



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 effectively treated by repeated brief (6min) exposure to 1072nm infrared light stimulation in order to increase cerebral blood flow, oxygenation (CBF), and facilitate removal of toxic proteins.

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 and treatment sessions of about 2hrs will be conducted at the Quietmind Foundation offices in Plymouth Meeting, PA. Additional treatment sites may be added based on recruitment response.

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 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 12 months which was consistent with a dementia diagnosis.
- 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.

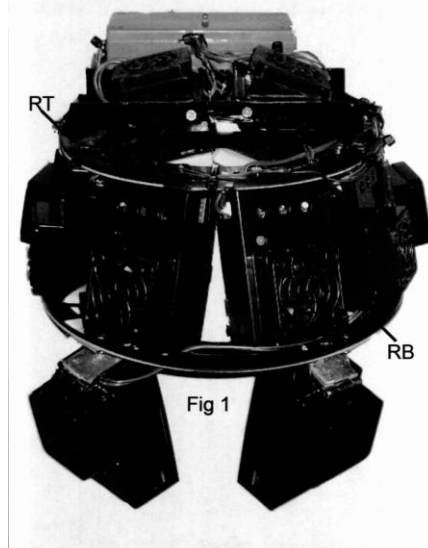
Exclusion criteria: Subjects with the following will not be considered eligible for this trial.

- 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.
- Not fluent in English.
- Depressed as assessed by Beck Depression Inventory score.
- Lacking the capacity to give informed consent.
- Dementia that may be due to other causes.
- 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 receive up to 28 treatment sessions, once daily, seven days a week. The full evaluation process will be repeated as soon after the 28th session as can be arranged. The 1072nm light stimulation 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 infrared stimulation portion of the session. Participants will wear the infrared stimulation 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 treatment period. 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

A presentation was made on the study by Dr. Berman and Dr. Dougal on December 12-13 at the Quietmind Foundation's offices. A copy of the powerpoint slides will be available for download.

4. COMPENSATION

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

5. PROJECT FUNDING AND SUPPORT

Additional funding is being sought to expand the number of people whom we can include. 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 home page.

Click [here](#) to read more media coverage about the 1072nm infrared treatment process.