Final Technical Report

for

Research Project

To develop and ascertain efficacy of Indian Neuropsychological continuum of healthcare model for stroke survivors and caregivers: A Randomized Control Trial

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Final Technical Report

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To ascertain the efficacy of 'Patient & Caregiver Indian Neuropsychological Continuum of Care' (PIN-CoC) Model: A Randomized Controlled Trial

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Abstract

The study assesses the efficacy of a developed neuropsychological rehabilitation termed 'Patient & Caregiver Indian Neuropsychological Continuum of Care (PIN-CoC) Model' on quality of life (QoL), cognitive decline, self-efficacy, health related locus of control and resilience. The purpose was to develop a hybrid rehabilitation (hospital and home based) model in which the caregiver and patient could be psychoeducated about the condition and trained to consistently engage in beneficial neuropsychological compensatory exercises, engage in lifestyle modifications and reframe karmic beliefs.The intervention has been designed for use by trained and qualified Mental Health Professionals, Eg. Clinical Neuropsychologists/ neuropsychologists/ Clinical psychologists (Neurosciences Center) (which is one of the specializations within Psychology, a discipline integral to neurosciences) who will undergo intensive training of the PIN-CoC intervention for effective outcome of neuropsychological rehabilitation. Eligible patients from the Neurology Out-Patient Department (OPD) of the hospital were screened, and recruited into an intervention (group 1) and control group (group 2). Patients were assessed at two time points i.e. at baseline and immediately after intervention. A total of 59 patients were included in the study (group1/group2=28/31). Data was analyzed using the statistical software Stata 14.0. Categorical data was expressed as frequency and percentage whereas quantitative data was presented as mean ± sd. The variables which did not follow normal distribution were expressed as median and interquartile range. Chi square/Fisher exact test was used to compare categorical variables between the two groups. Independent t-test/Mann Whitney test was used to compare scores between the two groups as found appropriate (based on normality of data collected). A value of $p < 0.05$ was considered as statistically significant. Analysis of data found statistically significant improvement in group 1 on the domains of attention and executive functioning ($p=0.049$) on cognitive assessment; and energy ($p=0.016$), mood ($p=0.034$) and self-care ($p= 0.009$) sub-domains of QoL assessment. Increased scores were also observed on memory, health related locus of control, caregiver preparedness, self-efficacy and resilience but this change was not statistically significant. Qualitative feedback was collected one month post the completion of intervention on a semi-structured interview schedule. Patients reported improvement in restoring functionality, formation of daily schedules and reduced dependence. It can be suggested, hence, that neuropsychological rehabilitation programs can bring about a positive change in the domains of attention, executive functioning, and quality of life of patients in terms of their mood, energy, and self-care abilities, given that the patient and caregiver is educated about the condition and trained to follow the rehabilitation activities consistently at home. The study further outlines policy recommendations at the national level that may benefit

the clinical population and reduce burden on patient, caregiver, and financial burden on government.

Introduction

Stroke is a focal neurological syndrome caused by sudden vascular injury or deficit to the central nervous system[1]. It is caused when a blood clot blocks a blood vessel or when there is bleeding in the brain. This interruption of blood supply to the brain reduces the supply of oxygen and nutrients to it, causing injury and death of brain tissue[2]. In India, about 1.29 million suffered from Stroke and 6, 99,000 died from the disease in 2019[3]. The non-communicable disease was ranked the leading contributor to the total disability adjusted life years (DALY) due to neurological conditions in India with a rate of 37.9%, and highest contributor to deaths due to neurological conditions in India with a rate of 68% [3] Stroke related burden is likely to exacerbate in future thus making it a major health, economic, social burden in low and middle economic countries like India[4,5].This demands serious attention towards prevention and treatment of stroke for developing countries[6].

Post stroke cognitive impairment (PSCI) is common after Stroke but remains underdiagnosed and carries a poor prognosis. Post an episode, an approximated 80% of all patients suffering experience some degree of cognitive impairment.[7,8], including non-cognitive factors. Deficits have been seen in attention, language, memory, and executive functioning, apraxia, and hemi-neglect[9], along with a doubled likelihood of developing dementia[10]. Cognitive impairments differ based on the artery compromised, for eg. neglect, aphasia, agraphia, and right/left confusion due to left middle cerebral artery infarct; visuospatial deficits, pragmatic language, aprosodia due to right middle cerebral artery; amnesia and agnosia due to posterior cerebral artery infarct; reduced ability to plan, initiate, monitor, and sensory loss due to anterior cerebral artery; reduced arousal, attention, motivation, and executive functioning due to subcortical infarcts; reduced attention, memory and problem solving due to caudate infarcts[11]. Although cognitive, including non-cognitive function improves or remains stable in most patients during the months following the event, it declines in a delayed fashion in approximately one third of patients[12].

Apart from PSCI, the disease also comes with manifold personal, emotional, social, vocational, and familial changes and connotations. Research suggests a deteriorated quality of life for stroke survivors[13]. According to WHO, Quality of Life is an individual's perception of life within the context of the culture and value systems of the society and in relation to the individual's goals, expectations, standards, and concerns. Given the nature of the condition, affected individuals often become disabled with profound effects on their QoL[14]. The disabling nature of the disease, physical restrictions due to symptoms, and psychological anxiety regarding a recurrence or possible death impacts the quality of life of patients. Another variable worth studying is self-efficacy which has been linked with greater ability to overcome post-stroke recovery and higher

well-being and psychosocial functioning(Schwarzer, 1996)[15,16]The International Classification of Functioning, Disability and Health (ICF) is a framework for health and disability developed by World Health Organization (WHO)[17] which emphasizes the role of inclusion of personal factors like self-efficacy which arenot directly a part of their health condition but still exert an effect on recovery[18].

Cognitive rehabilitation interventions have been associated with small but significant treatment effects. Effective treatments in memory and executive functioning are still lacking in the context of Stroke. Thus far, no therapeutic strategy has shown convincing clinical evidence for preventing cognitive decline after stroke in the country. Despite stroke guidelines recommending the provision of long-term support, most survivors do not receive regular ongoing support following hospital discharge[19,20]. A high proportion of survivors are left with disability without sufficient access to rehabilitation[21]. A critical review reported that several stroke patients who died of stroke received sub-optimal symptom control, information regarding illness, insufficient aid to overcome psychological and caregiver issues[22]. Hence, there was a need to develop and test the efficacy of a holistic, culturally sensitive, individually tailored neuropsychological healthcare intervention which integrates psychological, socio-cultural, spiritual aspects of neuropsychological continuum of care along with the biomedical model of treatment.

Development of Patient & Caregiver Indian Neuropsychological Continuum of Care' (PIN-CoC) Model

PIN-CoC Model was developed as part of a PhD Thesis (Ref. No. 890/2020, Under publication)) to educate and behaviorally train patients and caregivers to improve cognitive and non-cognitive issues and prevent another Stroke attack. The patientand caregiver centered intervention was developed to enable patients to become active agents in their own rehabilitation. It emphasizes a close collaboration between the patient, caregiver, and the therapist/investigator[23]. Developed after an in-depth systematic review, it has been standardized to include fixed components and features i.e. the psychoeducation content covered in each module (Refer to Fig. Schedule of Psychoeducation Modules), and flexible features and components i.e. counselling and elaboration of certain topics and techniques based on specific concerns of the patient.

Figure 1: Schedule of Psychoeducation modules and home based exercises

Week 1	Day 1		Screening, Consent
	Day 2		Baseline assessment
	Day 3		1st Module: Stroke education
	Day 4		
	Day 5		2nd Module: Psychosocial Triggers
Week 2	Day 1		3rdModule: Holistic Health and Karmic beliefs psychoeducation
	Day 2		
	Day 3		4th: Neuropsychology Psychoeducation
	Day 4		
	Day 5		5th: Importance and training of translating knowledge into action
Week 3	Day 1	Home-based Tasks	Monitoring Checklist (M-Checklist)
	Day 2		Physical domain – physiotherapy exercises + (M-Checklist)
	Day 3		Cognitive domain – three exercises (Video Call follow-up) + (M-Checklist)
	Day 4		Social & emotional domain – music & reminiscence therapy + (M-Checklist)
	Day 5		Spiritual domain – breathing, pranayama, and gratitude journaling +(M-Checklist)
Week 4	Day 1	Home-based Tasks	(M-Checklist)
	Day 2		Attention Exercises – Remediation Vowel exercise + (M-Checklist)
	Day 3		Executive functioning Exercise - Maze Task + (M-Checklist)
	Day 4		Compensatory Task + (M-Checklist)
	Day 5		Compensatory Task + (M-Checklist)

Week 5	Day 1	Hoe-based Tasks	Cognitive Rehabilitation: Attention, Memory & Executive functioning exercises + (M-Checklist)
	Day 2		
	Day 3		
	Day 4		
	Day 5		Follow-Up and Queries
Week 6	Day 1	Home-based Tasks	Cognitive Rehabilitation: Attention, Memory & Executive functioning exercises + (M-Checklist)
	Day 2		
	Day 3		
	Day 4		
	Day 5		Follow-Up and Queries
Week 7	Day 1	Home-based Tasks	Cognitive Rehabilitation: Attention, Memory & Executive functioning exercises + (M-Checklist)
	Day 2		
	Day 3		
	Day 4		
	Day 5		Follow-Up and Queries
Week 8	Day 1	Home-based Tasks	Monitoring Checklist (M-Checklist)
	Day 2		Physical domain – physiotherapy exercises + (M-Checklist)
	Day 3		Cognitive domain – three exercises (Video Call follow-up) + (M-Checklist)
	Day 4		Social & emotional domain – music & reminiscence therapy + (M-Checklist)
	Day 5		Spiritual domain – breathing, pranayama, and gratitude journaling +(M-Checklist)

Theoretical foundations of the model

The culture specific intervention was based on theoretical models including Health Belief Model[24], Problem Solving Model[25], Bandura's Self Efficacy Model[26], Rotter's Locus of Control Model[27], FRAMES (Feedback about personal risk, responsibility of the patient, advice to change, menu of strategies, empathetic style, and promote self-efficacy)[28] and Therapeutic Alliance Model[29].

Evidence-based activities included in the intervention

The intervention involves breathing exercises [30], reminiscence therapy [31], coping with here and now [32], exercise[33], music[34], control cognition[35], training diary[36], health belief education[37]and telephonic follow-up calls of encouragement[38] The behavioural strategies inspired from the review that encourage positive behavioural change and reduction in cognitive decline were: providing ratings of intention for change[39], Log/ Goal sheets[40] encouragement [41,42] problem solving strategies[43]calendar handbook[44], counselling techniques from supportive psychology to vent their negative emotions[45], active and reflective listening [46]. Music listening was found to enhance verbal memory and focused attention in stroke patients[47], defined goals (eg, proposed activities to prevent next stroke), towards the end of each day, participants indicated whether or not each goal had been achieved. Cognitive activities such as - Count the "Mai" in any 1 article (Executive function); Sentence Sequencing (Executive function); Positive & Negatives (Executive function), etc. were included.

Intervention to be delivered effectively by –
The intervention has been designed for use by trained and qualified Mental Health Professionals, Eg. Clinical Neuropsychologists/ neuropsychologists/ Clinical psychologists (Neurosciences Center) (which is one of the specializations within Psychology, a discipline integral to neurosciences) for informational, educational and guidance purposes who will undergo intensive training of the PIN-CoC intervention.

Study Aim
The current study aims to improve the holistic Quality of Life (QoL) and prevent cognitive decline of Stroke survivors through the Patient & Caregiver Indian Neuropsychological Continuum of Care (PIN-CoC) model developed.

Primary Objectives

1. To assess the effectiveness of the developed Patient & Caregiver Indian neuropsychological Continuum of Care (PIN-COC) model on the Quality of lifeof stroke survivors.
2. To assess the effectiveness of the developed Patient & Caregiver Indian neuropsychological Continuum of Care (PIN-COC) model on Cognitive declineof stroke survivors.
3. To assess the effectiveness of the developed Patient & Caregiver Indian neuropsychological Continuum of Care (PIN-COC) model on self-efficacyof stroke survivors.
4. To assess the effectiveness of the developed Patient & Caregiver Indian neuropsychological Continuum of Care (PIN-COC) model on health-related locus of control of stroke survivors.

Secondary Objectives

1. To assess the effectivenessof the developed PIN-CoC model on resilience of stroke survivors
2. To introduce lifestyle modifications to reduce the probability of recurrence of another stroke episode.
3. To reframe patients' fatalistic Karmic beliefs for better future outcomes.

Methodology

Study Design

A randomized controlled trial was conducted in the months of February to November, 2023 at the Neurosciences Centre of All India Institute of Medical Sciences, New Delhi. The Institute

ethical clearance and the Clinical Trials Registry India (CTRI) registration (Ref. No.:REF/2021/04/042824) of the study were done before commencing the research work. A single-blinded study was conducted using A-B-A study design [48,49,50] which includes baseline Neuropsychological psychodiagnostics 'A' followed by Neuropsychological intervention 'B' and a post-Intervention Neuropsychological psychodiagnostics 'A'.

The patients were randomized into two groups: the Intervention Group (Group 1) and Control Group (Group 2) using computer generated random sequence allocation. This was done with the help of the Biostatistics department of the Institute. The researchers were blinded to this allocation. All patients were assessed at baseline. The 8 week long intervention was provided to Group 1. Group 2 followed pharmacological treatment as per usual and did not receive any intervention. The last session was followed by a post assessment to test the effectiveness of the intervention.

A Comprehensive neuropsychological psychodiagnostics [which includes – clinical history taking + psychometric testing (non-cognition and cognition) + clinical observation] to understand the individual's cognitive, emotional, and functional strengths and weaknesses post-stroke as well as their suitability for the intervention. Assessments constituted of psychodiagnostic tools for cognitive parameters such as memory, executive functioning, and intelligence, quality of life domains, such as energy, family, language, mobility, mood, personality and self-care among others. (Refer to Table 1). The scores obtained on these assessments were compared at two time points, as well as with normative data available. As per the institute standards, a multidisciplinary approach of CoC model as recommended by WHO, is strictly emphasized upon as a standard practice in healthcare to attain best patient recovery outcomes (Refer to Figure 2,3,4)

Table 1:Psychodiagnostic tools for assessing cognitive and non-cognitive parameters

Domains	Tests	Duration
Screening tools	Hindi Mental Status Examination (HMSE)	2-3 minutes
	Preliminary Aphasia Screening Test (PAST)	10 minutes
	Mini screen	5 minutes
Quality of Life	Quality of Life-Index – Stroke	40-45 minutes
Cognitive	Auditory Verbal Learning Test (AVLT)	10 minutes
	Coloured Progressive Matrices (CPM)	20 minutes
	Controlled Oral Word Association (COWA)	2-3 minutes
	Digit span	5 minutes
Psycho-Spiritual	Multidimensional Health Locus of Control	5 minutes
Emotional	Brief Resilience Scale (BRS)	2-3 minutes

Social	General Self efficacy scale (GSE)	5 minutes

Inclusion and Exclusion Criteria

Consenting patients who have had an Ischemic or hemorrhagic stroke episode within the past 8 weeks were recruited from the Neurology Out-Patient Department and Neurology Wards. English/Hindi speaking patients with access to smart phones in the family were included for the study. Patients who were not oriented to place, person or time were excluded. Patients with visual or hearing impairment interfering with performance on assessments, and paralytic or psychiatric comorbidities were also excluded. Aphasia was later added to the exclusion criteria.

Sample Size Calculation

A pilot study was conducted prior to the RCT, based on which, an average difference of 3.04 units in the intervention arm with a reduction of 3 units in the control arm at 90% power and 5% level of significance was considered. A sample size of 23 was calculated keeping in consideration a 30% loss to follow-up. Final sample included a total of 59 patients (Refer to table 2 for sample characteristics).

Inclusion Criteria

1. Patient has had Stroke at least once
2. Ischemic/ hemorrhagic stroke, TIA confirmed by consulting neurologist
3. Conscious, Consenting, oriented (Time, Place, Person) patients
4. Constant caregivers (Caregivers living in the same house as the patient and willing to be consistently present throughout the therapy for support of the patient)
5. 18+ years, Males, Females
6. School educated patients + caregivers
7. Hindi/English speaking
8. With or without Substance abuse issues
9. Can use smartphone (patients + caregivers)

Exclusion Criteria

1. Moderate to Severe Cognitive impairment
2. Neurological/cardiological issues interfering with the therapy/ Psychiatric issues
3. Language expression/ comprehension issues
4. Hearing/ Visual Impairment
5. Non-consenting/ Unconscious/ not oriented patients/
6. Non-consenting caregivers (not being able to attend all sessions)
7. Non-constant caregivers (busy, staying away from the patients and changing in-between sessions

Sample

Table 2: Demographic distribution of recruited patients at baseline

Sample demographics		Group 1 (n=28)	Group 2 (n=31)	p-value
Age (in years)		51.96 ± 9.90	53.93 ± 13.58	0.5243
Gender	Male	21 (75%)	26 (83.87%)	0.506
	Female	7 (25%)	5 (16.12%)	
Education	School	22 (78.57%)	27 (87.09%)	0.508
	College	6 (21.42%)	4 (12.90%)	

Age has been denoted as mean ± standard deviation. Gender and education has been denoted as percentage.The p value denotes the probability of significance ($p<0.05$ considered statistically significant).

The sample included a total of 59 patients (Refer to table 2 for sample characteristics). A total of 183 patients encountered during the months of March to October, 2023. Out of which, 23 patients did not meet the eligibility criteria. Out of these 160 patients were screened for orientation to time, place and person (HMSE), Aphasia (PAST), and Psychiatric and paralytic comorbidities and, 23 patients were excluded (Refer to Figure 1-CONSORT diagram). A total of 72 patients were recruited and randomized into the two groups. Data of 28 patients in Group 1 and 31 patients in Group 2 was analyzed.

Figure 1–CONSORTDiagram depicting the flow of patient recruitment

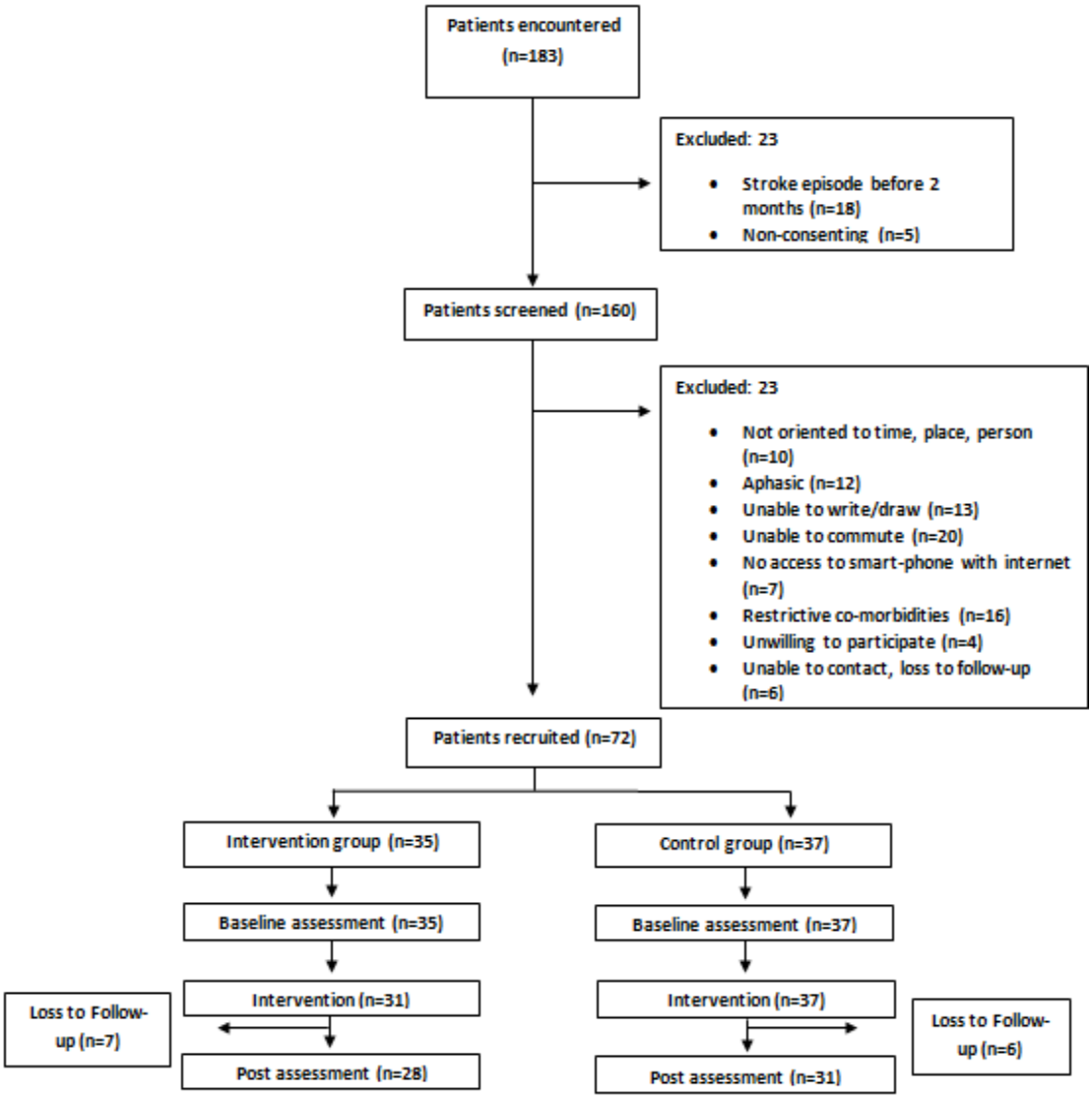


Table 3: Screening test scores expressed as median (p25-p75) at baseline

Screening functions	Group 1-Intervention (n=28)	Group 2-Control (n=31)	p-value
Orientation	26(25-26)	26(25-26.5)	0.2523
Psychiatric Comorbidity	0(0-2)	0.5(0-2)	0.9358
Naming	5(5-5)	5(5-5)	0.0401
Auto Speech	5(5-5)	5(5-5)	0.3161
Repetition	5(5-5)	5(5-5)	0.9810

Writing	5(4-5)	5(4-5)	0.2880
Verbal	5(4-5)	5(4-5)	0.6649
Yes/No Accuracy	5(4-5)	5(5-5)	0.3407
Object Recognition	5(5-5)	5(5-5)	0.6901
Instruction	5(5-5)	5(5-5)	0.9181
Reading	5(5-5)	5(5-5)	0.0819
Expressive total	23.5(20-25)	24.5(22-25)	0.4106
Receptive total	19(18-20)	20(18-20)	0.4840
PAST Total	42(39-45)	43(40-45)	0.3006

Statistical analysis done using Stata 14.0 StataCorp. The p value denotes the probability of significance ($p<0.05$ considered statistically significant).Hindi mental status examination was used for Orientation, Mini Screen was used for Psychiatric comorbidity, PAST: Preliminary Aphasia Screening test.

Statistical Analysis

Data was analyzed using the statistical software Stata 14.0. Categorical data was expressed as frequency and percentage whereas quantitative data was presented as mean ± sd. The variables which did not follow normal distribution were expressed as median and interquartile range. Chi square/Fisher exact test was used to compare categorical variables between the two groups. Independent t-test/Mann Whitney test was used to compare scores between the two groups as found appropriate (based on normality of data collected). A value of $p < 0.05$ was considered as statistically significant. CONSORT guidelines were used to report the findings of the research.

Results

Table 4: Results of Cognitive domains at baseline and post intervention assessment

Testing Domains		Group 1-Intervention (n=28)	Group 2- Control (n=31)	p-value
Intelligence test 1 (SPM)	Pre	26 (19-35)	23.5 (19-31)	0.495
	Post	26 (18-34)	23 (19-30)	0.590
	Change	0.06 ± 0.63	- 0.03 ± 0.49	0.483
Intelligence test 2 (IQ)	Pre	87 (81-93)	85.5 (81-91.5)	0.490
	Post	87 (80-92)	85 (81-90)	0.614
	Change	0 ± 0.83	-0.03 ± 0.49	0.738
Attention (COWA)	Pre	4.49 (3.33-7.33)	4.49 (2.66-6.66)	0.840
	Post	6 (3.33)	4.66 (3.33-6.66)	0.656
	Change	0.44 ± 0.96	0.19 ± 0.70	0.572
	p	0.762	0.418	
Memory - Learning	Pre	34 (27-37)	28 (34-38)	0.848
	Post	34 (30-41)	33 (29-38)	0.741
	Change	1.13 ± 3.27	-0.16 ± 3.53	0.210

	P	0.048*	0.768	
Memory - Immediate Recall	Pre	7 (5-8)	7 (6-9)	0.363
	Post	8 (6-10)	6 (5-8)	0.036*
	Change	0.2 ± 1.27	0.56 ± 1.71	0.188
	P	0.336	0.026	
Memory - Delayed Recall	Pre	6 (4-7)	5(3-6)	0.142
	Post	5 (4-7)	4(3-5)	0.007*
	Change	-1.53 ± 2.19	-0.46 ± 1.75	0.107
	P	0.004*	0.183	
Memory - Recognition	Pre	8 (7-11)	12 (10-13)	0.002*
	Post	8 (7-11)	10 (9-13)	0.026*
	Change	0.1 ± 1.68	0.13 ± 2.94	0.241
	P	0.885	0.347	
Attention & Executive functioning (DS-F)	Pre	4 (3-5)	4 (4-5)	0.287
	Post	4 (3-5)	4 (4-5)	0.302
	Change	0.16 ± 0.91	-0.13 ± 0.89	0.227
	P	0.411	0.371	
Attention & Executive functioning (DS-B)	Pre	3 (3-4)	2.5 (2-3)	0.01*
	Post	3 (2-3)	2 (2-3)	0.271
	Change	0.06 ± 1.08	-0.5 ± 1.07	0.049*
	P	0.812	0.027*	
Attention & Executive functioning (DS)	Pre	6 (3-7)	7 (6-9)	0.013*
	Post	6 (4-7)	7 (6-8)	0.103
	Change	1.23 ± 1.81	-0.63 ± 1.54	0.097
	P	0.686	0.053	

*The p value denotes the probability of significance ($p<0.05$ considered statistically significant).

The change in scores has been expressed as median(p25-p75) and mean ± sd. Statistical analysis done using Stata 14.0 StataCorp, level of significance is 0.05.

SPM: Standard progressive matrices, IQ: Intelligence quotient, COWA: Controlled Oral Word association, DS-F: Digit Span forward, DS-B: Digit span backward, DS: Digit span, Measures of Intelligence: Spm, IQ, measures of attention and executive functioning: COWA, Digit Span, digit span forward, digit span backward, measures of memory: learning, immediate recall, delayed recall and recognition.

Cognitive Domains

Table 4 shows the mean, median, standard deviation, 25th and 75th percentiles for the cognitive domains of executive functioning, verbal learning, immediate recall, delayed recall, recognition ability, and Intelligence quotient.

Executive Functioning

Executive functioning was measured using COWA (Controlled Oral Word Association Test) and Digit Span. A significant improvement in performance of Stroke patients was observed in the domain of attention and executive functioning post intervention. There was an increase in the forward subtest of digit spans assessment for the Intervention group (0.16± 0.91), while the change for the control group was -0.13 ± 0.89. On the backward subtest of digit span, there was no change in pre and post test median scores of group 1 (t1:3=t0:3) as compared to the control group which saw a decline in scores (t1:2<t0:2.5). The mean change in scores was 0.06 ± 1.08 in group 1 and -0.5 ± 1.07 in group 2, with a statistically significant difference ($p=0.049 < 0.05$).The total score for digit span saw a slight increment of 1.23 ± 1.81 in the Intervention group. However, this change was not significant ($p=0.097>0.05$). The patients' performance in the Intervention group in phonemic fluency showed an improvement (t1:6>t0:4.49) with a

change of 0.44 ± 0.96. There was a drop in the median scores in the control group (t0:4.49>t1:4.46). This change was, however, not statistically significant (p=0.572).

Intelligence

Intelligence quotient was measured using Standard progressive matrices (SPM). There was no change in median scores of intelligence quotients in the intervention group, however there was a change of -0.03±0.49; p=0.73in the control group.

Memory

Auditory Verbal Learning Test (AVLT) was administered as a measure of memory. Analysis found a positive increase in post test scores on learning capacity of group 1 patients as compared to the performance of group 2 (1.13 ± 3.27 > -0.16 ± 3.53), but this difference was not found to be significant. On immediate learning, a significant difference existed in the post follow-up between groups (8 (6-10) > 6(5-8). However, the change between pre and post intervention scores between the two groups was not significant. The results showed no significant improvement in performance for delayed recall. While the median for pre and post test scores of the Intervention group for recognition ability did not improve, there was a drop in the scores for the control group (t0:12>t1:10).

Table 5: Results for domains of Locus of Control, General Self-efficacy, Resilience, and Caregiver preparedness at baseline and post intervention assessment expressed as median(p25-p75) for Intervention and Control groups.

		Group 1-Intervention (n=28)	Group 2-Control (n=31)	p-value
Locus of Control (Form C)	Pre	71(68-77)	78(68-83)	0.0768
	Post	77(69-81)	78(72-84)	0.2445
	Change	2.76± 4.91	0.63± 2.99	0.088
	P	0.004*	0.256	
Self-efficacy (GSE)	Pre	48.5(36-58)	51(36-71)	0.3247
	Post	50(35-59)	51(38-69)	0.2897
	Change	1.56 ± 3.89	1.33 ± 4.17	0.623
	P	0.029*	0.060	
Resilience (BRS)	Pre	2.83(2.33-3.16)	3(2.33-3.33)	0.4417
	Post	3(2.33-3.14)	3.16(2.33-3.33)	0.1248
	Change	0.11 ± 0.71	0.108 ± 0.75	0.151
	P	0.579	0.248	
Caregiver preparedness	Pre	3(1-5)	3.5(2-4)	0.8740
	Post	4(3-5)	4(3-5)	0.9504
	Change	0.86±1.00	0.76±0.97	0.730
	P	0.0003*	0.0004*	

The p value denotes the probability of significance (p<0.05 considered statistically significant).
The change in scores has been expressed as median(p25-p75) and mean ± sd. Statistical analysis done using Stata 16.0 StataCorp, level of significance is 0.05.
GSE: General self-efficacy, BRS: Brief resilience scale, SSQoL: Stroke specific quality of life

On the function of Locus of Control, the intervention group performed better on this test post intervention with a mean change of 2.76 ± 4.91, as compared to the control group with a mean change of 0.63 ± 2.99. However, this change was not found to be significant. Median post test scores on General Self Efficacy increased in group 1 and remained the same in group 2. The mean change in scores was 1.56 ± 3.89 for group 1 and 1.33 ± 4.17 for group 2 with a p value not found to be significant. There was a slight difference observed in the post test scores on Brief Resilience Scale for both the Intervention group (0.11 ± 0.71) and Control group (0.108 ± 0.75). No significant difference was found between the two groups. Median post test scores on Caregiver Preparedness scale increased slightly in both the groups. The mean change in scores was 0.86±1.00 for group 1 and 0.76±0.97 for group 2 with a p value 0.730 not found to be significant.

Table 6: Results for subdomains of SSQL at baseline and post intervention assessment expressed as median (p25-p75) for Intervention and Control groups.

		Group 1-Intervention (n=28)	Group 2-Control (n=31)	P-value
Energy	Pre	10 (7-13)	10 (7-13)	0.846
	Post	11 (9-12)	10 (8-12)	0.681
	Change	0.5 ± 1.25	-0.36 ± 1.06	0.016*
	P	0.143	0.127	
Family	Pre	11 (8-15)	12 (7-15)	0.896
	Post	12 (8-15)	12 (8-15)	0.745
	Change	0.16 ± 1.31	0.56 ± 1.43	0.202
	P	0.702	0.05*	
Language	Pre	13 (9-20)	16 (12-20)	0.458
	Post	15 (11-22)	16 (12-20)	0.632
	Change	0.33 ± 1.18	0.2 ± 1.66	0.872
	P	0.110	0.393	
Mobility	Pre	20 (13-26)	21 (14-25)	0.812
	Post	20 (13-25)	21 (17-24)	0.554
	Change	-0.1 ± 1.53	-0.06 ± 2.70	0.574
	P	0.902	0.617	
Mood	Pre	16 (10-22)	19 (13-22)	0.356
	Post	17 (10-23)	20 (13-23)	0.178
	Change	0.46 ± 1.19	-0.16 ± 1.31	0.034*
	P	0.034*	0.354	
Personality	Pre	10 (8-13)	10 (9-13)	0.708
	Post	11 (10-13)	11 (9-13)	0.993
	Change	0.53 ± 1.04	0.26 ± 1.20	0.319
	P	0.009*	0.328	
Selfcare	Pre	20 (14-25)	21 (15-25)	0.263
	Post	20 (12-25)	21 (16-24)	0.636
	Change	1.1 ± 1.51	-0.46 ± 1.92	0.009*
	P	0.001*	0.265	
Social	Pre	18 (12-22)	19 (15-25)	0.262
	Post	18 (13-23)	21 (17-24)	0.141
	Change	0..43 ± 1.04	-0.03 ± 1.37	0.139
	P	0.028*	0.801	
Thinking	Pre	10 (9-12)	10 (9-12)	0.482
	Post	10 (9-13)	12 (10-14)	0.226
	Change	0.4 ± 1.49	0.23 ± 1.0	0.873
	P	0.126	0.138	
Upper extremity	Pre	19 (15-22)	19 (15-25)	0.718
	Post	20 (14-22)	17 (15-23)	0.774
	Change	-0.5 ± 1.75	-1.36 ± 2.17	0.080
	P	0.144	0.022*	
Vision	Pre	10 (7-14)	12 (9-15)	0.138
	Post	10 (6-13)	12 (9-14)	0.123
	Change	-0.1 ± 1.18	0 ± 0.58	0.461
	P	0.547	0.746	
Work	Pre	9 (5-15)	7 (4-15)	0.216
	Post	9 (5-14)	7 (5-15)	0.378
	Change	0.23 ± 1.77	-0.1 ± 1.61	0.592

	P	0.515	0.880	
SSQoL	Pre	168 (135-199)	176 (148-206)	0.848
	Post	166 (149-198)	178 (159-199)	0.419
	Change	3.46 ± 5.04	-1.3 ± 6.74	0.005*
	P	0.001*	0.880	

*The p value denotes the probability of significance (p<0.05 considered statistically significant).
The change in scores has been expressed as median (p25-p75) and mean ± sd. Statistical analysis done using Stata 16.0 StataCorp, SSQoL: Stroke specific quality of life.

Quality of Life

Quality of life was measured using SSQL (Stroke Specific Quality of Life) scale. It assesses quality of life in the context of energy, family, language, mobility, mood, personality, selfcare, social, thinking, upper extremity, vision, and work. On the subdomain of energy, there was a slight increase in pre and post test scores of group 1 (t1:11>t0:10) as compared to the control group which did not see an improvement in scores (t1:10=t0:10). The mean change in scores was 0.5 ± 1.25 in group 1 and -0.36 ± 1.06 in group 2, with a statistically significant difference (p=0.016). On the subdomain of family, the scores post intervention increased (t1:12>t0:11), while the scores remained the same in the control group. However, this change was not statistically significant. On language and mobility, performance of both groups improved slightly and the difference wasn't found to be significant. On the subdomain of mood, group 1 scores increased whereas group 2 scores saw a decline, and this change was found to be statistically significant (0.46 ± 1.19 > -0.16 ± 1.31, p=0.034). There was no significant difference in terms of personality of the patients in both the groups. On the domain of selfcare, the mean change in group 1 scores was significantly higher than the change in mean scores of group 2 (1.1 ± 1.51 > -0.46 ± 1.92, p=0.0009). On the subdomains of social, thinking, upper extremity, vision, and work, no significant difference was seen in the between group scores.

Discussion &Interpretation

Scientific consensus shows post-stroke neuro-cognitive impairment affects the patients' attention, working memory, language functioning[51], among others, leading to an overall decrease in Quality of life of these patients. Most non-pharmacological interventions developed globally require a healthcare professional to deliver the intervention. This study focused on the role of caregiver in and active participation of the patient in bringing about lifestyle changes. This focused on developing autonomy and gaining a sense of independence in the betterment of their condition. Recurring themes observed in post-stroke changes in patients, in sync with previously conducted researches are, alteration in personality, difficulty in arousal, loss of libido, heightened feelings of helplessness and dependency[52].
Analysis showed a significant improvement in sub domains of attention and executive functioning in Cognition, and energy, mood and self-care domains of Quality of life post intervention. It further showed improved performance on verbal learning, immediate recall, recognition ability, health related locus of control, caregiver preparedness and other domains of quality of life in the experimental group.

Under the domain of executive functioning, the mean phonemic fluency score was calculated and compared. A limited number of studies have been conducted on executive functioning of Stroke patients in India. On reviewing the same as an advance search on PubMed database with keywords “Stroke”, “Executive Functioning” and “India”, only 17 studies appeared out of which only one was aimed at executive functioning[53]. Most studies did not measure the effectiveness of a non-pharmacological intervention. This reduces the chance to make a comparison of the efficacy of this intervention. Internationally, there is evidence for improved executive functioning by early-stage cognitive interventions specifically aimed at goal management training and problem solving[54]. Better outcomes of cognitive strategies have also been linked with practical training of activities of daily living[55], which was part of the current model. Moreover, there has been support for multicomponent cognitive trainings in bringing about improvements in cognitive flexibility of stroke survivors[56 57 58].

Low energy, loss of centrality in decision making, decrease in earning potential, physical and social dependency have been major contributors for a decreased quality of life of Stroke patients. In the current study, an increase on the sub-domains of energy, family, mood and self-care shows an overall improvement of quality of life. Similar findings were seen in an Indian family-led post-stroke rehabilitative intervention aimed at incorporating behavioral change theories[59]. Similar to the current one, this study involved daily and weekly activity scheduling, mazes, psychoeducation, patient and caregiver training, use of compensatory strategies; and saw a statistically significant improvement in the quality of life and reduction in the level of caregiver burden. In instances where care outside of a hospital setting is provided within the community/ home, wherein family members, generally spouses or children, assume the role of caregivers, with little to no preparation, the quality of care provided to the patient is affected.[60] The situation may be worsened when the caregiver has additional responsibilities, or may feel emotionally overwhelmed. It is thus important to psychoeducate the caregivers regarding the course of the disease, probable symptoms and personality changes, and also equip them with techniques to improve their as well as the patients’ quality of life. The PIN-CoC Model (Sharma& Nehra, 2023, in publication) required the patients and their caregivers to work in tandem, with the caregivers given the responsibility to help the patients comply with the rehabilitation and develop a routine practice. It was observed on many instances while psychoeducating the caregivers about the neuropsychological symptoms of anger, emotional apathy, irritability, and personality changes that the caregivers realized that the behavioral changes observed in the patient are symptoms of the disease.

On subjective interviewing and feedback, it was observed, for patients with supportive caregivers who encouraged independence, progress observed in regaining confidence was better than when caregivers were overly protective with the patients and autonomy was low. In order to return to normalcy, the patient must be given the opportunity and responsibility to perform basic household tasks. It was also observed; the patients absorbed, modeled and started believing the primary caregivers’ narratives as true measures of their improvement/ deterioration of heath. It

is, thus, advised for family members to not be overly critical or dismissive of the patient's health and to maintain a positive outlook for the same. Caregivers may also feel burdened and frustrated as stroke to a family member has a direct impact for the primary caregiver and alters their quality of life as well. Unaware of the impact of their words and actions, caregivers may only focus on the physical symptoms, or be overtly expressive of their concerns. Counseling for patients, as well as, caregivers is recommended at the time of admission in hospitals.

It was also observed that a lack of knowledge and awareness creates a sense of uncertainty in patients, leading to feelings of hopelessness, fear and loss of control. Educating them about their symptoms, possible progressions and aspects under their control, helps them feel understood and in control. It may further help to connect patients to a community experiencing similar symptoms, where they do not feel estranged.

Future Directions for the developed Pin-CoC Model

It is ethical that clear definitions of role and responsibilities for each health expert as per their qualifications and specifications, caregivers as a home therapist and patient as an active agent of change in the context of hybrid rehabilitation interventions.

Intensive training of researchers administering the therapy should be mandatory along with the assessment of their clarity on the intervention content and protocol so that a standardized intervention can be provided to the patients and caregivers by trained and qualified therapists with clinical therapeutic expertise.

The Action (Karma) Belief Cultural Cognitive Model can be used as a standalone therapy in itself of 1 week so that internal health locus of control, self-efficacy, confidence and motivation can be enhanced and its effects can be sustained till greater than 1 Month. This can be especially beneficial for decreasing apathy, depressions, anxiety and increasing positive emotions in patients as well as caregivers and is the need of the hour, especially in eastern healthcare.

Limitations and Implications

The prevalence of the condition is higher older adults, with more males being affected than females.[6162] This was also seen in the study, with 79.66% patients being male and 20.34% being female. A study done on factors affecting patients' participation in rehabilitative services found a larger section of males receiving the services than females and attributed this disparity to lack of gender empowerment, cultural barriers, educational status, health literacy and gender preference[63]. Steps should be taken by the government, other stakeholders, as well as practitioners and scientists working in the field to bridge this gap as well. Social protection and social assistance programs intended to help vulnerable groups should be promoted.

Data collection with an out-patient sample is often complex with a fragmented fashion of service provided[64]. In the Indian context, most of the recruited stroke patients were found to be dependent on their caregivers and family members to bring and accompany them to the hospital for their treatment. Taking out time from their occupational schedule to fulfill the requirements of the standardized rehabilitation was an obstacle for the family members. Patients were lost to follow-up due to missing/postponing sessions due to possible dependency on others to accompany and financial burden. Hence, a hybrid (hospital cum home based) rehabilitation model was developed taking into account the lower socioeconomic status of patients that come to the hospital, and the financial burden incurred by them to commute till the center. Hospital based rehabilitations are less accessible to the clinical populations due to lesser beds available and financial costs of the same. There is further burden on the healthcare setting and government if the beds are occupied for longer periods of time, keeping other patients from receiving the same treatment. In India, home-based rehabilitations have shown promise in terms of feasibility and positive outcomes in stroke[65]. Despite the intentions and the patient pool at the centre being large, the sample was relatively small due to the lengthy nature of the intervention as well as the limited manpower in the study.

Recommendations for Policy Practice

Nationally, awareness about the warning symptoms of stroke is far from satisfactory[66]. A study done in Bangalore found that 40% of the sample population did not know the term “stroke”, only 22% identified the organ affected, and only 51% could name one symptom[67]. In another study, it was found that higher education and upper socioeconomic status was associated with increased knowledge about which organ was affected in stroke[68]. Better education and socioeconomic status also increased awareness of the warning symptoms for both rural and urban stroke survivors in India[691]. There is a dire need for Indian patients and caregivers to be psychoeducated about stroke and its long term physical, cognitive and psycho-social impact and the ways to prevent another episode after the first stroke attack, and blood relatives who are susceptible of having stroke genetically. Moreover, the neuropsychological impact and corresponding rehabilitative strategies need to be highlighted.

All India Institute of Medical Sciences (AIIMS), New Delhi is one of the few medical institutes in the country where research projects are sanctioned and interventions provided to patients in all the functioning departments. However, whether such facilities/alternative treatment methods for patient care are available in other parts of the country is not well known. More research is needed in other states of the country to confirm the effect of psychological treatments on Stroke as well as other neurological conditions. The government has taken steps towards bridging this gap, for eg., Department of Health Research, Ministry of Health & Family Welfare under the

[1]Pandian JD, Jaison A, Deepak SS, Kalra G, Shamser S, Lincoln DJ, et al. Public awareness of warning symptoms, risk factors, and treatment of stroke in northwest India. Stroke 2005;36:644-8

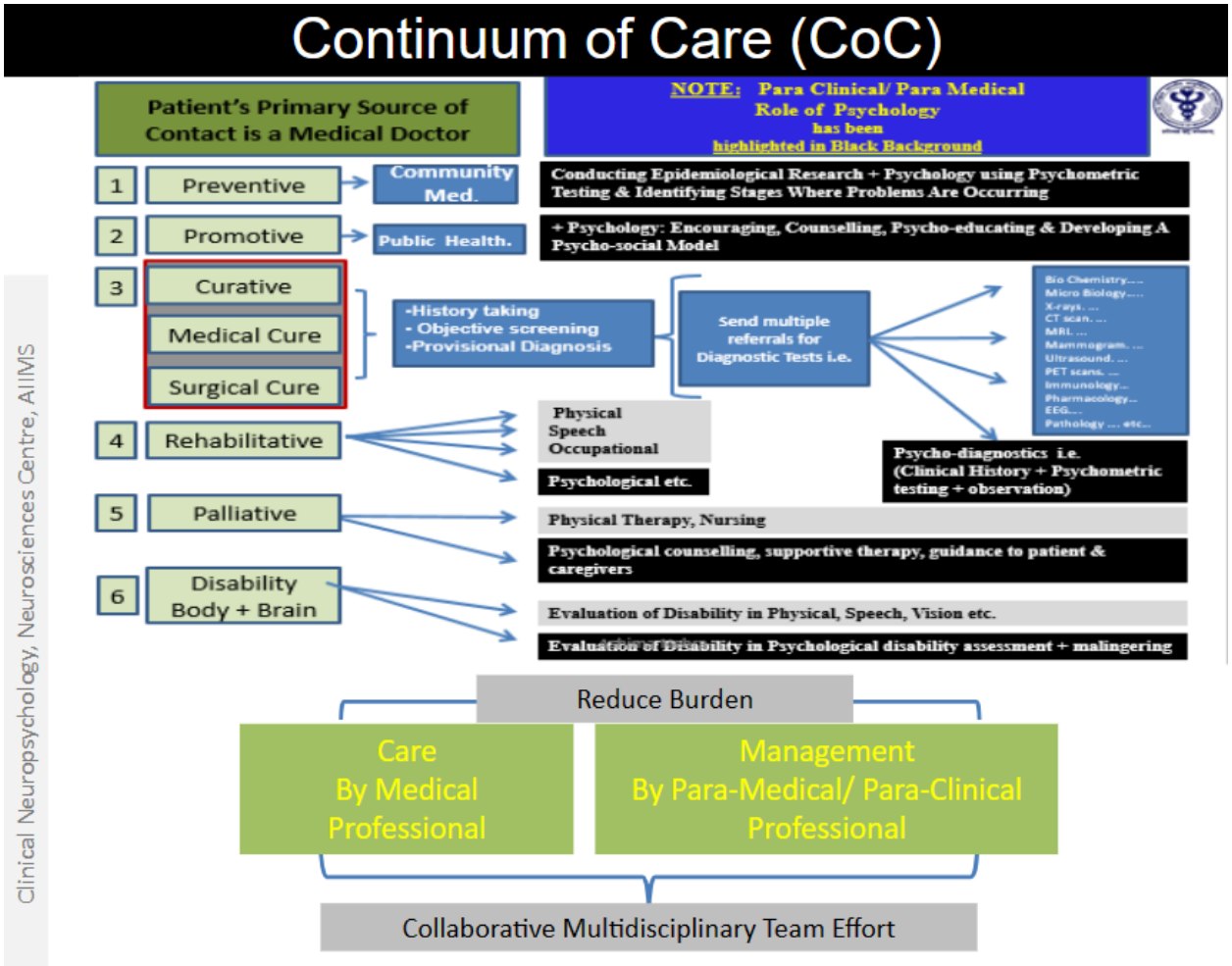
Government of India has proposed guidelines for establishing Model Rural Health Research Units (MRHRUs) in order to develop infrastructure for promotion of health research in the country. The initiation started from the year 2013-14, and till date i.e. since 12 years, only 23 MRHRUs have been implemented. Institutes and Faculties can utilize such opportunities to provide interventions in rural parts of the country.

While mental health awareness has grown exponentially in the past few decades, there is still a lack of understanding in the general public regarding neuropsychological symptoms, when and whom to consult for the same, and whether or not rehabilitation is needed or available. Emphasis on cognitive and non-cognitive impact of stroke is needed to be made an active part of holistic care and should be given the same importance as physical remediation in line with the recommendations given by United Nations guidelines.Prevention measures on health psychoeducationshould be prioritized upon as most of the cognitive and non-cognitive symptoms post-stroke can be prevented well in advance.Fatalistic health beliefs should be addressed positively and worked upon to enhance their positive stance towards free-will.

Another grave concern on a national level is the lack of qualified and trained psychologists with a specialization in neurological conditions and neuropsychological functioning, assessment, and rehabilitation. There is a lack of a uniform governing body of Psychology in the country. Moreover, even in the recently updated 2023 National Education Policy guidelines, there is no certified professional clinical neuropsychology course that trains psychologists on the intricacies of neurological conditions.

In terms of the eastern healthcare system, there is a need to bridge the cultural gap between latest evidence-based psychological practices and the culture specific needs of Eastern and specifically Indian stroke patients and caregivers. Globally, medical hospitals may benefit from development of department of Psychological health (a para-clinical service) to teach and develop evidence based practices for global health as per the ethical guidelines, within the Continuum of Care (CoC) (Refer to Figure 2) recommended by WHO. This is needed to reduce the health burden of the patients, their caregivers and the financial burden of the government.

Figure 2. Continuum of Care Model



Conclusion

The hybrid (home and hospital) based neuropsychological rehabilitation for stroke survivors and their caregivers brought about positive outcomes on the domains of attention and executive functioning on cognitive assessment; and energy, family, mood and self-care subdomains of QoL. Increased scores were also observed on self-efficacy, memory, health related locus of control, caregiver preparedness, and resilience. This intervention approach may be beneficial provided that the intervention is provided by trained and qualified professionals, and given that the patients and caregivers are thoroughly educated about the condition as well as the intervention, and they follow the rehabilitation consistently at home.

Registration

The trial has been registered under Clinical Trials Registry India (CTRI) with reference number REF/2021/04/042824.

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