ISRCTN27645313 https://doi.org/10.1186/ISRCTN27645313

The training effects of the pinnacle trainer and the elliptical trainer on walking ability and balance restoration in chronic stroke

Submission date
15/06/2021

Recruitment status
No longer recruiting

Registration date
22/06/2021

Overall study status
Completed

Last Edited
14/07/2021

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
A stroke happens when the blood supply to part of the brain is cut off. Balance deficits are a common problem after stroke. Pinnacle trainers (PT) are exercise trainers that involve major hip joint muscle effort, while elliptical trainers (ET) involve major effort on the shank muscles. The aim of this study is to investigate the training effects of PT and ET on the walking ability and balance of chronic stroke patients.

Who can participate?
Chronic stroke patients with hemiplegia (paralysis on one side of the body) in Taiwan

What does the study involve?
Participants are allocated into three groups to undergo an 8-week PT, ET or conventional therapy intervention. All participants are asked to perform walking tests and an obstacle crossing task at the start of the study and after the 8-week intervention.

What are the possible benefits and risks of participating?
The possible benefits are gait and balance improvements. The possible risks include falls during the obstacle crossing task, but during the measurements and intervention the therapist and research assistant are arranged around the participants to reduce the risk.

Where is the study run from?
National Cheng Kung University Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2016 to August 2018

Who is funding the study?
Ministry of Economic Affairs (Taiwan)

Who is the main contact?
Prof. Cheng-Feng Lin
connie@mail.ncku.edu.tw

Contact information

Type(s)
Scientific

Contact name
Prof Cheng-Feng Lin

ORCID ID
https://orcid.org/0000-0002-2466-0156

Contact details
Department of Physical Therapy
National Cheng Kung University
No.1, University Road
Tainan
Taiwan
701
+886 (6)2353535 ext. 5911
connie@mail.ncku.edu.tw

Additional identifiers

Study information

Scientific Title
Clinical efficacy test for the pinnacle trainer integrated with an intelligent suspension system

Study objectives
Walking ability improves after the intervention and balance ability improves after the pinnacle trainer (PT) intervention compared to the baseline measurements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/01/2016, Institutional Review Board of National Cheng Kung University Hospital (138 Sheng-Li Rd, Tainan 704, Taiwan; +886 (6)2353535 ext. 3635; em73635@mail.hop.ncku.edu.tw), ref: B-ER-101-059

Primary study design
Interventional

Study design

Interventional non-randomized study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic stroke with unilateral hemiplegia

Interventions
Participants were allocated into three groups, namely the pinnacle trainer (PT) group, the elliptical trainer (ET) group and the control group (conventional therapy).

The participants in the PT and ET groups undergo 8-week pinnacle and elliptical trainer interventions, respectively, in conjunction with conventional therapy.

The intervention sessions take place three days a week for about 60 minutes per session. The participants exercise on either the PT or ET for 30 minutes under the guidance of an experienced therapist and receive conventional therapy on the same day for 30 minutes.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline (before intervention) and after 8 weeks (after completing the intervention):
1. Walking distance measured using the 6-minute walk test
2. Walking speed measured using the 10-meter walk test
3. Balance ability measured using obstacle crossing

Key secondary outcome(s)
Gait symmetry measured using a motion capture system at baseline (before intervention) and after 8 weeks (after completing the intervention)

Completion date
13/08/2018

Eligibility

Key inclusion criteria
1. Unilateral hemiplegia occurred after the first stroke
2. Onset time is at least 6 months prior to the study
3. A Brunnstrom stage of above 3
4. A Mini-Mental Status Examination (MMSE) score above 24
5. A functional ambulation category (FAC) score of at least 2
6. The ability to stand for at least 10 seconds with/without assistance

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Total final enrolment
36

Key exclusion criteria
Bilateral hemiplegia occurred after the first stroke

Date of first enrolment
13/05/2016

Date of final enrolment
14/06/2018

Locations

Countries of recruitment
Taiwan

Study participating centre
National Cheng Kung University
No.1, University Road
Tainan
Taiwan
701

Study participating centre
National Cheng Kung University Hospital
138 Sheng-Li Rd
Tainan
Taiwan
704

Sponsor information

Organisation
National Cheng Kung University

ROR
https://ror.org/01b8kcc49

Funder(s)

Funder type
Government

Funder Name
Ministry of Economic Affairs

Alternative Name(s)
Ministry of Economic Affairs, R.O.C., MOEA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		14/07/2021	14/07/2021	No	No