

315 Yorktown Plaza Elkins Park, PA 19027

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**PROJECT TITLE:**

Clinical Trial: Efficacy of 1068nm Infrared Stimulation on Age Related Memory Impairment:

## **PARTICIPANT INFORMED CONSENT**

**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 five minute) exposure to 1068nm 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 be a 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 Age Related memory Impairment. Initial please\_\_\_\_\_\_\_\_\_\_\_

Study locations

I understand that I agree to be at the pre/post testing will be conducted at the QMF offices at 315 Yorktown Plaza Elkins Park, PA 19027.

Initial please\_\_\_\_\_\_\_\_\_\_\_

Enrollment and assignment to study conditions

The study will involve an evaluation of my cognitive functioning and a recording of my brain activity conducted by a member of the Quietmind staff, which will take 1 hourbefore and after completing the 60 consecutive (daily) sessions, which will take 5 minutes each twice daily. I understand that I will be RANDOMLY ASSIGNED (like flipping a coin) to either an active infrared light exposure group or a placebo (no infrared light stimulation) group. In the placebo group, participants will receive no IR stimulation during the sessions but it will follow the same procedure as the active treatment procedure. Neither I, nor the technician working with me, will know which group I am in. If I am in the control group and the infrared light stimulation is determined to be effective, I will be offered to begin the active infrared light stimulation within 45 days of the last ‘active infrared light stimulation group’ participant completing the 60-day infrared light stimulation program. A transcranial NIR phototherapy device will be provided for the 60 day period of study

Initial please\_\_\_\_\_\_\_\_\_\_

Participant Responsibilities

I agree to be responsible to be present and on time for these testing sessions which will take no more than 1 hour and consists of memory and executive function tests and I will use a computer to measure my reaction time. I understand that my medical records may also be reviewed. I understand that I will need to treat myself on 60 consecutive (daily) days with the near infrared helmet apparatus. Each of these twice daily sessions will last no more than 5 minutes. I will alert the research staff in the event I am unable to treat myself as soon as practical. My participation will be terminated by the researcher if I miss 10 consecutive infrared light stimulation sessions. I will cooperate with the researchers to complete the full evaluation process as soon after my 60th infrared light stimulation session as can been completed. I will return the near infrared helmet apparatus at the conclusion of the 60th day treatment period.

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Inclusion/Exclusion Criteria Certification

I certify that I have been informed by the researcher of the criteria for inclusion and exclusion for this study and further certify that I do not meet any of the conditions listed below that would prevent my being included in this study.

**Inclusion criteria for subjects:** we will seek to include subjects whose symptoms are not greater than moderately severe.

* Aged between 60 - 95 years.
* MMSE>25
* 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. (this is because low Vit B12 is a known, treatable cause of intellectual decline)

**Exclusion criteria**

* Uncontrolled or unstable chronic illness, e.g., hypertension, COPD.
* Diagnosed with dementia of any cause
* MMSE<=27
* 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 lesions or tumors.
* Not fluent in English.
* Depressed as assessed by Beck Depression Inventory score.
* Epilepsy.
* Lacking the capacity to give informed consent.
* Previous history of stroke.
* 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 my participation in a daily infrared light stimulation regimen.

I understand that I may be disqualified if my performance is above the normative mean or below the lowest interpretable score of the tests I 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), I will be dropped from the study.

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EEG recording

During the pre and post infrared light stimulation evaluation process, I will have a bathing cap containing 19 recording electrodes placed on my head and recordings made of my brainwave activity for 20-30 minutes. The recordings will be done in two segments, one with me keepng my eyes closed and the other with 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 my hair washed twice with no- residue shampoo, e.g., Neutragena prior to these assessments and not consume caffeine or other stimulants or nicotine within 6 hours of the testing.

I understand that at no time will there be any electrical stimulation of any kind directed into me. This procedure involves only the recording of the body’s own naturally occurring electrical activity. The entire process takes about one hour.

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Brain Stimulation Procedure

The light stimulation sessions will last five minutes twice daily including the placement and removal of the helmet. I will wear the infrared stimulation headset. I will need to sit relatively still for the entire infrared light stimulation period. The headset can be removed at this point. I will alert the investigator if I have any discomfort during any one of my sessions.

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#### Questions Regarding Participation

What if I am receiving 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 for me to stay in contact with my physician to determine whether any changes in my medicines should be made during the course of this study. I agree to be responsible for this.

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What if I am receiving counseling or psychotherapy?

This infrared light stimulation is not known to evoke emotional responses. If I am currently engaged in counseling or psychotherapy, I will stay in contact with my therapist throughout my participation in this study.

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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 I am 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 my symptoms.

This study has the following known risks: I 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 this type of 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 any pre-existing tumors and have no reason to suspect that there is an undiagnosed tumor present. Furthermore, I accept the (probably small, but unknown) risk that the IR light might encourage the growth of an undiagnosed tumor.

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**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, I will not be identified by name or any other personal information.

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**

No compensation is offered for participation in this trial.

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**6. COSTS STATEMENT**

I understand that if I am 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**

The researcher conducting this study is: Marvin Berman, Ph. D.

Phone 610-940-0488

email [marvinberman@quietmindfdn.org](mailto:marvinberman@quietmindfdn.org)

If I have concerns or questions about the conducting of this research I can also contact Dr. Allan Lundy, Chairperson Quietmind Foundation IRB, [Allan.Lundy@comcast.net](mailto:Allan.Lundy@comcast.net)

**8. TERMINATION STATEMENT**

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

Initial please\_\_\_\_\_\_\_\_\_\_\_

**9. FINAL STATEMENT AND SIGNATURE**

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

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Signature of Participant/Co-Participant with POA Date

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Signature of Co-Participant with POA Date

\_\_\_\_\_\_\_\_\_

Signature of Investigator and Witness Date

***Check certifies a signed copy was given to participant and caregiver.***