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Effect of a computer-based mental training programme on attention, self-control and treatment adherence in people with lupus

Submission date
22/01/2026

Recruitment status
No longer recruiting

Registration date
24/01/2026

Overall study status
Completed

Last Edited
25/09/2026

Condition category
Skin and Connective Tissue Diseases

[_] 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
This study focuses on people with systemic lupus erythematosus (SLE), an autoimmune condition that primarily affects women of childbearing age and can impair memory, attention, and other cognitive abilities. The objective of the research is to evaluate whether a computer-based cognitive training program can improve thinking skills (executive functions) and treatment adherence compared to a standard cognitive training program.

Who can participate?
Women diagnosed with systemic lupus erythematosus

What does the study involve?
The study will compare two types of computerized cognitive training: one adapted and one standard. Participants will be divided into two groups, one for each type of training, and the study will last 12 weeks. During this time, their cognitive abilities, quality of life, and treatment adherence will be assessed, and at the end of the program, to determine which type of training produces better results.

What are the potential benefits and risks of participating?
Participants may experience improvements in their cognitive abilities, quality of life, and treatment adherence. The treatments do not present significant risks, although some participants may feel tired or frustrated during the training sessions.

Where is the study being conducted?
In the city of Manizales, Colombia, at the facilities of the University of Manizales.

When does the study begin and what is its expected duration?
January 2026 to September 2026

Who is funding the study?
Initiated and funded by the researcher.

Who is the main contact?
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Study information

Scientific Title

Effect of computerized cognitive training on executive functioning and treatment adherence compared to standard intervention in patients with systemic lupus erythematosus (SLE): a randomized clinical trial

Acronym
EC-LES

Study objectives
General objective:
To determine the effect of computerized training on performance in executive function tasks and treatment adherence compared to standard cognitive training in patients with systemic lupus erythematosus (SLE).

Specific objectives:
1. To describe the sociodemographic and neuropsychological characteristics of a sample of patients with systemic lupus erythematosus (SLE).
2. To establish performance on the CSI, MMAS-8, MoCA, TONY-4, SDMT, RCFT, HVLT-R, TMT A and B, Stroop, M-WSCT, FAS, WAIS-IV subtests, FDT, and Neuropsi-3 motor functions in patients with SLE before and after computerized cognitive training. • To establish performance on the CSI, MMAS-8, MoCA, TONY-4, SDMT, RCFT, HVLT-R, TMT A and B, Stroop, M-WSCT, FAS, WAIS-IV subtests, FDT, and Neuropsi-3 motor functions in patients with SLE before and after standardized training.
3. To compare the performance of two groups of patients undergoing adapted or standardized cognitive training on the CSI, MMAS-8, MoCA, TONY-4, SDMT, RCFT, HVLT-R, TMT A and B, Stroop, M-WSCT, FAS, WAIS-IV subtests, FDT, and Neuropsi-3 motor functions, before and after the corresponding computerized cognitive training.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 08/05/2025, Universidad de Manizales (Cra. 9a # 19-03, Manizales, 170001, Colombia; +57 (606) 8879680; cium@umanizales.edu.co), ref: CBE05_2025

2. Approved 26/11/2024, Dirección territorial de salud de Caldas (Cra. 21 #Nº 29 – 29, Manizales, 170001, Colombia; +57 (606) 68801620; comite.eticaybioetica@saluddecaldas.gov.co), ref: SP-140-CU-13518-2024

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic, Prevention, Screening, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Cognitive intervention in patients with systemic lupus erythematosus

Interventions
Current interventions as of 25/09/2026:

The study will be conducted in the city of Manizales, Colombia, through referrals from specialists associated with the research and from referral medical centers specializing in the care of patients with autoimmune diseases who meet the inclusion criteria. Additionally, support groups for patients with SLE in Colombia will be contacted.
Participant selection will be rigorous and based on pre-established inclusion and exclusion criteria to ensure sample homogeneity; for participants from SLE support groups, the diagnosis will be confirmed via medical records dated within the last six months, and active pharmacological treatment must be documented. Random assignment of participants to intervention groups aims to ensure that observed differences in executive function and adherence outcomes are attributable to the interventions rather than confounding factors. Participants were randomly assigned in a 1:1 ratio to either the experimental or control condition using a computer-generated block randomization procedure. Randomization was performed using fixed blocks of four participants to ensure balanced group sizes throughout the recruitment process.
The random assignment sequence was generated using Research Randomizer (https://www.randomizer.org), an online computerized randomization tool. A total of 45 blocks were generated, corresponding to the planned sample size of 180 participants (4 participants per block). Within each block, four unique assignment codes were randomly ordered. The assignment codes were predefined as follows: codes 1 and 2 corresponded to the experimental group, and codes 3 and 4 corresponded to the control group. This coding scheme ensured that each block contained exactly two assignments to the experimental group and two to the control group, while maintaining a random order within each block. Participants were assigned sequentially based on their order of inclusion in the study, with each participant receiving the next available assignment from the previously generated randomization list. The randomization sequence was generated prior to the start of participant recruitment and was not accessible to the researchers involved in the inclusion or assessment processes. Assignments were implemented sequentially to maintain allocation concealment and prevent selection bias.

The original protocol specified three 50-minute sessions per week over three months. On 6 May 2026, following participant withdrawals, the schedule for both groups was amended to 20 sessions of 50 minutes, delivered twice weekly over 10 weeks. The amendment aimed to reduce participant burden and support retention. Seven participants had started the intervention under the original schedule before the amendment. The change was approved by the thesis supervisor and the ethics committee.

The thesis supervisor developed the Braining cognitive training programme evaluated in this study and supervised the research. This relationship is disclosed as a potential intellectual competing interest.

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Previous interventions:

The study will be conducted in the city of Manizales, Colombia, using referrals from specialists allied to the research and leading medical centers specializing in the care of patients with autoimmune diseases who meet the inclusion criteria. Participant selection will be rigorous, using predefined inclusion and exclusion criteria to ensure sample homogeneity. Random assignment of participants to intervention groups aims to ensure that any observed differences in executive function and adherence outcomes are attributed to the interventions and not to confounding factors. Random assignment helps balance baseline characteristics between groups, minimizing selection bias and improving the study's internal validity. The participation of an external and independent collaborator for random assignment using the Research Randomizer software (https://www.randomizer.org) guarantees impartiality in participant allocation, allowing for a fair and objective comparison of the intervention's effects.

The Computerized Cognitive Training (Braining) Group will participate in 50-minute sessions, three days a week for 12 weeks, using the Braining program to improve executive functions. Activities include specific tasks such as block, digit, and letter sequences, focusing on memory, attention, and recognition. The active control group will receive a standard intervention (lower cognitive load) for the same duration.

Intervention Type
Other

Primary outcome(s)
1. Training gain measured using CSI, MMAS8, MoCA, TONY4, SDMT, RCFT, HVLTR, TMT A and B, Stroop, MWSCT, FAS, WAISIV subtests, FDT, and Neuropsi3 motor functions at baseline and 10 weeks

2. Fluid intelligence measured using TONY4 and the WAISIV Figure Weights subtest at baseline and 10 weeks

3. Transfer to other cognitive domains measured using a battery of cognitive tasks - Montreal Cognitive Assessment (MoCA), Test of Nonverbal Intelligence, Fourth Edition (TONI-4), Symbol Digit Modalities Test (SDMT), Rey–Osterrieth Complex Figure Test (RCFT – copy), Hopkins Verbal Learning Test–Revised (HVLT-R), Trail Making Test (Parts A and B), Stroop Test, Modified Wisconsin Card Sorting Test (M-WCST), Phonemic and semantic verbal fluency tasks, Letter–Number Sequencing (WAIS-IV), Digit Span (WAIS-IV), Figure Weights (WAIS-IV), Five Digits Test (FDT), Motor functions subtests from NEUROPSI-3 at baseline and 10 weeks

Previous primary outcome(s):

1. Training gain measured using CSI, MMAS8, MoCA, TONY4, SDMT, RCFT, HVLTR, TMT A and B, Stroop, MWSCT, FAS, WAISIV subtests, FDT, and Neuropsi3 motor functions at baseline and 12 weeks
2. Fluid intelligence measured using TONY4 and the WAISIV Figure Weights subtest at baseline and 12 weeks

3. Transfer to other cognitive domains measured using a battery of cognitive tasks - Montreal Cognitive Assessment (MoCA), Test of Nonverbal Intelligence, Fourth Edition (TONI-4), Symbol Digit Modalities Test (SDMT), Rey–Osterrieth Complex Figure Test (RCFT – copy), Hopkins Verbal Learning Test–Revised (HVLT-R), Trail Making Test (Parts A and B), Stroop Test, Modified Wisconsin Card Sorting Test (M-WCST), Phonemic and semantic verbal fluency tasks, Letter–Number Sequencing (WAIS-IV), Digit Span (WAIS-IV), Figure Weights (WAIS-IV), Five Digits Test (FDT), Motor functions subtests from NEUROPSI-3 at baseline and 12 weeks

Key secondary outcome(s)

Completion date
08/09/2026

Eligibility

Key inclusion criteria
1. Be between 18 and 55 years of age.
2. Be biologically female.
3. Have a confirmed diagnosis of systemic lupus erythematosus (LUPUS), supported by medical reports.
4. Have the diagnosis made by a rheumatologist, who has ruled out other possible medical causes.
5. Be under pharmacological treatment that is monitored by healthcare professionals.
6. Have completed at least fifth grade of primary school.
7. Reside in a municipality of Manizales.
8. Sign the informed consent form.

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Total final enrolment
16

Key exclusion criteria
1. History of acquired brain damage prior to the diagnosis of systemic lupus erythematosus (LUPUS).
2. Current presence or unstable remission of affective symptoms (anxiety and/or depression) with remission lasting less than four months, or lack of clinical evidence confirming symptomatic

stability.
3. History of neurodevelopmental disorders.
4. Coexistence of unstable metabolic diseases or metabolic conditions without adequate management.
5. Not having undergone a neuropsychological evaluation within the last six months.
6. Current use of psychoactive substances.

Date of first enrolment
06/12/2025

Date of final enrolment
19/02/2026

Locations

Countries of recruitment
Colombia

Study participating centre
Universidad de Manizales
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Sponsor information

Organisation
Universidad de Manizales

ROR
https://ror.org/031n6w191

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date