

TCTR ID : TCTR20210511001

Overall Recruitment Status : Completed (Has Results)

OTHER ID :

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date : 10 May 2021
First Posted Date : 11 May 2021
Last Update Posted Date : 22 March 2024

Title

Public Title : Effect of Visual Cue Device to Gait Speed in Parkinsonism with Freezing of Gait
Acronym : No Data
Scientific Title : Effect of Visual Cue Device to Gait Speed in Parkinsonism with Freezing of Gait
Sponsor ID/ IRB ID/ EC ID : EC 616
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20210511001>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : COA. MURA2020/702
Date of Approval : 25 April 2020
Board Name : Human Research Ethics Committee
Board Affiliation : Faculty of Medicine Ramathibodi Hospital, Mahidol University
Board Contact : Business Phone : 6602012175 Ext. No Data
Business Email : raec.mahidol@gmail.com
Business Address : 270 Rama 6 Rd. Phayatai Ratchathewi Bangkok 10400

Sponsor

Source(s) of Monetary or Material Supports : Faculty of Medicine, Ramathibodi hospital
Study Primary Sponsor : Faculty of Medicine, Ramathibodi hospital
Responsible Party : Name/Official Title : Peeraya Ruthiraphong
Organization : Physical Medicine and Rehabilitation, Ramathibodi hospital
Phone : 66617265726 Ext. No Data
Email : peeraya.rut@mahidol.edu
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : To study efficacy of visula cue laser in people with Parkinson and Parkinsonism.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Parkinson Parkinsonism Freezing of gait Visual cue Falling
Keywords : Parkinson Parkinsonism Shuffling gait Falling

Eligibility

Inclusion Criteria : 1. Parkinson or Parkinsonism patients
2. Aged 18-90 years.
3. Hoehn & Yahr stage 1-4
4. able to walk at least 16 meters
5. no medical adjustment at least 3 months

Gender : Both
Age Limit : Minimum : 18 Years Maximum : 90 Years

Section A : Central Contact

Central Contact	First Name : Peeraya	Middle Name :	Last Name : Ruthiraphong
	Degree : MD	Phone : 66617265726 Ext. : No Data	Email : peeraya.rut@mahidol.edu
Central Contact Backup	First Name : thitiya	Middle Name :	Lastname : hupako
	Degree :	Phone : 66022012717 Ext. : No Data	Email : kwang.kwang999@gmail.com

Section B Facility Information and Contact

1. Site Name : Thitiya Hupako
 City : Bangkok State/Province : Bangkok Postal Code : 10400
 Country : Thailand Recruitment Status : Completed

Facility Contact First Name : Peeraya Middle Name : Last Name : Ruthiraphong
 Degree : MD Phone : 022011154 Ext. : No Data Email : peeraya.rut@mahidol.edu

Facility Contact Backup First Name : thitiya Middle Name : Last Name : hupako
 Degree : Phone : 66022012717 Ext. : No Data Email :
kwang.kwang999@gmail.com

Investigator Name First Name : Peeraya Middle Name : Last Name : Ruthiraphong
 Degree : MD Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Peeraya Middle Name : Last Name : Ruthiraphong
 Degree : MD Phone : 022011154 Ext. : No Data Email : peeraya.rut@mahidol.edu
 Postal Address : Physical medicine and rehabilitation department, Ramathibodi Hospital270 Rama 6 rd, Rajthevi
 State/Province : Bangkok Postal Code : 10400
 Country : Thailand Official Role : Study Principal Investigator
 Organization Affiliation : Ramathibodi Hospital, Mahidol University

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Peeraya Middle Name : Last Name : Ruthiraphong
 Degree : MD Phone : 66617265726 Ext. : No Data Email : peeraya.rut@mahidol.edu
 Postal Address : Physical medicine and rehabilitation department, Ramathibodi Hospital270 Rama 6 rd, Rajthevi
 State/Province : bangkok Postal Code : 10400
 Country : Thailand Official Role : Study Principal Investigator
 Organization Affiliation : Ramathibodi Hospital, Mahidol University

Summary Results

Date of posting of results summaries : 25 September 2021

Date of first journal publication of results : Not yet published

Baseline Characteristics : Parkinsonism patients were recruited from Physical Medicine and Rehabilitation outpatient clinic in Ramathibodi hospital. The inclusion criteria were 1. Parkinson or Parkinsonism patients. 2. Aged 18-90 years. 3. Hoehn & Yahr stage 1-4 4. able to walk at least 16 meters 5. no medical adjustment at least 3 months The exclusion criteria were 1. Unable to see the laser line projection on the floor 2. Other neurological disorders 3. Cannot communicate well. 4. Unable to use the device 5. Deny or reject from the study. The study was approved by the Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University. All participants gave written informed consent according to the declaration of Helsinki before entering the study.

Participant Flow : The participants were informed about the objective and procedure of the study, and then signed the informed consent before starting the trials. Each participant would be randomized by a sealed envelope and allocated into 2 groups, walking with laser-off first, and walking with laser-on first. There was 10-minute washout period between each group. Each participant walked at 10 meters twice and take a break for a few minutes or as the patient felt ready before continuing the Timed Up and Go (TUG) test twice. The gait speed was analyzed using the distance of 6 meters in the middle of the total 10-meter. Video recording during walking was used by two experienced physiatrists to analyze the stride length. To use the device properly, participants received at least 5 minutes to get familiar with the toolkit and adjust the distance of the laser line projecting in front of the foot at their preference, i.e., stride length or visual sight. Before beginning the first trial, each participant would step both feet 10 times alternately for warming up. One of the examiners followed the participants to prevent falls during all testing.

Adverse events : There were no adverse effects while using the device, such as dizziness while looking at the laser line or blurred vision.

Outcome Measures : The results showed favorable results of improvement in all parameters. Gait speed and stride length

improved by 0.07 m/s and 0.17 m, respectively, with laser-on. The TUG test duration was reduced by 7.69 s. The locomotor rehabilitation index (LRI) improved by 4.46%. When using the device, there were no adverse effects, such as dizziness or blurred vision.

Brief Summary of Results : The ankle bracelet laser improved walking performance in parkinsonism patients with FOG immediately and might have the potential to provide cueing during daily life.

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : Yes

Plan description : IPD and documents will be available for sharing 1 year after publication for a period of 2 years. Access to the IPD and documents will be open on the IPDShare website with registration. The information will be freely available and can be used for any purpose. There will not be any review process or no Data Use Agreement will be necessary.

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data
