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Neurofeedback in healthy elderly at risk of cognitive decline

Submission date	Recruitment status	[X] Prospectively registered
10/06/2020	Suspended	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/08/2020	Suspended	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/04/2025	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Age is the main risk factor for the incidence of neurocognitive disorders (such as Alzheimer's disease, among others). Past research has shown that quantitative electroencephalography (qEEG), which measures the electrical activity of the brain using sensors placed on the scalp, might be a good tool to evaluate the risk of developing future cognitive decline in the healthy elderly population. Particularly, an excess of theta activity (4.0-8.0 Hz) has been proposed as the best predictor of cognitive decline in the absence of clinical evidence. This means that qEEG might detect if someone is at risk of developing symptoms of dementia in the medium term even when there are no symptoms at present. Moreover, among the characteristics of the EEG in aging are 1) reduction of the amplitude and frequency of the alpha rhythm, and 2) reduction of the total mean frequency. Neurofeedback teaches the individual to regulate their own brainwaves in order to improve their cognition and their behavior. In healthy seniors, downtraining of theta absolute power and uptraining of alpha peak frequency using neurofeedback have shown to be successful in terms of enhancing cognitive performance and a normalization of the EEG. The aim of this study is to find out whether downtraining the theta /alpha ratio in healthy seniors with an excess of theta absolute power will enhance their cognitive function.

Who can participate?
Healthy seniors aged 60 or older with an excess of theta absolute power compared to normal

What does the study involve?
Participants will undergo neurofeedback in order to reduce the theta/alpha ratio of their EEG. They will receive 30 sessions three times a week for an estimated total duration of 10 - 12 consecutive weeks. The partiicipants' cognitive functions will be assessed 3 months after treatment.

What are the possible benefits and risks of participating?
A possible benefit is to delay the onset of clinical symptoms associated with age-related cognitive decline. In general, the adverse effects of neurofeedback are very infrequent.

Where is the study run from?
National Autonomous University of Mexico (Mexico)

When is the study starting and how long is it expected to run for?
January 2015 to September 2023

Who is funding the study?
National Autonomous University of Mexico (Mexico)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
IN200817

Study information

Scientific Title
Theta/alpha neurofeedback in healthy elderly at electroencephalographic risk of cognitive decline

Acronym
NF-E-theta/alpha

Study objectives
Downtraining the theta/alpha ratio in healthy elderly with an excess of theta absolute power will enhance the cognitive function of those participants who successfully learn to regulate their EEG activity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/01/2017, Committee of Ethics of the Institute of Neurobiology (Instituto de Neurobiología, Universidad Nacional Autónoma de México, Blvd Juriquilla 3001, Queretaro, Mexico, 76230; +52 (0)442 2381002; mdiaz@comunidad.unam.mx), ref: 030.H-RM

Study design
Single-centre non-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of cognitive decline in healthy elderly individuals at risk

Interventions
The assignment of participant to the groups will be made a posteriori, based on the learning success of the treatment. Therefore, it is a non-randomised controlled trial.

Participants will undergo downtraining of the Theta/Alpha ratio using neurofeedback (NFB). They will receive 30 NFB sessions three times a week, for an estimated total duration of 10 - 12 consecutive weeks. After treatment, participants will be assigned to one of two groups, according to the success in the regulation of the EEG: 1) responders and 2) non-responders.

The duration of the intervention is 10-12 weeks (3 sessions/week) and follow-up will be assessed three months after treatment.

Intervention Type

Procedure/Surgery

Primary outcome(s)
Brain electrical activity measured using qEEG. The measure of interest will be the z-value of the Theta/Alpha ratio. Measured before training, immediately after training and 3 months after training.

Key secondary outcome(s))
1. Brain electrical activity measured using qEEG:
1.1 Normative absolute power with geometric power correction of delta, theta, alpha and beta frequency bands in the 19 leads of the 10-20 international system referenced to linked earlobes before training, immediately after training and 3 months after training
1.2. Current Source Density distribution using e-LORETA before training, immediately after training and 3 months after training
2. Cognitive assessment:
2.1. Intelligence quotient and verbal comprehension, perceptual reasoning, working memory and processing speed indices measured using the Wechsler Adult Intelligence Scale (WAIS-IV) before training and 3 months after treatment. It is not possible to make the three timepoints evaluation due to the nature of the battery.
2.2. Attention and memory assessed using a neuropsychological battery standardized in Mexican population and with norms by age group and years of schooling (NEUROPSI-2) before training and 3 months after treatment. It is not possible to make the three timepoints evaluation due to the nature of the battery.
2.3. Executive functions assessed using a neuropsychological battery standardized in Mexican Population and with norms by age group and years of schooling (BANFE-2) before training and 3 months after treatment. It is not possible to make the three timepoints evaluation due to the nature of the battery.

Completion date
20/09/2023

Eligibility

Key inclusion criteria
1. Healthy seniors aged 60 years or older
2. Right-handed
3. At least 9 years of formal schooling
4. IQ >80 (Shippley-2)
5. Normal Cognitive Assessment (MMSE >24)
6. Score of 1 or 2 in the Global Deterioration Scale
7. An excess of theta absolute power in at least one lead of their EEG (zPA[theta] > 1.96)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 years

Sex
All

Key exclusion criteria
1. History of psychiatric or neurological condition
2. Uncontrolled medical conditions such as hypertension, diabetes, thyroid dysfunction, hypercholesterolemia, anemia
3. General anesthesia in the year previous to enrollment in the study
4. History of cranioencephalic trauma with loss of consciousness
5. Use of drugs that are known to affect the EEG (e.g. benzodiazepines)
6. History of substance abuse (e.g. alcohol)
7. Presence of paroxysmal activity in the range of alpha frequencies

Date of first enrolment
01/11/2020

Date of final enrolment
20/09/2022

Locations

Countries of recruitment
Mexico

Study participating centre
Instituto de Neurobiologia, Universidad Nacional Autonoma de Mexico
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Sponsor information

Organisation
National Autonomous University of Mexico

ROR
https://ror.org/01tmp8f25

Funder(s)

Funder type
University/education

Funder Name
Universidad Nacional Autónoma de México

Alternative Name(s)
National Autonomous University of Mexico, UNAM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Mexico

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in an available repository of the National Autonomous University of Mexico, following the local rules for data storage and sharing. Consent from participants are obtained and all confidentiality of the data is granted. More exact details will be made available later in the process of the study.

IPD sharing plan summary
Stored in repository