



521 Plymouth Road Ste. 111, Plymouth Meeting, PA 19462 Tel. 610-940-0488 Fax 215-359-0630 www.quietmindfdn.org

PROJECT TITLE:

Clinical Trial: Efficacy of 1072nm Infrared Stimulation on Cognitive Symptoms of Dementia:

CAREGIVER INFORMED CONSENT

Caregiver _____

Participant: _____

Address: _____

City/State/Zip: _____

Telephone: (H) _____ (cell) _____

INVESTIGATOR: Marvin H. Berman, Ph.D, CBT, BCN, Principal Investigator

1. PURPOSE OF THE STUDY

I've been informed by the researcher that 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 (6-minute) exposure to 1072nm infrared light stimulation in order to increase cerebral blood flow (CBF) and oxygenation. I have been informed by the researcher that this particular frequency of light has been shown to increase the activity of brain cells and to provide support for the cells' ability to repair and be protected against further damage.

Initial please _____

2. DESCRIPTION OF THE PROJECT

I understand that I am being asked to support the participant in research concerning a new approach to improving mental functioning. The Quietmind Foundation (QMF) is a research and educational foundation devoted to bringing neurofeedback into the healthcare mainstream and studying ways to use biofeedback and related technologies to improve cognitive and behavioral problems associated with degenerative brain disorders.

Initial please _____

Study locations

I understand that I agree to have the participant be at the pre/post testing and infrared light stimulation sessions, which will be conducted at the QMF offices. Infrared light stimulation sessions can also be provided at 2328 Pinnacle Court. Hebron, KY 41048 pending prior approval by Dr. Berman.

Initial please _____

Enrollment and assignment to study conditions

The study will involve an evaluation of the participant's cognitive functioning and a recording of their 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, which will take 15 minutes each. I understand that the participant will be RANDOMLY ASSIGNED (like flipping a coin) to either a infrared light stimulation group or a placebo (no-infrared light stimulation) group. In the placebo group, participants will receive no infrared light stimulation but it will follow the same procedure as the active infrared light stimulation. Neither you, nor the participant, nor the technician working with the participant, will know which group the participant is in. If the participant is assigned to the control group and the infrared light stimulation is determined to be effective, the participant will be offered the active infrared light stimulation within 45 days of the last active infrared light stimulation group participant completing the infrared light stimulation program. I agree to support the participant in obtaining the active infrared light stimulation at that time.

Initial please _____

Caregiver Responsibilities

I agree to be responsible to have the participant present and on time for these testing sessions which will consist of paper and pencil testing as well as computerized neuropsychological assessment batteries. I understand that the participant's medical records may also be reviewed. I will support the participant in being available for all 28 daily sessions including scheduling makeup sessions in the event of illness, etc. I understand that the participant will be terminated from the study if they miss more than 5 consecutive sessions. Each infrared light stimulation session will last about 15 minutes. The full 3.5 hour evaluation process will be repeated as soon after the 28th session as can be arranged. I further agree to complete any caregiver-specific assessment instruments as may be necessary for the infrared light stimulation study. These forms will require no more than 1 hour to complete.

Inclusion/Exclusion Criteria Certification

I certify that I have been informed by the researcher of the criteria for the subject's inclusion or exclusion from this study and further certify, to the best of my knowledge, they do not meet any of the conditions listed below that would exclude them from this study.

Inclusion criteria for subjects

- Aged between 50 - 85 years.
- Have established cognitive impairment, Mini Mental Status Examination (MMSE) score between 15– 25 (from a possible score of 30).
- Generally healthy otherwise as indicated by recent physical examination.
- 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

- Uncontrolled or unstable chronic illness, e.g., hypertension, COPD.
- Diagnosed actively growing intracranial pathology (tumors etc).
- An associated psychotic illness.
- Misusing illegal substances or alcohol.
- On regular systemic steroids or anti-metabolites.
- Systemic malignancies or space occupying head and/or neck lesions or tumors.
- Not fluent in English.
- Depressed as assessed by Beck Depression Inventory score.
- Epilepsy.
- 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 infrared light stimulation regimen.

I understand the subject may be disqualified if their performance is above the normative mean or below the lowest interpretable score of the tests they will be given during the initial assessment. I understand that if preliminary testing indicates performance above or below study parameters, or the presence of an exclusionary condition (e.g., depression), they will be dropped from the study

Initial please_____

EEG recording

During the pre and post infrared light stimulation evaluation process, the participant will have a bathing cap containing 19 recording electrodes placed on their head and recordings made of their brainwave activity for 20-30 minutes. The recordings will be done in two segments, one with the participant keeping their eyes closed and the other eyes open with normal blinking. The placement of the cap and preparation of the sensors for the recordings may take 20-30 minutes to complete in addition to the recordings themselves. I will be required to have the participant's hair washed twice with 'no-residue' shampoo (Neutrogena Brand) prior to these assessments and not allow the participant to consume caffeine or other stimulants or nicotine within 6 hours of the testing. Please note that at no time will there be any electrical stimulation of any kind directed into the subject. These procedures involve only the recording of the body's own naturally occurring electrical activity.

Initial please_____

Brain Stimulation Procedure

The 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 the participant will have their blood flow measured for two minutes using the headband placed around their forehead. This device will remain in place during the infrared stimulation portion of the session.

The participant will wear the infrared stimulation headset and maintain an upward gaze for the duration of the session with normal blinking. The participant will need to sit relatively still for the entire six minute infrared light stimulation period. The headset will be removed at this point and after another minute there will be another two minute recording of the participant's blood flow using the headband device. The participant will alert the technician to any discomfort and adjustments will be made to assure their comfort during the session.

Initial please_____

Questions Regarding Participation

What if participant is receiving medications?

The participant will not be asked to stop or alter their current medications as a condition of participation in this study. I understand that if the participant is currently taking any prescription medications, it will be necessary to stay in contact with their physician to determine whether any changes in their medicines should be made during the course of this study. I agree to be responsible for this.

Initial please_____

What if participant is receiving counseling or psychotherapy?

This infrared light stimulation is not known to evoke emotional responses. If the participant is currently engaged in counseling or psychotherapy, I am aware that the participant should stay in contact with their therapist throughout their participation in this study. I agree to support this action.

Initial please_____

Benefits and risks of participation

The benefit of participating in this study is to improve scientific knowledge about whether this infrared light stimulation is effective for treating symptoms like those the participant is experiencing. However, I understand that the experimental nature of this infrared light stimulation means that there is currently no conclusive scientific evidence that this infrared light stimulation will improve the participant's symptoms.

This study has the following risks. The participant may experience a tightness or pressure from the helmet that some people occasionally find uncomfortable and may result in a brief headache. No other negative effects have been reported from the use of this device.

Initial please_____

Infrared (IR) light similar to the light that will be used in this study is also used to encourage healing of wounds, as it encourages the growth and efficiency of blood vessels. In many applications this is desirable. In theory, there is a possibility that if a person has a diagnosed or undiagnosed tumor, either at the place where the light is placed or possibly at a more distant location, the IR light treatment might encourage the growth of the tumor. There is no published scientific evidence nor reason to suspect that IR light can create a tumor where there was none before, only that it might encourage the growth of a tumor that already exists.

We have been unable to locate any research studies of this specific potential risk. In other words, there appears to be no evidence that IR light treatment DOES pose a risk of encouraging tumor growth and there also appears to be no proof that this does NOT occur. By agreeing to participate in this study, I am confirming that I am not aware of the subject having any pre-existing tumors and have no knowledge or reason to suspect that there is an undiagnosed tumor present. Furthermore, I understand the (probably small, but unknown) risk that the IR light might encourage the growth of an undiagnosed tumor.

Initial please_____

3. CONFIDENTIALITY STATEMENT

All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. I understand that data generated by the study may be reviewed by the United States Food and Drug Administration (FDA) and the Quietmind Foundation Institutional Review Board to assure proper conduct of the study and compliance with federal regulations. I understand that the results of this study may be published. If any data are published, neither I nor the participant will be identified by name.

Initial please_____

4. VOLUNTARY PARTICIPATION STATEMENT

I understand that my participation in this study is entirely voluntary and that I am free to withdraw from this trial at any time.

Initial please_____

5. COMPENSATION STATEMENT

I understand that the participant will receive \$250 compensation upon completion of the trial period or if they chose to withdraw, a pro-rated amount based on their aggregate hours of participations.

Initial please_____

6. COSTS STATEMENT

I understand that if my participant is accepted as a subject for this study, the infrared light stimulation and tests required by the study will be provided at no cost to me.

Initial please_____

7. INSTITUTIONAL CONTACTS

Person conducting this study: Marvin Berman, Ph.D Tel. 610-940-0488
Email marvinberman@quietmindfdn.org

If I have questions regarding the conducting of this research I may contact Dr. Allan Lundy, Chairperson, Quietmind Foundation IRB at Allan.Lundy@comcast.net.

8. TERMINATION STATEMENT

The investigator or the sponsor may terminate my participation in the study without my consent.

Initial please _____

10. FINAL STATEMENT AND SIGNATURE

This study has been explained to me, I have read the consent form and I agree to participate. I have been given a copy of this consent form.

Signature of Participant Caregiver

Date

As participant caregiver, I understand that I will be asked to complete a form that asks for my observations about the participant's symptoms during each evaluation session. I will also be empowered to withdraw consent and terminate their participation in the event that he or she becomes unable to do so.

Signature of Participant and/or Power of Attorney

Date

Signature of Investigator and Witness

Date