Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 recive general physical therapy exercise including muscle stretching and strengthening exercise Participants in the visual deprivation training group are going to 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 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 impedes 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 02/20/1991.

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 exteremity 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 behehsti university of medical sciences
Street address
No.15, Yaman St, Arabi St, Next to Taleghani Hospital, Chamran High way,
City
Tehran
Province
Tehran
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 Baqerkhan st, Chamran highway, Tehran

City

Tehran

Province

Tehran

Postal code

1333625445

Phone

+98 21 5102 5345

Email

tnpt2378@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

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

City

Tehran

Province

Tehran

Postal code

985717443

Phone

+98 21 23781

Email

info@sbmu.ac.ir

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

Street address

No 152, kamali St, Makhsoos St, South Karegar Ave, Loghman Hakim hospital

City

Tehran

Province

Tehran

Postal code

1333625445

Phone

+98 21 5102 5345

Email

na_tahan@sbmu.ac.ir

Person responsible for scientific 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

Street address

Loghman Hakim Hospital, South Karegar Ave., Makhsoos St., Qazvin St.

City
Tehran
Province
Tehran
Postal code
1333625445
Phone
+98 21 5102 5345
Email
na_tahan@sbmu.ac.ir

Person responsible for updating data

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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Loghman Hakim Hospital, South Karegar Ave., Makhsoos St., Qazvin St.
City
Tehran
Province
Tehran
Postal code
1333625445
Phone
+98 21 5102 5345
Email
tnpt2378@gmail.com

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