

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Compare the effect of task oriented training and conventional physiotherapy on balance in hemiplegic patients following stroke

Protocol summary

Summary

Objectives: The effect of task oriented training and conventional physical therapy on balance in hemiplegic patients following stroke will be compared. **Design:** In this clinical trial, 20 hemiplegic patients following stroke will be divided randomly (people with odd inclusion number in the control group and those with even inclusion number in experimental group) in two groups of task oriented training and conventional physical therapy. **Setting and conduct:** Individuals will participate in 4-weeks therapy sessions 3 times a week for about 2 hours. **Major inclusion and exclusion criteria:** Inclusion criteria include: hemiplegia secondary to stroke; clear asymmetry in weight bearing; the ability to independent walking for at least 10 meters; passing less than three months after stroke and the Berg Balance Scale in the range of 30 to 40 and Exclusion criteria include: impaired vision; the absence of any neurological or orthopedic diseases affecting patients postural disorder and any disease that limited patient's participation in the study. **Interventions:** Task-oriented training and conventional physiotherapy exercises **Main outcome variables include:** The Berg Balance Scale will be used to measure functional balance and pressure distribution of foot, the center of pressure path length and the center of pressure confidence ellipse area will be used to evaluate static balance by means of pressure distribution zebris system while standing with open eyes before and after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100224297N1**

Registration date: **2015-10-12, 1394/07/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-12, 1394/07/20

Registrant information

Name

Soodeh Arabzadeh

Name of organization / entity

Tabriz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-10-21, 1394/07/29

Expected recruitment end date

2015-12-16, 1394/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of task oriented training and conventional physiotherapy on balance in hemiplegic patients following stroke

Public title

Compare the effect of task oriented training and conventional physiotherapy on balance in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include: hemiplegia secondary to stroke; clear asymmetry in weight bearing; the ability to independent walking for at least 10 meters; passing less than three months after stroke and the Berg Balance Scale in the range of 30 to 40 and Exclusion criteria include: impaired vision; the absence of any neurological or orthopedic diseases affecting patients postural disorder and any disease that limited patient's participation in the study.

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Assistance Research and Technology, Third floor,
Central Building (2), Tabriz University of Medical
Sciences, Golgasht St, Tabriz

City

Tabriz

Postal code

51665118

Approval date

2014-03-03, 1392/12/12

Ethics committee reference number

92223

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

G96.8

ICD-10 code description

Other disorders of central nervous system

Primary outcomes

1

Description

Functional balance

Timepoint

Before and after treatment

Method of measurement

Berg Balance Scale

2

Description

Sway

Timepoint

Before and after treatment

Method of measurement

The center of pressure path length and the center of
pressure confidence ellipse area

3

Description

Symmetry

Timepoint

Before and after treatment

Method of measurement

The plantar pressure distribution of foot

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: Task oriented training, three times a week for four weeks over twelve sessions. Each session takes about 2 hours. 1) sitting on a chair and reaching objects in all directions at a distance of more than arm's length; 2) forward, backward and side way stepping up; 3) flexion and extension the affected knee, while the affected foot located on the exercise step; 4) stepping over obstacles with different heights; 5) standing up from a chair, walking four steps forward, touching a stool and then returning to the chair; 6) sitting on a Swiss ball while doing range of motion and balance exercise in the trunk and upper extremities; 7) double leg stand for 10 seconds; 8) tandem stand (the heel of one foot in front of the other foot) for 10 seconds; 9) standing up from a chair without using the arms; 10) tandem walking forward and backward^{7, 16}. The four last exercises have been done in different situation as follows: 1) with open eyes and a hard surface, 2) with open eyes and a soft surface, 3) with closed eyes and hard surface; 4) with closed eyes and smooth surface

Category

Rehabilitation

2

Description

Control group: conventional physiotherapy, three times a week for four weeks over twelve sessions. Each session takes about 2 hours. Exercises to improve balance, increase muscle strength, range of motion and walking through weight training or weight transfer in the parallel bars, mats exercise (strengthening, stretching, range of motion) and correct gait training in parallel bar

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

physiotherapy cilinic of Asadabady hospital

Full name of responsible person

Abbas Soltani Somee, PhD of Physiotherapy, Assistant professor

Street address

Asadabadi Hospital, Adjacent Agricultural high schools, Spring Street before the intersection Azerbaijan , Tabriz

City

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2

Recruitment center

Name of recruitment center

physiotherapy clinic of Razi

Full name of responsible person

Sakineh Goljaryan, PhD of Physiotherapy, Assistant professor

Street address

Elgoli road, Razi hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Center of Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

Street address

Vice chancellor for research and technology, Third floor, Central Organization², Tabriz University of Medical Sciences, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Center of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Rehabilitation, Tabriz University of Medical Sciences

Full name of responsible person

Abbas Soltani Somee

Position

PhD of Physiotherapy, Assistant professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty