

# The ability of a new, non-invasive, combined treatment protocol to improve abnormal walking following stroke

<b>Submission date</b> 07/04/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/04/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/04/2022	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

During the year prior to the study, the Evexia Centre began a clinical evaluation of the potential for the combined therapy offered in TVMPS. Vibration stimulus to the skull proved to be able to identify brain damage sites. A static magnet complex, when placed on the skull over the identified area, was found to activate a specific pain response along either the arms or upper legs. This area on one of the limbs, when manipulated while the magnet complex was on the skull, was found to improve abnormal walking in stroke patients. This treatment was found to accelerate and improve the rehabilitation on these patients.

A new form of non-invasive brain stimulation diagnosis and therapy is being scientifically evaluated for its effect on post-stroke walking recovery.

### Who can participate?

Patients aged 18 years and above who were referred to the Evexia Centre for stroke rehabilitation therapy could be included in the trial as long as they met the inclusion and exclusion requirements.

### What does the study involve?

Those who were selected were randomly divided into two groups - one for fake and the other for real treatments. During 5-days, each group was measured for their ability to get up and go, rise up from a chair and sit again and with sophisticated walking parameters. In that same period, the placebo (fake) group received 3 fake treatments and the real group received 3 real treatments.

### What are the possible benefits and risks of participating?

Since the methods used were non-invasive, no participant had risk of harm or bad side-effects. The possible benefit from the study results would be a better ability for stroke patients to recovery that is simple and cost-effective.

### Where is the study run from?

Evexia Rehabilitation Centre (Greece)

When is the study starting and how long is it expected to run for?  
August 2019 to July 2020

Who is funding the study?  
Evexia Rehabilitation Centre (Greece)

Who is the main contact?  
Joseph Shafer, therapy@evexia.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Joseph Shafer

**Contact details**  
Evexia Rehabilitation Centre  
Thessaloniki-N.Moudania National Road  
Nea Kallikrateia, Chalkidiki  
Greece  
63080  
+39 333 686 0421  
drjps3@gmail.com

**Type(s)**  
Scientific

**Contact name**  
Dr Emmanouil Kandylakis

**Contact details**  
Evexia Rehabilitation Centre  
Thessaloniki-N.Moudania National Road  
Nea Kallikrateia, Chalkidiki  
Greece  
63080  
+30 231 444 4100  
kand\_man@yahoo.gr

**Type(s)**  
Public

**Contact name**  
Dr Andrea Cecchi

**Contact details**  
Evexia Rehabilitation Centre  
Thessaloniki-N.Moudania National Road

Nea Kallikrateia, Chalkidiki  
Greece  
63080  
+39 011 385 0161  
chirocecchi@yahoo.it

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

Nil known

## **Study information**

### **Scientific Title**

Post-stroke efficacy of transcranial vibration, magnetic and peripheral stimulation: a preliminary randomized controlled trial

### **Acronym**

TVMPS

### **Study objectives**

Post-stroke recovery efficacy of transcranial vibration, magnetic and peripheral stimulation as measured through gait outcomes.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 01/12/2019, Evexia Rehabilitation Centre Ethics Committee (Thessaloniki-N.Moudania National Road, Nea Kallikrateia, 63080, Greece; +30 23990 76700; info@evexia.com), ref: 01.12.2019-001

### **Study design**

Single center randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Hemiparetic limb and gait recovery in patients with chronic unilateral cerebral hemispheric stroke

## **Interventions**

Chronic stroke patients of the Evexa rehabilitation center agreed to participate in a controlled, gait outcome study. Through simple randomisation, participants were divided into placebo and treatment groups, each receiving either 3 sham or real treatments and 5 outcome parameter measurements. Seven measurement parameters - TUG, 5XSST, and Stride Velocity, Stride Length, Step Time, Stride Time and Cadence were measured on each of the trial days. Measurements were made, by staff who were unaware of participant group status, at the same time of day, prior to any sham or treatments.

Treatments consisted of imparting a transcranial vibration (TVS), through the use of a hand-held device, on the skull of the damaged hemisphere. Ipsilateral joint fixation capacity is simultaneously evaluated through a functional manual muscle test (fMMt). When TVS induces a fMMT failure, a static transcranial magnetic stimulation (sTMS) is made over the area and a peripheral stimulus zone (PSZ), located through a local pain response linked to the sTMS. The PSZ will either be on one of the arms or the upper legs and is located through a heightened pain-response that occurs with sTMS application to the skull. A treatment intervention is then made.

The Sham treatments consisted of placing the hand-held, non-vibrating device on the skull and having the patient perform a sham manual muscle test. Participants had no knowledge the methodology and had no interaction during the trial period. Seven standardised gait and movement outcomes were measured.

From trial onset to trial end was 5-days with day one as the baseline score and first real or sham treatment. On days two and four another sham or real treatment was made. Outcome measurements were made prior to treatment intervention on each of the five days.

Randomisation was a 'simple coin flip' where the coin was flipped 3-times and landed on its own. Two or more out of three flips was considered the choice.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

transcranial vibration (TVS)

## **Primary outcome(s)**

Measured at baseline, and daily for 5 days:

1. The timed up and go (TUG) test measures movement disorders related to gait and balance.
2. The five times sit to stand (5XSST) test is used to evaluate lower limb strength and falls risk through repetitive trials.
3. Instrumented gait (Kinesis Instrumented Gait System) measurements of five gait parameters (stride and step times, stride velocity, stride length and cadence were measured.

TUG and 5XSST measurements are stand-alone and taken individually.

The gait parameters are statistically evaluated as individual elements and analysed with respect to their dynamic interaction.

## **Key secondary outcome(s)**

There are no secondary outcome measures

**Completion date**

30/07/2020

## Eligibility

**Key inclusion criteria**

1. 18 years of age or older at time of presentation to the Evexia Centre for rehabilitation due to a right or left hemiparesis caused by a unilateral cerebral hemispheric stroke
2. A manifested a gait disorder, yet with the ability to ambulate (with or without a mobility aid) without assistance for at least 20 meters

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

15

**Key exclusion criteria**

1. Younger than 18 years old
2. No gait disorder
3. Inability to ambulate with or without mobility for 20 metres
4. Pacemaker, defibrillator and/or an intracerebral clip
5. Any cognitive deficit that could interfere with testing comprehension
6. Lower limb surgery less than 6 months prior to the study
7. Any concomitant, progressive or systemic disease.

**Date of first enrolment**

03/12/2019

**Date of final enrolment**

30/06/2020

## Locations

**Countries of recruitment**

Greece

**Study participating centre**  
**Evexia Rehabilitation Centre**  
National road Thessaloniki-N.Moudania  
Nea Kallikratia  
Greece  
63080

## Sponsor information

**Organisation**  
Evexia Rehabilitation Centre

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Evexia Rehabilitation Centre

## Results and Publications

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

### **IPD sharing plan summary**

Stored in repository