

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effects of a dual-task exercise course with and without ankle-foot orthosis on walking retraining in stroke patients

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Investigating the effect of using a dual training course with and without AFO on walking rehabilitation in stroke patients.

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

Registration date

2023-07-29, 1402/05/07

Design

A randomized control trial with a control group, parallel, is performed on 32 patients. randomization method: random number table

Registrant information

Name

Negin Mizangir

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Settings and conduct

The type of study is a open-label randomized controlled clinical trial. Therapeutic interventions for each group will be carried out in 3 weeks. The sampling location is only one rehabilitation center.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Criteria for entering the study: All participants are stroke patients, at least six months and at most one year have passed since their stroke. Hearing and vision are healthy The degree of spasticity of the gastrosoleus muscle should be less than 2 according to the Ashworth scale. Exclusion criteria: People with very poor balance Inability to perform the cognitive task used in the dual walking task Severe cognitive deficits

Expected recruitment start date

2023-07-11, 1402/04/20

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Patients in the study group will receive dual exercises while wearing the orthosis, and patients in the control group will receive dual exercises alone. Dual walking exercises for stroke patients include dual cognitive-motor and movement exercises.

Main outcome variables

Spatio-temporal parameters, and kinetic and kinematic parameters of hip, knee and ankle joints

Scientific title

Effects of a dual-task exercise course with and without ankle-foot orthosis on walking retraining in stroke patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220806055629N1**

Registration date: **2023-07-29, 1402/05/07**

Public title

Effects of a dual-task exercise course with and without ankle-foot orthosis on walking retraining in stroke

patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All participants are stroke patients that at least six months and at most one year have passed since their stroke. Having normal/healthy Hearing and vision
 Absence of neurological disorders and pain while walking
 Be able to follow verbal instructions and provide verbal responses to questions
 No previous history of using any type of orthosis
 The degree of spasticity of the gastrosoleus muscle should be less than 2 according to the Ashworth scale
 Having the ability to walk independently for at least 12 meters with or without the use of an aid such as a cane or a walker
 Needing to gait training under the supervision of a physiotherapist
Exclusion criteria:
 History of balance deficits unrelated to stroke
 Individuals with very poor balance
 Inability to perform the cognitive task used in the dual walking task
 Severe cognitive deficits
 Any complex medical history that could interfere with the intervention such as pulmonary problems or Orthopedic disorders

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method is used to assign the participants to two groups of sixteen. In the block randomization method, we create blocks of four and randomly select a block of four for each four people. The block modes of four are as follows: AABB, ABAB, ABBA, BAAB, BABA, BBAA. We randomly choose one of the six quadruple block modes. For example, if the first mode is AABB, the first and second players are in group A, and the third and fourth players are in group B. We put them in the envelope and number each one from 1 to 32.

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

Research Ethic Committees of Vice Chancellor in Research Affairs Shahid Beheshti University of Medic

Street address

Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2022-07-24, 1401/05/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.200

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I60-I69

ICD-10 code description

Cerebrovascular diseases

Primary outcomes

1

Description

Walking speed

Timepoint

At the beginning of the study and after three weeks of intervention

Method of measurement

3D analysis motion system

Secondary outcomes

1

Description

Kinematic parameters of ankle, knee and hip joints

Timepoint

At the beginning of the study and after three weeks of intervention

Method of measurement

3D analysis motion system

2

Description

Kinetic parameters of ankle, knee and hip joints

Timepoint

At the beginning of the study and after three weeks

Method of measurement

3D analysis motion system and force plate

Intervention groups**1****Description**

Intervention group: performing dual-task exercises along with wearing ankle-foot orthosis. Patients receive therapeutic interventions for two weeks and 5 sessions per week. Dual-task exercises are performed for 30 minutes and 5 times a week, with 3-4 repetitions each time.

Category

Rehabilitation

2**Description**

Control group: only performing dual-task exercises. Patients receive therapeutic interventions for two weeks and 5 sessions per week. Dual-task exercises are performed for 30 minutes and 5 times a week, with 3-4 repetitions each time.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Physiotherapy Clinic, Faculty of Rehabilitation,
University of Medical Sciences Shahid Beheshti

Full name of responsible person

Negin Mizangir

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School of Rehabilitation., Shahid Beheshti University
of Medical Sciences., Damavand St., Emam Hossein
Sq

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Negin Mizangir

Position

Master student of Shahid Beheshti

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Position

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Latest degree

Bachelor

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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

It is not possible to share all the data and only the demographic information of the participants and the results of the study evaluation variables are shared.

When the data will become available and for how long

The data access period starts 6 months after the publication of the article

To whom data/document is available

Working researchers and students in academic centers

Under which criteria data/document could be used

Other researchers as well as therapists in the field of medicine and rehabilitation can use this study after printing the article.

From where data/document is obtainable

Negin Mizangir

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

After requesting the documents, the person in charge of the research project must receive written permission from the university and send the documents after obtaining the permission. Therefore, the data will be sent approximately 6 months after the request.

Comments