

Will participating in this study benefit me?

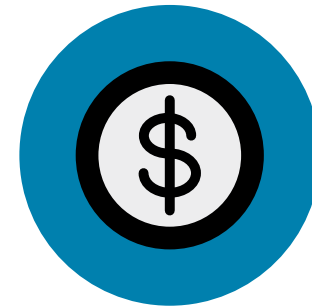
It is not possible to predict whether you will benefit directly from participation in this study. By participating in this study, you will receive 45 sessions of arm and leg exercise sessions, which may or may not benefit you.

CONTACT US:

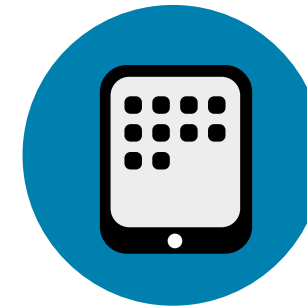
Researchers and clinicians at Brooks Rehabilitation and the University of Florida are conducting this study. Emily Fox, DPT, MHS, PhD is the study principal investigator. University of Florida and Brooks Rehabilitation
Contact the study team at (904) 544-5315 (call or text)
Brooks.research@brooksrehab.org
UF IRB protocol #202102400

Study ID:IRB202102400 Date Approved: 11/17/2021

What else should I know about this study?



You will not miss any usual treatment as prescribed by your doctor by taking part in this study, and the participation in this study is free of cost.



The device is controlled using an app on a tablet which will be provided.



It is required that a caregiver join a few of the sessions in the clinic and be approved by study staff so that during home sessions they can carry out the treatment sessions independently.

To learn more about the BQ5 clinical trial, please speak with your medical team

BrainQ

Study of Electromagnetic Central Nervous System Stimulation to Increase Stroke Recovery



About the BQ5 Clinical Trial

What is the purpose of this study?

- To find out if very low frequency and intensity electromagnetic field stimulation of the nervous system reduces long-term disability following an ischemic stroke for people with trouble moving their arm.
- The device used in this study is called the BQ 2.0 Device and is non-invasive, developed by BrainQ Technologies Ltd. It is an investigational device, meaning that it is still being tested and is not yet approved by the FDA.



What will happen in the study?



Participants in this study will be assigned with equal chance to receive either active or non-active (sham) treatment. They will not know which treatment they will receive.



Participants will receive 45 treatments over a course of approximately 9 weeks, 5 times a week, for about 60 minutes each treatment session.



Each session will last 60 minutes, with an active or sham field turned on for 40 minutes of the session. During the session participants will also perform physical and occupational therapy exercises for the arms and legs.



During your stay in a medical center, sessions will be done with a therapist present. Once the participant is discharged home, sessions will be completed with the assistance of an approved family member or other caregiver of your choice.



During certain sessions a study member may join via audio or video conferencing as part of the study oversight and supervision, and might visit at the home from time to time to ensure everything is okay.



The progress of the participant will be evaluated three times, at approximately one, three and six months after the stroke. The first two evaluations will take place in the clinic and the final evaluation will be via a call from home.

Is it possible that participating in this study can hurt me?

The risks of using this device are not fully known. To date, there have been no side effects related to the BQ 2.0 Device. In somewhat similar devices, some users reported tickling, numbing, seeing small specks of light or dark and fatigue and pain due to arm and leg exercises.

