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Effect of adapted computerized cognitive training on executive functions and anxiety symptoms compared with standard cognitive training in older adults with mild neurocognitive disorder: a randomized clinical trial

Submission date
03/09/2024

Recruitment status
No longer recruiting

Registration date
06/09/2024

Overall study status
Completed

Last Edited
22/09/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mild neurocognitive disorder can affect memory, executive functions, and other cognitive abilities while allowing people to maintain relative independence in their daily activities. This study aims to compare the effects of adapted computerized cognitive training and standard cognitive training on executive functions and anxiety symptoms in older adults with mild neurocognitive disorder.

Who can participate?
Adults aged 60 years or older with a diagnosis of mild neurocognitive disorder who meet the eligibility criteria established for the study.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive adapted computerized cognitive training using the Braining program, and the other group will receive standard cognitive training using paper-and-pencil activities and other materials. Both interventions will include 24 individual, face-to-face sessions delivered twice weekly over 12 weeks. Executive functions and anxiety symptoms will be assessed before and immediately after the interventions.

What are the potential benefits and risks of participating?
Participants may experience changes in some of the cognitive abilities exercised during the intervention, although individual benefit cannot be guaranteed. No significant risks are expected. Some participants may experience temporary tiredness, frustration, or discomfort while completing the assessments or training activities.

Where is the study run from?
Plenamente Salud Mental Integral IPS in Manizales, Colombia.

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

Who is funding the study?
The study is investigator initiated and funded.

Who is the main contact?
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Additional identifiers

Protocol serial number
CBE06_2024

Study information

Scientific Title
Effect of adapted computerized cognitive training on executive functions and anxiety symptoms compared with standard cognitive training in older adults with mild neurocognitive disorder: a randomized clinical trial

Acronym
ECAM-TNL

Study objectives
Current study objectives as of 22/09/2026:

Main objective
To determine the effect of adapted computerized cognitive training on executive functions and anxiety symptoms, compared with standard cognitive training, in older adults with mild neurocognitive disorder receiving care at Plenamente IPS in Manizales.

Specific objectives:
1. To describe the sociodemographic and clinical characteristics of older adults with mild neurocognitive disorder receiving care at Plenamente IPS in Manizales
2. To establish executive-function performance and anxiety symptom severity before and after adapted computerized cognitive training
3. To establish executive-function performance and anxiety symptom severity before and after standard cognitive training
4. To compare the pre-intervention and post-intervention changes in executive functions and anxiety symptoms between the group receiving adapted computerized cognitive training and the group receiving standard cognitive training.

Null hypothesis:
Adapted computerized cognitive training will not have a superior effect to standard cognitive training on executive functions or anxiety symptoms in older adults with mild neurocognitive disorder receiving care at Plenamente IPS in Manizales.

Alternative hypothesis:
Adapted computerized cognitive training will have a superior effect to standard cognitive training on executive functions and anxiety symptoms in older adults with mild neurocognitive disorder receiving care at Plenamente IPS in Manizales.

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Previous 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

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild neurocognitive disorder

Interventions
Current interventions as of 22/09/2026:

Participants will be randomly allocated in a 1:1 ratio to adapted computerized cognitive training or standard cognitive training. Both interventions will consist of 24 individual, face-to-face sessions delivered twice weekly over 12 weeks and supervised by trained neuropsychology professionals.

Adapted computerized cognitive training
Participants assigned to this group will complete 24 sessions using the Braining program. Each session will last approximately 50 minutes. The program will include six activities designed to exercise executive functions: Cubes, Digits, Find Me, Letters, Change, and Rotation.

In the Cubes activity, participants will reproduce sequences of illuminated cubes in the same order. In Digits, they will enter number sequences in reverse order. In Find Me, they will remember and identify the location of a specific letter after the stimuli disappear. In Letters,

they will remember the locations of letters presented in a grid. In Change, they will identify the element that differs between two similar sequences. In Rotation, they will identify previously illuminated cubes after a 90-degree rotation.

The training difficulty will increase progressively according to each participant's performance. Correct responses will result in a greater number of stimuli or longer sequences. When errors occur, the difficulty will not decrease; participants will remain at the level reached and continue practising until their performance allows them to advance.

Standard cognitive training
Participants assigned to the active control group will complete 24 individual sessions delivered twice weekly over 12 weeks. Each session will last approximately 45 to 50 minutes. The intervention will be conducted mainly through paper-and-pencil activities, printed materials, puzzles, figures, cards, and other manipulable materials.

The program will target the same executive-function components evaluated in the study: working memory, cognitive flexibility, and inhibitory control. Working memory will be exercised through sequential mental operations, retention and manipulation of information, multiple-step instructions, ordering of words and numbers, reverse sequences, and organization of everyday activities. Cognitive flexibility will be exercised through changes in rules and categories, stimulus classification, alternative problem-solving strategies, and adaptation to changes in instructions. Inhibitory control will be addressed through selective cancellation tasks, stimulus selection according to specific criteria, suppression of automatic responses, incompatible-rule exercises, and decision-making activities requiring participants to stop and consider different alternatives.

The activities will be progressively distributed across the 24 sessions and will include structured tasks and everyday situations, such as organizing purchases, planning weekly activities, and managing limited resources. Unlike the computerized program, the standard intervention will not use an automated adaptation algorithm. However, the therapist will provide feedback and adjust the complexity of some exercises according to each participant's progress while maintaining the sequence and content established in the protocol.

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Previous 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)
Current primary outcome(s) as of 22/09/2026:

1. Direct score on Trial 2 of the Alphabetical Ordering Test from the BANFE-2, assessed at baseline and immediately after completion of the 12-week intervention
2. Direct score on Trial 3 of the Alphabetical Ordering Test from the BANFE-2, assessed at baseline and immediately after completion of the 12-week intervention
3. Direct score on the Arithmetic subtest of the WAIS-IV, assessed at baseline and immediately after completion of the 12-week intervention
4. Total direct score on the Digit Span subtest of the WAIS-IV, assessed at baseline and immediately after completion of the 12-week intervention
5. Direct score on the backward condition of the Corsi Block-Tapping Test, assessed at baseline and immediately after completion of the 12-week intervention
6. Direct score on the Spatial Addition subtest of the WMS-IV, assessed at baseline and immediately after completion of the 12-week intervention
7. Composite score on the Working Memory Index of the WAIS-IV, assessed at baseline and immediately after completion of the 12-week intervention
8. Number of perseverative responses on the Card Sorting Test from the BANFE-2, assessed at baseline and immediately after completion of the 12-week intervention
9. Word-colour score on the Stroop Test from the BANFE-2, assessed at baseline and immediately after completion of the 12-week intervention

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Previous 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)
Current key secondary outcome(s) as of 22/09/2026:

Anxiety symptom severity will be assessed using the total score of the Beck Anxiety Inventory (BAI) at baseline and immediately after completion of the 12-week intervention. The BAI total score ranges from 0 to 63, with higher scores indicating greater anxiety symptom severity

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Previous 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
Current key inclusion criteria as of 22/09/2026:

1. Adults aged 60 years or older
2. Diagnosis of mild neurocognitive disorder according to DSM-5 criteria, with symptom onset within the previous two years and a neuropsychological diagnosis established at least six months before enrolment in the study
3. Montreal Cognitive Assessment (MoCA) score compatible with mild neurocognitive disorder according to education-adjusted reference values for the Colombian population: 18-21 for primary education or less, 19-23 for secondary education, and 19-24 for higher education
4. Preservation of independence in instrumental activities of daily living, indicated by a score of 7 or 8 on the Lawton and Brody Scale. Mild reductions will be permitted when they do not represent a substantial loss of independence and activities are maintained through greater effort or compensatory strategies
5. Preservation of basic activities of daily living, indicated by a Barthel Index score between 90 and 100
6. At least five years of formal education
7. Beck Anxiety Inventory (BAI) score between 0 and 21
8. Evidence of impairment in at least one of the executive-function indicators evaluated in the study, according to the cut-off scores established in the protocol
9. Sufficient visual and auditory acuity, with usual corrective aids if required, to understand the instructions and complete the assessments and interventions
10. Ability to understand the study procedures and provide written informed consent

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Previous 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
Mixed

Lower age limit
60 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
29

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
Manizales - Caldas

Colombia
170001

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