International Journal of Clinical Trials
Kanmani AS et al. Int J Clin Trials. 2025 May;12(2):142-152
http://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259

DOI: https://dx.doi.org/10.18203/2349-3259.ijct20251210

Protocol

Caregiver-driven cognitive training program for dementia: a treatment development and feasibility study protocol in Indian population

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Received: 24 December 2024
Revised: 18 March 2025
Accepted: 02 April 2025

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ABSTRACT

Background: Cognitive training (CT) is an efficacious intervention for promoting experience-dependent neuroplasticity, especially in modifying cognitive decline in neurodegenerative conditions. Despite its immense potential, there exist clinical and logistic challenges in delivering the intervention to the dementia population. Given the cultural context of collectivistic societies like India, where family involvement is integral in illness-related care, a caregiver-supported CT program may overcome current challenges and help promote accessible and affordable dementia care.
Methods: The prospective study holds two main objectives that is to develop a caregiver-driven CT program called the Individualized Cognitive Augmentation Regimen for Elderly (iCARE) and to assess the feasibility of iCARE for mild to moderate dementia. The intervention is designed systematically through literature review, item generation, expert validation, field trials, iterative feedback modification and pilot testing. Rooted in principles of neuroplasticity, iCARE targets the core cognitive abilities of attention, executive functions, language and memory. It employs an integrative approach combining bottom-up and top-down strategies, potentially loading on the frontoparietal or central executive networks. The feasibility testing protocol of iCARE aims to build a sustainable model by empowering caregivers as co-therapists through adequate training, thereby reducing the existing treatment gap for dementia in India.
Conclusion: The interactive and individualized nature of iCARE may contribute to delaying/slowing cognitive decline in dementia patients while supporting caregivers' well-being. This paper addresses the technical 'what,' 'how,' and 'why' questions in developing and feasibility-testing a culturally specific CT program for dementia.
Trial Registration: Clinical Trial Registry of India (7th October 2022) - CTRI/2022/10/046281.

Keywords: Cognitive retraining, Dementia, Ageing, Cognitive decline, Neuropsychological rehabilitation, Geriatric care

INTRODUCTION

Cognitive training (CT) is proven efficacious in improving cognitive functions in various neurological conditions. It aims to drive learning and adaptive neuroplastic changes in an individual's neural representational systems through specifically defined, neuroscience-based, and controlled tasks.[1] In the recent past, increased efforts have been made to use CT with normal ageing, mild cognitive impairment and dementia to promote healthy ageing.[2–6] Studies on ageing support

for transfer over time, over different functional contexts and modalities.[7]

Studies often conceptualize the mechanism of CT as a symptom-based treatment model by describing treatment efficacy based on outcomes or in comparison with control. Instead, it is crucial to understand the theoretical phenomenon behind the approach as it forms the driving principle for the design of the exercises. The recovery of neural network systems following brain lesions uses the principle "cells that fire together, wire together".[8] The Cognitive training hypothesis for Alzheimer's disease (AD) focuses on inducing synchronized activity in specific brain regions.[9] The underlying principle is that repeated task-related co-activation of these regions leads to increased resting-state functional connectivity.[10] Given the selective impact of Alzheimer's pathology on the brain's default-mode network, a set of exercises is designed to elicit co-activation in the central hubs of this network.[11]

While the benefits of CT are well established through the literature, accessibility to treatment for dementia is often hindered by a lack of feasible, culturally appropriate, and sustainable models that can help reduce hospital/clinician dependency. Most CT models used in dementia are found to have clinical heterogeneity and lack agreement on the mechanism of change.[9,12] The effectiveness of these programs is often tied to practical difficulties such as feasibility, transport, caregiver support, proximity of treatment centres, mobility, physical health conditions, choices available in a group activity, and moderation of difficulty of sessions, which makes it less suitable for the Indian population.

With an estimated treatment gap of nearly 90%, where only one in 10 people with dementia receive a diagnosis, treatment or care, there is a dire need for feasible programs to compensate for the decline in cognition.[13] While most studies focus on improvement in the core cognitive abilities as the outcome variables, it is more important to focus on sustaining current cognitive status, delay of deterioration, improvement in quality of life and independence in functional abilities.[5] The pronounced neuroplasticity contingent upon learning increases the capability to administer specific and controlled learning interventions to the brain, thereby enabling precisely targeted training regimens conducive to substantial and enduring change in neural systems implicated in behavioural disorders.[1]

The study attempts to develop a neuroscience-informed, culturally relevant, caregiver-driven model of cognitive training called the individualized cognitive augmentation regimen for elderly (iCARE) for dementia. The iCARE program aims to target core cognitive abilities such as attention, executive functions, memory and language. Integrating processes like semantic content processing, memory retrieval, and executive control forms the basis of task-induced co-activation within multiple regions of the default-mode network, including the hippocampus, lateral temporal cortex, posterior cingulate, and medial prefrontal cortex.[9] This targeted approach aims to enhance resting-state functional connectivity among these areas, proposing a specific strategy for addressing the neural correlates associated with Alzheimer's disease. The iCARE model will employ a blended approach, combining bottom-up and top-down strategies, thereby designed to load on the front-parietal or central executive networks.

Collectivistic societies hold family as an integral unit in an individual's life, especially when accounting for illness-related support. The iCARE program uses the innate strength of Indian family structure and dynamics in favour of dementia management through this model, which in turn increases the support system, provides a better understanding of the condition, reduces hospital visits, reduces dependence on the therapist, and reduces the caregiver burden. Including the caregivers as part of the treating team can be advantageous making a caregiver-driven model of CT more culturally relevant for the Indian Population.[14,15]

Study objectives

Objective 1

To develop a caregiver-driven cognitive training model (iCARE program) for patients with mild to moderate dementia.

Objective 2

To assess the feasibility of iCARE for patients with mild to moderate dementia in Indian society.

METHODS

Objective 1 (iCARE development)

The Medical Research Council (MRC) guidelines suggest a systematic framework for intervention development through phases of development, feasibility testing, evaluation and implementation.[16] It encourages answering questions beyond the outcome of the intervention by considering the context, theory, stakeholders, barriers, resource availability, and implementation capacity, which may be of utmost value.

Keshavan, Vinogradov, Rumsey, Sherrill and Wagner (2014) describe four major critical issues to address in the development and testing of the cognitive training model in any neuropsychiatric condition. Accounting for the baseline neurocognitive heterogeneity apart from the diagnostic criteria, multi-domain baseline assessments to understand the feasibility of assessing putative moderators in successful target engagement, understanding the mechanisms driving the proximal and distal changes and reducing delays in research to practice

translation.[17] The current study protocol describes an efficacious, sustainable cognitive intervention that overcomes these challenges.

Procedure

The development of the iCARE program employs the following steps.

Literature review

An extensive review on CT for various neurological and psychiatric conditions (such as head injury, schizophrenia, depression, normal ageing and MCI), neuropsychological deficits in dementia, CT for mild to moderate dementia, the theoretical foundations of CT, functional brain network changes underlying CT tasks, neuroscience-based domain-wise (attention, working memory, executive functions and language) task development and existing protocols and guidelines of development of cognitive interventions.

Item generation

Ten items that are relevant to the goal of the training will be generated based on the tasks and principles of cognitive training observed through a literature review. Tasks will be designed based on fundamental principles of neuroplasticity and rehabilitation.

Expert rating

The newly developed tasks will be rated by five professionals (clinical psychologists with a minimum of five years' experience in research/clinical aspects of Neuropsychology) for content relevance, difficulty level, overall ease of administration, ease of understanding of the test instructions and overall feasibility.

Field trial

The first trial will be done with three participants meeting inclusion and exclusion criteria to obtain feedback on the order of administration, the subjective difficulty of tasks, agreeable duration of session, ease of comprehension instructions, caregiver involvement, feasibility and overall adherence.

Modification

Based on the feedback, modifications will be made to the modules to make them suitable for the pilot study.

Pilot testing

The module thus obtained will be administered on 10 dyads (includes a patient and their primary caregiver)-5 intervention and 5 treatments as usual (TAU)-meeting the inclusion and exclusion criteria.

The intervention will be provided for 5 weeks. Further corrections will be made, and modules will be finalized for the feasibility evaluation.

Theoretical framework

Approaches to CT can be categorized as bottom-up (restorative) or top-down (compensatory).[18,19] Bottom-up specific stimulation involves providing perceptual, motor, or other externally generated inputs to the lesioned network, specifically aimed at fostering connections within the damaged area while minimizing the risk of forming incorrect connections with other networks.[18]

These interventions emphasize practising basic to higher-level cognitive skills and enhancing foundational abilities through repetitive drills. In contrast, top-down specific stimulation pertains to attentional control circuits, or executive functions, primarily modulated by the prefrontal cortex, potentially promoting synaptic activity and plasticity.[8]

The experience-dependent synaptic reorganization facilitates the deployment of attention to relevant domains, enabling the top-down influences on plastic reorganization in the brain. This approach targets deficits in higher-order executive functions, teaching principles applicable across situations for better generalization.

When developing a new cognitive training program, studies have often chosen one of the two approaches where tasks involve intensive, systematic practice of lower-level cognitive processes that gradually build up to higher-level processes (bottom-up) or contrarily focus more on high-level cognitive processes that naturally integrate and organize lower-level ones (top-down).

Though different approaches have their strengths and weaknesses, there is a tendency to demonstrate sporadic single-domain improvement, only leading to generalizable differences in other domains.[7] Nevertheless, the accurate mechanism of change is still unclear. Insights from cognitive training literature across various conditions, such as brain injury, schizophrenia, and depression, underscore the importance of a blended approach that simultaneously trains both bottom-up (attention and perceptual functions) and top-down (executive functions) processes.[18–20] However, there is scarce literature exploring the application in dementia, where cognitive decline is progressive. Our current intervention employs an integrative approach, combining both bottom-up and top-down strategies, thereby designed to load on the fronto-parietal network or central executive network (CEN).

Each session uses targeted multimodal training to provide specific stimulation that enables plasticity, as recommended for profiles with cognitive impairment across multiple domains, like mild to moderate dementia.[21] As substantiated by the literature, The iCARE program is also designed to potentially facilitate the

disengagement of the default mode network (DMN) and the frontoparietal network. Such training has been shown to enhance functional connectivity integration within these networks following cognitive training, thereby improving cognitive function, along with evidence for potential anti-correlation between the DMN and CEN particularly responsive to cognitive training.[11]

Among CT studies, moderate evidence exists suggesting a focus on core cognitive abilities such as executive functions and attention 2 along with other areas such as speed of processing and memory as it helps to promote learning and neural changes.[5] The intervention was aimed to target these core domains (Figure 1), and ecologically valid tasks were thus designed for attention, verbal working memory, visual working memory, cognitive flexibility, planning, fluency, response inhibition and memory.[22]

Every domain is facilitated by relevant neural substrates and functional networks that support the development process.[23–25] Besides the solid cognitive neuroscience-based theoretical background, the iCARE program also integrates caregiver involvement and support in the model, which is hypothesized to support the maintenance/enhancement of cognitive function and symptom reduction, enabling the transfer of gains to re-engage within the family/society and demonstrate optimum autonomy (Figure 2).[26]

Intervention details

Based on the literature, Table 1 describes the structure of the iCARE program proposed by the author with guidance from a senior neuropsychologist. Each task has multiple levels, is presented in a graded manner, and will be standardized based on expert rating and a pilot study.

Ten simple, home-based tasks designed to be engaging, interactive, cognitively stimulating, ecologically valid, and supportive of neuroplasticity (Figure 1). Lower levels of each task focus on basic cognitive functions, gradually progressing to higher-order functions.

The stimulus book aims to minimize language and education demands to accommodate illiterate individuals and uses culturally relevant stimuli for the Indian population.

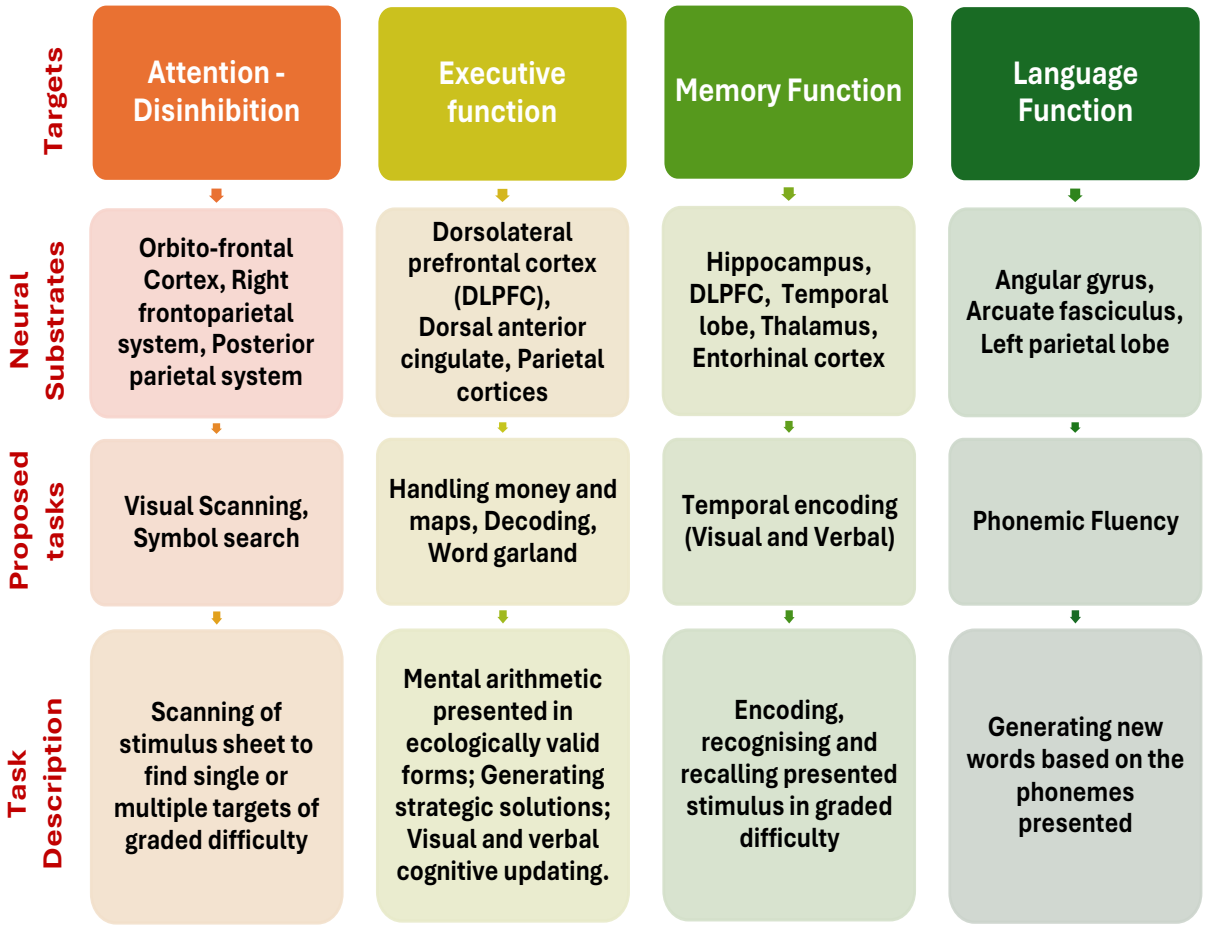

Figure 1: Theoretical basis of task development in iCARE program.

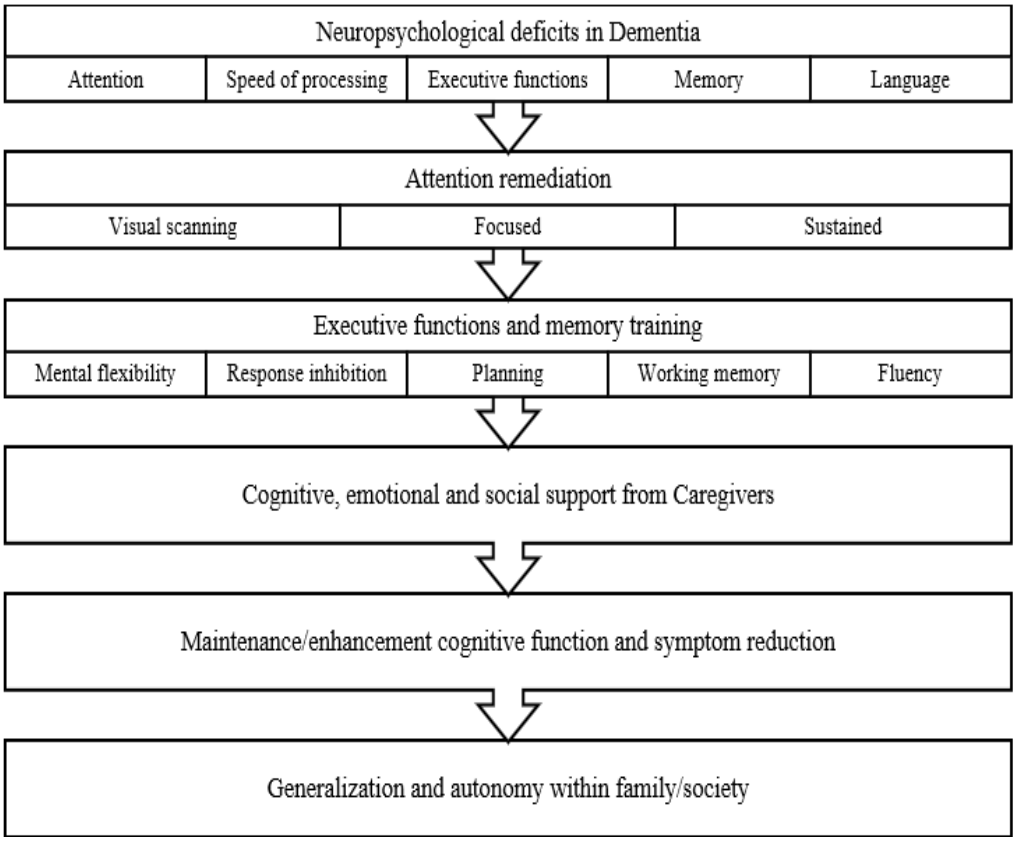

Figure 2: Proposed training model.

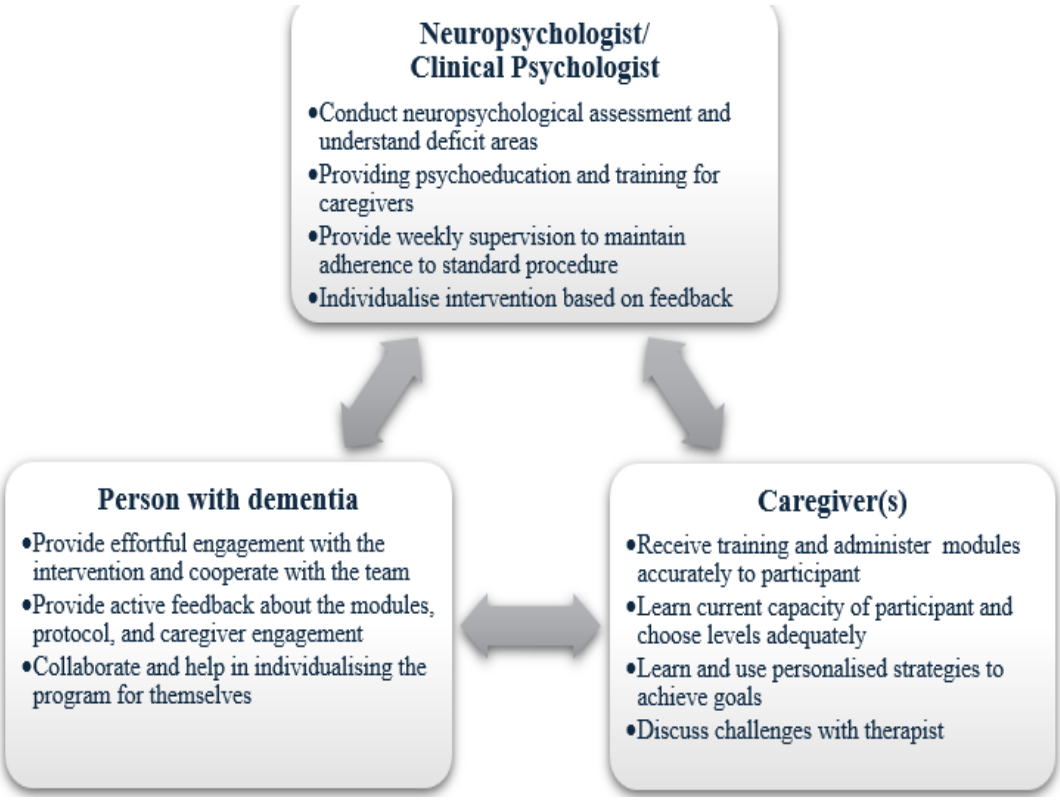

Figure 3: Specific roles of iCARE team.

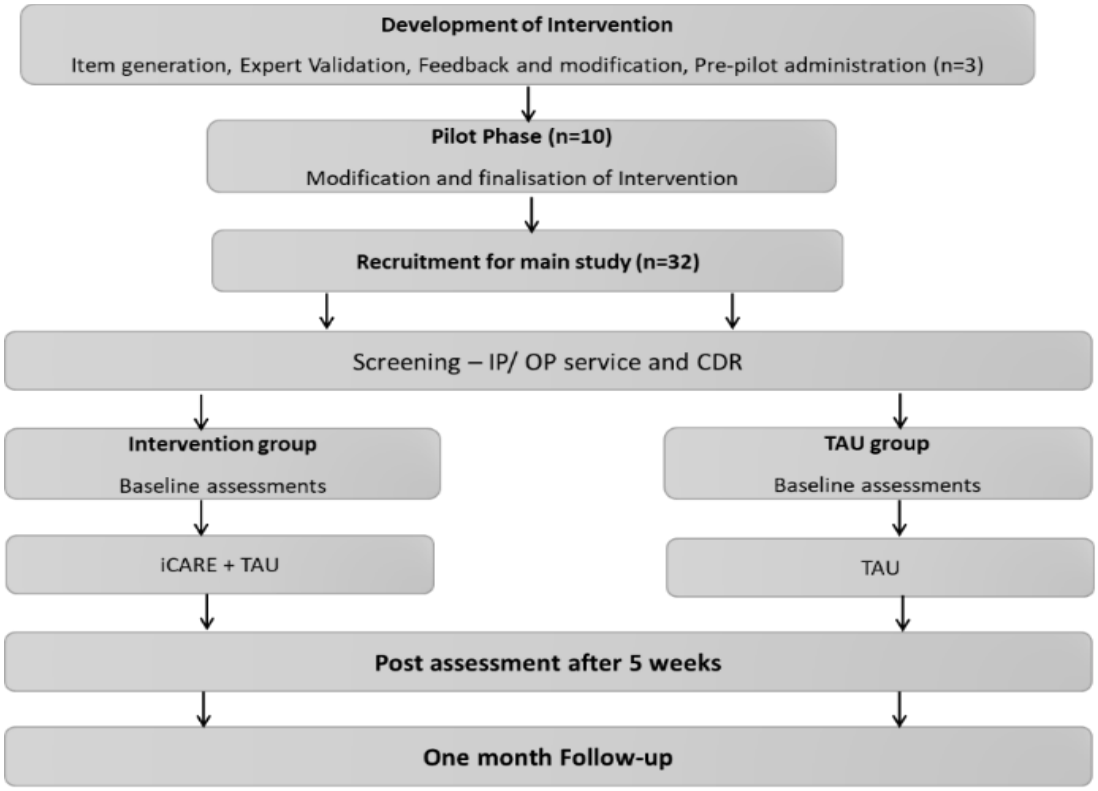

Figure 4: Flowchart of the study.

	STUDY PERIOD									
	Enrolment	Allocation	Baseline	Intervention / Control Conditions					Post intervention	
TIMEPOINT	t_{-1}	t_0	t_1	t_2	t_3	t_4	t_5	t_6	t_7	$t_{1\text{-}month}$
ENROLMENT:										
Eligibility screen	X									
Screening tool (CDR)	X									
Informed consent	X									
Allocation		X								
INTERVENTIONS:										
iCARE										
TAU										
ASSESSMENTS:										
Neuropsychological functions (NNB-E, 9 subtests)			X						X	X (3/9)
Quality of life (DEMQoL)			X						X	
Cognitive symptoms (IQCODE, NCS, HMSE)			X						X	X
Activities of daily life (EASI)			X						X	
Behavioural and psychological symptoms (NPI)			X						X	
Insight (CIR)			X						X	
Depressive symptoms (CSDD)			X						X	
Caregiver Health (GAD, PHQ)			X						X	
Caregiver burden (ZBI)			X						X	
Subjective rating (VAS)			X						X	
Feasibility outcome measure									X	
Fidelity checklist				X	X	X	X	X		

Figure 5: Spirit diagram (standard protocol items for reporting clinical trials) for the schedule of enrolment, interventions, and assessment.

CDR - clinical dementia rating; NNB-E - NIMHANS neuropsychological battery for elderly; DEMQoL - quality of life in people with dementia-proxy; IQCODE - informant questionnaire on cognitive decline in elderly; NCS- NIMHANS cognitive complaints scale; HMSE - Hindi mental status examination; EASI - everyday abilities scale for India; NPI - neuropsychiatric inventory; CSDD - Cornell scale for depression in dementia; PHQ - patient health questionnaire scale; GAD - generalized anxiety disorder scale; ZBI - Zarit burden interview; CIR - clinical insight rating scale; VAS - visual analogue scale.

Materials

The module is envisioned as a flip book targeting cognitive domains that include attention, verbal working memory, visual working memory, fluency, response inhibition, cognitive flexibility, planning, and memory. It will comprise of seven books on graded difficulty, with two books exclusively for attention and memory. Patients will receive three books initially, which are upgraded weekly based on progress. A detailed instruction manual will also be provided to the caregiver.

Training and supervision

Training will involve direct demonstration by the neuropsychologist, followed by caregiver practice under supervision. Weekly supervision sessions over five weeks will include reviewing participant progress, adjusting tasks, and addressing caregiver concerns.

Administration

Primary caregivers will administer the modules after receiving training from a Neuropsychologist. The intervention will be conducted for 45 minutes daily, five days a week. Apart from supervision, caregivers can contact the neuropsychologist for support if needed.

Individual roles

The members of this team are aimed to complement each other with reciprocal interactions, as in Figure 3, to provide the utmost support and care for people with dementia.

Neuropsychologist

Provides history taking, cognitive assessment, caregiver training, supervision, and evaluates intervention feasibility.

Caregiver

Administers intervention, monitors participant feedback, personalizes the approach, and communicates challenges to the therapist.

Person with dementia

Actively engages with the intervention, providing feedback to help tailor the modules.

Objective 2 (feasibility testing)

Study design and setting

The study has a Quasi-experimental design. Patients for all phases will be recruited from IP/OP services of the Department of Geriatric Psychiatry and Department of Neurology, National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore, India.

Table 1. Structure of the proposed intervention.

iCARE program	
No. of sessions	25 sessions (45 mins each)
Duration	5 weeks
Frequency	Minimum 5 days a week+1 supervision session
Mode	Home-based cognitive retraining
Difficulty level	5 levels of difficulty + 2 extensions (upward and downward)
Materials	Presented in a flip book format 5 books (+2 books)
Administration	Caregiver administered upon receiving regular training
Progression of task	At least 80% mastery
Theoretical basis	Principles of neuroplasticity and rehabilitation

Study period

The protocol has been designed as a part of the doctoral program with a duration from January 2021 to December 2025. The study is currently in the data collection phase.

Inclusion criteria

The dyad recruited will include patients of any gender above the age of 55 years, diagnosed with mild-moderate dementia (DSM V criteria for Major Neurocognitive Disorder), with a Clinical Dementia Rating, CDR (1 or 2), who can engage in the session for at least 20 minutes.

Caregivers of any gender (family or professional) above the age of 18 years, educated at least till 10th standard, who have been the primary caregiver for at least three months and have access to and knowledge of at least one digital device. Both participant and caregiver must be able to comprehend (basic reading and writing) at least one of the following languages - English, Tamil, Kannada and Hindi.

Exclusion criteria

Excludes patients with a history of any major neurological, neurosurgical and/or psychiatric illness other than a major neurocognitive disorder (DSM V); Clinical evidence of intellectual disability; Patients with severe sensorimotor/language deficits indicating them not amenable to testing; and Individuals currently receiving any form of cognitive/psychological interventions.

Sample characteristics

The sample size is calculated based on the Stick construction test (Mean=2.30; SD=4.05) using the R

package with the Power as 80%, Level of Significance as 0.05 and Minimum clinically significant difference as 4. Thus, the sample size was estimated to be 32 dyads (16 in the intervention and 16 in the TAU group).

Outcome measures

Sociodemographic data

A data sheet for the participant and the caregiver will be used with details of their age, sex, education, occupation, severity of dementia, type of dementia, medical and treatment history, family history of dementia, substance use history, covid history, caregiver demographics, type of caregiver (family/professional), duration of caregiving, and access and familiarity to digital aids.

Screening tool

CDR 27, a five-point scale spread over the six domains (Memory, Orientation, Judgment and Problem-solving, Community Affairs, Home and Hobbies, and Personal Care), will be used as a screening tool to identify patients falling between a CDR-1 to 2, indicating mild to moderate dementia range.

Primary outcome measure

The NIMHANS Neuropsychological Battery for elderly by Dr. Ravikesh Tripathi (Unpublished doctoral dissertation, NIMHANS, 2013) will be used as the primary measure as it is a comprehensive battery developed for assessing cognitive functions in Indian older adults. It is a brief battery covering tests spread across eight cognitive domains namely, attention–symbol cancellation task; verbal working memory–digit span test; visual working memory–corsi block test fluency–category fluency task verbal learning and memory–word list; logical memory–story memory test; visual learning and memory–stick construction test, visuospatial constructions–BGT, 2D/3D construction and Parietal focal signs. It takes 60 minutes to administer where all sub-tests are significantly correlated with the Hindi mental status examination scores (HMSE; r=0.4-0.73) and negatively correlated with CDR (r=-0.7-0.88) and everyday abilities scale for India scores (EASI; r=-0.1-0.53).

Secondary outcome measures

Eight secondary outcome variables will be assessed using the following scales: The health-related quality of life of people with dementia will be assessed using the 31-item quality of life in people with dementia-proxy (DEMQOL-Proxy).[28] The cognitive symptoms will be assessed using the informant reports of the 16-item informant questionnaire on cognitive decline in elderly (IQCODE) and the 20-item NIMHANS cognitive complaints scale (NCS) by Sowparnika (unpublished MPhil dissertation, NIMHANS, 2021) to understand the longitudinal and current cognitive changes.[30] The HMSE will also be used to measure global cognition. The 12-item EASI will capture the functional abilities.[31,32] The Neuropsychiatric Inventory (NPI) will be used to assess behavioural and psychological symptoms of dementia.[33] The scale looks at ten domains of behavioural disturbances rated on frequency and severity according to the information given by the caregiver. The 19-item Cornell scale for depression in dementia (CSDD) instrument will additionally be used to rate the severity of depressive symptoms, if any. [34]

The caregiver's health will be observed using self-rated measures of patient health questionnaire scale (PHQ-9) and generalized anxiety disorder scale (GAD-7) to understand the predisposing mood disturbances in the caregivers, which may interfere with the caregiving needs.[35,36] The self-administered 22-item Zarit burden interview (ZBI) will measure the subjective burden experienced in caring for a person with dementia.[37] A 4-item clinical insight rating scale (CIR) will be used to assess the participant's insight.[38]

A subjective rating of perceived change in various domains of the cognitive deficit will be taken from the caregiver on a scale of 0-100 percent using the visual analogue scale (VAS). A feasibility outcome measure and a treatment fidelity checklist developed by the author will also be administered to record the feasibility of the novel intervention received and ensure adherence to the recommended intervention format.

Procedure

Figures 4 and 5 inform the enrolment, interventions, and assessment procedures according to the SPIRIT guidelines. Participants who receive a confirmed diagnosis of mild to moderate Dementia (DSM V and CDR score of 1 or 2), contacted through OP/IP from NIMHANS, Bangalore, will be provided with the Subject Information Sheet to discuss the risks and benefits of participation in the research study. The dyads who provide Informed consent to participate will then be allotted (1:1 ratio) to the Intervention or TAU group and will be administered with the Pre-intervention measures.

On obtaining baseline measures, dyads in the intervention group will be given the iCARE program in an online/offline format. The individuals who receive at least 20 out of the total 25 sessions (80%) would be considered Completers in the study. Meanwhile, the TAU group will continue their usual treatment routine involving regular medication and psychoeducation. Post-intervention measures will be administered to the participant and caregiver at the end of 5 weeks. After one month, a follow-up will be done to assess the participant's cognitive functions using selective tests (Figure 5).

Statistical methods

The data obtained using the tools will be tabulated and subjected to statistical analysis. Descriptive statistics such

as mean and standard deviation, frequencies and percentages will be used to describe the demographic, clinical and neuropsychological profile of the patients. The normality of the data will be tested using the Shapiro-Wilk normality test.

Student's t-test/Mann-Whitney Test will be used to compare the two groups on continuous variables. A paired t-test/Wilcoxon Signed Rank Test will be used to find significant differences between pre- and post-measurement in each group. Chi-Square will be used to compare a categorical variable between the two study groups. Repeated measures ANOVA will be used to compare the change of outcome variables between the two groups. The data will be analyzed using the R package.

Ethical considerations

Approval was obtained from the Institutional Ethics Committee and the Departmental Ethics Committee, Department of Clinical Psychology, NIMHANS, Bangalore. Written informed consent from the participant and caregiver will be obtained after the purpose, risks and benefits of participating in the study are explained. Confidentiality of the information and anonymity of participant's identities will be maintained throughout the study.

Participants will be informed about their freedom to discontinue participation at any point in the study. It will be ensured that the intervention does not interfere with their ongoing treatment and that refusal to participate will not adversely affect their treatment. Feedback about the results will be given to the patients and treating team. Provision for referral to psychiatry services of NIMHANS in case of any psychological distress reported during the assessment.

Strengths and limitations

The goal of the development is to improve the availability and accessibility to a standardized intervention with tangible multi-tiered cognitive exposure backed by the theoretical understanding of cognitive neuroscience. Being able to achieve this by recruiting the caregiver as a co-therapist and delivering a culturally relevant and ecologically valid module in the safe space of a person with dementia is a unique initiative.

The format of delivery, mode of administration, cost of materials, and clinical support in executing the model all make it a feasible model for a collectivistic society like India, in reducing the social and economic burden caused by the condition. However, the study focuses only on development and feasibility testing within the limited study duration. Methodological rigour, such as a larger sample size, randomized controlled trials and matching of type and severity of dementia, may provide more generalizable findings.

Implication and future direction

The clinical and societal relevance of the developed model may go a long way in reducing familial, social and economic burden. The model's ease of implementation and affordability will make it possible to reach a large and wide range of people in need of the service. The training-of-trainer model enables the training of a heterogeneous group of clinicians, family members, professional caregivers, or volunteers, thus creating a snowball effect that improves the scalability of the intervention.

Future studies may also focus on adapting the program to a group format used in assisted living setups through iCARE-trained professional caregivers or volunteers, making the existing model more interactive and sociable.

CONCLUSION

The study protocol outlines the development process of the iCARE program and the feasibility testing methods to suit the Indian population. This novel caregiver-supported program is intended to be used by families with dementia from various social, educational, and occupational backgrounds. It can serve immensely in reducing the burden and encouraging a better quality of home-based disease management.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kanmani AS, Kumar KJ, Sivakumar PT, Mathuranath PS. Caregiver-driven cognitive training program for dementia: a treatment development and feasibility study protocol in Indian population. Int J Clin Trials 2025;12(2):142-52.