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Photobiomodulation for Early Stage Alzheimer’s Disease (PhESAD)

This clinical trial will examine whether a non-invasive brain stimulation technique is safe and tolerable as a potential intervention for individuals with early stage Alzheimer’s.

PI

- M.D., University of Medicine and Pharmacy, Bucharest Romania 1992
- Associate Professor of Psychiatry, New York University School of Medicine
- Director of Clinical Research, Nathan Kline Institute for Psychiatric Research, NY

Background

Recent studies suggest that specialized structures inside cells called mitochondria – a powerhouse of energy generation for cells – may undergo damage early on, in Alzheimer’s. Studies in genetically engineered Alzheimer’s-like mouse models have shown that near infrared light generated by a laser source may directly penetrate the brain and stimulate the function of mitochondria and improve brain blood flow. Dr. Iosifescu believes that this non-invasive brain stimulation technique called “transcranial photobiomodulation” (t-PBM) could thereby potentially improve brain changes observed in Alzheimer’s. Dr. Dan Iosifescu will test this technology in humans.

STUDY

- CADRO category: Translational Research & Clinical Interventions

Research Plan

Building on studies in the animal models, Dr. Iosifescu and colleagues will conduct a Phase 2 clinical trial in 50 individuals with amnesic Mild Cognitive Impairment (aMCI) (a cognitive impairment that primarily impacts memory) and test the safety and tolerability of the t-PBM technique. Participants will either receive t-PBM or an inactive device (which will create the experience of t-PBM without actually receiving the laser stimulation associated with t-PBM). Using cognitive tests, the researchers will study whether t-PBM improves cognitive function in the participants. In addition, they will monitor behavioral symptoms (such as depression) and sleep quality in the participants in response to receiving t-PBM. Furthermore, the researchers will collect brain scans (functional Magnetic Resonance Imaging – fMRI) from the participants. Using these measures, the researchers will evaluate the impact of t-PBM on brain changes (for instance, decrease in the level of plaques in the brain and improved mitochondrial function) as well as improved brain blood flow. They will then prepare to test it in larger clinical trials.

Impact

The study results will evaluate whether a non-invasive technique is safe and tolerable for individuals with aMCI and early stage Alzheimer's, and whether it could potentially improve cognitive function.

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