The Effect of Rhythmic Auditory Stimulation on Gait in Chronic Stroke Patients

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Main Information

Primary registry identifying number
LBCTR2021024744

Protocol number
CEUA 056

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
20/01/2021

Primary sponsor
Farah Ayoubi

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
14/02/2021

Date of registration in national regulatory agency
20/01/2021

Public title
The Effect of Rhythmic Auditory Stimulation on Gait in Chronic Stroke Patients

Acronym

Scientific title
The Effect of Rhythmic Auditory Stimulation Tempo Shifts Application on Gait Parameters in Chronic Stroke Patients: A Pilot Study

Acronym

Brief summary of the study: English

To examine the effect of rhythmic auditory stimulation tempo shifts on gait in stroke patients. Ten to twenty chronic stroke patients with an onset of six months and above will be recruited based on the proposed criteria and after a thorough assessment and obtaining their consent. Participants will be instructed to walk under a self selected tempo based on their average walking cadence followed by three randomly applied conditions (-10%, +10%, and +20%) calculated based on the self-selected tempo, then finally each participant will walk without stimulation to monitor immediate effect. Kinovea (motion analysis software) and 10 meter walk test will be used to evaluate gait parameters at session 1 and session 12 respectively through all applied walking conditions to monitor short term effect.

Brief summary of the study: Arabic

لفحص تأثير التحفيز الايقاعي على المشي لدى مرضى السكتة الدماغية. سيتم توظيف عشرة إلى عشرين مريضا بالسكتة المزمنة (ستة أشهر وما فوق). بناء على المعايير المقترحة وبعد تقييم دقيق والحصول على موافقة المرضى سيتم توجيه المشاركين للسير وفقا للايقاع المحدد ذاتيا متبوعا + محددة استنادا إلى متوسط معدل سرعة المشي. ثم أخيرا سيمشي كل مشارك دون تحفيز ٢٠+ , ١٠٪-. ١٠٪بثلاثة شروط وظيفية عشوائية ٪ أمتار و برنامج١٠المراقبة تأثير العلاج الفوري. سيستخدم إختبار المشي على مسافة Kinovea لرصد اثر العلاج على معلمات المشي في على التوالي١٢ و الجلسة رقم ١الجلسة رقم .

Health conditions/problem studied: Specify

Health Condition: Chronic Stroke Patients (Hemiplegia)

Problems Studied: Gait (spatio-temporal parameters)/ Walking Issues/ Motor Issues/ Impairment/ Function

Interventions: Specify

Each participant will walk along a wide unobstructed 10-m walkway at preferred speed with the possibility to use a uniform walking aid when needed, based on this each participant's cadence will be calculated using a pedometer and then averaged over 3 trials to obtain the mean cadence. The acceleration and deceleration periods will be neglected, and this step is to be repeated each session. The self selected tempo will be set each session according to the mean cadence (number of steps/min= number of beats/min). Each participant will then walked under three randomly applied conditions which will be administered based on block randomization (-10%, +10%, and +20%) calculated from self-selected tempo (0%). Each participant will walk 3 times under baseline tempo (0%), followed by 3 times under each condition. Finally, each participant will be asked to walk for a distance of 10m without any stimulation to monitor short term effects. The obtained data will be analyzed using Kinovea software and 10-m walk test.
Conventional approach (ethical considerations): The conventional treatment will consist of customized functional tasks targeting transfers such as; weight shifting while in sitting and standing, transfers from sitting to standing, and from one chair to another (with and without arm support) as well as enhancing static balance; while sitting and standing in addition to management of the upper extremity; through stretching, range of motion exercises of high repetition, and functional reaching exercises.

Key inclusion and exclusion criteria: Inclusion criteria

The inclusion criteria were as follows: 1) able to walk for a 10-m distance. 2) Able to follow instructions. 3) Doesn't suffer from cognitive impairment with a Modified Mini Mental State Examination (3MS) score of 79 or higher. 4) Brunnstrom recovery scale of stages (4-6).

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

35

Key inclusion and exclusion criteria: Age maximum

65

Key inclusion and exclusion criteria: Exclusion criteria

Individuals were excluded if any demonstrated one or more of the following conditions: 1) Auditory or visual problems. 2) Chronic pain and/or an orthopedic condition which affects gait. 3) Symptomatic cardiac failure. 4) Neurologic condition other than initial stroke. 5) Major depression or psychological issues.

Type of study

Interventional

Type of intervention

Rehabilitation strategies

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Single Arm Study

Study design: Masking

Blinded (masking used)

Study design: Control

Active

Study phase

N/A

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

N/A

Therapeutic indication

Such approaches are essential and crucial for stroke individuals which are hemiplegic or have a functional impairment in their lower extremities or have a motor control issues in addition to hemiparesis. Additionally such an approach is very beneficial for other neurologic populations as a primary treatment method.

Therapeutic benefit

- Optimizing Gait and Gait parameters (deviations, symmetry, cadence, velocity, step length,etc...)
- Improving Balance (Static+Dynamic)
- Decreasing postural issues and optimizing postural control
- Motor Relearning
- Inducing and Optimizing Brain plasticity
- Optimizing quality of life
- Optimizing independence
- Optimizing functional capacities
- Decreasing morbidity rates
- Decreasing mortality rates
- Prevention of recurrence of health issues
- Improving Mental state and cognition

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

30

Actual enrollment target size

10

Date of first enrollment: Type

Actual

Date of first enrollment: Date

04/01/2021

Date of study closure: Type

Actual

Date of study closure: Date

04/03/2021

Recruitment status

Recruiting

Recruitment status: Specify

Date of completion

14/02/2021

IPD sharing statement plan

No

IPD sharing statement description

At this current point we would prefer to keep our data disclosed, as soon as we are done with the study as eligible we will be submitting the trial to a journal for a prospect publication.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Ethics Committee at the Antonine University (CEUA)	CEUA 056

Sources of Monetary or Material Support

No Sources

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Farah AYOUBI	Tripoli	Lebanon	71765367	farah.ayoubi@ua .edu.lb	Research Advisor/ Supervisor / Research Instructor/ MPT/ PhD/ PT at Antonine University
Scientific	Marie Catherine Baradhii	Baabda	Lebanon	70686738	mariecatherine2 @hot mail.com	Researche r/ Research Supervisor / Clinical Instructor/ DPT/ MPT/ PT

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Arc en ciel (Jesr l Wate)	Dr. Jeanine Matar (yet, researcher conducted trial)	DPT	Approved
Mousawat Foundation	N/A (researcher conducted trial)	PT	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Other Ethics committe of the Antonine University (CEUA)	26/11/2020	Nidaa Abou Mrad	nidaa.aboumrad@ua.edu.lb	05927000

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Stroke/ Hemiplegia	Hemiplegia (G81)	stroke/ hemi/ gait/ function/ RAS

Interventions

Intervention	Description	Keyword
Gait Re-education under Rhythmic Auditory Stimulation	Rhythmic Auditory Stimulation is a neurologic technique used to facilitate the rehabilitation of movements that are intrinsically biologically rhythmical, most importantly gait. RAS uses the physiological effects of auditory rhythm on the motor system to improve the control of movement in rehabilitation of functional, stable, and adaptive gait patterns in patients with significant gait deficits due to neurologic impairment.	RAS

Primary Outcomes

Name	Time Points	Measure
Angle measurements	At session 1 and session 12	Angles in degrees via Kinovea software
Angle symmetry	At session 1 and session 12	SI (symmetry index)
Velocity	At session 1 and session 12	10m walk test
Cadence	At session 1 and session 12	Number of steps/min using pedometer
Step Length	At session 1 and session 12	Steps in cm using kinovea software

Key Secondary Outcomes

Name	Time Points	Measure
Cognition (pre-requisite to enrollment)	At session 1 (pre-experiment)	3MS (Modified Mini Mental State examination)
Muscular strength/ Motor ability (global)	At session 1 (pre-experiment)	Brunnstrom scale

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files