Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 sience

Country
Iran (Islamic Republic of)

Phone
+98 915 381 9224

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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
Mashhad

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Razavi Khorasan

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9137913316

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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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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

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Person responsible for updating data

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Full name of responsible person
Zohre Najafi
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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