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# 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
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# Contact information

### Type(s)
Scientific

### Contact name
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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
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

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

## 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 measure
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

## Secondary outcome measures

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

### Overall study start date
21/01/2016

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
70

### 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
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### Study participating centre
**National Cheng Kung University Hospital**
138 Sheng-Li Rd
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## Sponsor information

### Organisation
National Cheng Kung University

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### Sponsor type
University/education

### Website
https://www.ncku.edu.tw/

### 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

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

### Intention to publish date
01/02/2022

### 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 |