



Clinical Trial of 1072nm Infrared Stimulation for Dementia

INVESTIGATOR:

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1. PURPOSE OF THE STUDY

This study measures whether problems with executive functioning (including attention, working memory, strategies of learning and remembering, planning, organizing, self-monitoring, inhibition, and flexible thinking) can be positively influenced by repeated brief exposure to 1072nm infrared light stimulation in order to increase cerebral blood flow and oxygenation (CBF).

2. DESCRIPTION OF THE PROJECT

This study involves the assessing of a new approach to improving mental functioning. The Quietmind Foundation (QMF) is a research and educational foundation devoted to bringing EEG biofeedback or neurofeedback and related technologies into the healthcare mainstream. We're currently studying ways to use these tools to improve cognitive and behavioral problems associated with degenerative brain disorders.

Study locations

Pre/post testing (3.5 hours) and study-related sessions of about 15 minutes will be conducted at the Quietmind Foundation offices in Plymouth Meeting, PA. Treatment sessions will also be provided at 2328 Pinnacle Court. Hebron, KY.

Enrollment and assignment to study conditions

The study will involve an evaluation of cognitive functioning and a recording of brain activity conducted by a member of the Quietmind staff, which will take 3.5 hours to complete before and after completing the 28 once daily sessions. Testing sessions will consist of paper and pencil testing as well as computerized neuro-psychological assessment batteries and a recording of my brain activity with eyes open and closed.

Subject Inclusion/Exclusion Criteria

We seek to include subjects whose symptoms are not greater than moderately severe and are:

- Aged between 50 - 85 years.
- Have established cognitive decline, Mini Mental Status Examination (MMSE) score between 15–25 (out of a possible score of 30).
- Generally healthy otherwise as indicated by recent physical examination.
- Subjects should have had a CT MRI scan in the previous 6 months which was consistent with a dementia diagnosis and no space occupying lesions or tumors of the head or neck.
- Have a caregiver/informant who has cared for the patient at least 5 days a week and is willing to attend study visits and provide information about the patient.
- If taking any psychotropic medication should have been stable for the previous 3 months.
- Must have had B12, folic acid, full blood count and ferritin screen within the previous 6 months or be on B12 and/or folic acid replacement.s

Exclusion criteria: Subjects with the following will not be considered eligible for this trial.

- Uncontrolled or unstable chronic illness, e.g., hypertension, COPD.
- Diagnosed actively growing intracranial pathology (tumors etc).
- Misusing illegal substances or alcohol.
- On regular systemic steroids or anti-metabolites.
- Systemic malignancies or tumors of the head and/or neck.
- Not fluent in English.
- Depressed as assessed by Beck Depression Inventory score.
- Lacking the capacity to give informed consent.
- Previous history of stroke or heart attack.
- History of aggression or violence.
- Inability to travel to the research venue for multiple assessments.
- A history of major psychiatric illness, seizure disorder, or physical illness that would compromise their participation in a daily treatment regimen.
- A participant may be disqualified if their performance is above the normative mean or below the lowest interpretable score of neuropsychological tests provided during the initial assessment (see #6, Sources of research material obtained from study participants, below).

Treatment Program

Participants will be randomly assigned to receive 28 active or inactive (placebo) treatment sessions, once daily. The full evaluation process will be repeated as soon after the 28th session as can be arranged. The sessions will last 15 minutes including the placement and removal of the helmet and blood flow measurement headband. During the first part of the session, blood flow is measured for two minutes using the headband placed around the forehead. This device will remain in place during the stimulation portion of the session. Participants will wear the headset and maintain an upward gaze for the duration of the session with normal blinking and they will need to sit relatively still for the entire six-minute process. The headset will be removed at this point and after another minute there will be another two-minute recording of blood flow using the headband device.

The 1072nm device is pictured below



3. CLINICAL TRIAL RECRUITMENT

Subjects are being recruited to begin this protocol on or about 1/5/2010 and will continue until the full subject pool is obtained.

4. COMPENSATION

Subjects will be compensated \$250 for their full participation in the project. Reasonable travel expenses will also be reimbursed.

5. PROJECT FUNDING AND SUPPORT

This project is funded by the Quietmind Foundation at this time. Acceptance into the study is independent of donor status. Additional funding is being sought to expand the number of people whom we can serve. Quietmind Foundation is a 501c3 charitable corporation and all donations are fully tax deductible.

Please make checks payable to Quietmind Foundation or click the Donate button on the top of the Quietmind Foundation home page at www.quietmindfdn.org .

Check our website to read more about the 1072nm infrared treatment process in the Clinical Trials section s.