

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The Effect of Biofeedback on the Quality of life and self-efficacy in Rehabilitation of Stroke Patients

Protocol summary

Study aim

The purpose of this study was to investigate the effect of biofeedback on the Quality of life and self-efficacy of stroke patients

Design

In this study, 60 stroke patients with a Inclusion criteria are referred to the physiotherapy department are selected. The participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct

This study included all patients with stroke who attended the physiotherapy center of Imam Raza Hospital in Mashhad, Iran. The participants were randomly divided into two groups based on block randomization (case and control) after screening based on the inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patients with stroke for first time according to computed tomography (CT) scan and magnetic resonance imaging (MRI); the length of disease more than 3 months and lower than 3 years; age of stroke patients was 18-65 years; ability to walking for 10 meters with or without assist devices; hemiplegia and without any cognitivedisorders Exclusion criteria:Unwilling to Participate in the Study; Absent for 3 Sessions in Biofeedback Exercise

Intervention groups

In the Intervention Group, Biofeedback (20-min sessions, twice weekly, for 8 weeks) was performed

Main outcome variables

Improving Quality of Life and Self-Efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171023036970N1**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

zohre najafi

Name of organization / entity

shahid beheshti university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 915 381 9224

Email address

zohrenajafi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2006-03-20, 1384/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Biofeedback on the Quality of life and self-efficacy in Rehabilitation of Stroke Patients

Public title

The Effect of Biofeedback on Stroke Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The Patients With Stroke For The First Time Age of Stroke Patients Was 18-65 Years Hemiplegia Without Any Cognitive Disorders

Exclusion criteria:

Unwilling to Participate in the Study Absent for 3 Sessions in Biofeedback Exercise

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were randomly divided into two groups based on block randomization (case and control) after screening based on the inclusion and exclusion criteria.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and their caregivers (family) were unaware of intervention. The completion of questionnaires in the control and intervention group was done by researcher and researcher's assistance separately.

Placebo

Not used

Assignment

Parallel

Other design features

randomized clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad- daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MUMS.REC.1395.191

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Quality of Life

Timepoint

8 Weeks

Method of measurement

Quality of Life Questionnaire

Secondary outcomes

1

Description

Self-Efficacy

Timepoint

8 weeks

Method of measurement

Questionnaire

2

Description

Quality of Life

Timepoint

8 weeks

Method of measurement

Questionnaire

Intervention groups

1

Description

In the intervention group, biofeedback exercises are performed twice a week for 8 weeks each session for 20 minutes at the physiotherapy center of Imam Reza Hospital.

Category

Rehabilitation

2

Description

In the control group, conventional physical therapy is performed twice a week for 8 weeks each session for 20 minutes in the physiotherapy center of Imam Reza Hospital.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Raza Hospital

Full name of responsible person

zohre najafi

Street address

Imam Reza Hospital Square - Imam Reza Hospital (AS)

City

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Postal code

9137913316

Phone

+98 51 3841 3007

Email

vcresearch@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Ebne Sina Street

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Province

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Email

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Web page address

Grant name

zahra sadat manzari

Grant code / Reference number

940947

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Sadat Manzari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Medical Surgical Nursing Department, Nursing and Midwifery school

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data is published in the form of original results.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Medical Education Faculty

Under which criteria data/document could be used

Data and analysis of the main variables

From where data/document is obtainable

Email

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

Data is available to applicants after 1 month.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zohre Najafi

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Nursery

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