

The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full [disclaimer \(https://clinicaltrials.gov/about-site/disclaimer\)](https://clinicaltrials.gov/about-site/disclaimer) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read [Learn About Studies \(https://clinicaltrials.gov/study-basics/learn-about-studies\)](https://clinicaltrials.gov/study-basics/learn-about-studies).

RECRUITING

Alzheimer's Disease Treatment With Combination of 40Hz Light and Cognitive Therapy (AlzLife)

ClinicalTrials.gov ID  NCT03657745

Sponsor  Alzheimer's Light LLC

Information provided by  Alzheimer's Light LLC (Responsible Party)

Last Update Posted  2023-02-01

Study Details Tab

Study Overview

Brief Summary

Electrical activity in the brain known as "gamma" brainwaves help connect and process information throughout the brain. These gamma waves are diminished in Alzheimer's disease. New research in Alzheimer's disease mouse models shows that exposure to light flickering at the rate of 40 flashes per second or 40Hz increased gamma brainwaves and led to clearing of beta amyloid plaques in the brain, a key abnormality in Alzheimer's disease. This project will test the ability of a novel iPad App (AlzLife <https://www.alz.life/>) that delivers light therapy at 40 Hz combined with cognitive therapy to improve cognition, function, and quality of life in Alzheimer's disease.

Detailed Description

New research suggests that exposure to a light flickering at 40Hz may promote gamma brain wave activity through the photic entrainment phenomenon. These waves have the potential to activate critical cleaning cells in the brain that could eliminate beta amyloid plaques. The most recent research on light therapy for Alzheimer's disease appeared in the journal Nature in 2017, entitled "How flashing lights and pink noise might banish Alzheimer's, improve memory and more" (the full article can be freely accessed at: <https://www.nature.com/articles/d41586-018-02391-6>) and in 2016, entitled "Gamma frequency entrainment attenuates amyloid load and modifies microglia" (the article abstract can be accessed at: <https://www.nature.com/articles/nature20587>). Researchers from MIT found that shining a strobe light into the eyes of mice with a rodent version of Alzheimer's disease encouraged protective cells to phagocytize the harmful proteins that accumulate in the brain. The perfect rate of flashes was determined to be 40 per second. Exposure to the flashing light for an hour (light therapy) led to a noticeable reduction in beta amyloid levels the next day in regions of the neocortex and hippocampus. When done every day for a week, beta amyloid levels were greatly reduced.

In addition, there is a significant body of evidence that computerized brain training (cognitive therapy) improves the memory of patients with Alzheimer's and dementia, which could help avert some symptoms of cognitive decline.

The synergistic combination of light and cognitive therapy utilized in AlzLife has the potential to improve the brain's function better than either of these therapies alone. This project will test the ability of a novel iPad App ("ALZLIFE") that delivers light therapy at 40 Hz combined with cognitive therapy to improve cognition, function, and quality of life in Alzheimer's disease.

Official Title

An Observational Trial of Alzheimer's Disease Treatment With Combination of 40Hz Light and Cognitive Therapy

Conditions

Alzheimer Disease

Mild Cognitive Impairment

Dementia

Cognition Disorders in Old Age

Cognitive Decline

Cognitive Deterioration

Intervention / Treatment

- Device: Combination of 40Hz light and cognitive therapy (ALZLIFE)

Other Study ID Numbers

- AlzLife001

Study Start (Actual) ⓘ

2018-01-01

Primary Completion (Estimated) ⓘ

2025-12-31

Study Completion (Estimated) ⓘ

2025-12-31

Enrollment (Estimated) ⓘ

2000

Study Type ⓘ

Observational

Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](https://medlineplus.gov/genetics/) (<https://medlineplus.gov/genetics/>), related topics: [Alzheimer disease](https://medlineplus.gov/genetics/condition/alzheimer-disease) (<https://medlineplus.gov/genetics/condition/alzheimer-disease>).

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>), related topics: [Alzheimer's Disease](https://medlineplus.gov/alzheimersdisease.html) (<https://medlineplus.gov/alzheimersdisease.html>).

[Genetic and Rare Diseases Information Center](https://rarediseases.info.nih.gov/gard) (<https://rarediseases.info.nih.gov/gard>), resources: [Familial Alzheimer Disease](https://rarediseases.info.nih.gov/diseases/632/familial-alzheimer-disease) (<https://rarediseases.info.nih.gov/diseases/632/familial-alzheimer-disease>).

[Other U.S. FDA Resources](https://classic.clinicaltrials.gov/ct2/info/fdalinks) (<https://classic.clinicaltrials.gov/ct2/info/fdalinks>)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.


Study Contact ⓘ**Name:** Andrey Vyshedskiy, Ph.D.**Phone Number:**

(617) 433-7724

Email: vysha@bu.edu

United States

Florida Locations

-  **Miami, Florida, United States, 33156**
Recruiting
Andrey Vyshedskiy
Contact: Andrey Vyshedskiy
617-433-8577 vysha@bu.edu



Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- Alzheimer's disease
- Cognitive Impairment

Exclusion Criteria:

- any previously noted epileptic seizures, including febrile seizures.
- any significant disease of the eye, such as macular degeneration. Since the 40Hz light therapy is delivered via eye stimulation, healthy eyes are required.

Study Population

Alzheimer's disease and Cognitive Impairment

Ages Eligible for Study

50 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

Yes

Sampling Method

Non-Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Observational Model ⓘ : Cohort

Time Perspective: Prospective

Cohorts and Interventions

Group/Cohort ⓘ	Intervention/Treatment ⓘ
<p>Participants who adhere to the protocol</p> <p>All participants are encouraged to exercise with AlzLife daily for 30 minutes a day. The actual duration is to be measured through participant's interactions with ALZLIFE. Participants adhere to the protocol if they exercise with AlzLife the minimum of 1 hour/week.</p>	<p>Device: Combination of 40Hz light and cognitive therapy (ALZLIFE)</p> <ul style="list-style-type: none"> Combination of 40Hz light and cognitive therapy delivered by iPad application ALZLIFE
<p>Participants who do not adhere to the protocol</p> <p>All participants are encouraged to exercise with AlzLife daily for 30 minutes a day. The actual duration is to be measured through participant's interactions with ALZLIFE. Participants do not adhere to the protocol if they exercise with AlzLife less than 1 hour/week.</p>	<p>Device: Combination of 40Hz light and cognitive therapy (ALZLIFE)</p> <ul style="list-style-type: none"> Combination of 40Hz light and cognitive therapy delivered by iPad application ALZLIFE

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
In-app cognitive test	<p>The cognitive therapy delivered by ALZLIFE consist of cognitive games: Sudoku, Tic-Tac-Toe, Analog clock comparison, etc. The changes in performance score in these cognitive games are used to calculate the participant's Cognitive Index.</p> <p>Cognitive Index maximum score = 100. The lower score indicates worse performance.</p>	through study completion, an average of 1 year

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Alzheimer's Disease Cooperative Study-activities of daily living (ADCS-ADL)	<p>The ADCS-ADL assesses the competence of patients with Alzheimer's Disease (AD) in basic and instrumental activities of daily living (ADLs). ADCS-ADL is assessed by an in-app evaluation completed by a caregiver every month. All responses relate to the 4 weeks prior to the time of rating. The six basic ADL items each take an ADL (e.g., eating) and provide descriptions of level of competence, with the rater selecting the most appropriate option (e.g., ate without physical help and used a knife; used a fork or spoon but not a knife; used fingers to eat; was usually fed by someone else). ADCS-ADL maximum score = 30. The lower score indicates worse outcome.</p>	through study completion, an average of 1 year

Collaborators and Investigators

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

Sponsor ⓘ

Alzheimer's Light LLC

Collaborators ⓘ

No information provided

Investigators ⓘ

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

- [Iaccarino HF, Singer AC, Martorell AJ, Rudenko A, Gao F, Gillingham TZ, Mathys H, Seo J, Kritskiy O, Abdurrob F, Adaikkan C, Canter RG, Rueda R, Brown EN, Boyden ES, Tsai LH. Gamma frequency entrainment attenuates amyloid load and modifies microglia. Nature. 2016 Dec 7;540\(7632\):230-235. doi: 10.1038/nature20587. Erratum In: Nature. 2018 Oct;562\(7725\):E1.](https://pubmed.ncbi.nlm.nih.gov/27929004/) (https://pubmed.ncbi.nlm.nih.gov/27929004/)
- [Thomson H. How flashing lights and pink noise might banish Alzheimer's, improve memory and more. Nature. 2018 Mar 1;555\(7694\):20-22. doi: 10.1038/d41586-018-02391-6. No abstract available.](https://pubmed.ncbi.nlm.nih.gov/29493598/) (https://pubmed.ncbi.nlm.nih.gov/29493598/)
- [Martorell AJ, Paulson AL, Suk HJ, Abdurrob F, Drummond GT, Guan W, Young JZ, Kim DN, Kritskiy O, Barker SJ, Mangena V, Prince SM, Brown EN, Chung K, Boyden ES, Singer AC, Tsai LH. Multi-sensory Gamma Stimulation Ameliorates Alzheimer's-Associated Pathology and Improves Cognition. Cell. 2019 Apr 4;177\(2\):256-271.e22. doi: 10.1016/j.cell.2019.02.014. Epub 2019 Mar 14.](https://pubmed.ncbi.nlm.nih.gov/30879788/) (https://pubmed.ncbi.nlm.nih.gov/30879788/)

* Find [Publications about Study Results](#) and related [Pubmed Publications](#) in the "Results" section of the study record.

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

First Submitted ⓘ

2018-08-16

First Submitted that Met QC Criteria ⓘ

2018-09-04

First Posted ⓘ

2018-09-05

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2023-01-31

Last Update Posted ⓘ

2023-02-01

Last Verified ⓘ

2023-01

More Information

Terms related to this study

Keywords Provided by Alzheimer's Light LLC

Alzheimer Disease

Alzheimer's

Dementia

Additional Relevant MeSH Terms

Brain Diseases

Central Nervous System Diseases

Nervous System Diseases
Tauopathies
Neurodegenerative Diseases
Neurocognitive Disorders
Mental Disorders
Alzheimer Disease
Dementia
Cognitive Dysfunction
Cognition Disorders

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

Study Documents 

No study documents available

Helpful Links Provided by Alzheimer's Light LLC

[ALZLIFE website](https://www.alz.life/) (https://www.alz.life/).

[ALZLIFE application in the App Store](https://itunes.apple.com/us/app/alzheimers-light-therapy/id1327175926?mt=8) (https://itunes.apple.com/us/app/alzheimers-light-therapy/id1327175926?mt=8).