Trial record **1 of 3** for: Baylor Scott White | Dementia

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Assessing Feasibility of Prolonged Repetitive Near Infrared Light Stimulation in Early to Mid-Stage Dementia

ClinicalTrials.gov Identifier: NCT03750409

Recruitment Status : Recruiting
First Posted : November 22, 2018
Last Update Posted : November 28, 2018

See **Contacts and Locations**

Sponsor:
Baylor Research Institute

Collaborator:
Quietmind Foundation

Information provided by (Responsible Party):
Baylor Research Institute

Study Description

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Brief Summary:

This study will gather data to see if infrared and near infrared light frequency can increase the activity of brain cells and provide support for the cell's ability to repair and protect themselves against further damage.

Condition or disease	Intervention/treatment	Phase
Mild to Moderate **Dementia**	Device: Helmet	Not Applicable

Detailed Description:

Research suggests that impaired regional cerebral blood flow (rCBF) [flow of blood in certain parts of the brain] plays an important role in dementia. Infrared and near infrared light frequency has been shown to increase the activity of brain cells and provide support for the cell's ability to repair and protect themselves against further damage. This study will evaluate the effects of repeated brief exposure to near infrared light stimulation twice a day on subjects that have problems such as attention span, working memory, strategies of learning and remembering, planning, organizing, self-monitoring, inhibition and flexible thinking for an 8 week period.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	100 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description:	Double blind
Primary Purpose:	Treatment
Official Title:	Assessing Feasibility of Prolonged Repetitive Near Infrared Light Stimulation on Cognitive and Behavioral Symptoms in Early to Mid-Stage **Dementia**

Actual Study Start Date : October 15, 2018
Estimated Primary Completion Date : October 15, 2020
Estimated Study Completion Date : October 15, 2020

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Dementia

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Helmet Active Device Patients will be randomized 2:1 ratio to receive either the helmet active device or the helmet sham matched device. EACH device will be delivered with a highly visible tag with either an 'A' or 'B' respective to the study group the patient was randomized to.	Device: Helmet The portable device covers the head and weighs about 3.5 lb., and is made of light-weight, durable plastic, it is placed on the head with eye panels facing forward. Elastic straps holding the arrays together easily expand to conform to each subjects' head. Patients may notice slight warming of scalp after usage. This warming effect is similar to wearing a regular motorcycle helmet for a similar duration. Other Name: Photobiomodulation device
Sham Comparator: Helmet Sham Patients will be randomized 2:1 ratio to receive either the helmet active device or the helmet sham matched device. EACH device will be delivered with a highly visible tag with either an	Device: Helmet The portable device covers the head and weighs about 3.5 lb., and is made of light-weight, durable plastic, it is placed on the head with eye panels facing forward. Elastic straps holding the arrays together easily expand to conform to each subjects' head. Patients may notice slight warming of scalp after usage.

'A' or 'B' respective to the study group the patient was randomized to.	This warming effect is similar to wearing a regular motorcycle helmet for a similar duration. Other Name: Photobiomodulation device

Outcome Measures

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Primary Outcome Measures :

1. Memory Score [Time Frame: Before first treatment, at 4 weeks and then at 8 weeks.]

   Mini Mental State Exam will be performed in beginning of the study (before first treatment), in the middle of the treatment (in 4 weeks) and in the end of treatment (in the end of 8 weeks). This quick assessment will be able to score assessed individuals using 0-30 scoring range. Collected scores will be compared at different time points and any numerical change in score will be evaluated.

2. Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog test) test [Time Frame: Before first treatment, at 4 weeks and then at 8 weeks.]

   ADAS-Cog test will be performed in beginning of the study (before first treatment), in the middle of the treatment (in 4 weeks) and in the end of treatment (in the end of 8 weeks) to measure cognition. This comprehensive test will measure patient's ability of language and memory. Test consist of 11 parts and will help to assess baseline and determine cognitive change over period of treatment using patient's ability to answer questions and given score.

3. Quantitative Electro Encephalography (QEEG) [Time Frame: Before first treatment, at 4 weeks and then at 8 weeks.]

   QEEG measurement will be performed in beginning of the study (before first treatment), in the middle of the treatment (in 4 weeks) and in the end of treatment (in the end of 8 weeks). This measurement will use modern analytic software to process activity of the brain during cognitive task in the forms of electrical signals received from the surface of the scalp. Analytical software uses algorithms to assess recorded brain impulses and evaluate brain function, helping to track changes in the brain function due to treatment.

   Waveforms of EEG being assessed:

1. Delta frequencies (1-4 HZ) are produced during sleep are widespread in the frontal central region. Delta is necessary for sleep and stillness.
2. Theta frequencies (4-8 HZ) are associated with selective attention, retrieving newly learned information, and preceding sleep. Theta aids creativity and problem solving.
3. Alpha frequencies (8-12 HZ) appear in the posterior when the eyes are closed. It is associated with idling and

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	50 Years to 85 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Aged 50-85 years with an independently provided diagnosis of dementia, probable Alzheimer's type.
- Dementia symptoms not greater than early to mid-stage dementia
- Generally healthy as indicated by recent physical examination within the last 6 months
- If labs are available within the last 6 months, renal function, hepatic function, cardiac function should be normal

Exclusion Criteria:

- Diagnosed actively growing intracranial pathology (tumors etc.)
- Misusing illegal substances or alcohol
- Previous history of stroke
- History of aggression or violence
- History of major psychiatric illness
- No underlying CNS pathology (confined to tumor, epilepsy only)

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03750409***

Contacts

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Contact: Damir Nizamutdinov, MD/PhD	254-239-4228	Damir.Nizamutdinov@BSWHealth.org

Locations

United States, Pennsylvania

Quietmind Foundation **Recruiting**

Elkins Park, Pennsylvania, United States, 19027

Contact: Marvin Berman, PhD 610-940-0488 marvinberman@quietmindfdn.org

United States, Texas

Baylor Scott and **White** Medical Center, Temple **Recruiting**

Temple, Texas, United States, 76508

Contact: Richard Castillo 254-724-7727 Richard.Castillo@BSWHeatlh.org

Contact: Damir Nizamutdinov, MD/PhD 254-239-4228 Damir.Nizamutdinov@BSWHealth.org

Sponsors and Collaborators

Baylor Research Institute

Quietmind Foundation

Investigators

Principal Investigator: Jason H Huang, MD **Baylor Scott** and **White** Healthcare

Principal Investigator: Marvin H Berman, PhD Quiet Mind Foundation

Study Documents (Full-Text)

Documents provided by Baylor Research Institute:

Informed Consent Form [PDF] May 31, 2018

Study Protocol [PDF] October 24, 2018

More Information

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Responsible Party:	Baylor Research Institute
ClinicalTrials.gov Identifier:	NCT03750409 History of Changes
Other Study ID Numbers:	018-209
First Posted:	November 22, 2018 Key Record Dates
Last Update Posted:	November 28, 2018
Last Verified:	November 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Baylor Research Institute:

dementia

Additional relevant MeSH terms:

Dementia
Brain Diseases
Central Nervous System Diseases
Nervous System Diseases
Neurocognitive Disorders
Mental Disorders