

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 14/07/2021	Condition category Nervous System Diseases	<input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

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

Study design

Interventional non-randomized study

Primary study design

Interventional

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	Participant information sheet	14/07/2021	14/07/2021	No	No

