PROJECT TITLE: Efficacy of Infrared Phototherapy and EEG Biofeedback on Cognitive Symptoms of Dementia

Initiation Date:

INFORMED CONSENT

PARTICIPANT'S NAME AND ADDRESS:

INVESTIGATOR:
James P. Halper, MD – Medical Director Co-Investigator, Marvin H. Berman PhD, President Quietmind Foundation 315 Yorktown Plaza Elkins Park, PA 19027. Phone: 610-940-0488 Fax: 215-539-0630

1. PURPOSE OF THE STUDY: This study measures whether cognitive and behavioral symptoms, e.g., memory loss and related diminished cognitive functioning can be effectively treated by repeated short-term exposure to near-infrared light stimulation to increase regional cerebral blood flow (rCBF) and biofeedback training to normalize brain electrical connectivity.

2. DESCRIPTION OF THE PROJECT: I understand that I am being asked to participate in research concerning a new approach to improving physical and mental functioning. The Quietmind Foundation (QMF) is a not-for-profit research and educational foundation devoted to bringing neuromodulation techniques into the healthcare mainstream and studying ways to use biofeedback and related technologies to improve cognitive and behavioral problems associated with degenerative brain disorders. This is a single subject study.

Study location: Pre/post testing of about 2hrs and periodic evaluation sessions will be conducted at the QMF offices or a designated clinician's office convenient to the subject. All ongoing treatment sessions will be conducted at subject's home over the period of this trial.

Enrollment and assignment to study conditions: The study will involve an evaluation conducted by a Quietmind staff person or designated local clinician, which will take 1.5 hours to complete**.** I understand that my medical records will also be reviewed by the Medical Director, Consulting Neurologist and Principal Investigator. I will participate in quarterly evaluation of my symptoms either at Quietmind Foundation's offices in Plymouth Meeting, PA or at a designated clinic chosen by the Principal Investigator and study Medical Director. I will be required to complete a Quantitative EEG and series of assessments of my memory and other cognitive functions including following a series of instructions and some computer-based activities that measure my cognitive abilities.

Medical evaluation by my personal physician is required to independently monitor my treatment progress with reports sent to the study Medical Director. I will arrange for these periodic assessments to be conducted immediately prior to initiating treatment sessions and again quarterly for the duration of the trial.

EEG recording: During the ongoing evaluation process, I will have a cap containing 19 recording electrodes placed on my head and recordings made of my eyes open and closed brainwave activity for 8-10 minutes respectively. The placement and preparation for the recordings may take 20-30 minutes to complete in addition to the recordings themselves. I will be required to wash my hair twice with clarifying shampoo prior to these assessments.

Brain Stimulation Procedure: The light stimulation sessions will last 5 minutes not including placement and removal of the helmet. During the sessions, I will wear the infrared stimulation headset as instructed and maintain an upward gaze for the duration of the session with normal blinking. I will need to sit relatively still for the entire treatment period. I agree to make Dr. Berman aware of any discomfort so that adjustments can be made to assure my comfort during future sessions.

EEG Biofeedback Training: I will have electrodes placed on my earlobes and one or two on my scalp using conductive paste. I will attend to the computer display and/or listen to music of my choosing while the EEG amplifier is connected to the computer. The music and/or video display will be interrupted briefly whenever my brain activity is not within the parameters setup by the experimenter. I will focus my attention on the display for 15-30minutes. I will do these training sessions at a frequency of 3-5 times a week. Comprehensive training and supervision of neurofeedback sessions will be conducted in person and remotely via internet connection by Dr. Berman and/or a qualified clinician

Questions Regarding Participation

What if I am receiving other medications? I will not be asked to stop or alter my current medications as a condition of participation in this study. I understand that if I am currently taking any prescription medications, it will be necessary to stay in contact with my physician to determine any changes in my medication.

What if I am receiving counseling or psychotherapy? This treatment is not known to evoke emotional responses. If I'm currently engaged in counseling or psychotherapy, I am aware that I should stay in contact with my therapist throughout my participation in this study.

Benefits and risks of participation: The benefit of participating in this study is to improve scientific knowledge about whether this treatment is effective for treating symptoms like those I am experiencing. However, I understand that the experimental nature of this treatment means that there is currently no conclusive scientific evidence that this treatment will improve my symptoms. This study has the following risks. You 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. The EEG biofeedback training has no recognized negative side effects when sessions are properly conducted. Mild allergic responses to the conductive gel are sometimes observed and resolve with repeated cleansing the affected area with alcohol.

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 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, I will not be identified in any way that could compromise my privacy.

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 and that my participation may be discontinued by the study director Dr. Berman if he determines, in consultation with your primary physician and James P. Halper, MD Medical Director that the treatment is having a countertherapeutic effect.

6. COSTS STATEMENT
I understand that if I am accepted as a subject for this study I will pay a $15,000 equipment fee covering the full 24-month protocol duration and includes the exclusive use of the infrared helmet and neurofeedback training equipment. Full payment either by check payable to Quietmind Foundation or wire transfer will be made prior to the study being initiated. Continuation beyond 24 months requires additional funding support to be negotiated prior to the termination of the initial trial period. Purchase of the study related equipment for $1.00 will occur after QMF obtains FDA approval for the use of this technology in the treatment of cognitive symptoms of dementia.

7. INSTITUTIONAL CONTACTS
The researcher supervising this study
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IRB CONTACT
Allan Lundy, Ph.D., IRB Chairman
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email alundy@quietmindfdn.org

9. 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 Date _____

_____
Signature of QMF Representative Date
Do Not Write Below This Line

Study # _____ IRB Approval # _____

Trial initiation date: _____ Trial Termination date: _____