

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Assessing the effect of the Otago exercise program on quality of life of stroke patients.

Protocol summary

Study aim

Determining the effect of the Otago exercise program on the quality of life of stroke patients.

Design

A clinical trial with a control group, with parallel groups without blinding, randomized on 60 patients.

Settings and conduct

The research population is all the admitted stroke patients to Vali-Asr-Arak Hospital. The participating patients are placed in two control and test groups by random method. The demographic information questionnaire and the stroke impact scale (SIS) questionnaire are filled by the control and test group patients at the beginning of the research. Then, the patients from the intervention group will receive the Otago exercise program in addition to taking the usual care. Moreover, the patients of the control group will only take the usual care after the stroke. The (SIS) questionnaire will be filled by the patients of the test and control groups 1 and 3 months after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion and exclusion criteria: Diagnosis of stroke by a neurologist, Passing less than 2 weeks after the patient's stroke, Being older than 60 years old, Getting a score 7 and higher in Abbreviated Mental Test (AMT), Getting the score of 3 and less in Modified Rankin Scale in the stroke, Having the companion, Not having chronic renal failure, Not suffering from chronic diseases, Not Having musculoskeletal problems in the lower organs, Access to cell phone and EITAA application.

Intervention groups

The control group will take the usual care after the stroke. Moreover, the patients of the test group will take the Otago exercise program in addition to the usual care after the strokes, and will execute it for 8 weeks and 3 times a week.

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221027056319N1**

Registration date: **2023-02-12, 1401/11/23**

Registration timing: **prospective**

Last update: **2023-02-12, 1401/11/23**

Update count: **0**

Registration date

2023-02-12, 1401/11/23

Registrant information

Name

Sajad Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-10, 1401/12/19

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of the Otago exercise program on quality of life of stroke patients.

Public title

Effect of Otago exercise program on stroke

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of stroke by a neurologist
Passing less than 2 weeks after the patient's stroke
Being older than 60 years
Getting a score 7 and higher in Abbreviated Mental Test (AMT)
Getting the score of 3 and less in Modified Rankin Scale (MRS) in the stroke
Having the companion Access to cell phone and EITAA application (by the patient or the companion) to contact and remember the exercises.

Exclusion criteria:

Having an experience of stroke in the past
Having neurological disorders (dementia, Alzheimer's, Parkinson's, amyotrophic lateral sclerosis)
Having musculoskeletal problems in the lower organs such as significant muscular weakness as severe joint osteoarthritis and pelvic bone fracture complications
Having chronic renal failure
Heart complication (congestive heart failure) and lung disorder.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, the block randomization method will be used. The randomization unit was personal in this research, and afflicted patients to stroke had inclusion criteria to the research based on the file number, and people's intention to participate in this research was convenience non-random. Then, they were attributed to groups A and B by the block randomization method (quadruple block). In this research, 6 various modes can be imagined based on having a quadruple volume of blocks which include AABB, ABAB, ABBA BBAA, BABA, and BAAB. The various modes of blocks will be written on cardboard cards of the same size and color. According to the sample volume (60 patients) and 6 modes for blocks, ten cards were selected randomly with the re-substitution and indicated the order of blocks and order of patients in group A (control) and group B (intervention).

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 Arak University of Medical Sciences

Street address

Management of Research and Medical Information, Deputy of Research and Technology, University Complex of the Prophet (pbuh), Basij Square

City

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Province

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Approval date

2022-12-10, 1401/09/19

Ethics committee reference number

IR.ARAKMU.REC.1401.275

Health conditions studied**1****Description of health condition studied**

patients with stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes**1****Description**

Quality of life

Timepoint

Measuring the quality of life at the baseline (before the start of the intervention) and 1 and 3 months after the end of the intervention.

Method of measurement

Stroke Impact Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Description of intervention: the test group will receive the educational intervention including the Otago exercise program in person and 5-member groups by gender separation with the companion's participation in 3 sessions. The educational program will be executed for all groups by the researcher and based on the published booklet by Otago University with the supervision of a physiotherapist. In addition, an illustrated book containing transparent instructions and an educational video about how to perform the exercises are given to the patients to fix the presented information and to have more accurate performance. The exercise level is determined based on the patient's condition by the physiotherapist. Then, an exercise schedule will be given to the patients, and they will be asked to do and record the rigid exercises three times a week for 30- 40 min at home under the supervision. Moreover, the 15-minute walking program is given to the patient 2 times a week. The researcher will contact the patients at the end of each week to follow up on these exercises. Furthermore, the phone number of the researcher is given to the patients to call whenever they have a problem with their exercises, how to do them, or the level of exercises. Generally, this exercise program includes walking, turning the head to the sides, bending the body back, turning the body to the sides, moving the ankle up and down, straightening the knee (with weights), bending the knee, opening legs from the sides, standing on the toes, standing on the heels, bending the knees, walking on the toes, walking on the heels, putting the feet together, walking backward, standing on one leg, walking sideways, walking backward, getting up and sitting down from a chair, walking and turning, going up and down stairs, and stretching the muscles of the back of the leg and thigh. In addition to strength exercises, weights of 0.5-2 kg will be given to the patients based on their ability and the diagnosis of the physiotherapist. The patients were asked to make a video of their performed exercises each week to increase the assurance of doing the exercises accurately and sending it by EITA software. The exercise duration will be 8 weeks. The test groups will receive the usual care after the stroke in addition to the Otago exercise program.

Category

Rehabilitation

2

Description

Control group :The control group will receive the usual care after the stroke in all research period. In addition, the Otago exercise program will be given to the control group at the end of research for the ethical considerations.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Vali-asr

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Sajad Salehi

Position

Nursing master student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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