Original Article

Development and Validation of a Comprehensive Neuropsychological and Language Rehabilitation for Stroke Survivors: A Home-Based Caregiver-Delivered Intervention Program

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Abstract

Context: Aphasia is a major disabling condition after a stroke that profoundly affects the quality of life of stroke survivors (SS) and their caregivers. Comprehensive neuropsychological rehabilitation has emerged as a complementary intervention that helps in improving the associated cognitive and psychological deficits and quality of life following a brain injury. A standardized, simple, and easy to administer intervention that can be delivered as a home-based intervention can assist in faster recovery. **Aims:** To describe the development, validation, and feasibility of a home-based, caregiver-delivered comprehensive neuropsychological and language rehabilitation for SS. **Methods and Material:** A culture-specific picture and task-based 8-week training workbook and manual were developed based on extensive review and focused group discussions. This intervention targeted areas of language (comprehension, fluency, and naming) and cognition (working memory, attention and concentration, executive functioning, and response inhibition). It was standardized on 40 healthy controls (HC) and 15 SS. Before recruitment, written informed consent was obtained from each patient, their primary caregiver, and the HCs. **Results:** All tasks were found to be effective in discriminating the performance of SS from the HC. The performance of the HC with respect to the errors and the time taken for each task was used for the hierarchical arrangement of the tasks. The developed intervention was later validated on 15 SS where they significantly improved in the pre-post assessment of language functioning ($P < 0.001$), quality of life ($P < 0.001$), and depression ($P < 0.001$). **Conclusions:** This intervention can be feasible to administer as a home-based intervention and may help to alleviate language and neuropsychological complaints after stroke in low-literate or mixed-cultural populations. Further, large sample size studies are recommended.

Keywords: Aphasia, cognition, cognitive remediation, India, neuropsychology

Guest editor's notes: 'Workbooks' are an important part of armamentarium of SLT. They are large, comprehensive, varied, and standardised compilation of home-based exercises to be practiced by PWA, with or without the help of caregivers and SLP. Only a few workbooks exist in Indian languages. Digital versions are proving useful. The one reported in this paper appears elaborate, covering not only language but also neuro-psychological and cognitive functions. Though the number of subjects was small, and the follow-up was short, yet we need more of such works, albeit better designed.

Key Messages:

This study provides one of the first home-based, caregiver-delivered interventions for stroke survivors (SS) developed in India. The intervention includes culturally appropriate, verbal, and nonverbal tasks for ameliorating the cognitive, language, and psychological deficits faced by SS. The results show improvement in the language and quality of life of the SS and their caregivers.

Introduction

Stroke is one of the major disabling noncommunicable diseases in India and worldwide, with Disability Adjusted Life Years (DALYS) between the age group of 20 to 64 years.[1,2] An increasing number of young stroke survivors (SS) imposes significant social and financial implications on their families due to the loss of their major productive years of life.[3] Globally, most strokes occur in low- and middle-income countries where many of the affected people have limited or no access to rehabilitation services.[4] India has seen a change in terms of the stroke care units and physical rehabilitation following a stroke

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after the introduction of telemedicine and telerehabilitation. This paradigm shift has also encouraged tertiary care hospitals to come out with family-led interventions, especially when it becomes challenging for people living in rural parts of the country to avail rehabilitation which are mostly available in urban parts of the country.[5] Thus a majority of the SS have limited or no access to poststroke rehabilitation services.

SS not only experience physical deficits but also exhibit language, cognitive, emotional, and psychological deficits.[6] These factors are often predictors for return-to-work after which increases the cost of their DALYS.[7] Post-stroke rehabilitation services in India primarily focus on physical deficits and are largely driven by physiotherapists, with limited or no input from other healthcare professionals such as neuropsychologists, occupational therapists, and speech-language therapists.[8] SS and their caregivers usually identify a lack of information, affordability, and accessibility as major barriers to rehabilitation services.[9] The role of family/caregivers in delivering poststroke care and rehabilitation at inpatient and outpatient services are promising in developing nations like India.[10] India has seen a change in terms of the establishment of specialized stroke clinics that focus on pharmacological management and physical rehabilitation, however, cognitive rehabilitation has conspicuously been absent.[11] To cater to the rehabilitative needs (apart from pharmacological management and physical rehabilitation) of the SS and their caregivers who come from various, sometimes remote, parts of the country, a need was felt to create a caregiver-delivered intervention.

This paper describes the development, validation, and feasibility of a home-based caregiver-delivered comprehensive neuropsychological and language rehabilitation intervention, to address and retrain the language, cognitive, and psychological deficits in SS suffering from language disturbances.

Subjects and Methods

The intervention was developed as a part of a larger clinical trial which was registered prospectively (CTRI number: CTRI/2014/04/004554; Scientific Title: To Study the Effectiveness of 'Comprehensive Neuropsychological Rehabilitation' as an Adjunct to Standard Pharmacological Treatment for Improving Language and Quality of Life in Patients with Post Stroke Aphasia: A Randomized Controlled Clinical Trial). The comprehensive neuropsychological and language rehabilitation intervention was developed in the following process [Figure 1]:

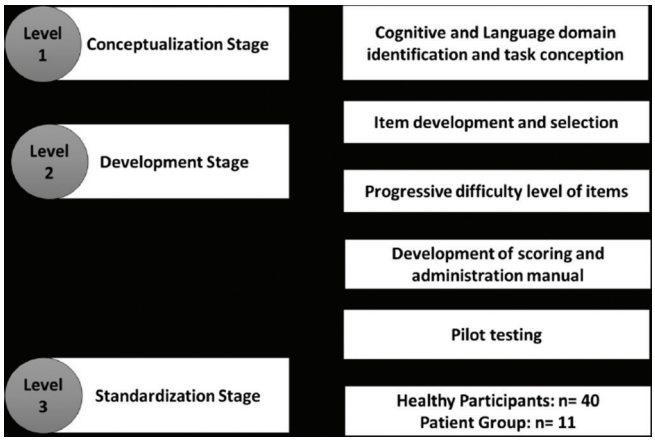

Figure 1: Process of development of the intervention

Level 1: Conceptualization of the intervention

In the first phase, the intervention manual and tasks were developed based on extensive conceptual and empirical review and focused group discussions (FDGs). The FDGs comprised of three moderators (two professors in clinical psychology and one professor of neurology) and three psychologists (who were not directly related to the study). Inputs were taken from experts in the area of speech and language (professor of ENT, professor of linguistics, and professor of speech and language pathology). An unstructured facilitative approach of discussion was adopted to gather open view-points. The tasks were selected based on three major viewpoints: a) applicability of the tasks (b) validity of the tasks, and (c) feasibility of the tasks with the target population.[12]

Level 2: Development of the intervention

The steps used for the development of the intervention were a) development of the blueprint, b) development of the items, c) reviewing items, d) conducting a task analysis, e) administration of the intervention on healthy controls (HCs), f) analyzing data from HCs, g) revising and reviewing items, h) rearrangement of tasks based on difficulty level, and i) administering the intervention on patient group.[13]

Item development and selection

The most commonly occurring, language,[14] cognition,[15], and neuropsychological deficits,[16,17] were the three major components that were addressed in the intervention. The language component included structured exercises for comprehension, naming, mathematical problems, and fluency. The cognitive and neuropsychological components included remediation exercises for attention, working memory, executive functioning, and response inhibition. The neuropsychological component formed a strong basis for improving the relationship between the SS and the caregivers. It was based on existing literature that encourages the use of stepped psychological care and providing strategies that can maximize life participation across all of a person with aphasia's social roles.[18,19] Counselling, psycho-education, activity scheduling, life-participation approach, and supportive communication were used during each session with the stroke survivor and caregiver. The intervention was based on Specific, Measurable, Attainable, Realistic, and Timely (SMART) goals.[20]

The items for the stimulus in the intervention consist of verbal and nonverbal tasks that were selected based on familiarity, cultural context, and usage of that item in day-to-day life. After extensive review, the tasks and items which were relevant and fit the demand of the domains to be targeted were selected [Table 1].

Principles of the intervention

The increasing difficulty of the tasks in the intervention was done

Table 1: Domain-specific tasks used in the intervention

Domain	Sub-domains	Task
Language*	Comprehension	Following commands
		Yes/No task
	Naming	Picture naming
		Object naming
	Fluency	Sound Breakdown
		Repetition
Cognitive*	Mathematical ability	Handling cash
		Setting up a clock
	Working memory	Playing cards
	Executive functioning	Mazes
	Response inhibition	Coloring
Neuropsychological	Activity scheduling	Daily and weekly activity schedule
	Psychoeducation	Patient and Caregiver training
	Stepped psychological care	Use of compensatory strategies
		Life-participation
		Supportive communication

*The instructions for each task were modified depending upon the severity and type of aphasia.

at two levels. First, at the content level and second at the number of items in the task. At the content level, the tasks in the intervention were applied based on cognitive load theory which states that there is a limit to how much information people can process simultaneously, and this impacts how information is stored.[21] For working memory, the task was arranged hierarchically on the bases of ambiguity, detailing, and spatial density. The practice is more effective when spaced out over time, instead of massed or grouped.[22] Spaced practice enhances memory, problem-solving, and transfer of learning to new contexts.[22] Therefore, repetition trials for language remediation were spaced for two sessions with massed practice. Repetition is the most basic technique for learning. Despite its limitations, repetition plays an important role in learning. Repeated exposure to information can help us to learn it better, however, repetition alone often is not enough, and therefore, the abovementioned techniques are needed.[23] For the tasks relating to the retraining of language functioning, such as comprehension, naming, fluency, repetition was used which was dependent upon the severity of the aphasia. The rehearsal hypothesis suggests that spaced presentations allow for a greater mental rehearsal of stimuli between presentations and greater consolidation of learning. Consequently, stimuli are encoded more deeply and retrieved more effectively.[24] Standard errorless learning method (classified as errorless/effortless), vanishing cues (classified as errorless/effortful), accumulating cues (errorful/effortful), and face-name matching (errorful/effortless) were used as strategies for retraining.[25,26] Furthermore, it was the more errorful (hence, effortful) of these (i.e., accumulating cues) that was associated with the most robust learning. Yet, psychological research in learning and memory identifies this factor, which is referred to as retrieval practice, as perhaps the most important determinant of successful learning.[25,27]

Development of administration manual and scoring

The intervention was developed as a workbook with an administration manual having standard operating procedures so that it can be delivered by the caregiver after training [Table 1]. It

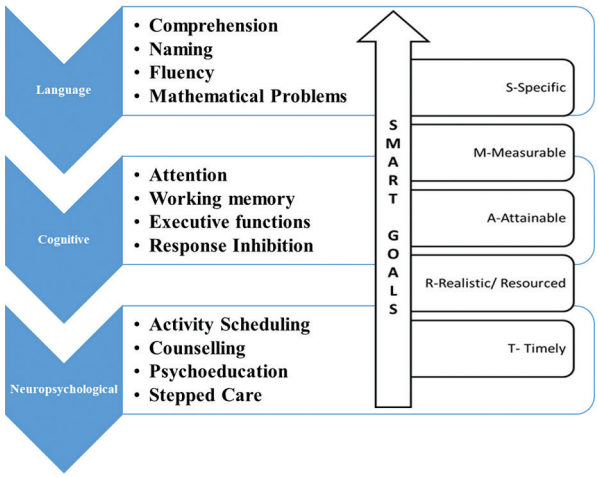

Figure 2: Brief overview of the comprehensive neuropsychological and language rehabilitation

contained 56 modules, equivalent to 616 worksheets for 8 weeks of home-based tasks for the different domains. A brief overview of the domains for the intervention has been given in Figure 2.

Figure 2: Brief overview of the comprehensive neuropsychological and language rehabilitation

All the tasks of the intervention were scored in terms of time taken to complete the tasks and the errors committed while completing the task. The total time taken to recognize the correct item or reach the correct response, inclusive of the errors committed, constituted of the "total time" for each trial. The total number of errors and correct responses were calculated for each task for each day. A plotted graph gave a brief overview of the improvement in the patient. It also aided in depicting the progress or decline of the patient during rehabilitation. After the conceptualization of the task based on cognitive and linguistic principles, the administration procedures were built separately for the participant and the caregiver in two languages (Hindi and English) for each

Table 2: Comparison of the baseline sociodemographic characteristics between healthy participants group (HC) and stroke survivors (SS) for the development phase

Characteristics		Stroke survivors ($n=11$)	Healthy Controls ($n=40$)	*P*-value
Age (in years)	20–30 years	0 (0%)	13 (32.5%)	0.16
	31–40 years	3 (27.2%)	8 (20%)	
	41–50 years	4 (36.3%)	9 (22.5%)	
	51+years	4 (36.3%)	10 (25%)	
Sex	Males	10 (90%)	19 (47.5%)	0.02
	Females	1 (10%)	21 (52.5%)	
Education (in years of schooling)	Illiterates	2 (18.1%)	4 (10%)	0.65
	1–5	1 (9.0%)	2 (5%)	
	6–10	4 (36.3%)	8 (20%)	
	11–15	2 (18.1%)	12 (30%)	
	15 +	2 (18.1%)	14 (35%)	
Family Type	Nuclear	4 (36.3%)	25 (62.5%)	0.58
	Joint	7 (63.6%)	15 (37.5%)	
Lesion Location	Left Middle Cerebral Artery (MCA) territory	10 (90%)	-	
	Right Posterior Cerebral Artery (PCA) territory	1 (10%)	-	
Stroke Onset	0–6 months	7 (46%)	-	
	7–12 months	5 (34%)	-	
	More than 12 months	3 (20%)	-	

*The level of Significance was tested at 0.05 level

task as per the colloquial background. The psychological component could not be scored as it included counseling and support strategies.

Level 3: Standardization of the intervention

After the conceptualization of the interventional domains, tasks, and its internal components, it was subjected to preliminary testing on SS and HCs.

- Healthy Controls (HC): The healthy participants were above the age of 18–65 years, with or without formal education, any gender, monolingual, bilingual, or multilingual, and with no previous history of any major neurological and psychiatric disorder.
- Stroke Survivors (SS): The patient group included acute and chronic SS suffering from language problems, 18 to 65 years of age, any gender, any educational level, and monolingual, bilingual, or multilingual. Patients suffering from any other neurological disorder affecting cognition, any major psychiatric disorder, use of psychoactive drugs, and active participation in other stroke recovery trials testing experimental intervention about cognition were excluded.

SS were included in this stage to assess the feasibility of the designed tasks. The time taken and errors by the HC were recorded for arranging the tasks for each domain to maintain progressive difficulty order.

The developed intervention was later validated on 15 SS using a pre-post assessment to ascertain the feasibility of the developed intervention to be used as a home-based caregiver-delivered program. The abovementioned inclusion and exclusion criteria for SS were followed. The pre-post assessment was done using the Indian Aphasia Battery (IAB) which included five sub-domains, namely, acoustic problems, speech and language problems, simple mathematical problems, perceptuo-motor, and writing problems, visual and reading problems, and global aphasia quotient.[28] Scores are expressed in terms of percentage of impairment, here, any score of less than 15% is indicative of no impairment.[28] Quality of Life was measured using Stroke-Specific Quality of Life (SS-QOL) and depression using the Hindi version of Stroke Aphasia Depression Questionnaire (SADQ-H).[29,30] The scores on SSQOL are expressed on a 5 point scale where 1- Total help and 5-No help are needed. The scores on SADQ if are 6 or more points indicated mood problems. A visual analog scale (VAS) was administered on the patients and their caregivers for their health-related quality of life.[31]

Delivery of the intervention

The intervention was developed as an 8-week home-based comprehensive neuropsychological and aphasia rehabilitation which was given along with the standard of care treatment based on standard operating procedures (SOPs). The duration of each session with the therapist for the intervention group lasted for 2 h. The only prerequisite for the intervention was that the caregiver should be a primary care provider who stays with the patient and was willing to accompany the patient in all the therapy sessions. The home-based therapist was given the training session once a week for approximately 2 h where he/she had to observe the tasks being done by the therapist and perform the same in front of the therapist.

Follow-up

The SS and the home-based therapist had to maintain a weekly follow-up for a minimum of 8 weeks i.e., once a week for 8 weeks. At each follow-up, the tasks were introduced based upon the performance and adherence of the SS. The performance and adherence to the intervention were assessed

Table 3: Comparison of pre-post scores on neuropsychological assessment of stroke survivors

Domains			Stroke Survivors ($n=15$)		
			Pre Intervention	Post-intervention	*P*-value
Language*	Acoustic Problems (AP)	Mean±SD	35.7±24.05	20.73±16.96	<0.01
		Median (min-max)	39.62 (1.88–90.5)	20.73 (0–52.83)	
	Speech and Language Problems (SLP)	Mean±SD	52.4±31.84	32.4±30.81	<0.01
		Median (min-max)	59 (0–100)	15.53 (0–77.66)	
	Simple Mathematical Problems (SMP)	Mean±SD	34.6±24.73	14.9±19.15	<0.001
		Median (min-max)	28 (0–100)	8 (0–64)	
	Perceptuo-Motor & Writing Problems (PMWP)	Mean±SD	39±23.51	19.2±16.12	<0.01
		Median (min-max)	39.02 (0–88.8)	26 (0–48.88)	
	Visual & Reading Problems (VRP)	Mean±SD	49.7±31.90	30.3±28.16	<0.001
		Median (min-max)	56 (2.22–100)	20 (0–90.9)	
	Global Aphasia Quotient (GAQ)	Mean±SD	42.3±22.10	23.5±18.18	<0.001
		Median (min-max)	47.77 (0–90.37)	27 (0–60.37)	
Depression#	Stroke Aphasia Depression Questionnaire (SADQ)- Hindi	Mean±SD	12.13±2.61	7.26±2.08	<0.001
		Median (min-max)	12 (9–17)	8 (4–10)	
Quality of Life#	Stroke Specific Quality of Life (SSQOL)	Mean±SD	2.26±0.59	4.2±0.77	<0.001
		Median (min-max)	2 (2–4)	4 (3–5)	
Caregiver Burden#	Visual Analog Scale (VAS)	Mean±SD	6.3±1.39	3.13±1.59	<0.001
		Median (min-max)	6 (1-9)	3 (1-6)	

*Wilcoxon signed-rank test; #Paired *t*-test

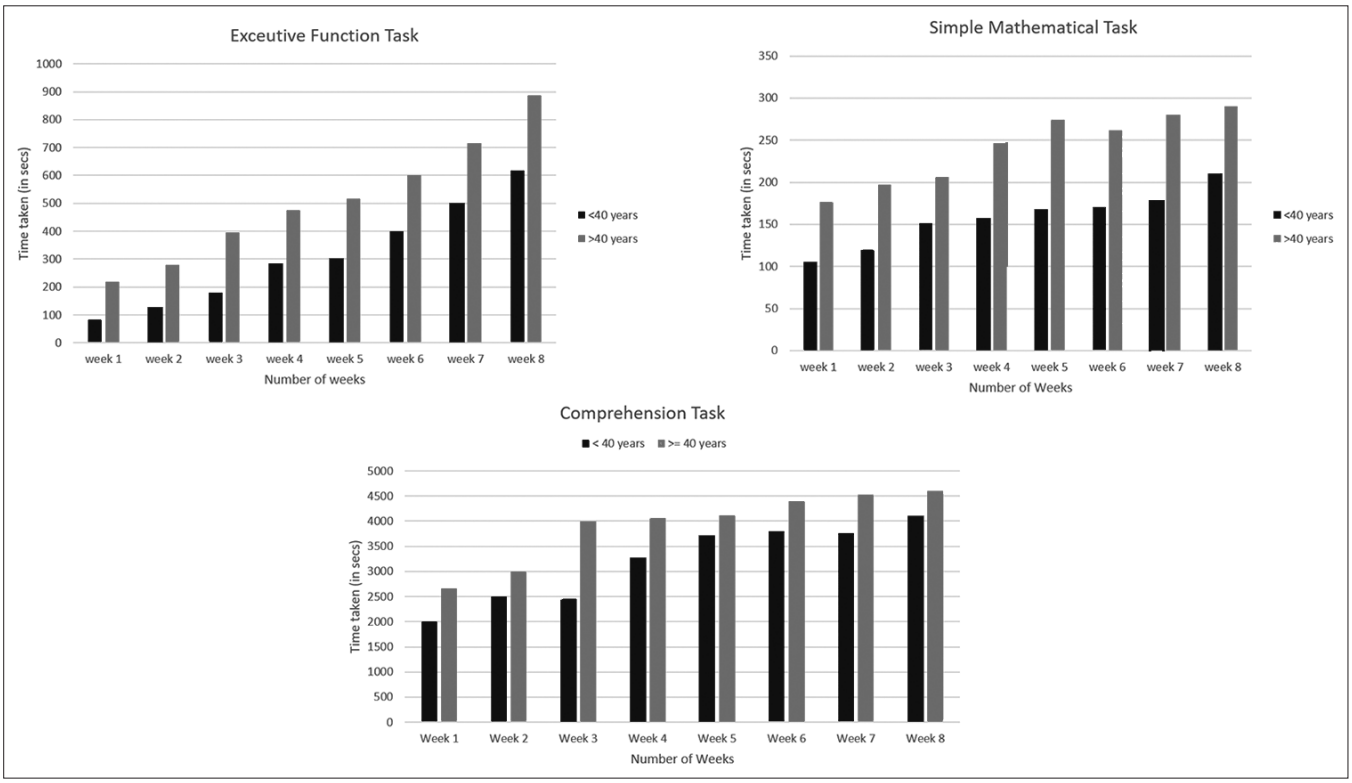

Figure 3: Time taken (in seconds) for the different task domain across age for healthy controls

by evaluating the time taken and errors committed by the SS on each task for each domain. Based on the successful completion of the tasks after attaining the ceiling effect, new tasks were introduced in the following week.

Results

Table 2: Comparison of the baseline sociodemographic characteristics between healthy controls (HC) and stroke survivors (SS) for the development phase

Figure 3: Time taken (in seconds) for the different task domain across age for healthy controls

The above results depict the hierarchical arrangement of the tasks for different domains. The total time taken to complete each task for each week is shown in the above graphs. The number of errors was examined for the SS group as it was difficult for them to perform the tasks or took a long time to complete it due to impairment in language and cognitive functioning.

Table 3: Comparison of pre-post scores on Neuropsychological Assessment of Stroke Survivors

Table 3 shows the scores of the neuropsychological assessment done pre-post intervention. Nonparametric test i.e., a Wilcoxon signed-rank test was used for the statistical analysis of the pre-to-post assessment of language parameters. Paired *t*-test was also for depression, quality of life, and caregiver burden. The results reveal statistically significant results on the global aphasia quotient along with the sub-domains post-intervention. Lower scores on IAB post-intervention were indicative of an improvement in the language functioning. The scores on the SADQ-H, SSQOL, and VAS also reveal significant results when compared to pre-post intervention. ($P = <0.001$).

Discussion

The high global prevalence and incidence of stroke have increased the financial and psychological burden worldwide. The co-occurrence of cognitive, language and psychological deficits in SS impacts their course of rehabilitation and recovery. Gender differences are also observed in the severity of aphasia with men exhibiting more severe aphasia than women.[16,17,32]

The current intervention was developed with an objective to the target language, cognition, and neuropsychological deficits during the process of rehabilitation. The intervention was developed keeping in the multilingual and diverse population of India, and the need to deliver effective, easy to use, administer, and score intervention. Owing to limited trained manpower and rehabilitation setups providing poststroke neuropsychological interventions, home-based intervention is the need of the hour. Therefore, it becomes imperative to bring in the caregiver to facilitate the process of rehabilitation. The initial pilot testing has shown fairly promising results and good feasibility of the intervention in the SS with aphasia, specifically in the domains of language. This method of home-based caregiver-delivered intervention thus will help develop the neuropsychology continuum of the healthcare model for neurological conditions.[33]

Language functioning: The current intervention includes exercises with an aim that therapy should be conducted within natural communication environments. It included exercises for comprehension, naming, and fluency and the tasks included following commands, Yes/No questions, abstracts, and concrete categories.[34] Functional communication, repetition, and naming exercises have also been found effective in the treatment of poststroke aphasia.[35,36]

Cognition and Neuropsychological functioning: The use of cognitive interventions along with aphasia has been advocated by healthcare professionals.[25,37] Several longitudinal studies have shown a significant decline in the neuropsychological functioning of patients suffering from poststroke aphasia.[16-18] Besides, neuropsychological consensus too exists stating that poststroke neurocognitive impairment is also likely which affects their attention, working memory, and language functioning.[15,17,32] Many non-pharmacological interventions have emerged that have provided significant improvement in the quality of life of SS experiencing aphasia.[34,38,39] However, all of them most often require a healthcare professional that can deliver the intervention.

Need for home-based intervention: Though it is highly advised to provide specialized rehabilitation services for a favorable outcome, poststroke rehabilitation should be provided with a multidisciplinary team with inputs from neurologists, psychiatrists, physiotherapists, neuropsychologists, speech and language, and occupational therapists.[37] This intervention comes as a promising alternative in situations where specialized conventional rehabilitation programs and professionals are unavailable. In such cases, medical, paramedical, and nursing staff can be trained to facilitate the intervention. Results from previous studies that have used family-led interventions have emphasized on the need to incorporate behavioral change theories while developing such caregiver-based intervention.[5,10] Internationally, rehabilitation services are the major cost drivers for the economic burden for poststroke care.[40] In India, the higher economic burden of stroke on society is mostly attributable to hospital and inpatient rehabilitation.[41] Thus, this home-based caregiver led intervention comes as a promising rehabilitation intervention for SS where the daily costs of caregiving add to the financial burden of stroke in India.

From India, home-based rehabilitations have been used and have generated positive research outcomes in favor of their feasibility and utility in the areas of largely traumatic brain injury,[13] early Alzheimer's disease,[12] and other neurological and psychiatric conditions.[42] The use of this developed intervention for SS with aphasia can show promising results to be used as a home-based caregiver-led intervention which is cost-effective.[43]

To test the further efficacy of the intervention, a formal randomized clinical trial has been conducted taking into account the effectiveness, fidelity, estimates of recruitment, and retention effects of using the comprehensive neuropsychological and aphasia rehabilitation as a home-based caregiver-led intervention in comparison to the standard medical care. Nonetheless, future longitudinal research with a larger sample size will evaluate the efficacy of the intervention and assess the acceptability and feasibility of the intervention for the rural and urban population.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient and caregiver consent forms. In the form, the patient(s) and their caregivers have given his/her/their consent for the patient's images and other clinical information to be reported in the journal.

The patients and their caregivers understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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