

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

To compare the effect of visual restriction exercise and proprioception exercise in balance of stroke patients.

Protocol summary

Study aim

To compare effects of balance training on an unstable surface with balance training under visual deprivation conditions in persons with stroke

Design

A randomized, placebo-controlled clinical trial, parallel group trial with blinded outcome assessor and data analyzer .

Settings and conduct

All groups will receive general physical therapy exercise including muscle stretching and strengthening exercise. Participants in the visual deprivation training group are going to be instructed to perform balance training exercise on a firm floor while they are keeping their eyes closed. The unstable base group will perform balance training on a foam (unstable surface) with open eyes. Subjects in the control group are going to get standard physiotherapy treatment. Each exercise session consisted of 4 sets in 20 minutes with one minute of rest interval between each set. The interventions will be carried out for one month, 3 sessions per week in the selective stroke rehabilitation center in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 25-65 and stroke at least 6 months ago. Exclusion criteria: Any musculoskeletal, cardiac or respiratory problems that impede the exercise therapy.

Intervention groups

Grouping consisted of 3 groups of 15 persons:
Intervention group 1: Exercise on stable surface with visual restriction, Intervention group 2 Exercise on unstable surface with open eyes and control group

Main outcome variables

Timed Up and Go (TUG), Five Times Sit to Stand (FTSS) and Four Square Step (FSS) tests at baseline and after completing their intervention

General information

Reason for update

Impossibility of sampling due to corona virus. The start date of sampling will be corrected on 02/20/1399.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190812044516N1**

Registration date: **2020-04-15, 1399/01/27**

Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**

Update count: **2**

Registration date

2020-04-15, 1399/01/27

Registrant information

Name

Nahid Tahan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1723

Email address

na_tahan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare the effect of visual restriction exercise and

proprioception exercise in balance of stroke patients.

Public title

The effect of visual restriction exercise on balance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients had experienced stroke at least 6 months ago

Patients who could perform independent standing no cognitive problems

Exclusion criteria:

Unwillingness to participate to the study Inability to exercise Any orthopedic deformity in lower extremity Previous stroke

Age

From **50 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The random sequence will be performed using the simple randomization. The random number table is used to perform the simple randomization. Allocation concealment is performed using Sequentially numbered, sealed, opaque envelopes To execute the random allocation process, the person involved in randomization is separated from the investigator to reduce possible bias

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 shahid beheshti university of medical sciences

Street address

No.15, Yaman St, Arabi St, Next to Taleghani Hospital, Chamran High way,

City

Tehran

Province

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Postal code

1985717443

Approval date

2020-02-24, 1398/12/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.819

Health conditions studied

1

Description of health condition studied

cerebro vascular disease

ICD-10 code

I63.50

ICD-10 code description

Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery

Primary outcomes

1

Description

Timed Up-and-Go Test score, Five Times Sit-to-Stand test

Timepoint

Before and after intervention

Method of measurement

Timed Up and Go test

Secondary outcomes

1

Description

Quality of life score

Timepoint

Before and after training

Method of measurement

Questionare

Intervention groups

1

Description

Subjects in the intervention group 1 will perform a general physical therapy exercise(including muscle stretching and strengthening exercise) and balance training exercise on a stable surface (floor) with their eyes close. The intervention will be done for a period of 4 weeks, 3 days a week, with a total of 10 sessions. Each session will be at least 30 minutes .

Category

Rehabilitation

2

Description

Intervention group 2 group will receive a general

physical therapy exercise and balance training exercise on an unstable surface. The training will be done for a period of 4 weeks, 3 days a week, with a total of 10 sessions. Each session will be at least 30 minutes.

Category

Rehabilitation

3**Description**

Control group only perform a general physical therapy program for a period of 4 weeks, 3 days a week, with a total of 10 sessions. Each session will be at least 30 minutes.

Category

Rehabilitation

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

Tabasom rehabilitation center

Full name of responsible person

Nahid Tahan

Street address

No.26, West Baqer Khan st, Chamran highway, Tehran

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr 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

Nahid Tahan

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Nahid Tahan

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No additional informations

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable