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The use of sling exercise therapy for weakness and functional disability on one side of the body after a stroke

Submission date
13/05/2022

Recruitment status
No longer recruiting

Registration date
27/05/2022

Overall study status
Completed

Last Edited
26/05/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Stroke patients have problems with trunk control, which is linked with restricted balance, an increased risk of falls, poor walking performance, and dependence on people in daily activities. The goal of physical therapy is to improve the trunk stability of stroke patients. In addition, recent studies have found that trunk exercises performed on an unstable surface are more effective than those performed on a stable surface. Sling exercise therapy (SET), one of the common unstable surfaces, can help patients perform the training program more effectively by supporting their body weight with an elastic cord. The aim of this study is to determine the effects of core stability exercises using sling exercise training on balance, walking, and activities of daily living for patients with subacute hemiparesis (weakness of one side of the body).

Who can participate?
Patients diagnosed with their first stroke with hemiplegia within the last 6 months who can walk independently

What does the study involve?
Participants are randomly allocated to the sling exercise training or conventional physical therapy. Participants receive the training for 8 weeks and their trunk function, balance, walking and daily living activities are assessed before and after 8 weeks of training.

What are the possible benefits and risks of participating?
Balance, walking and daily living activities may be improved after the training, and trunk function may be improved after the sling exercise intervention.

Where is the study run from?
Yuan's General Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
October 2017 to March 2018

Who is funding the study?
1. Ministry of Science and Technology (Taiwan)
2. National Sun Yat-sen University (Taiwan)
3. Kaohsiung Medical University (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of core stability exercises using sling exercise therapy on trunk function, balance ability, walking performance and daily living activities in subacute hemiparesis patients

Study objectives
The sling exercise training improved balance ability, walking performance and activities of daily living significantly compared to baseline measurement and the conventional therapy intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/12/2017, Institutional Review Board of Yuan's General Hospital (No. 162, Chenggong 1st Road, Lingya Dist., Kaohsiung City, Taiwan (R.O.C.); +886 (0)7 3350205; irb@yuanhosp.com.tw), ref: 20171031B

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available

Health condition(s) or problem(s) studied
Subacute stroke

Interventions
Participants were randomly assigned to study groups by sealed envelopes to receive sling exercise training for the experiment group and conventional physical therapy for the control group. All participants receive a total of 20 intervention sessions, 3 intervention sessions a week and 1 hour per session, over 8 weeks.

Intervention Type
Other

Primary outcome measure
1. Balance ability measured by Timed Up & Go, Berg Balance scale and postural assessment scale at baseline and post-intervention (8 weeks)
2. Walking performance measured by 5-meter walking test and 6-minute walking test at baseline and post-intervention (8 weeks)

Secondary outcome measures
1. Trunk function measured by the Trunk Impairment Scale and the pelvic backward tilt force by using stabilizer pressure biofeedback at baseline and post-intervention (8 weeks)
2. Daily living activities measured by the Barthel index and the activities-specific balance confidence scale at the baseline and post-intervention (8 weeks)

Overall study start date
30/10/2017

Completion date
12/03/2018

Eligibility

Key inclusion criteria
1. Less than 6 months since diagnosis of first stroke with hemiplegia
2. Modified Rankin Scale scores less than or equal to 4 (MRS ≤ 4)
3. Independent walking

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
56

Total final enrolment
40

Key exclusion criteria
1. Trunk Impairment Scale (TIS) score of 17 or more
2. Other musculoskeletal or neurologic problems

Date of first enrolment
25/12/2017

Date of final enrolment
15/01/2018

Locations

Countries of recruitment
Taiwan

Study participating centre
Yuan's General Hospital
No. 162, Chenggong 1st Rd., Lingya Dist.

Kaohsiung
Taiwan
802

Sponsor information

Organisation
Kaohsiung Medical University

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Sponsor type
University/education

Website
http://english2.kmu.edu.tw/front/bin/home.phtml

ROR
https://ror.org/03gk81f96

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology, Taiwan

Alternative Name(s)
Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

Funder Name
National Sun Yat-sen University

Alternative Name(s)
NSYSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Taiwan

Funder Name
Kaohsiung Medical University

Alternative Name(s)
-, Kaohsiung Medical University | Kaohsiung Medical University, Kaohsiung Medical University in Taiwan, Kaohsiung Medical University (KMU) - Taiwan, Kaohsiung Medical University, Taiwan, Kaohsiung Medical University | , Kaohsiung Medical College, KMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Taiwan

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication