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Impact of a cognitive training program on executive functions and anxious symptomatology in older adults: a study in a mental health institution in Manizales

Submission date
03/09/2024

Recruitment status
No longer recruiting

Registration date
06/09/2024

Overall study status
Completed

Last Edited
06/09/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study focuses on individuals with mild cognitive impairment (MCI), a condition that can affect memory and other cognitive abilities. The objective of the research is to evaluate whether a computer-based cognitive training program can better improve thinking skills (executive functions) and reduce anxiety symptoms compared with a traditional cognitive training program.

Who can participate?
Men and women diagnosed with mild cognitive impairment

What does the study involve?
The study will compare two types of cognitive training: one conducted on a computer and another using traditional methods. Participants will be divided into two groups, one for each type of training, and the study will last for 12 weeks. During this time, their cognitive abilities and anxiety levels will be assessed at the beginning and end of the program to determine which type of training yields better results.

What are the potential benefits and risks of participating?
Participants may improve their cognitive abilities and experience reduced anxiety by the end of the study. The treatments pose no significant risks, although some participants may feel tired or frustrated during training sessions.

Where is the study run from?
Plenamente Comprehensive Mental Health IPS (Colombia)

When is the study starting and how long is it expected to run for?
July 2024 to March 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
CBE06_2024

Study information

Scientific Title
Effect of adapted computerized cognitive training on executive functions and anxiety symptoms, compared to a standard intervention in patients with mild neurocognitive disorder at a mental health institution in Manizales: a randomized clinical experimental study

Acronym
ECAM-TNL

Study objectives
H0: An adapted computerized cognitive training has the same effect on executive function tasks and anxiety symptoms as standard cognitive training in patients with mild neurocognitive disorder (MND) at Plenamente IPS Comprehensive Mental Health in the city of Manizales.

H1: An adapted computerized cognitive training has a greater effect on executive function tasks and anxiety symptoms than standard cognitive training in patients with MND at Plenamente IPS Comprehensive Mental Health in the city of Manizales.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/08/2024, Bioethics Committee of the University of Manizales (Carrera 9 N° 19-03, Manizales, 170004, Colombia; +57 (0)8879680; info@umanizales.edu.co), ref: acta CBE06_2024

Study design
Randomized blinded longitudinal experimental clinical trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The study will be conducted in the setting of the IPS Plenamente Comprehensive Mental Health using the diagnostic database of this institution. Participant selection will be rigorously carried out with predefined inclusion and exclusion criteria to ensure the homogeneity of the sample. The reason for the random allocation of participants to intervention groups is to ensure that any observed difference in the outcomes of executive functions and anxiety symptoms can be attributed to the interventions and not to confounding factors. Random allocation helps balance

baseline characteristics between the groups, minimizing selection bias and enhancing the internal validity of the study. The use of an external and independent collaborator to perform random allocation using the Research Randomizer software (https://www.randomizer.org) ensures impartiality in the distribution of participants, allowing a fair and objective comparison of the intervention effects.

The Computerized Cognitive Training Group (Braining) will participate in 50-minute sessions, 2 days a week for 12 weeks, using the Braining program to enhance executive functions. The activities include specific tasks such as sequences of cubes, digits, and letters, focused on memory, attention, and recognition. The Traditional Cognitive Training Group will conduct 24 sessions divided into six phases, focusing on crossing out tasks, solving everyday situations, and practising cognitive strategies.

Intervention Type
Behavioural

Primary outcome(s)
1. Working memory measured using the Working Memory Index of the WAIS-IV (subtests of Arithmetic and Digit Span), the Corsi Blocks test, the Alphabetical Ordering (trials 2 and 3) from the BANFE-2, and the Spatial Addition test from the WMS-IV at baseline and post-intervention
2. Cognitive flexibility measured using the Card Sorting from the BANFE-2 at baseline and post-intervention
3. Inhibitory control measured using the Stroop (Forms A and B) from the BANFE-2 at baseline and post-intervention

Key secondary outcome(s))
Severity of anxiety symptoms measured using the Beck Anxiety Inventory (BAI) at baseline and post-intervention

Completion date
30/03/2025

Eligibility

Key inclusion criteria
1. Diagnosis of MCI according to Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria, with symptom onset within the last 2 years and diagnosed by the neuropsychology department at least 6 months prior to inclusion
2. Score on the Montreal Cognitive Assessment (MOCA) between ≥15.1 and ≤20.5
3. Preservation of complex instrumental activities of daily living with the possibility of using compensatory strategies according to a score of 8 on the Lawton and Brody scale
4. Preservation of basic activities of daily living with a Barthel Index score between 91 and 100, indicating "mild dependence" or "complete independence," sufficient for participation in the study
5. A minimum of 5 years of formal education
6. Mild anxiety symptoms according to the Beck Anxiety Inventory (BAI) score, between 8 and 15
7. Impairment in executive functions according to scores obtained in the study tests (Card Sorting from the BANFE-2: Standardized score ≤7, Alphabetical Ordering from the BANFE-2 (trial 2 and 3): Standardized score ≤7, Digit Retention from the WAIS-IV: Scaled scores ≤7, Arithmetic

from the WAIS-IV: Scaled scores ≤7, Corsi Blocks: Scaled score ≤7, Stroop Test Form A and B from the BANFE-2: Standardized score ≤7, Working Memory Index from the WAIS-IV: Scores ≤85)
8. Sufficient visual and/or auditory acuity to perform neuropsychological tests

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
50 years

Upper age limit
79 years

Sex
All

Key exclusion criteria
1. Associated neurological disorders
2. Scores on the Yesavage Geriatric Depression Scale (GDS-15) that do not indicate moderate to severe depressive symptoms (scores <6)
3. Psychiatric comorbidity other than anxiety symptoms
4. History of addiction within the last 10 years
5. Receiving cognitive training during the last 6 months prior to starting participation in the study
6. Hospitalization in an Intermediate Care or Intensive Care Unit within the last year

Date of first enrolment
09/08/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Colombia

Study participating centre
Plenamente salud mental integral IPS
-Calle 65 # 23B - 79, Av Lindsay
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Sponsor information

Organisation
Universidad de Manizales

ROR
https://ror.org/031n6w191

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available as a supplement to the publication of the results

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes