Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of frontal plane-focused balance training on balance performance and falls in chronic stroke

Protocol summary

Study aim
To investigate the effect of frontal plane-focused balance training on balance performance and falls in chronic stroke

Design
A randomized, double blinded, parallel controlled group trial on 60 participants (30 post-stroke patients in each group) who randomized by block randomization.

Settings and conduct
Participants will be requited from all stroke clients who went to physiotherapy clinics in Mashhad. They will assess in the biomechanics laboratory of Paramedical college, Mashhad university of medical science, and will receive treatment in a private physiotherapy clinic. Participants will be randomly assigned to one of the groups: 1) “frontal plane-focused” balance training group (test) and 2) “traditional” balance training (control). Task-specific exercises, done with dual-tasks (motor & cognitive), will accomplish in 3 one-hour sessions per week for 8 weeks. Balance assessment will be done by a force platform to investigate center of pressure (COP) measures in both directions, and two “core outcome set”, and fall assessment will be record before, after intervention and after 6 months follow-up period.

Participants/Inclusion and exclusion criteria
1. The first ischemic or hemorrhagic cerebrovascular accident (CVA) 2. At least 6 months post stroke 4. Be able to stand and walk for 1 minute and stand semi-tandem independently 4.Not to suffer from any other diseases that affect balance except stroke 5. Not to suffer from sever cognitive disorder

Intervention groups
30 participant in the test group will do frontal plane focused balance exercises, while 30 participants in the control group will do traditional balance exercises.

Main outcome variables
center of pressure (COP) parameters; Berg balance scale score & Mini-Best score (clinical assessment);Activities-specific Balance Confidence (ABC) score; cognitive performance score, motor performance score; fall history

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220703055350N1**
Registration date: **2022-10-04, 1401/07/12**
Registration timing: **prospective**

Last update: **2022-10-04, 1401/07/12**
Update count: **0**

Registration date
2022-10-04, 1401/07/12

Registrant information

Name
Mitra Parsa

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3876 5444

Email address
mitra.parsaa@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-17, 1401/07/25

Expected recruitment end date
2023-08-16, 1402/05/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of frontal plane-focused balance training on balance performance and falls in chronic stroke

Public title
The effect of lateral balance training on falls in stroke

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
First ischemic or hemorrhagic stroke attack At least 6 months post stroke Only half of body was involved Be able to stand and walk for 1 minute and stand semi-tandem independently Have stable condition and not to suffer from any other diseases that affect balance Get 24 score or more in Mini-Mental State Examination (MMSE) Get standard deviation less than ±1 in Line Bisection test (not to suffer from hemineglect) have the score 2 or less in Modified Ashworth Scale in Gastrosoleos muscle

Exclusion criteria:
Had a surgery on upper or lower extremity during last year Have contracture or deformity in lower limb Suffer from visual or auditory disorder Begin to take vitamin D at the same training time

Age
From **20 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The 4-volume random block allocation method will be used. All possible 4 permutations will be listed in two groups (permutations 1 to 6 are as follows) A is the intervention group and B is the control group. 1-AABB 2-ABAB 3-BAAB 4-BABA 5-BBAA 6-ABBA Then, from a random number table with a random starting point, 6 numbers between 1 and 6 will be randomly selected (either using software or randomaize.com). For example, if the 6 random numbers obtained are 3 5 4 3 4 6 , It will mean that the first four people similar to block 3, the second four people similar to block 5 and ... will be allocated.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be performed in a double-blind manner and the blinding includes the participants, the person who analyzes the data and the experimenters who perform the pre- and post-treatment and 6-month follow-up evaluation are blind to the group allocation. Furthermore, physiotherapists who perform training are blind to pre-test, post-test and follow-up results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of university of social welfare and rehabilitation

Street address
kodakyar Ave., daneshjo Blvd.,Evin

City
Tehran

Province
Tehran

Postal code
1985713834

Approval date
2019-11-25, 1398/09/04

Ethics committee reference number
IR.USWR.REC.1398.136

Health conditions studied

1

Description of health condition studied
stroke

ICD-10 code
G46

ICD-10 code description
Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description
center of pressure parameters (postural control or balance)

Timepoint
before training (pretest), after training (post test) and after 6 months follow-up

Method of measurement
force platform (Kistler)

2

Description
fall history (rate of falling [Rate ratio] and risk of falling

[Odds ratio])
Timepoint
from CVA incidence to beginning of training
Method of measurement
self-reporting

3

Description
Berg balance scale score
Timepoint
pre-test, post-test and after 6 months follow-up
Method of measurement
Berg balance scale

4

Description
Mini- Balance Evaluation Systems Test (Mini-BEST) score
Timepoint
pre-test, post-test and after 6 months follow-up
Method of measurement
Mini-Best

5

Description
Activities-specific Balance Confidence (ABC) test score
Timepoint
pre-test, post-test and after 6 months follow-up
Method of measurement
ABC test

6

Description
Falls risk for older people in the community (FROP-Com) screening tool score
Timepoint
pre-test, post-test and after 6 months follow-up
Method of measurement
FROP-Com screening tool test

Secondary outcomes

1

Description
motor task performance score
Timepoint
pre-test, post-test and after 6 months follow-up
Method of measurement
reversed average of acceleration absolute value (three directions) measured by an accelerometer attached to the tray

2

Description
cognitive task performance score
Timepoint
pre-test, post-test and after 6 months follow-up
Method of measurement
rate of correct words to total words in Stroop test

Intervention groups

1

Description
Intervention group: Frontal plane-focused balance training, including static and dynamic exercises focused on maintaining lateral balance. In the first 8 sessions single-task exercises will be accomplished. In the second 8 sessions motor dual task exercises will be done and in the third 8 sessions cognitive dual task exercises will be done.
Category
Rehabilitation

2

Description
Control group: Traditional balance training, including static and dynamic balance exercises focused on maintaining general and specially anterior- posterior balance. The same as intervention group, three 8-session therapeutic periods will be accomplished for the control group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Private physiotherapy clinics in Mashhad
Full name of responsible person
Mitra Parsa
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No.198, 2nd Khaghani, Khaghani Blv., Rezashahr
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
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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
University of social welfare and rehabilitation sciences

Proportion provided by this source
50

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
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr. Iraj Abdollahi
Position
Head of Physiotherapy department
Latest degree
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Person responsible for updating data

Contact

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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

After hiding of personal information, demographic data will be shareable

When the data will become available and for how long

Data will be accessible 6 months after publishing.

To whom data/document is available

It will be available to all scholars and researchers working in an academia or a research center.

Under which criteria data/document could be used

For academic researches, confirming the ethics code is needed to access data .

From where data/document is obtainable

To receive data, send an e-mail to Dr. Iraj Abdollahi via irajabdollahi@hotmail.com or to Mitra Parsa via mitra.parsaa@gmail.com containing reasons for data access.

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

It is imperative to explain the reasons for data access and features of research plan comprehensively.

Comments