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AlzCare™ for Alzheimer’s disease

Submission date 31/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/02/2024	**Overall study status** Ongoing	
Last Edited 01/07/2025	**Condition category** Nervous System Diseases	

Plain English summary of protocol

Background and study aims
This study is being delivered to answer the following research question(s):
1. Is the AlzCare™ device safe and well tolerated when used by people with mild or moderate Alzheimer's disease?
2. Does the AlzCare™ device show any clinical benefit when used by people with mild or moderate Alzheimer's disease?
The AlzCare device is a photobiomodulation device, designed to be used at home for the treatment of neurodegenerative conditions, in particular Alzheimer’s disease. The device is worn on the head ensuring contact with the forehead, with a nasal stimulator. To ensure effective treatment, it is important both the headset and nasal stimulator are used for the full 30-minute session, 6 days a week.
The device delivers near-infrared light to stimulate the pre-frontal cortex region of the brain. This part of the brain is involved with complex planning, cognitive behaviour, personality expression, decision making and moderating social behaviour. Stimulation of this area can prevent the rate of neurodegeneration, helping to slow the regression of cognitive function and treat the symptoms of Alzheimer’s disease.

Who can participate?
Patients aged 60-85 years of age who have mild or moderate Alzheimer's disease

What does the study involve?
Following a 4-week screening period to collect medical history information and complete assessments to assess participant eligibility for the study, participants will receive a study device for use at home for up to 78 weeks in the treatment period, and will be randomly allocated to one of the two treatment groups:
1. An active AlzCare™ study device, delivering near-infrared light when in use
2. A sham (or ‘placebo, or ‘dummy’) study device
The maximum total duration of study participation for each participant, including screening and the post-treatment follow-up period, is up to 88 weeks (about 20 months). Participants can expect to have 11 onsite study visits and four phone calls during the 20-month period. Onsite study visits will last 1-3 hours, dependent on the number of assessments being performed.

What are the possible benefits and risks of participating?
Participants may not receive any direct benefit from taking part in the study. It is hoped that the

results of this study will help other people with Alzheimer's disease in the future. Participants may receive information about their health from any physical examinations and cognitive assessments done in the study.
There may be risks to participants who take part in this study. Treatments and assessments in this study may have unwanted or harmful effects (side effects).
Exposing the head to light at power levels less than that received in direct sunlight (but without harmful ultraviolet wavelengths) is intrinsically safe. In studies of Low-Level Light Therapy (LLLT) such as the near-infrared light therapy delivered by this device, any side effects reported have been rare, mild in intensity and lasting a short time. Side effects have consisted of minor headache, difficulty sleeping and mild itching on the scalp.
Women not of childbearing potential and males may participate in this study. Male participants will need to use a double-barrier contraceptive method during the study. There is currently no information on the effects of the AlzCare™ device on an embryo, developing foetus or nursing infant. If a participant becomes pregnant during the study or think they/their partner are pregnant they will be asked to tell the study doctor right away. If a participant is pregnant, the study treatment will be stopped, and the participant might be discontinued from the study.
All participants will receive standard of care for Alzheimer’s disease during this study. At any time during this study, participants may have a return, or worsening, of their symptoms and/or they may be advised to take supportive medication to treat symptoms that may arise during the study. The study doctor will discuss any risks with them.
During the study, participants will continue to take their current medication unless it is not allowed in the study, which the study doctor will discuss with them. There may be unknown risks of possible harmful interaction with other medication they may be taking.
Some people may find that doing the questionnaires is upsetting or embarrassing. Cognitive testing may cause some individuals to become upset, frustrated, bored, or tired. Participants will complete two types of cognitive testing and one questionnaire during the trial:
The Alzheimer’s Disease Assessment Scale–Cognitive Subscale (ADAS-Cog14) (to test memory /cognition) will be completed by the participant with an Assistant Psychologist, seven times during the study, at approximately 6-month intervals. The results of this assessment will be discussed with the trial doctor.
The Mini Mental State Examination (MMSE) (to test memory/cognition) will be completed by the participant with an Assistant Psychologist once during the screening visit and once at the end of the study. MMSE takes about 7-8 minutes to complete. The results of this assessment will be discussed with the trial doctor.
The Columbia Suicide Severity Rating Scale (CSSR-S) is a questionnaire which will completed by the participant with the doctor, three times during the study, at approximately 6-month intervals. CSSR-S takes around 5 minutes to complete. Results of this questionnaire may be notified to the General Practitioner (GP) if a concern is raised, to ensure participants get the right support needed.

Where is the study run from?
AlzCare Ltd (UK)

When is the study starting and how long is it expected to run for?
May 2022 to January 2026

Who is funding the study?
AlzCare Ltd (UK)

Who is the main contact?
1. James Jamieson-Black, jblack@re-cognitionhealth.com
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3. Vicky Eyre, veyre@re-cognitionhealth.com

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333582

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 333582

Study information

Scientific Title
A Phase II, multi-centre, randomised, sham-controlled trial of the AlzCare™ medical device, to assess the safety, tolerability and clinical benefit of the AlzCare™ device in patients with mild to moderate Alzheimer’s disease

Acronym
Alz-Care-01

Study objectives
The AlzCare™ medical device will be safe, well tolerated and provide clinical benefit in patients with mild to moderate Alzheimer’s disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/05/2024, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen , AB15 6RE, United Kingdom; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 24/NS/0018

Study design
Phase II multi-centre randomized sham-controlled device trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Alzheimer's disease

Interventions
Current interventions as of 04/06/2024:

The randomisation process will be conducted via sealed envelope design, using a double-blinded permuted block design with blocks of 3. Unique participant identification numbers will be assigned sequentially, with devices identified and allocated using unique serial numbers. Participants within each clinical trial centre will be allocated to the sham and live device groups in a 2:1 ratio within each block.

Participants are randomised in a 2:1 ratio to the AlzcareTM device or a sham device. Device use is 1 x 30-minute session, 6 days per week. The treatment period is 18 months (78 weeks).

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Previous interventions:

The randomisation process will be conducted via sealed envelope design, using a double-blinded permuted block design with blocks of 4. Unique participant identification numbers will be assigned sequentially, with devices identified and allocated using unique serial numbers. Participants within each clinical trial centre will be allocated to the sham and live device groups in a 1:1 ratio within each block, maintaining treatment balance.

Participants are randomised in a 1:1 ratio to the AlzcareTM device or a sham device. Device use is 1 x 30-minute session, 6 days per week. The treatment period is 18 months (78 weeks).

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase II

Drug/device/biological/vaccine name(s)
AlzcareTM

Primary outcome measure
Cognition measured using the 14-item Alzheimer's Disease Assessment Scale – cognitive subscale (ADAS-Cog 14) at screening, week 13, week 26, week 52 and week 78

Secondary outcome measures
1. Cognition measured using the Mini-Mental State Examination (MMSE) at screening and 78 weeks
2. The safety and tolerability of AlzCare™ measured using adverse event reporting over 78 weeks
3. The device compliance of AlzCare™ measured using downloaded device use data over 78 weeks

Overall study start date
31/05/2022

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Male and female participants aged 60 to 85 years of age inclusive, at the time of signing the informed consent
2. Has an MMSE score of 16 to 26 (inclusive) at the screening visit
3. Has an ADAS-Cog14 score of ≥15 at the screening visit
4. If a historic magnetic resonance imaging (MRI) is available, findings must exclude other causes of dementia
5. Has Mild to Moderate dementia due to AD, consistent with the NIA-AA Working Group Criteria [Albert et al. 2011; Jack et al. 2018; McKhann et al. 2011]
6. Women not of childbearing potential and males may participate in this study. Contraceptive use by participants should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies.
7. Capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the ICF and in this protocol
8. Can complete the cognitive testing and all other required study procedures
9. Have a study partner who will provide written informed consent to participate, is in frequent contact with the participant, and will accompany the participant to study visits or be available by telephone at designated times
10. Are reliable and willing to make themselves available for the duration of the study
11. If treated with an AChEI, must be on a stable treatment for at least 12 weeks prior to the Baseline Visit and must be able to continue on the same drug for the duration of the study

Participant type(s)
Patient

Age group
Senior

Lower age limit
60 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
69

Key exclusion criteria
1. Have significant neurological disease affecting the central nervous system other than AD, that may affect cognition or ability to complete the study, including but not limited to, other dementias, serious infection of the brain, Parkinson’s disease, multiple concussions, or epilepsy or recurrent seizures, except febrile childhood seizures.
2. Have a condition requiring treatment, that in the investigator’s opinion could interfere with the analyses of this study, or a current serious or unstable illness, including:
2.1. Cardiovascular

2.2. Hepatic
2.3. Renal
2.4. Gastroenterologic
2.5. Respiratory
2.6. Endocrinologic
2.7. Neurologic other than AD
2.8. Psychiatric
2.9. Immunologic, or
2.10. Hematologic
3. Have a life expectancy of less than 24 months.
4. Any history of malignancy in the head or brain region.
5. Any radiotherapy in the head or brain region within 6 months prior to baseline or planned during the course of the trial.
6. Are in the investigator's opinion, actively suicidal and deemed a significant risk for suicide.
7. Have a diagnosis of alcohol or drug use disorder, (except tobacco use disorder), within 2 years of the screening visit.
8. Have any medical condition (e.g. photophobia or abnormally high sensitivity to light) which makes the skin sensitive to sun or light or if they are allergic to this specific wavelength of light (800-820nm).
9. Have taken photosensitising medications or used photosensitising skincare products, within 12 weeks of baseline.
10. Are suffering from sunburn on the face or head at the time of the baseline visit.
11. Have a chronic skin condition on the head and/or face, which in the opinion of the investigator, could impact the use of the Alzcare™ device.
12. Have used low light therapy device(s) within 12 weeks of baseline, including sun beds, low light therapy beauty masks and devices for hair growth.
13. Are currently enrolled in any other interventional clinical study involving an investigational product or any other type of medical research judged not to be scientifically or medically compatible with this study.
14. Have ever received an Anti-amyloid or Anti-tau vaccine: Subjects who received active drug in a vaccine study are not eligible (subjects who received placebo are eligible).
15. Have participated in a clinical study and received active drug within 24 weeks of baseline (subjects who received placebo are eligible):
15.1. Anti-amyloid or anti-tau antibodies (passive immunotherapy)
15.2. β-secretase or β-site amyloid precursor protein cleaving enzyme (BACE) inhibitors
15.3. Amyloid anti-aggregation agents
15.4. Anti-complement, anti-inflammatory, kinase inhibitors or other mechanisms
16. Have previously completed or withdrawn from this study. This does not apply to participants who are allowed to rescreen before randomization in this study.
17. Are investigator site personnel directly affiliated with this study or their immediate families. Immediate family is defined as a spouse, parent, child, or sibling, whether biological or legally adopted.
18. Are AlzCare Ltd employees or are employees of third-party organisations involved in the study that require exclusion of their employees or have study partners who are Alzcare Ltd employees or are employees of third-party organisations that require exclusion of their employees

Date of first enrolment
07/08/2024

Date of final enrolment

01/07/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Re:Cognition Health Ltd
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Study participating centre
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
AlzCare Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact journal

Intention to publish date
31/05/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date