

Protocol

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Tele-cognitive training on patients with stroke: a protocol of a feasibility randomized controlled study

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ABSTRACT

Background: Traditional in-person cognitive rehabilitation is often inaccessible to patients due to physical limitations, travel constraints, and financial barriers. On the other hand, home-based cognitive training programs frequently lack therapist supervision. This study protocol aims to explore the feasibility of therapist-led tele-cognitive training (TCR) delivered through videoconferencing for patients with post stroke cognitive impairment (PSCI).

Methods: In this randomised feasibility study, 58 patients will be randomly assigned to intervention or treatment-as-usual (TAU) groups. The intervention group will receive 18 comprehensive tele-cognitive training sessions (4-5 per week). Cognitive assessments will include the digit span, Corsi-block tapping, controlled oral word association, animal naming, Stroop, auditory verbal learning, and design construction tests. Secondary outcomes will include the modified Barthel index, stroke-specific quality of life questionnaire, hospital anxiety and depression scale, NIMHANS cognitive screening scale, perceived deficit questionnaire, neuropsychiatric inventory questionnaire (NPI-Q), and visual analogue scale (VAS). Assessments will be conducted at baseline (T0) and post-intervention (T1). A feasibility questionnaire will be completed post-training by the intervention group and the researcher, and a three-month follow-up (T2) with rating scales will assess longer-term outcomes.

Conclusions: This study protocol aims to enhance remote access to cognitive retraining, particularly in low- to middle-income countries.

Trial registration: Trials registry of India, no. CTRI/2023/02/049481.

Keywords: Post-stroke cognitive impairment, Cognitive rehabilitation, Stroke rehabilitation, Remote cognitive training, Teleneuropsychology, Feasibility

INTRODUCTION

Stroke is a major contributor to multi-domain disability and global mortality, placing a heavy burden on healthcare systems.¹ Long-term cognitive impairment is observed in over one-third of stroke survivors, which affects the patient's response to neurorehabilitation and significantly impacts daily functioning and social interactions.^{2,3}

The cognitive deficits of stroke can be unique to site and size of stroke lesion, making cognitive profiling of stroke challenging. Research have shown that PSCI is marked by processing speed and executive dysfunction rather than diffuse involvement.⁴ Previous studies have established that stroke events affect the lesion site and the distant connections between hemispheres.⁵ Studies on systems neuroscience of PSCI showed an association between structural covariance network degradation and cognitive decline, with default mode and dorsal attention

networks (DAN) exhibiting faster degradation than other resting state networks.²

Cognitive rehabilitation is a systematic, functionally oriented therapeutic service addressing brain-behaviour deficits through tailored interventions. The goal is to improve daily functioning and quality of life by targeting cognitive domains such as attention, memory, reasoning, problem-solving, and self-awareness.⁷ Rooted in principles of neuroplasticity, the rationale is to practice carefully selected tasks that promote recovery of the disrupted neural circuits and possibly restore functions in the impaired cognitive processes. Several studies have demonstrated the effectiveness of cognitive training over TAU in improving cognitive deficits.⁸ Neuroimaging studies have linked cognitive training to white matter changes, reorganization of attention networks, and enhanced functional connectivity (particularly between the hippocampus and fronto-parietal regions).⁹ Improvements also involve strengthened task-positive networks (fronto-parietal and central executive networks) and disengagement from default mode network (DMN).¹⁰ While numerous studies highlight cognitive recovery following cognitive training, most fail to demonstrate significant improvements in functional outcomes or quality of life, raising concerns about the far-transfer effects of cognitive training in stroke rehabilitation.^{11,12}

Research in cognitive rehabilitation for stroke survivors faces challenges due to symptomatic presentations such as hemiplegia, neglect, and aphasia, making both assessment and rehabilitation challenging. Additionally, physical impairments and geographical barriers often make in-person rehabilitation inaccessible. Thus, remote interventions, leveraging information and communication technology for cognitive rehabilitation, ensure flexibility and accessibility. While some studies have demonstrated the effectiveness of virtual cognitive training over in-person training using paper-pencil tasks, others fall short, possibly due to a lack of therapist involvement.^{13,14} In this paper, we present the methodology of a study protocol that aims to evaluate a therapist-guided TCR program's feasibility and preliminary effectiveness for individuals with PSCI in the Indian context. Using videoconferencing as the modality, the study investigates whether such an intervention is practical, acceptable, and beneficial for stroke survivors.

Research question and objectives

Primary objective

The main aim of the study protocol is to determine the feasibility of TCR and to evaluate the effect of TCR on neuropsychological functions.

Secondary objectives

Secondary objectives were to determine the feasibility of TCR on subjective cognitive complaints, quality of life,

activities of daily living, and psychological symptoms in patients with stroke and to determine the effect of TCR on subjective cognitive complaints, quality of life, psychological symptoms, and activities of daily living, 3 months after cognitive retraining for patients with stroke.

METHODS

Trial design

The study is a feasibility randomized controlled trial. An overview of the flow of the study is presented in Figure 1.

Study setting

Patients will be recruited from the outpatient services of the neurology and neurosurgery department of the National institute of mental health and neurosciences, a tertiary care hospital in Bangalore, India.

Eligibility criteria

The study would include patients aged 18-65 years, of any gender, who could read and write and had a history of ischemic stroke.

Participants with a minimum duration of 3 months after stroke, exhibiting cognitive impairment in at least one domain confirmed by neuropsychological assessment, and having access to a device with a stable internet connection will be recruited.

Patients must have normal or corrected vision and hearing and be right-handed.

Patients having non-ischemic strokes, a history of mental retardation or severe psychiatric illnesses (such as psychosis or bipolar disorder), having other neurological conditions causing severe cognitive impairments, recurrent strokes, more than two-year-old stroke, and patients unable to undergo neuropsychological assessments will be excluded.

Lesion characteristics (e.g., location, lateralization, size, and type) will not be used as exclusion criteria in this feasibility study. These data will be used descriptively and may be examined in exploratory analyses, acknowledging the heterogeneity inherent in post-stroke populations.

Sample size

The sample size was determined using G*Power 3.1.9.7 software, employing a repeated measures ANOVA within-between interaction approach. Given the feasibility nature of the study, 10% types I error rate and a moderate effect size of 0.25 were fixed. With eight primary outcome variables and assuming a correlation of 0.4 between pre- and post-measurements, a minimum of 29 subjects per group after Bonferroni correction

(adjusted for eight primary outcome variables) is required to achieve 80% power. Therefore, approximately 30 participants will be allocated to each group, resulting in a sample size of 60. This sample size is also supported by

recommendations from feasibility trial literature suggesting 24-50 participants per arm as adequate for estimating standard deviations and feasibility outcomes.^{15,16}

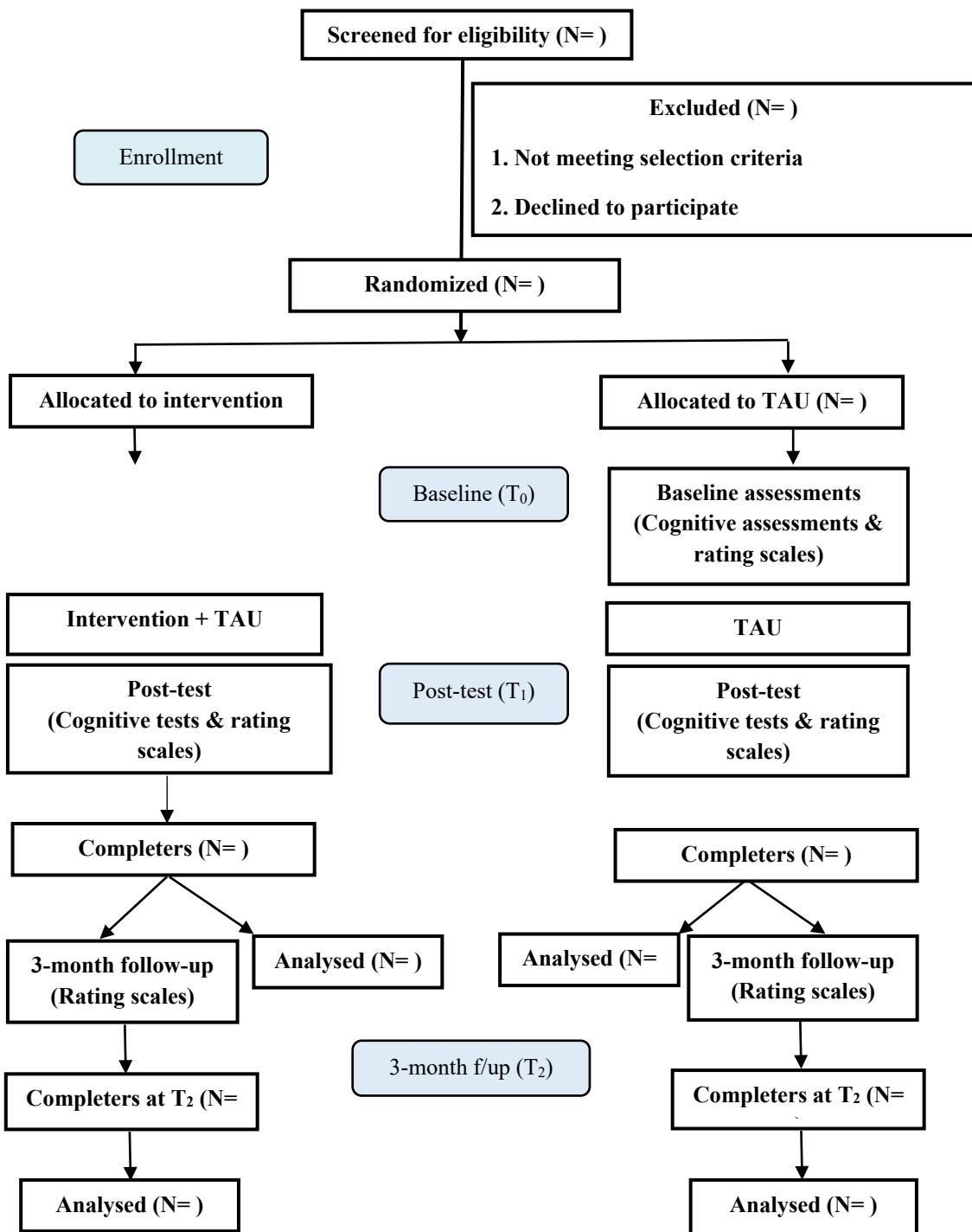


Figure 1: General flow of the study.

Ethical considerations

Ethical approval has been secured from the institutional ethics committee (behavioral sciences division) of NIMHANS, Bangalore. Participants and their caregivers will provide written informed consent after thoroughly

explaining the study's purpose, risks, and potential benefits. Confidentiality and anonymity will be strictly adhered to in accordance with the Helsinki and Tokyo declarations. Participants can withdraw at any time without impacting their treatment. No app-based data will be collected. Photos of progress data and session notes

will be stored separately by the researcher on a hard disk and no session recordings will occur. Psychiatric referrals will be facilitated if required. Cognitive rehabilitation will be offered to the TAU group after the third assessment (T2) and resumed for intervention group if residual cognitive deficits persist and patients want to continue intervention.

Intervention description

A comprehensive cognitive retraining package, initially developed for schizophrenia, with necessary modifications tailored to the stroke population, will be administered to the intervention group.¹⁷ An overview of the package tasks is listed in Table 1. The cognitive retraining program integrates tasks postulated to target multiple functional brain networks, facilitating neuroplasticity and aiding cognitive recovery. Tasks are structured to target specific cognitive domains, including attention, executive functions, learning, and memory. The levels in the tasks are organized in an increasing order of difficulty. Completing at least 80 percent of correct responses on each task at a particular difficulty level enables the patient to go to the next level.

Two tasks were explicitly developed to target visuospatial functions, drawing from established theoretical frameworks and tailored to suit the unique needs of stroke patients (shaded boxes in Table 1). The Figure-matching task was developed to target visuospatial ability. This required patients to match a three-dimensional target figure with multiple similar figures. The patient has to indicate the ones that exactly match target figure at the top of the slide. The task likely relies on the ventral pathway for object perception and comparison and could engage both dorsal and ventral attention networks in reorienting visuospatial attention.¹⁸ Dysfunctions in DAN are also associated with hemispatial neglect, a common symptom in stroke patients. Furthermore, DAN collaborates with the visual network to guide eye movements and facilitate visual scanning processes.¹⁹ The embedded figures task (EFT), derived from Witkin and colleagues' theory of cognitive processing style, aims to enhance visual processing by extracting target information from complex backgrounds and fostering field-independence. Neuroimaging studies have linked the disembedding process underlying the EFT to a bilateral frontoparietal network, including the superior parietal cortex, precuneus, and middle frontal gyrus.²⁰ Figure 2 shows how the tasks appear to patients on screen sharing in a videoconferencing platform.

Table 1: Description of tasks in the intervention package.

Cognitive domains	Tasks
Sustained attention	Grain sorting
Sustained attention and visual scanning	Letter cancellation
Verbal fluency	Word generation task
Response Inhibition	Shading
Working memory and cognitive control	Jumbled numbers
	Jumbled sentences
	Jumbled alphabets
	Adding numbers
Visuospatial ability	Figure matching task*
	Task based on embedded figures*
Verbal and visual learning and memory	Temporal and spatial encoding

*New tasks developed for this study.

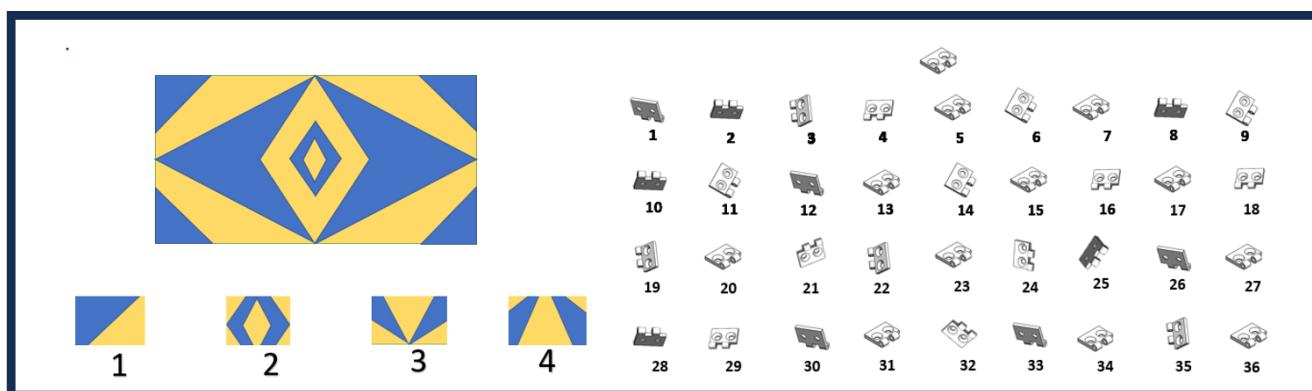


Figure 2: Visuospatial tasks were developed for the intervention.

Examples of items from the figure matching task (right) and task based on embedded figures (left) as they would appear to patients on screen sharing during intervention.

Outcomes

Screening tools

The researcher will prepare a sociodemographic and clinical datasheet to collect relevant sociodemographic and clinical details. The Edinburgh Handedness inventory will be used to determine handedness and hemispheric dominance. The 11-item National institutes of health stroke scale (NIHSS) will be administered to record the current clinical symptoms, and the scale's language and speech segments will be used to screen out patients with severe aphasia.²²

Primary outcome measures

Phonemic fluency would be assessed using the controlled oral word association test (COWAT), and category fluency would be assessed by the animal names test.²³ Digit span test from the "Wechsler memory scale-3rd Edition, India (WMS-III India)," was administered to assess attention and verbal working memory.²⁴ Corsi block-tapping test from NIMHANS neuropsychological battery for elderly (NNB-E) will be used to evaluate attention and visual working memory.²⁵ This study will separately analyze forward and backward sequences of the Digit span and Corsi-block tapping tests to assess complex attention and working memory, respectively. The Stroop word and color test is a widely used cognitive tool for assessing response inhibition and would be used to determine the patient's ability to inhibit cognitive interference, known as "Stroop interference".²⁶ Rey's Auditory verbal learning test, as adapted and standardized in the NIMHANS neuropsychological battery, would be used to evaluate verbal learning and memory.²⁷ Design construction test from NIMHANS neuropsychological battery for elderly (NNB-E) would be used to assess visuospatial ability and visual memory.²⁵ The patient is asked to copy and construct five designs using sticks in

copy phase, followed by immediate reproduction of each design in the immediate recall phase and reproduction of the same designs after 20 minutes in the delayed recall phase. Presence/absence of pathognomonic parietal focal signs like apraxia, unilateral neglect, visuospatial construction, etc, will be documented.

Secondary outcome measures

Modified Barthel index is a 10-item tool to measure functional disability that would be administered to assess the extent to which patients can function independently in their activities of daily living. Stroke specific quality of life questionnaire, a self-report scale containing 49 items across 12 domains, will be administered to assess health-related QoL specific to patients with stroke.²⁹ NIMHANS cognitive screening scale is a 20-item tool to understand cognitive complaints in Indian population.³⁰ This scale assesses domains of attention, response inhibition, executive functioning, memory, spatial orientation, motivation, arithmetic, and language. It is scored on 3-point Likert scale (Never=0, sometimes=1, and always=2) with total score indicating mild/severe cognitive problems. Perceived deficit questionnaire (PDQ), self-report measure of cognitive dysfunction, would be used to assess subjective cognitive symptoms across several domains of cognitive functioning, including attention, retrospective memory, prospective memory and planning and organization.³¹ Hospital anxiety and depression scale (HADS) is 14-item measure designed to assess anxiety and depression symptoms in medical patients, commonly seen in patients with stroke.³²

The NPI-Q is a brief, informant-based assessment tool that would be administered to evaluate neuropsychiatric symptoms and their impact on caregivers in patients with cognitive impairment.³³ VAS will be used to assess the subjective or perceived complaints following a stroke.³⁴ In the present study, the patient and informant will be asked to rate the severity of symptoms separately on a scale of 0-10. The higher the score, the greater the severity. Table 2 indicates the corresponding time points of all outcome measures.

Table 2: Overview of measures, and corresponding timepoints.

Variables	Tools	T ⁰	T ¹	T ²
Handedness	Edinburgh handedness inventory (Oldfield, 1971)	✓		
Sociodemographic and clinical variables	Sociodemographic and clinical datasheet prepared by the researcher	✓		
Record neurological symptoms of stroke	NIHSS (Ortiz and Sacco, 2008)	✓		
Attention	Digit span forward and Corsi-block tapping test forward	✓	✓	
Fluency	COWAT and animal names test	✓	✓	
Working memory	Corsi-block tapping Backward and Digit Span backward	✓	✓	
Response inhibition	Stroop word and colour test (Golden)	✓	✓	
Verbal learning and memory	Rey's auditory verbal learning test (Schmidt)	✓	✓	
Visual learning and	Design construction test IR and DR (Tripathi et al)	✓	✓	

Continued.

Variables	Tools	T ⁰	T ¹	T ²
memory				
Visuo-spatial functions	Design construction test copy (Tripathi et al)	✓	✓	
Quality of life	Stroke specific quality of life questionnaire (Williams et al)	✓	✓	✓
Subjective cognitive deficits	Perceived deficit questionnaire (PDQ) and NIMHANS cognitive complaints scale (Soparnika)	✓	✓	✓
Activities of daily living	Modified Barthel index (Shah et al)	✓	✓	✓
Psychological symptoms	Hospital anxiety and depression scale (Zigmond and Snaith)	✓	✓	✓
Subjective impact	VAS	✓	✓	✓
Caregiver's report	NPI-Q	✓	✓	✓
Feasibility outcome measure (TCR group)	To be prepared by the researcher after the pilot phase		✓	

Table 3: Proposed comprehensive feasibility framework for this study.

Feasibility domain	Operational Definition	Measure(s)
Acceptability	Perception of participants and the therapist about intervention suitability and burden	Post-intervention feedback using Likert ratings; Will be assessed using the feasibility questionnaire.
Demand	Evidence of expressed interest and actual usage	Recruitment rate, session attendance, dropout rate
Implementation	The degree to which the intervention can be successfully delivered as planned	Session completion logs; percentage of module delivered as per planned
Practicality	The extent to which intervention can be carried out using existing resources and systems	Access to remote platforms, Time taken for each session, technical issues encountered, and some aspects covered in the feasibility questionnaire

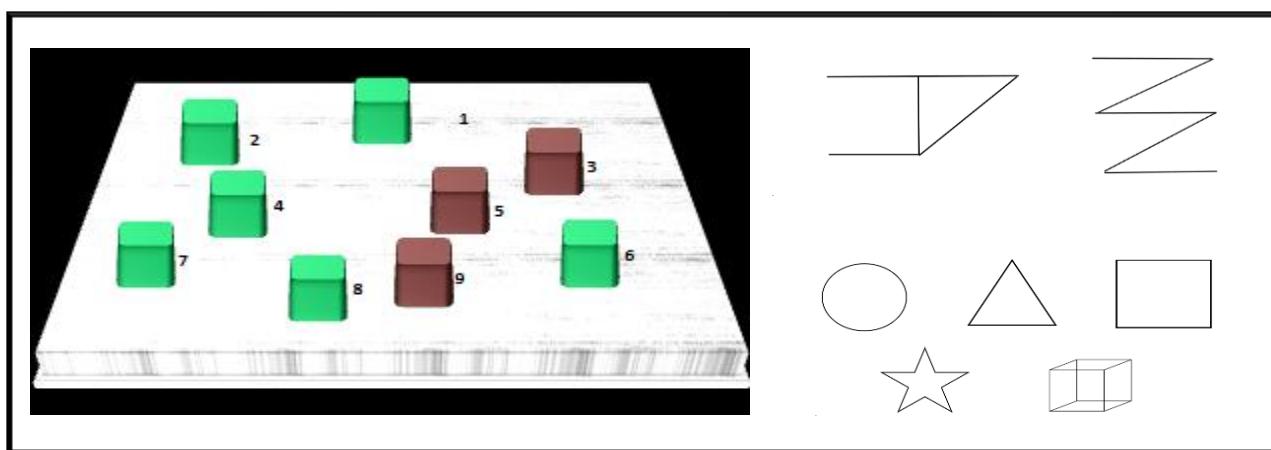


Figure 3: Tele-cognitive assessments.

Corsi-block test (left), design construction (top right), and stimulus for 2-D & 3-D construction (bottom right), as it would appear on screen sharing during tele-cognitive assessments

Plan for assessment for feasibility

After pilot study, researcher will prepare a feasibility outcome measure to assess feasibility of TCR in improving cognitive deficits in stroke. Feasibility of TCR program will be assessed using a structured framework derived from key literature, including Bowen et al, Eldridge et al, Orsmond and Cohn, and Pfeddere and

Gadke.^{35,36} This approach evaluates multiple dimensions of feasibility to determine whether a larger, more definitive trial is warranted (Table 3).

Modification for videoconferencing-based assessment

The Corsi block-tapping test, Stroop test, design construction test, and specific aspects of parietal focal

signs would undergo adjustments to facilitate virtual administration. This adaptation involves recreating stimuli for these tests using PowerPoint slides, which would be shared via screen sharing during videoconferencing sessions for test administration. For the Corsi-block tapping test, the patient would be presented with a slide depicting a 3-D board with nine blocks. On pressing a key, the colors of a few blocks will change in a predetermined order. The patient would have to recall the order of change of colors and indicate them to the therapist with the help of random numbers that would appear below each block. Five designs would be presented, with one design per slide for the design construction test. The patient would have to copy each design with the help of matchsticks, followed by an immediate recall where the design would have to be recalled without seeing it. For the delayed recall phase, the patient must remember the designs in any order after 20 minutes. The construction of the designs should be visible to the therapist so that the therapist can document them through the video camera.

For the Stroop test, three parts of the Stroop phenomenon will be shared on screen one after the other using advanced screen sharing: naming the color of words that represent colors printed in black, naming the colour of the ink of semantically meaningless symbols, and naming the ink colour of coloured words (while ignoring the word's semantic meaning) printed in incongruent colours. A few aspects of pathognomonic parietal focal signs would be assessed through screen sharing, like copying 2-D and 3-D shapes as presented on slides, reading a text from a

slide, and written mathematical calculations. Patients would be asked to send pictures of these performances to the therapist for evaluation. Figure 3 illustrates how some tests appear to patients during the online assessment.

Corsi block-tapping test (left), Design construction test (top right), and stimulus for 2-D and 3-D construction (bottom right), as it would appear on screen sharing during tele-cognitive assessments.

Procedure and recruitment

The entire study will be in 2 phases: pilot phase and main study. Participants who meet the inclusion and exclusion criteria and provide informed consent will be included in the study. Table 4 illustrates the SPIRIT diagram for the study's enrolment schedule, interventions, and assessments. Participants will receive a subject information sheet detailing the study's risks and benefits. In the pilot phase, 2 patients in the intervention group and 2 from the TAU group, meeting the inclusion and exclusion criteria, will be recruited. Necessary modifications may be made to the intervention program to meet the specific needs and requirements of the stroke population based on the clinical experience and outcome from the intervention delivered during the pilot phase, such as modifications of tasks and the inclusion of other online platforms. Additionally, any amendments to the tools and measurements will be addressed.

Table 4: SPIRIT diagram (Standard protocol items for reporting clinical trials) for the enrollment, interventions, and assessment schedule.

Timepoint	Study period			
	-T ₁ (enrollment)	T ₀ (pre- intervention)	T ₁ (post- intervention)	T ₂ (3 m follow-up)
Enrollment				
Eligibility screen	x			
Informed consent	x			
Allocation				
TCR			—	
TAU		—	—	
Assessments				
Cognitive variables (administered on patient)				
Digit and Corsi block tapping test, COWAT and ANT, Stroop word and colour test, AVLT, design construction test, parietal focal signs	x	x		
Secondary variables (Rating scales)				
MBI, SSQOL, HADS, PDQ, NCS, VAS (Patient rated)	x	x	x	
NPI, VAS (administered on caregiver)	x	x	x	
Feasibility measure (administered on patients (TCR) and therapist)			x	

*COWAT-Controlled oral word association test, ANT-Animal names test, AVLT-Rey's Auditory verbal learning test, SSQOL-Stroke specific quality of life questionnaire, NCS-NIMHANS cognitive screening scale, MBI- Modified Barthel index, HADS-The hospital anxiety and depression scale, VAS-Visual analogue scale, NPI-The neuropsychiatric inventory questionnaire.

In the main phase, screened participants will be allotted to either intervention (tele-cognitive retraining) (30) or TAU (30) group using dynamically balanced randomization, which will be stratified into left-hemispheric (15) and right-hemispheric stroke patients (15) groups.³⁷ When each stratum's target number of participants is reached, the remaining participants will be assigned to the other group until the sample size is met.

The modified intervention, finalized after the pilot phase, along with TAU, will be administered to the intervention group, while the control group will be given just TAU.

Allocation will involve computer-generated random numbers (1 for treatment, 2 for TAU) placed in sequentially numbered opaque sealed envelopes by the supervisor. The researcher will assign participants using these random numbers. Upon obtaining baseline measures (T0), the intervention group will receive virtual intervention facilitated by the researcher and standard care recommended by the neurology team. Participants will undergo 18 sessions, 4-5 times per week, each lasting one hour, delivered via online platforms like Zoom or Google Meet. The TAU group will follow regular stroke protocol, including medication, speech therapy, and physiotherapy, with weekly contacts to ensure adherence and prevent dropouts. A primary caregiver may assist participants with setting up the device and virtually connecting with the therapist. Post-intervention measures (T1) will be administered after the intervention module's completion, and the same measures will be given to the TAU group 4-6 weeks post-recruitment.

A telephonic follow-up at 3 months will assess the quality of life, daily activities, psychological distress, cognitive complaints, and subjective distress for both groups. Completers would be defined as those who complete at least 80% of the intervention, while those who do not are considered dropouts. A feasibility measure focusing on feedback regarding various aspects of the intervention will be administered to the intervention group post-intervention to evaluate the feasibility of tele-cognitive retraining.

Statistical analysis

Descriptive statistics such as mean and standard deviation (or median and interquartile range) will be used for continuous variables based on data normality assessed by the Shapiro-Wilk test. Frequencies and percentages will summarize categorical variables. Feasibility outcomes will be described using descriptive statistics. The two groups will be compared on sociodemographic and clinical measures and baseline outcome measures, using an independent samples t test or the Mann-Whitney test for continuous variables and the Chi-square test for categorical variables. Changes in outcome variables within and between groups and interaction effects will be analysed using either repeated measures ANOVA, or

linear mixed models (LMM) or ART ANOVA, based on factors like data normality, missingness of data, and balance between groups.

Statistical analyses will be performed using JAMOVI or Rstudio. All results will be interpreted with a two-tailed significance threshold of $p < 0.05$. Effect sizes and confidence intervals will be reported. Depending on the nature of the missing data, appropriate imputation methods will be used to handle the missing data.

DISCUSSION

The proposed randomized feasibility study aims to investigate the feasibility of the TCR delivered through synchronous videoconferencing to enhance cognitive function in individuals with PSCI.

We will offer an comprehensive cognitive training program that addresses multiple cognitive domains in a graded manner. Most of the tasks in the package have been previously implemented within Indian clinical contexts.³⁸ The tele-delivery format uses accessible platforms (e. g., Zoom or Google Meet) with which participants or caregivers are already comfortable. The effectiveness of this TCR program will be evaluated by comparing it to a TAU group, which will receive standard management recommended by the neurology team as part of the stroke protocol. The feasibility of TCR for the stroke patients will be assessed after the program for the intervention group through a dedicated measure prepared by the researcher.

The proposed study aims to evaluate the far-transfer effects of virtual cognitive training on activities of daily living, quality of life, symptoms of depression and anxiety, perceived cognitive symptoms, and subjective distress. Going by the taxonomy of the far transfer effect, it would be interesting to see how training cognitive functions transfers learning to other physical, functional, and social contexts, which the secondary outcome measures in this study would capture.³⁹ Furthermore, both groups will undergo a 3-month tele-follow-up using identical rating scales to evaluate any sustained effects of the intervention, which would also target the temporal dimension of the far transfer effect.

Stroke frequently heightens caregiver burden, causing emotional stress, disrupted routines, poor sleep, and reduced social engagement.⁴⁰ The study employs the NPI-Q and VAS to gauge the caregiver's perception of the patient's illness and how their symptoms impact the caregivers at all three assessment time points.

While numerous studies have explored the efficacy of computerized, virtual reality, and app-based cognitive training, there is a paucity of work on synchronous remote cognitive training using videoconferencing. Potential challenges in delivering teleneuropsychology in India would be technical difficulties interfering with the

intervention process, low technological proficiency among rural patients, and supervision of specific performance tasks in the package. Therapist supervision would ensure adherence to the program and comprehension of tasks among participants.

CONCLUSION

The present study will use a videoconferencing platform to deliver the cognitive training program, which retains the benefits of traditional face-to-face training while alleviating the barriers to accessibility of rehabilitation at the same time. In conclusion, demonstrating the feasibility of a remote synchronous protocol for cognitive training holds significant promise for enhancing accessibility and improving the efficiency and cost-effectiveness of cognitive training interventions in low to middle-income countries.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee National institute of mental health and neurosciences (NIMHANS), Bangalore, India, approved the study via letter NIMH/DO/BEH.Sc. Div./ 2021-22 dated 13/07/2022.

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