TCTR ID : TCTR20210511001

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

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

Exclusion Criteria : 1. Unable to see the laser line projection on the floor
2. Other neurological disorders
3. Unable to communicate well.
4. Unable to use the device
5. Deny or reject from the study.

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates		
	Study Start Date (First enrollment) : 15 June 2020	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 01 October 2020	Indicate Type : Actual
	Study Completion Date : 01 October 2020	Indicate Type : Actual

Design

Study Type : Interventional
Primary Purpose : Device Feasibility
Study Phase : Phase 2
Intervention Model : Crossover
Number of Arms : 2
Masking : Open Label
Allocation : Randomized
Control : No treatment / Standard of care
Study Endpoint Classification : Efficacy Study
Sample size
Planned sample size : 10
Actual sample size at study completion : 10
Intervantion Arm 1
Intervention name : Ankle-bracelet laser
Intervention Type : Active Comparator
Intervention Classification : Device
Intervention Description : Ankle bracelet laser with laser-on
Intervantion Arm 2
Intervention name : laser-off
Intervention Type : Sham Comparator
Intervention Classification : Device
Intervention Description : Ankle bracelet with laser-off

Outcome

Primary Outcome

1. Outcome Name : Gait speed
Metric / Method of measurement : meter/second
Time point : immediate

Secondary Outcome

1. Outcome Name : Timed Up and Go test
Metric / Method of measurement : second
Time point : immediate
2. Outcome Name : Step lenght
Metric / Method of measurement : meter
Time point : immediate

Location

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 projetion 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