

THERAPEUTICS

PhotoBioModulation

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OVERVIEW

Name: PhotoBioModulation

Synonyms: Low level light therapy, Low level laser therapy, Cold laser therapy, Transcranial infrared brain stimulation, Transcranial photobiomodulation, Transcranial near-infrared laser therapy (NILT), Transcranial low-level light therapy

Therapy Type: Procedural Intervention

Target Type: Inflammation ([timeline](#)), Unknown

Condition(s): Alzheimer's Disease, Mild Cognitive Impairment, Parkinson's Disease

U.S. FDA Status: Alzheimer's Disease (Not Regulated), Mild Cognitive Impairment (Not Regulated), Parkinson's Disease (Not Regulated)

BACKGROUND

Photobiomodulation is a form of light therapy that exposes tissue to red or near-infrared (NIR) light. Low-energy lasers or light-emitting diodes are placed on or near the skin. Their light penetrates tissue, where endogenous chromophores absorb it, and cause physical and chemical changes in cells. This non-heating therapy employs wavelengths from ~600 to ~1100 nm. Near-infrared light, with its longer wavelengths, penetrates tissues more deeply than shorter wavelengths of red light. This treatment causes no notable side effects, and can be done at home.

Red or NIR light is claimed to promote cell health by enhancing mitochondrial energy production, and by increasing blood circulation. Absorption of NIR light by the mitochondrial enzyme cytochrome C oxidase and subsequent stimulation of the respiratory chain is the commonly claimed mechanism of action (reviewed in [Hamblin, 2018](#)). This therapy has been studied in animal models, where it is reported to increase ATP production, stimulate anti-inflammatory, anti-apoptotic, and antioxidant responses, promote neurogenesis and synaptogenesis, and improve cognition (reviewed in [Salehpour et al.](#),

2018). In healthy rats, photobiomodulation (PBM) improved the metabolic profile, spatial memory, and neuroinflammation markers in young and aged animals (Dos Santos Cardoso et al., 2021; Cardoso et al., 2022).

Literature in animal models of Alzheimer's disease reports improved mitochondrial function, reduced A β plaques, tau tangles, inflammation, and oxidative stress, and lessening of cognitive deficits after transcranial PBM (e.g. De Taboada et al., 2011; reviewed in Su et al., 2023; Salehpour et al., 2021). Targeting abdomen, bone marrow, or lymph nodes with light therapy also improved outcomes in mouse models of AD and PD (Oron and Oron, 2016; Johnstone et al., 2014; Wu et al., 2022; Farfara et al., 2015). PBM is claimed to activate microglia, stimulate glymphatic clearance of A β , and improve gut flora (Salehpour et al., 2022; Chen et al., 2021; Liebert et al., 2019; Stepanov et al., 2022). In a negative study, transcranial PBM with 810 nm light had no benefit in the 5XFAD mouse model (Sipion et al., 2023).

For a recent review on preclinical and clinical development of PBM for AD and PD, see Shen et al., 2024.

Parameters of time, wavelength, power, and light source for PBM are under investigation (e.g. Spera et al. 2021; Joshi et al., 2024). In extracranial low-energy applications, only a tiny fraction of light penetrates the skull to reach the brain, although applying higher light intensity can increase penetration (Henderson and Morries, 2015). Human cadaver studies have shown near-infrared wavelengths can penetrate 40 mm through the scalp and skull into the brain (Tedford et al., 2015). Alternative approaches such as intracranial and intranasal delivery are being investigated to reach deeper brain structures (e.g., Salehpour et al., 2020).

Many different PBM devices are sold directly to consumers for home use. Some are FDA-approved for treating pain and inflammation, wound healing, promoting hair growth, and decreasing fat deposits; many are not. Hundreds of clinical trials are registered for a wide range of applications. A Phase 3 trial in stroke patients was terminated for futility (Hacke et al., 2014). More recently, a placebo-controlled trial found no effect on cognitive impairment in people with schizophrenia (Kheradmand et al., 2022). Evidence for cognitive improvement in healthy adults is mixed (Salehpour et al., 2019; Lee et al., 2023).

FINDINGS

Case reports and pilot studies claim benefits of PBM in people with mild cognitive impairment or dementia. For example, one patient with dementia reversed cognitive and olfactory dysfunction after daily PBM therapy to the head, lower back, and intranasally (Salehpour et al., 2019). In MCI, a trend was claimed toward improved blood flow and cognition after eight weeks of red light to the main arteries supplying the brain (Baik et al., 2021). A single session of light therapy was claimed to acutely improve memory in adults

with MCI ([Chan et al., 2021](#)). Among 42 women with MCI, five sessions of transcranial PBM reportedly improved MMSE scores and measures of attention over sham treatment ([Papi et al., 2022](#)).

From 2010-2012, the Quietmind Foundation sponsored a pilot trial in 11 people with early and mid-stage dementia, to assess whether repeated scalp exposure to six minutes of 1,072 nm infrared stimulation daily for 28 days improves cognitive and behavioral functioning as indicated by normalization of EEG activity, increased cerebral oxygenation and performance on standardized neuropsychological measures. The sham-controlled study lists a sole outcome of ADAS-Cog. Results are published, claiming trends toward a benefit in some parts of the ADAS-Cog related to executive functioning, and improvements in EEG parameters and functional connectivity ([Berman et al., 2017](#)). A follow-up study with 100 participants began in October 2018. This trial combined PBM with neurofeedback, and ran for eight weeks. Sixty people were enrolled, and the results are published ([Nizamutdinov et al., 2021](#)). Treatment was associated with improvements in the MMSE and several parts of the neuropsychological test battery, sleep, anxiety, mood, and daily routine.

Several device makers have sponsored trials for treatment of mild cognitive impairment or dementia. The Vielight Neuro Gamma device consists of five LEDs placed on the scalp to target default mode network nodes, plus an intranasal LED to target the hippocampus. All LEDs deliver 810 nm light, at either 10 or 40 Hz frequency. Both frequencies have been shown to modulate EEG alpha, beta, and gamma waves in healthy adults (e.g. [Zomorodi et al., 2019](#)). An early study in five people with AD used 10 Hz and reported significant improvement on the MMSE and the ADAS-Cog after 12 weeks of treatment. Caregivers reported that patients slept better, had fewer angry outbursts, and less anxiety and wandering ([Saltmarche et al., 2017](#)).

In May 2017, a single-center trial at University of California, San Francisco, began testing the Vielight device in 20 dementia patients. It compared 12 weeks of 40 Hz therapy, delivered for 20 minutes three days a week at home, to usual care, reporting improvements in the ADAS-Cog and neuropsychiatric symptoms, increased cerebral blood flow, and increased connectivity within the default mode network in the first eight treated patients ([Chao, 2019](#)). A follow-up trial, completed in January 2021, tested active versus sham 40 Hz treatment for 16 weeks in 14 AD patients, against a primary outcome of change in ADAS-Cog. Results posted on clinicaltrials.gov indicate no changes with treatment in cognition or biomarkers of A β 42, tau, and neurofilament light.

In December 2017, Vielight began a study in 60 people with moderate to severe AD at two sites in Ontario, comparing 12 weeks of active to sham home treatment with 40 Hz therapy for 20 minutes daily, six days a week. The primary outcome was change in the Severe Impairment Battery score. The company claims sham treatment is indistinguishable from active, as their device produces no heat and no visible light. This study was completed in February 2022. No results have been made public.

In June 2019, Vielight began a pivotal trial of the 40 Hz device. This trial planned to enroll 228 participants with severe dementia, for active versus sham treatment against endpoints of SIB and ADCS-ADL. This trial was supposed to finish in May 2023, but was suspended due to slow recruitment.

In June 2019, an academic study in Florida and Arizona began to study whether PBM could improve age-related cognitive and mood changes in older healthy adults and those with PD. The study plans to enroll 135 participants to be randomized to 12 weeks of photobiomodulation combining lab-based cranial stimulation with the MedX health Console plus intranasal stimulation at home with the Vielight device. The primary outcome is change in performance on the Arena task, a virtual reality version of the Morris water maze ([Parslow et al., 2004](#)). Completion is anticipated in October 2024.

The same university groups began a preventive trial in August 2020, involving 168 older adults at risk for AD, defined by subjective cognitive complaints and a first-degree family history of Alzheimer's disease. Participants are randomized to 12 weeks of in-lab cranial plus at-home intranasal treatment, against the primary outcome of the ARENA score. Completion was expected in April 2024.

In April 2021, the TRAP-AD trial began testing transcranial PBM in 125 people with MCI or mild AD dementia ([Iosifescu et al., 2023](#)). This academic, multisite, sham-controlled study is assessing the effects of continuous 808 nm NIR light delivered bilaterally to the forehead for 11 minutes, in 24 sessions over eight weeks. The device is an investigational helmet made by LiteCure medical laser company. Target engagement is to be confirmed by changes in fMRI blood oxygen-level dependent (BOLD) signal after one treatment ([Gaggi et al., 2024](#)). RBANS total score after eight weeks serves as the primary outcome; secondary outcomes include RBANS and other cognitive tests out to three months. This study also uses MRS imaging to assess change in mitochondrial function, and tau-PET to relate treatment effects to baseline tau burden. Completion is expected in November 2025.

In March 2023, a pilot trial began at Unity Health Toronto testing the Vielight device in 20 people with mild cognitive impairment due to AD. The treatment regimen involves 20 minutes per day, six days a week, for six weeks, and includes a sham control. The primary outcomes are MMSE, and memory and executive function tests. The trial will assess quality of life, blood and MRI biomarkers, sleep, and neuropsychiatric and depressive symptoms. Completion was expected in March 2024.

From September 2018 to May 2020, the French company REGEnLIFE ran a feasibility trial of its RGN530 device, which features a helmet and abdominal belt that deliver 10 Hz pulses of NIR and red light from a laser and LEDs. The study randomized 53 people with mild to moderate AD to active or sham treatment, before being terminated due to COVID. Results are published ([Blivet et al., 2022](#)). No serious adverse events were recorded. Patients

complied, with most completing the prescribed 40 treatment sessions of 25 minutes each over eight weeks. The investigators claimed trends toward improvement on some cognitive measures.

In July 2023, REGENLIFE began recruiting for the pivotal LIGHT4Life study. This sham-controlled trial plans to enroll 108 people with mild to moderate AD in multiple centers in France. Treatment consists of six months of 20 minute in-clinic sessions, beginning at five per week, and gradually ramping down to two per week ([Blivet et al., 2024](#)). The primary outcome is ADAS-Cog; 34 secondary and exploratory outcomes include other cognitive and functional tests, safety, blood biomarkers of amyloid, inflammation, tau, and neurodegeneration, as well as analysis of fecal microbiota, and metabolomics. Primary completion is expected in May 2025.

REGENLIFE is also running a pilot in 50 people with concussion. This follows on clinical studies of transcranial NIR in people with traumatic brain injury that claim improvements in executive function, learning, and memory ([Naeser et al., 2014](#)).

A pilot study of an NIR device in Iran reported safety and benefits in people with AD ([Razzaghi et al., 2024](#)); studies on other devices began in late 2023 in China and Japan.

PBM is also being tested for Parkinson's disease (for review, see [Bicknell et al., 2024](#)). A sham-controlled study in people with PD suggested that red light targeting the substantia nigra could speed walking ([Santos et al., 2019](#)). In an open-label study of 12 people, Australian investigators claimed better mobility, cognition, dynamic balance, and fine motor skills after 12 weeks to one year of in-clinic and at-home PBM to the abdomen, neck, head, and nose ([Liebert et al., 2021](#)). The treatment induced changes in the gut microbiome ([Bicknell et al., 2022](#)). Some patients improved with at-home PBM to just the abdomen and neck ([Liebert et al., 2022](#)). A sham controlled pilot subsequently tested an Australian company's transcranial device in 20 people with PD, finding a 12-week course of treatment to be safe and feasible ([Herkes et al., 2023](#)). Another study in Australia reported that four weeks of transcranial plus intraoral treatment did not change cognition measured by the MoCA, although some improvement was measured in writing and walking. A placebo effect was seen ([Bullock-Saxton et al., 2021](#)). An ongoing trial in France is testing endoventricular PBM using an implanted light source (see [Darlot et al., 2016](#)).

For more on photobiomodulation trials for AD, see clinicaltrials.gov.

For more on photobiomodulation trials for PD, see clinicaltrials.gov.

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COMMENTS

No Available Comments

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