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Altering brainwaves to help symptoms of mild cognitive impairment

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/05/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/06/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Research has demonstrated that certain brain waves are distorted as you age. This may be related to cognitive decline, specifically conditions such as Mild Cognitive Impairment (MCI) or dementia. Previous studies show that specific sound stimulations can manipulate these brain waves to attenuate symptoms of these conditions. Researchers are investigating a non-invasive method called Continuous Amplitude Modulated Sound Stimulation (CAMSS) that aims to modulate brainwaves in specific frequencies using sound. Unlike conventional methods that use artificial sounds, CAMSS seamlessly embeds these frequencies into familiar environmental sounds, making the experience natural and unobtrusive for individuals with MCI. This research holds immense potential for individuals dealing with dementia-related conditions. By introducing a simple method - listening to modified sounds - the aim is to offer a new accessible way to alleviate dementia symptoms, potentially enhancing the quality of life for those affected.

Who can participate?
Adults aged 55 – 75 years with a diagnosis of Mild Cognitive Impairment

What does the study involve?
Participants will engage in a single session lasting 2 to 2.5 hours at King’s College London. During this time, they will undergo brain imaging, specifically, electroencephalogram (EEG) monitoring, while listening to different types of sounds. Additionally, they will perform cognitive tasks designed to assess attention, memory, and cognitive control.

What are the possible benefits and risks of participating?
There are no current direct benefits to participants individually, but the research may benefit people with mild cognitive impairment and Alzheimer's disease in the future if the research successfully develops CAMSS into a therapeutic method for attenuating the pathology of the conditions. Moreover, participants will have the opportunity to learn more about research using EEG methods.
If all standard procedures are followed there are no known risks of using electroencephalogram (EEG). Participants may feel the gel is cold or they may feel the blunt needle during the EEG

preparation, but this will not be painful. All details of the EEG procedure will be outlined in the information sheet before their visit. The researchers will constantly monitor the participants to ensure they are comfortable.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
February 2024 to December 2024

Who is funding the study?
Tianqiao and Chrissy Chen Institute (USA)

Who is the main contact?
Dr Gráinne McLoughlin, grainne.mcloughlin@kcl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Gráinne McLoughlin

ORCID ID
http://orcid.org/0000-0001-5785-9527

Contact details
Memory Lane
London
United Kingdom
SE5 8AF
+44 (0)20 7836 5454
grainne.mcloughlin@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320617

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 320617

Study information

Scientific Title
SoundMind-MCI: sound entrainment of brain oscillations in mild cognitive impairment

Acronym
SM-MCI

Study objectives
To conduct a comparison study of electroencephalogram spectral changes between Continuous Amplitude Modulated Sound Stimulation and classic sound stimulation in a clinical sample of participants with Mild Cognitive Impairment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/03/2024, London - Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8229; brent.rec@hra.nhs.uk), ref: 24/PR/0231

Study design
Single-centre observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Laboratory

Study type(s)
Efficacy

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

Health condition(s) or problem(s) studied
Mild cognitive impairment

Interventions
The primary aim is to conduct a comparison study of electroencephalogram (EEG) spectral changes between Continuous Amplitude Modulated Sound Stimulation (CAMSS) and classic sound stimulation in a clinical sample of age-matched (to Sample A of healthy older participants aged 55-75 years old, Ethical Clearance Reference Number: LRS/DP-22/23-33852) participants with Mild Cognitive Impairment (MCI). To do so, the researchers will measure EEG spectral changes while MCI participants listen to (1) CAMSS, (2) identical unmodulated sounds and (3) click trains. As a secondary, exploratory objective the researchers will also measure the cognitive effects of modified spectral states induced by CAMSS. Specifically, they aim to (1) examine reaction time and errors during the arrow flanker task, (2) examine event-related indices of

cognitive control during the arrow flanker task, including the N2 and theta power, (3) examine reaction time and errors during a semantic and source memory task, and (4) examine event-related potential indices during the semantic and source memory task, including theta power and the N2. To do so, the researchers will repeat the same three sound conditions while the MCI participants complete the arrow flanker task and the semantic and source memory tasks. All participants will complete every stage of the study.

Intervention Type
Other

Primary outcome measure
1. The entrainment of gamma oscillations measured by electroencephalogram (EEG) during testing (only one timepoint)

Secondary outcome measures
1. Cognitive function measured by EEG, specifically the N2 and theta power during the cognitive task during testing (only one timepoint)
2. Cognitive function measured by reaction time during the cognitive task during testing (only one timepoint)

Overall study start date
01/02/2024

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged between 55 and 75 years old
2. Has a diagnosis of MCI recognised by the South London and Maudsley Hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
55 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Hearing levels not within sufficient range (normal and mild hearing loss [presbycusis] is accepted) as determined by the hearing test
2. Any psychiatric or neurological disorder indicated by the participant other than MCI
3. Cardiac disease
4. Uncorrected visual problems
5. Unable to follow the protocol e.g. due to language barriers meaning questionnaires /interviews cannot be conducted
6. Currently taking part in interventional studies
7. Participants who have allergies or sensitivity to gel

Date of first enrolment
01/05/2024

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Memory Lane
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London

Sponsor details
Memory Lane
London
England
United Kingdom
SE5 8AF
+44 (0)20 7836 5454
slam-ioppn.research@kcl.ac.uk

Sponsor type

University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
Tianqiao and Chrissy Chen Institute

Results and Publications

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

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to IP restrictions.

IPD sharing plan summary
Not expected to be made available