ACTA MÉDICA PORTUGUESA
A Revista Científica da Ordem dos Médicos

Digital and Analogical Cognitive Stimulation in Older Adults with Alzheimer's Disease: A Multicenter Randomized Controlled Trial Study Protocol

Estimulação Cognitiva Digital e Analógica em Adultos Mais Velhos com Doença de Alzheimer: Protocolo de um Ensaio Clínico Randomizado Multicêntrico

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Acta Med Port 2026 Apr;39(4):281-286 ▪ https://doi.org/10.20344/amp.24360

ABSTRACT

The growing incidence of neurodegenerative diseases in older adults, with the prevalence of Alzheimer's disease, progressively affects their quality of life. Cognitive stimulation is a psychosocial intervention that has shown consistent benefits in the lives of people with dementia from mild to moderate stages. The present study aims to evaluate the effectiveness of digital and analogical cognitive stimulation, when compared with usual care, on overall cognitive function, emotional state, and quality of life. It also aims to investigate whether institutional and territorial characteristics of social care services moderate these effects. This is a three-arm multicenter randomized controlled trial with repeated measures (pre-intervention, post-intervention, and follow-up). The intervention consists of 24 individually applied (digital and analogical) cognitive stimulation sessions, twice a week, for 12 weeks, in two intervention groups. The control group receives usual care. The study follows the recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2025), including the extension for non-pharmacological interventions. The sample size is estimated at 222 older adults with a probable diagnosis of mild to moderate Alzheimer's disease. Sociodemographic, social, health and clinical data, as well as information on care provider institutions, will be collected and analyzed. Outcomes include cognition (global cognition, memory, and executive function), emotional state (anxiety and depression), and quality of life. All outcomes will be assessed at baseline, endpoint, and follow-up, with comparisons between the intervention groups and the control group.
Keywords: Aged; Alzheimer Disease; Cognitive Dysfunction; Dementia; Quality of Life; Randomized Controlled Trial

RESUMO

O crescimento da incidência de doenças neurodegenerativas nos adultos mais velhos, com prevalência de doença de Alzheimer, afeta de forma progressiva a sua qualidade de vida. A estimulação cognitiva é uma intervenção psicossocial que tem demonstrado benefícios consistentes na vida da pessoa com demência em fase inicial a moderada. O presente estudo tem como objetivo avaliar a eficácia da estimulação cognitiva, nos formatos digital e analógico, na função cognitiva global, no estado emocional e na qualidade de vida, em comparação com os cuidados habituais. Adicionalmente, pretende analisar de que modo as características institucionais e territoriais das respostas sociais atuam como moderadoras dos efeitos da estimulação cognitiva. Trata-se de um estudo de três braços, com um desenho experimental de medidas repetidas (linha de base, pós-intervenção e seguimento), multicêntrico, controlado e aleatorizado. A intervenção consiste em 24 sessões de estimulação cognitiva (digital e analógica) aplicadas individualmente, duas vezes por semana, durante 12 semanas, em dois grupos de intervenção. O grupo de controlo mantém os cuidados habituais. O estudo segue as recomendações do *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT 2025), incluindo a extensão para intervenções não farmacológicas. Estima-se o dimensionamento amostral de 222 adultos mais velhos que apresentem diagnóstico de provável doença de Alzheimer em estado inicial a moderado. Serão recolhidos e analisados dados sociodemográficos, sociais, de saúde e clínicos, assim como informações sobre as instituições que prestam cuidados. Os *outcomes* incluem cognição (cognição global, memória e função executiva), o estado emocional (ansiedade e depressão) e a qualidade de vida. Todos os *outcomes* serão avaliados na linha base, no pós-intervenção e no seguimento, com comparação entre os grupos de intervenção e o grupo de controlo.
Palavras-chave: Demência; Disfunção Cognitiva; Doença de Alzheimer; Ensaio Clínico Randomizado; Idoso; Qualidade de Vida

INTRODUCTION

Population aging represents one of the most significant social and health challenges of our time. As a result of increased longevity, the incidence of neurodegenerative diseases is also growing. According to the World Health Organization,[1] it is estimated that more than 55 million people live with dementia worldwide, with Alzheimer's disease (AD) being the most prevalent form, accounting for about 60% to 70% of all cases. Alzheimer's disease is a progressive condition that affects multiple dimensions of a person's life, from cognitive functions to emotional well-being and functional capacity, thus requiring multidimensional and person-centered interventions.

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Revisto por/*Reviewed by*: Susana Pedras
Recebido/*Received*: 30/12/2025 - **Aceite/*Accepted*:** 09/02/2026 - **Publicado/*Published*:** 01/04/2026

In the absence of an effective treatment, non-pharmacological approaches have been gaining relevance, among which cognitive stimulation (CS) stands out. Cognitive stimulation is an evidence-based psychosocial intervention consisting of a structured set of activities aimed at promoting cognitive functioning through the activation of domains such as memory, language, attention, reasoning, and executive functions.[2,3] It differs from other approaches such as cognitive training or cognitive rehabilitation by being more general, flexible, and oriented toward the overall stimulation of mental abilities in a relational context.

When applied systematically and tailored to participants' profiles, CS has shown consistent benefits in overall cognition, mood, and quality of life.[2,4-6] The effectiveness of CS is particularly evident in early to moderate stages of dementia, and this approach is recommended in international guidelines such as those of the National Institute for Health and Care Excellence.[7]

In Portugal, studies such as those conducted by Justo-Henriques *et al*[8-11] reinforce the applicability of CS, indicating significant improvements in cognitive function, emotional state, and quality of life in older adults with neurocognitive disorder.

In recent years, digital technologies have increasingly been incorporated into cognitive stimulation interventions, leading to the development of computerized programs targeting specific cognitive domains. Evidence suggests that digital cognitive interventions, including RehaCom®-based programs, may improve cognitive functioning in people with AD and other neurocognitive disorders, with studies reporting cognitive benefits comparable to paper-and-pencil approaches.[12]

Nevertheless, randomized clinical trials directly comparing digital and analogue cognitive stimulation formats in AD remain scarce, particularly in social care settings. The influence of institutional and territorial characteristics on the effectiveness of different CS formats has been largely overlooked. It is therefore essential for evidence-based intervention planning to clarify whether digital or analogue CS better preserves or improves cognitive, emotional, and quality of life outcomes.

The objectives of this study are: (i) to test the effectiveness of CS after the intervention and follow-up period, in digital (i.e., using the RehaCom® software) and analogical formats (i.e., using the materials *Memórias de Norte a Sul*©[13] and *Domínios Cognitivos*[14]) , on global cognitive function (with an emphasis on executive function and memory), emotional state (anxiety and depressive symptoms), and quality of life; and (ii) to analyze how the institutional and territorial characteristics of social care services moderate the effects of CS.

METHODS

Study design

A multicenter three-arm randomized controlled trial with a repeated-measures design at three different time points: pre-intervention (baseline), post-intervention (after 12 weeks), and follow-up (12 weeks after the end of the intervention). The intervention consists of 24 individual CS sessions delivered twice a week, for 12 weeks, in the intervention groups (Group 1: digital intervention; Group 2: analogical intervention). The control group receives the usual care provided by the institution (i.e., social care and support services from which the participant already benefits), including the activities specified in the individual care plan. The study follows the recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2025; Table 1).[15,16] Data collection will take place from September 1st, 2025, to March 13, 2026.

Sample size estimation and statistical analysis

Using R in the RStudio environment with the stats package,[17,18] a sample size of 222 participants was estimated, with around 74 participants allocated to each group (222/3). The sample size was calculated based on the following parameters: type I error rate (α) = 5%; statistical power (1 - β) = 90%, number of study arms = 3; number of repeated measurements per participant = 3 (T0, T1, T2), and an expected attrition rate of 20%.

The calculation targeted the detection of a group x time interaction effect in a repeated-measures framework, reflecting the primary hypothesis of differential change over time between the three study arms. Several standardized effect sizes were explored (Cohen's f = 0.25, 0.30, 0.35, and 0.40), and an effect size of f = 0.30 was retained as a small-to-moderate, clinically meaningful and feasible effect size, given previous studies of CS in AD. This resulted in an estimated total sample size of 220 participants, which was rounded to 222 to allow equal allocation across groups.

The primary statistical analysis will be conducted using linear mixed-effects models (LMMs). This approach allows for the inclusion of participants with incomplete data (missing cases), the modelling of repeated measurements over time (T0, T1, and T2), the estimation of group x time interaction effects (if any), and the accommodation of within-subject correlations due to the dependence of repeated observations. Models will be estimated using maximum likelihood, which provides valid inference under the missing at random (MAR) assumption. The plausibility of the MAR assumption will be examined by comparing baseline characteristics and observed outcome patterns between participants with complete and incomplete follow-up data.

For each outcome variable, a separate LMM will be fitted including fixed effects for group, time and the group

Table 1 – Participant timeline: Schedule of enrollment, interventions, and assessments (SPIRIT 2025)

	Study period			
	Enrollment		Post-randomization	
Timepoint	$-t_0$	t_0	t_1	t_2
Enrollment:				
Eligibility screening	X			
Informed consent	X			
Recruitment	X			
Randomization		X		
Interventions:				
Digital intervention		X →	X	
Analogical intervention		X →	X	
Assessments:				
Sociodemographic data (age, place of birth, sex, marital status, level of education)		X		
Social data (type of institution attended, length of institutionalization, number of weekly visits, kinship of weekly visitors, prior experience and self-perception of digital technology use, previous profession and sector of activity)		X		
Health or clinical data (clinical condition and pharmacological treatment)		X		
Geographic data (place of residence, type of territory)				
Data on institutions providing care (type of entity, municipality, type of territory, proximity to health services, number of residents or users, number of residents or users diagnosed with dementia, availability of rooms and equipment for CS, number of professionals trained in CS, prior experience of professionals with CS and familiarity with digital technologies)		X		
Cognitive evaluation		X	X	X
Mini-Mental State Examination				
Alzheimer's Disease Assessment scale Cognitive subscale				
Memory Alteration test				
Frontal Assessment Battery				
Behavioral evaluation		X	X	X
Geriatric Depression scale				
Geriatric Anxiety inventory				
Quality of life		X	X	X
Quality of Life – Alzheimer's Disease				
Adherence to the intervention			X	
Degree of collaboration			X	

CS: cognitive stimulation; $-t_0$: enrollment phase; t_0: baseline; t_1: endpoint; t_2: 12-week follow-up

× time interaction, and a random intercept for participants to account for within-subject correlation. Continuous outcomes (e.g., cognitive scores and quality of life) will be analyzed using Gaussian LMMs, whereas emotional state outcomes will be modeled according to their empirical distribution. Baseline values of the outcome and relevant sociodemographic and clinical covariates will be included as fixed effects when appropriate. Estimated marginal means and their contrasts will be used to compare changes over time between groups.

Participants

Adults aged 65 years or older who are volunteers and who: (i) are attending a social support service (e.g., residential care facility, day care center, or home support service) for older adults in Portugal for at least three months; (ii) have a probable diagnosis of neurocognitive disorder due to AD, established according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders, 5th edition, text revision (DSM-5-TR),[19] based on clinical phenotype and cognitive-behavioral assessment, and confirmed by a

clinical report from a specialist or assistant, or by syndromic assessments carried out by clinical psychologists or neuropsychologists; (iii) have the ability to communicate and understand instructions; (iv) are native Portuguese speakers; and (v) score between 10 and 26 points on the Mini-Mental State Examination (MMSE), corresponding to mild to moderate stages of dementia according to reference values.[7] Exclusion criteria: (i) inability to read or write; (ii) severe sensory, physical, acute or serious medical conditions preventing participation in the CS sessions; (iii) evidence of aggressive and/or disruptive behavior; and (iv) initiation or re-initiation of psychoactive medication with potential effects on cognition or behavior, including antipsychotics and benzodiazepines, within the two months preceding recruitment. A favorable opinion was issued by the Ethics Committee of the Instituto São João de Deus, Portugal (approval number 29072025).

Variables and instruments

The variables will be assessed by a clinical psychologist, who will be blinded to the participant's group allocation, at three-time points: before the start of the intervention (baseline, T0), 12 weeks post-baseline (endpoint, T1), and 12 weeks after the end of the intervention (follow-up, T2). Instruments that have been previously validated for the Portuguese population will be used to carry out the evaluations.

Primary variables: global cognitive function, memory, and executive function. Global cognitive function will be assessed using the MMSE[20,21] and the Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-Cog).[22-24] Memory will be assessed using the Memory Alteration Test (MAT)[25,26] and executive function will be assessed using the Frontal Assessment Battery (FAB).[27,28]

Secondary variables: emotional state and quality of life. The Geriatric Depression Scale (GDS-15)[29,30] assesses depressive symptoms, and the Geriatric Anxiety Inventory (GAI)[31,32] assesses anxiety levels. Quality of life will be assessed using the Quality of Life – Alzheimer's Disease (QoL-AD) instrument.[33,34]

Other variables include sociodemographic data (age, place of birth, sex, marital status, level of education), social data (type of institution attended, length of institutionalization, number of weekly visits, kinship of weekly visitors, prior experience and self-perception of digital technology use, previous profession and sector of activity), health and clinical data (clinical condition and pharmacological treatment) and geographic data (place of residence, type of territory). These data will be collected through a structured questionnaire designed specifically for this study. In addition, data on care provider institutions will be collected (type of entity, municipality, type of territory, proximity to health services, number of residents or users, number of residents or users diagnosed with dementia, availability of rooms and equipment for CS, number of professionals trained in CS, prior experience of professionals with CS and familiarity with digital technologies). Adherence to the intervention and degree of collaboration will be recorded in an evaluation record sheet for each session.

Intervention

The intervention program will consist of 24 individual CS sessions, each lasting approximately 45 minutes, and will have the following structure: (i) welcome and greeting (5 minutes); (ii) orientation to place and time (10 minutes); (iii) main CS activity (25 minutes); and (iv) session review (5 minutes).[35] The individual CS sessions will be delivered in both intervention groups (digital and analogical) and conducted by professionals with prior experience in CS, who will receive study-specific training (minimum of six hours, provided by the research team) and have access to a detailed intervention guide for the respective sessions.

In the digital intervention (Appendix 1: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24360/15906), sessions will be conducted using RehaCom® software, which allows for computerized adaptative exercises based on specific cognitive domains. In the analogical intervention (Appendix 2: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24360/15907), sessions will use structured physical materials, namely the resources *Memórias de Norte a Sul*©[13] (Memories from North to South) and *Domínios Cognitivos*[14] (Cognitive Domains), applied in an alternating manner across sessions. To ensure standardization of the intervention, the professional will receive the respective detailed program, prepared by two members of the research team.

In both intervention modalities, there will be no repetitions of activities, i.e., all 24 sessions will be different, and throughout the CS program, the degree of difficulty of the exercises will be adjusted according to the participant's stage of AD.

Individual CS sessions will be conducted according to the schedule established by the institution supporting the participant, in an appropriate setting (i.e., an accessible, comfortable, and quiet space that allows uninterrupted activity) - Appendices 1, 2 (Appendix 1: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24360/15906 & Appendix 2: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/24360/15907).

DISCUSSION

This three-arm randomized controlled clinical trial aims to evaluate the effects of 24 individual CS sessions delivered in two formats (digital *versus* analogical) immediately

after 12 weeks of intervention and 12 weeks after completion, in older adults with a probable diagnosis of AD, attending Portuguese care provider institutions and support services. It is also planned to investigate how institutional/organizational (e.g., legal status, staff-to-user ratio) and territorial characteristics (e.g., population density) influence the effects of CS.

Recent evidence has revealed that a 12-week program of individual CS in older adults with mild to moderate AD was effective in improving memory, and showed a trend toward significant effects on global cognitive function.[11] Based on this evidence, it is hypothesized that the present individual CS program may lead to improvements in overall cognitive function, particularly memory and executive function, as well as in quality of life. Reductions in depressive symptoms and anxiety following participation in CS programs have also been described,[8,9] and it is expected that similar effects may be observed in the present study.

Another recently published study compared the effects of computerized cognitive training using RehaCom® technology *versus* paper-and-pencil cognitive training in people with early-stage AD and reported that after 15 weeks (two one-hour sessions per week), both groups showed significant cognitive improvements.[12] Specifically, RehaCom® users showed improvements in memory, word naming, and processing speed. Sarpourian *et al*,[36] in a systematic review, confirmed the effectiveness of RehaCom® in improving cognitive function among individuals with cognitive impairment (e.g., due to multiple sclerosis, Parkinson's disease, mild cognitive impairment), reinforcing the need for well-designed randomized controlled trials to confirm the positive effects observed,[36] particularly in people with other neurocognitive disorders such as AD.

According to the evidence published to date, this multicenter study may be considered pioneering in Portugal, particularly with respect to two of its characteristics: (1) the comparison of two CS interventions (digital *versus* analogical) in older adults with a probable diagnosis of AD who are users of a social care service; and (2) the inclusion of territorial and organizational variables in the evaluation of results, in order to understand how the spatial context, local resources, and institutional organization models modulate the effect of CS interventions. If the results confirm the expected effects, this CS intervention program with older people living with AD may have relevant implications for professional practice in the context of social care services in Portugal. The relatively low costs and high replicability of digital and analogic programs may facilitate their implementation in a larger number of institutions and, consequently, promote improvements in the health and quality of life of people with AD who have limited access to these interventions outside the social services they currently receive.

TRIAL REGISTRATION

Clinicaltrials.gov ID: NCT07041008; Digital and Analogical Cognitive Stimulation in Older Adults with Alzheimer's Disease: Effects on global cognition, well-being and quality of life across distinct Institutional and Sociogeographic Contexts.

ACKNOWLEDGMENTS

The authors have declared that no AI tools were used during the preparation of this work.

AUTHOR CONTRIBUTIONS

SJH, JM: Design, methodology, and writing of the manuscript.

MP, RS, RSJ, OR: Methodology, review, and editing of the manuscript.

FBM: Methodology, writing of the manuscript

All authors have read and approved the present version of the manuscript.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

FUNDING SOURCES

This study did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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