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
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
easy

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
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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. 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

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 bars.

Category: Rehabilitation

Recruitment centers

1. Recruitment center
   Name of recruitment center: physiotherapy clinic 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: Tabriz

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
   City: Tabriz

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: empty
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
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Person responsible for scientific inquiries

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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