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Recruiting

Study Application of LED Therapy to Improve Thinking and Memory in Veterans With Gulf War Illness

ClinicalTrials.gov ID NCT06182578
Sponsor Veterans Affairs Office of Research and Development
Information provided by (Responsible Party) VA Office of Research and Development (Responsible Party)
Last Update Posted July 8, 2024

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Study Overview

Official Title
Study Application of LED Therapy to Improve Thinking and Memory in Veterans With Gulf War Illness

The purpose of this study is to learn if an experimental treatment can help improve thinking and memory in Veterans with Gulf War Illness (GWI). The experimental treatment is called light emitting diodes (LEDs), and you will be randomly assigned to receive either active LED treatment or a sham (inactive) LED. LEDs are also placed in the nostrils (one red diode, and one infrared diode) and in the mouth (infrared diode) for 20 minutes, while you sit in a reclining chair. There are no known risks associated with the LED treatment. The hypothesis is: Veterans taken about 20 minutes of active LED treatment will show improvements in thinking and memory compared to Veterans with GWI who receive 20 minutes of sham LED treatment. The PI's consider the hamlet LED device and twice, to be a non-significant risk device. The device is not being used to treat, diagnose, or monitor a disease or affliction. The device will be used according to the manufacturer's instructions. The hamlet LED device is used on each eye. The LEDs do not touch your eyes.

Research Hypothesis

Rationale:

Impaired cognition is one of the 3 major symptom areas of GWI. Mitochondrial dysfunction is reported in Gulf War Illness (GWI) veterans, and is associated with impaired cognition, including impaired cognitive processing speed, and impaired verbal learning and memory.

Improved mitochondrial function with increased production of adenosine triphosphate (ATP) have been reported in Veterans with Gulf War Illness and other PTSD populations.

Recent evidence in humans has shown an increase in regional cerebral blood flow subjected to where the area of LED is exposed, given to the scalp (Zhang et al., 2020). Increased blood flow, in turn, increases ATP.

Hypothesis:

Veterans taken about 20 minutes of active LED treatment will show improvements in cognitive processing speed, and verbal learning and memory, compared to Veterans with GWI who receive 20 minutes of sham LED treatment.

Research Design:

Impaired cognition is one of the 3 major symptom areas of GWI. Mitochondrial dysfunction is reported in Gulf War Illness (GWI) veterans, and is associated with impaired cognition, including impaired cognitive processing speed, and impaired verbal learning and memory.

Improved mitochondrial function with increased production of adenosine triphosphate (ATP) have been reported in Veterans with Gulf War Illness and other PTSD populations.

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Design:

Veterans 2. Twice (Gulf War Veterans) (Twice) were used simultaneously on each eye. Twice (Gulf War Veterans) (Twice) were used simultaneously on each eye.

Each participant wore a sham (inactive) device for between 20 minutes to protect the participant's eyes from the light emitted from the active device, and to be blind to the treatment. The sham device was assigned to each participant and only used by that participant. It was begun in a reclining Veteran's chair in the treatment room, and discontinued after participant's completion of the study.

Each participant wore a sham (inactive) device for between 20 minutes to protect the participant's eyes from the light emitted from the active device, and to be blind to the treatment. The sham device was assigned to each participant and only used by that participant. It was begun in a reclining Veteran's chair in the treatment room, and discontinued after participant's completion of the study.

Participant will be randomized to receive active or sham LED treatment, and then participant will be given a 1 week washout period, and then participant will be given the other treatment (active or sham).

Sequence and Timing of LED treatment, each session:

Part 1: The LEDs in the left and right eyes for about 14 minutes, then

Part 2: The LEDs in the left and right sides of the hamlet are on for about 14 minutes, for a total of 20 minutes.

During Parts 1 and 2, the infrared diode are on for about 20 minutes.

Part 3: Red LED hamlet (eyes each simultaneously on this), and Red LED for 4 mins, turned on towards the end of treatment.

Approximate treatment time is about 20 minutes, per session. The participant was treated in a soft reclining chair. Each visit lasts about 2 hrs (6 hrs total for the study participation).

There were 12 visits in all (1 screening visit and 11 treatment visits). Visits 1-5 (weeks 1-5) consisted of a scheduled twice per week, with a 3 day minimum between visits, and a 4 day maximum between appointments that appointment is scheduled. However, if the participant only made 1 appointment, and a least period, he/she was ambulatory from Visits 1-5 (weeks 1-5) consisted of a scheduled twice per week, with a 3 day minimum between visits, and a 4 day maximum between appointments. There are small fees with the LED hamlet (to assist in carrying out the study, and to be able to pay for the study, and to be able to pay for the LEDs and, or, the sham.

CVLT-II Long Delay Cued Recall	California Verbal Learning Test- II, Long Delay (20 min) Cued Recall measures Recall Memory, with a min score of 0 and a max score of 16, higher score = better outcome After 20 minute delay participant is given cues of 4 categories and asked to recall the words within each category. Total number of items recalled across all categories.	1-2 weeks before LED treatment series; within 1 Week and 1 Month after the last LED treatment
Conner's Continuous Performance Test II (CPT) False Alarms	CPT, False Alarms (Administered on laptop computer) measures Selective and Sustained Attention percent errors; lower = better outcome Participant presses space bar when an X appears on screen. False alarms is number of errors made (responding to non-targets), reported as percentage.	within 1 week before LED treatment series, within 1 Week and 1 Month after the last LED treatment
CPT Correct Detections, Reaction Time (RT)	Conner's Continuous Performance Test II; Mean Correct Detections, Reaction Time, (Administered on laptop computer) measures Selective and Sustained Attention, shorter = better outcome Participant must press the space bar when they see an X. Reaction Time for correct responses only.	within 1 week before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Conner's Continuous Performance Test II (CPT), D'	Conner's Continuous Performance Test II (CPT), D' (sensitivity index) (Administered on laptop computer) measures Selective and Sustained Attention; ability to detect the signal (x) within noise; values range 2 to 2; higher value better Value d' is a measure of the difference between the signal (X) and noise (non-target letters) distributions, assessing the participant's discriminative power.	within 1 week before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Rey Osterrieth Complex Figure Test (ROCFT), Immediate Recall	ROCFT; Immediate Recall measures Visuospatial memory with min 0 and max 36; higher score better outcome Participant is presented with a figure. They are asked to copy the figure. Then they are immediately asked to recall and draw the figure. Figure is scored on 18 units; up to 2 points per unit Scoring based on accuracy and placement of figure parts: A score of 6, 0.5 recognizable and incorrectly placed, 1 accurate or correctly placed or 2 both accurate and correctly placed; 0 is given if part is omitted or unrecognizable.	within 1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
ROCFT, Delayed Recall	Rey Osterrieth Complex Figure Test (ROCFT), Delayed (20-min) Recall measures Visuospatial memory with min 0 and max 36; higher = better outcome Participant is asked to draw the figure from memory after a 20 minute delay (other tasks completed during this time). Figure has 18 units; Scoring is based on accuracy and placement: 0 if unrecognizable or omitted, 0 recognizable, 1 either accurate or correctly placed or 2 both accurate and correctly placed, per unit.	within 1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Beck Depression Inventory (BDI)	BDI; 21 item Questionnaire; Mood. With min 0 and max 63; 0-13 minimal; 14-19 mild; 20-28 moderate; 30-63 severe; lower scores = better outcome Score per item: 1-3	within 1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
PCL-Civilian Survey	Post Traumatic Stress Disorder 17-item, symptom questionnaire; higher scores indicates greater endorsement of symptoms with min 17 and max 85; Reliable decrease 5-10; Clinically meaningful decrease 10-20 points (Monson et al., 2008); Lower scores = better outcome Score ranges from 1-5 for each item.	within 1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Visual Analog Pain Rating	Visual Analog Pain Rating Scale (VAS); Current Pain Rating scale of 1-10; lower score = better outcome *must be lower than 7 at entry into study for study inclusion Participant rates current level of pain (includes body, muscular, headache etc) by marking a line on a continuous scale from 1-10.	within 1-2 weeks before LED treatment, within 1 Week and 1 Month after the last LED treatment
Short Form McGill Pain Questionnaire	Short Form McGill Pain Questionnaire; Pain Rating (for the last 30 days) with min 0 and max 45; lower = better outcome Participant rates 15 types of pain (None = 0, mild = 1, moderate = 2, severe = 3). Totaled for all types of pain.	within 1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Pittsburgh Sleep Quality Index (PSQI)	Global Sleep Score with min score of 0 and max score of 27; lower score = better outcome 9 item questionnaire- make up 7 component scores (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction) with a min of 0 and max of 3 per component. Global score is total of the 7 component scores.	1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Karolinska Sleepiness Scale	Measure of Sleepiness; Participant indicates current level of sleepiness on a scale of 1 extremely alert to 10 extremely sleepy; lower score = better outcome	1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Short Form-36V Plus (PCS)	36 Question General Health Survey/Questionnaire for Veterans; Physical Composite Score (PCS) measures endorsement of physical health symptoms related to physical functioning, which affect 7 areas (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, mental health); Z-Score; lower = better outcome.	within 1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Short Form-36V Plus (MCS)	36 Question General Health Survey/Questionnaire for Veterans; Mental Composite Score (MCS) measures endorsement of mental health symptoms which affect 7 areas (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, mental health); Z-Score; lower score is better (based on scoring of the Veterans RAND 36 Item Health Survey (SV-36) formerly Veterans SF-36.	within 1-2 weeks before LED treatment series; within 1 Week and 1 Month after the last LED treatment
Multidimensional Fatigue Inventory (MFI), General Score	Measures General Fatigue Levels; lower = better; General Fatigue Subscale = sum of items numbers 1, 5, 12 and 16 (max = 5, min =0 for each item) Max possible sum is 20.	1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Multidimensional Fatigue Inventory, Physical Score	Physical Score Subscale Measures Physical Fatigue Levels; lower = better outcome; sum of items numbers 2, 8, 14 and 20 (max = 5, min =0 for each item)	1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Multidimensional Fatigue Inventory, Reduced Activity Score	Reduced Activity Subscale measures fatigue levels during activity; lower = better outcome; sum of items numbers 3, 6, 10 and 17 (max = 5, min =0 for each item) Max possible sum is 20.	1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Multidimensional Fatigue Inventory, Reduced Motivation Activity	Reduced Motor Activity subscale measures if fatigue affects motivation levels; lower score = better outcome; sum of items numbers 4, 9, 15, and 18 (max = 5, min =0 for each item) Max possible sum is 20.	1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment
Multidimensional Fatigue Inventory, Mental Fatigue	Mental Fatigue subscale measures mental fatigue levels; lower = better outcome; sum of items numbers 7, 11, 13 and 19 (max = 5, min =0 for each item) Max possible sum is 20.	1-2 weeks before LED treatment series, within 1 Week and 1 Month after the last LED treatment

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

VA Office of Research and Development

Investigators

- Principal Investigator: Margaret Naeser, PhD; VA Boston Healthcare System Jamaica Plain Campus, Jamaica Plain, MA
- Principal Investigator: Linda L Chao, PhD; San Francisco VA Medical Center, San Francisco, CA

Publications

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- Martin PI, Chao L, Krengel MH, Ho MD, Yee M, Lee R, Knight J, Hamblin MR, Naeser MA. Transcranial Photobiomodulation to Improve Cognition in Gulf War Illness. Front Neurol. 2021 Jan 21;11:574386. doi: 10.3389/fneur.2020.574386. eCollection 2020.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates	Results Reporting Dates	Study Record Updates
First Submitted 2013-01-30	Results First Submitted 2019-10-03	Last Update Submitted that met QC Criteria 2020-01-17
First Submitted that met QC Criteria 2013-01-30	First Submitted that met QC Criteria 2020-01-17	Last Update Posted 2020-01-22
First Posted (Estimated) 2013-02-01	Results First Posted 2020-01-22	Last Verified 2020-01

More Information

Record History

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Terms related to this study

Keywords Provided by VA Office of Research and Development

Gulf War Veterans Illness
Veterans Health
Executive Function
Memory
Attention
Cognition
Laser Therapy, Low-Level
Phototherapy
Light Therapy
Depression
Light-Emitting Diodes

Additional Relevant MeSH Terms

Neurologic Manifestations
Nervous System Diseases
Memory Disorders
Neurobehavioral Manifestations

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

No

Product Manufactured in and Exported from the U.S.

No

Study Documents Provided by VA Office of Research and Development

- Study Protocol and Statistical Analysis Plan [PDF, 2.22MB, 2017-12-15]