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

 $Keywords: \ \ Parkinson \ Parkinson is m \ Shuffling \ gait \ Falling$

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

> Study Start Date (First enrollment): 15 June 2020 Key Trial Dates 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

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)

Degree:

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.

 $Brief\ Summary\ of\ Results:\ The\ ankle\ bracelet\ laser\ improved\ walking\ performance\ in\ parkinson is m\ patients\ with\ FOG\ immediately\ and$

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

 $\begin{tabular}{ll} \textbf{MEDLINE Identifier}: & No\ Data \\ \\ \textbf{URL link to full text publication}: & No\ Data \\ \\ \end{tabular}$