

Altering brainwaves to help symptoms of mild cognitive impairment

Submission date 25/04/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/05/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/01/2026	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

320617

Protocol serial number

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

Study type(s)

Efficacy

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

55 years

Upper age limit

75 years

Sex

All

Total final enrolment

10

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

United Kingdom

England

Study participating centre

King's College London

Memory Lane

London

England

SE5 8AF

Sponsor information

Organisation

King's College London

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Research organisation

Funder Name

Tianqiao and Chrissy Chen Institute

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available

