the summer of 1400.

To whom data/document is available

People working in academic and scientific institutions can access the documents.

Under which criteria data/document could be used

It can only be used to raise awareness and raise scientific literacy.

From where data/document is obtainable

People can correspond by email eghasemi@rehab.mui.ac.ir.

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

After correspondence with the announced email, your request will be reviewed and answered immediately.

Comments