Original Article

A Single-Blind Randomized Control Trial on the Effectiveness of Adjunct Cognitive Stimulation Therapy on Cognitive Outcomes in Dementia

Soumya Bhowmik, Mina Chandra[1], Kuljeet Anand, Shrishti Dahuja[1]

Departments of Neurology and [1]Psychiatry, ABVIMS and Dr. RML Hospital, New Delhi, India

Abstract

Background: Dementia is characterized by neurocognitive decline which interferes with daily function and independence. Cognitive stimulation therapy (CST) is an evidence-based cognitive psychosocial intervention for people with dementia. **Materials and Methods:** A prospective interventional study of single-blind RCT design conducted in the Department of Neurology at ABVIMS and Dr RML Hospital amongst patients with DSM-V major neurocognitive disorder aged more than 50 years. Participants were randomized to CST and control groups using a block-randomized design. The control group participants received treatment as usual while the CST group delivered 45-min virtual group CST sessions for a total of 14 sessions over seven weeks. All participants in both groups were assessed at baseline and eight weeks using the Montreal Cognitive Assessment Scale (MoCA), Alzheimer's Disease Assessment Scale Cognitive Subscale (ADAS-Cog), neuropsychiatric inventory, instrumental activities of daily living, and Zarit Burden Interview for Caregiver Burden (ZBI) by a rater blind to group randomization. **Results:** Total MoCA scores improved significantly in the CST group, compared to the control group which showed a statistically significant decrease. The mean total ADAS-Cog score in the CST group improved significantly compared to controls. The Lawton Instrumental Activities of Daily Living Scale showed a statistically significant change in the control group compared to the intervention group. From the comparison of the mean total neuropsychiatric inventory scale, it was observed that there was a statistically significant decrease in the severity of Behavioural and Psychological Symptoms of Dementia (BPSD) symptoms in the CST group. The mean total ZBI score decreased significantly in the CST group favoring less caregiver burden. **Conclusion:** This study proved that CST has a significant impact on cognitive outcomes in dementia and it also proved its effectiveness in controlling the BPSD outcomes and caregiver burden in dementia.

Keywords: Cognitive stimulation therapy, dementia, randomized controlled trial

Introduction

Dementia is an acquired deterioration in cognitive abilities, characterized by a neurocognitive decline that can impair the activities of daily living by eroding into various mental functions like language, calculation, visuospatial and problem-solving skills.[1]

Globally, it is estimated to be affecting nearly 46.8 million people throughout the world.[2] The increased prevalence of dementia is an increasing public health concern that has a devastating impact on those living with the disease, as well as their families. In India alone, about 4.4 million people are living with dementia now and it is estimated to exceed more than 10 million in 2040.[2] Owing to the scarcity of properly trained professionals, only 5% of dementia patients are diagnosed formally and get appropriate treatment.[3]

Cognitive stimulation therapy (CST) is a brief psychological intervention consisting of fourteen twice-weekly group sessions that are spread over the course of seven weeks. It has been reported to be a cost-effective intervention for mild to moderate dementia with significant improvements in cognitive functioning and quality of life.[4] It was formulated initially in the United Kingdom but has had several cultural adaptations. Previous studies conducted from across the globe have already documented the significant impact of CST on various cognitive outcomes in dementia patients.[4-7]

However, CST has not been explored as an adjunct intervention for the management of dementia in low- and middle-income countries (LMICs) like India despite the advantages of its cost-effectiveness, cultural acceptability, and sustainability as community-supported programs. This study was conducted to evaluate the effectiveness of adjunct CST on cognitive outcomes in dementia.

Address for correspondence: Dr. Soumya Bhowmik, Department of Neurology ABVIMS and Dr. RML Hospital, New Delhi – 110001, India.
E-mail: sbhowmik025@gmail.com

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Materials and Methods

A prospective interventional study with a single-blind randomized controlled trial design was conducted in the Department of Neurology at Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital from November 2019 to August 2021.

Inclusion criteria for cases: patients of both genders diagnosed with DSM-V major neurocognitive disorder, with Montreal Cognitive Assessment Scale (MoCA), score more than or equal to 10, and aged more than 50 years were recruited for our study.

Inclusion criteria for caregivers: any person engaged in caregiving for a person with dementia without any history of major neurocognitive disorder was recruited as a caregiver in our study.

Exclusion criteria for cases: patients with MoCA scores below 10 or a history of previous significant organic CNS disease or trauma, a history of severe visual and auditory deficits impeding participation in CST, or severe psychiatric disorders like schizophrenia and bipolar disorder, or substance dependence other than tobacco and mental retardation were excluded from the study.

Exclusion criteria for caregivers: caregiver himself/herself has a neurocognitive disorder.

All those meeting the study criteria and providing written informed consent along with their caregivers were enrolled in the study.

The sample size was calculated based on the study by Spector *et al*. (2003).[4] The improvement in cognitive outcomes amongst those receiving CST was reported as 30%, while in the control group, improvement was reported as 13%. Assuming an attrition rate of 10%, the sample size was determined to be 194. However, considering the feasibility of the study duration, fifty patients were recruited for each group. Even after recruiting a total of hundred of study participants after screening 144 dementia patients, numerous problems were faced in continuing a CST trial, as the study was conducted amidst the COVID-19 pandemic and it was not advisable for them to gather in groups in hospital settings due to COVID-19 restrictions. There was significant attrition due to the withdrawal of consent from the care providers for follow-up assessment. At the end of the stipulated study period, 57 patients (27 in the CST group and 30 in the control/treatment as usual group) could be assessed for statistical analysis. (Refer to Figure 1-Study flow chart).

A sociodemographic profile and detailed clinical evaluation were recorded at baseline for all participants. A Cognitive assessment was performed using MoCA Scale. Alzheimer's Disease Assessment Scale Cognitive Subscale (ADAS-Cog) was administered to assess the severity of cognitive deficits of dementia. Neuropsychiatric Inventory

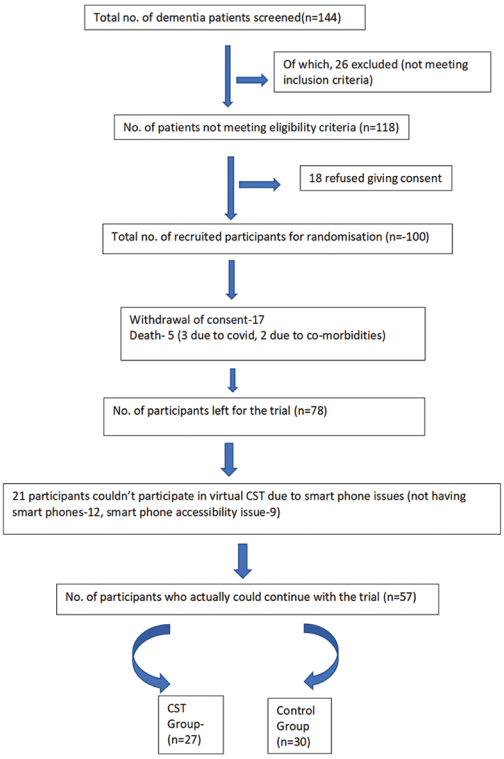

Figure 1: Showing study flow chart

Questionnaire (NPI-Q) for Behavioral and Psychological Symptoms of Dementia was used to assess the frequency and severity of various psychological and behavioral symptoms of dementia. Lawton Instrumental Activities of Daily Living Scale (IADL) was used to assess independent living skills. Zarit Burden Interview for Caregiver Burden (ZBI) was administered to a caregiver actively participating in the care of a person with dementia to rate the impact of the person's disabilities on the caregiver's life to assess the effect of the patient's disease or disability on the caregiver's physical, emotional, social and financial condition. All five cognitive scales used in our study were adopted as per Indian culture and were available in both English and Hindi literature. Prior copyright consents were undertaken separately for every scale from the respective authorities. The normative values were also available for the adoptive versions. For the convenience of application, a google form had been formulated using every subsection of the individual scorings of all the concerned cognitive scales.

Participants were randomized to CST and control groups using a block-randomized design from an online computer-based program planned to take a block size of eight for all participants. The randomization sequence was kept confidential with access only to the supervisor and co-supervisor. The rater was blind to randomization and had no access to the randomization sequence. Participants in the control group received treatment as usual while the patients in the CST group were delivered a manual-based group therapy adapted and validated for the north Indian population for a group of eight to ten participants.

Anti-dementia drug therapy was uninterrupted in either of the study arms throughout the study period. CST has been given as an adjunct therapy with continued drug treatment. Each CST session lasted for 45 min and consisted of 10-min non-cognitive warm up, themed activities designed to stimulate cognition for 25 min, and a 10-min closing activity. Two sessions with a gap of 30 min between them were conducted weekly for seven weeks (a total of 14 sessions).

Initially, it was decided to conduct all the group CST sessions at ABVIMS and RML Hospital and a provision of virtual CST session (maximum 6/14 CST sessions) was also kept for the participants who would not be able to come to the hospital. Due to the ongoing COVID-19 Pandemic, as it was not possible to bring elderly dementia patients with multiple comorbidities to the hospital premises, the proposal for the delivery of group CST sessions was modified and it was decided to give all fourteen CST sessions via virtual modality (instead of maximum 6/14). Official permission was undertaken from the ethical committee at a review meeting. The adoption of a virtual CST session was done by the manual-based group CST therapy as per the Indian context. The virtual CST sessions were administered by a trained clinical psychologist/counselor with prior intimation to the respective caregivers regarding the schedule and preferred modality of virtual CST (formulation of WhatsApp CST groups/video calling/telephonic interactions/ Google meet/zoom platforms). The completer was defined as those who had attended 12 sessions out of 14 virtual mandated sessions.

All participants in both the CST group and the control group were assessed at 8 weeks (one week after completion of CST sessions) using MoCA, ADAS-Cog, neuropsychiatric inventory, instrumental activities of daily living, and ZBI by a rater blind to group randomization.

The data were analyzed with Statistical Package for Social Sciences version 21.0. The comparison of categorical data between the two or more groups was done using the Chi-square test. The comparison of continuous data over some time in the study group was done using paired *t*-test. The comparison of continuous variables between two groups was done using an independent *t*-test, and between more than two groups was done using one-way ANOVA.

Results

The mean age for patients in the CST group was 66.07 ± 8.11 years and in the control group, it was 68.33 ± 9.33 years. There were 17 men and 10 women recruited in the CST arm, compared to the control group, in which there were 18 male and 12 female patients. A comparable proportion of patients in the CST Group belonged to low and middle socio-economic status while more than half had attained education up to 12th standards. Most caregivers are either their respective spouse or their son/daughter. Most patients in the CST group had hypertension, followed by type 2 diabetes mellitus. Out of the 57 patients recruited in our study, 22 patients had Alzheimer's disease (AD), 25 patients had vascular dementia (VD), 5 patients had combined AD with VD dementia, 3 patients had frontotemporal dementia and 2 patients had Lewy body dementia.

There was no statistically significant difference in baseline sociodemographic parameters between the CST and control arms.

The total MoCA score increased significantly in the CST group, while in the control group, there was a statistically significant decrease. In sub-scale analysis, attention, delayed recall, and orientation showed significant change over the follow-up assessment period. In the CST group, there was a significant improvement in the digit list, serial-seven subtraction, delayed recall, and orientation, while there was a significant worsening in the same sub-groups in the control group. [See Table 1 and Figure 2]

Assessment using ADAS-Cog in the two groups showed no statistically significant difference between the two groups at baseline assessment. After eight weeks, the mean total ADAS-Cog score in the CST group improved significantly while in the control group, it worsened, which was not statistically significant. In sub-group analysis, word recall, commands, constructional praxis, naming, orientation, word recognition, and remembering test instructions all showed a statistically significant change over the follow-up period. On the other hand, there was no statistically significant change was observed in the sub-scales of ideational praxis, comprehension, word finding, spoken language ability, and concentration. [See Table 2 and Figure 2]

On the IADL scale, there was a statistically significant change in the control group in the sub-scales of ability to use the telephone, shopping, housekeeping, mode of transport, and ability to handle finances. In the sub-groups of laundry and responsibility of medication, there was a statistically significant change in both groups. [See Table 3]

On assessment using the NPI scale for the severity of neuropsychiatric symptoms in dementia, change in subscales of agitation, irritability, and depression was statistically significant in the control group. In the sub-group of anxiety, the change was statistically significant in both groups. Change in sub-scales of caregiver distress due to agitation was statistically significant in the control group. In the sub-group of caregiver distress related to anxiety, depression, and irritability, the change was statistically significant in both groups. There was a statistically significant increase in the NPI severity and caregiver distress score in the control group, while there was a statistically significant decrease in the CST group. [See Tables 4, 5, and Figure 2]

A comparison of mean total ZBI scores assessing caregiver burden related to dementia in the two groups at baseline and follow-up showed that the ZBI scores decreased significantly in the CST group over the period of follow-up, while it significantly increased in the control group. [See Table 6 and Figure 2]

Table 1: Comparison of scores on MoCA testing between the two groups

	Mean (SD)		*P*
	CST group (*n*=27)	Control group (*n*=30)	
Visuospatial examination at baseline assessment			
TMT	0.15 (0.36)	0.13 (0.35)	0.875
Cube	0.36 (0.49)	0.20 (0.41)	0.408
Clock	1.04 (0.76)	0.97 (0.81)	0.737
Visuospatial examination at follow-up assessment			
TMT	0.23 (0.43)	0.13 (0.35)	0.386
Cube	0.36 (0.49)	0.20 (0.41)	0.196
Clock	1.14 (0.83)	0.97 (0.81)	0.464
P TMT (Intragroup)	0.162	No change	
P cube (Intragroup)	No change	No change	
P clock (Intragroup)	0.329	No change	
Naming at baseline assessment	2.67 (0.62)	2.63 (0.61)	0.839
Naming at follow-up assessment	2.68 (0.57)	2.63 (0.61)	0.773
P (Intragroup)	0.162	No change	
Attention to baseline assessment			
Digit list	1.11 (0.58)	1.23 (0.63)	0.448
Letter list	0.26 (0.45)	0.10 (0.30)	0.119
Serial 7 subtraction	1.93 (0.92)	2.10 (0.96)	0.448
Attention to follow-up assessment			
Digit list	1.36 (0.66)	1.10 (0.55)	0.122
Letter list	0.36 (0.49)	0.10 (0.30)	0.021
Serial 7 subtraction	2.32 (0.94)	1.93 (0.98)	0.162
Digit list P (Intragroup)	0.042	0.043	
Letter list P (Intragroup)	0.162	No change	
Serial subtraction P (Intra-group)	0.005	0.023	
Language at baseline assessment			
Language A	1.56 (0.58)	1.57 (0.63)	0.945
Language B	0.07 (0.27)	0.07 (0.25)	0.915
Language at follow-up assessment			
Language A	1.68 (0.57)	1.50 (0.63)	0.289
Language B	0.14 (0.35)	0.07 (0.25)	0.410
Language A P (Intra-group)	0.162	0.161	
Language B P (Intra-group)	0.329	No change	
Abstraction at baseline assessment	1.52 (0.64)	1.57 (0.68)	0.785
Abstraction at follow-up assessment	1.64 (0.58)	1.50 (0.63)	0.453
P (intra-group)	0.162	0.161	
Delayed recall at baseline assessment	1.81 (0.74)	1.83 (0.95)	0.935
Delayed recall at follow-up assessment	2.27 (0.77)	1.30 (0.95)	0.001
P (intra-group)	0.001	0.001	
Orientation at baseline assessment	3.74 (1.02)	3.90 (0.96)	0.547
Orientation at follow-up assessment	4.09 (1.02)	3.40 (1.07)	0.023
P (intra-group)	0.030	0.001	
Total score			
Total score at baseline assessment	16.15 (3.88)	16.30 (4.03)	0.886
Total score at follow-up assessment	18.27 (4.08)	14.83 (4.36)	0.006
P (intra-group)	0.001	0.001	

Discussion

The aim of the study was to evaluate the effectiveness of adjunct CST on the cognitive outcomes of dementia in the Indian context. We also aimed to evaluate the effectiveness of adjunct CST for BPSD and ADL outcomes in dementia as well as to evaluate the effect of CST on caregiver burden in dementia.

The sample size calculation was powered to assess the short-term improvement in cognition from CST intervention in all causes of dementia. No subtype matching was done. The sample size had to be lowered due to the COVID-19 pandemic as the elderly were a high-risk group. Sample size calculation was not powered to determine

Table 2: Comparison of scores on ADAS Cog scales between the two groups (*n*=57)

	Mean (SD)		*P*
	CST group (*n*=27)	Control group (*n*=30)	
Word recall at baseline assessment	7.26 (1.13)	7.07 (1.17)	0.536
Word recall at follow-up assessment	6.41 (1.01)	7.27 (1.11)	0.006
P (intragroup)	0.001	0.500	
Commands at baseline assessment	1.78 (1.25)	1.33 (1.03)	0.147
Commands at follow-up assessment	1.27 (1.12)	1.63 (1.16)	0.266
P (intragroup)	0.001	0.001	
Constructional praxis at baseline assessment	1.44 (1.19)	1.20 (1.06)	0.416
Constructional praxis at follow-up assessment	1.14 (1.12)	1.40 (1.16)	0.417
P (intragroup)	0.011	0.012	
Naming objects at baseline assessment	2.11 (0.80)	1.87 (0.63)	0.211
Naming objects at follow-up assessment	1.36 (0.58)	1.93 (0.69)	0.003
P (intragroup)	0.001	0.726	
Ideational Praxis at baseline assessment	1.22 (1.19)	1.13 (1.04)	0.765
Ideational Praxis at follow-up assessment	1.00 (0.93)	1.20 (1.16)	0.507
P (intragroup)	0.057	0.326	
Orientation at baseline assessment	2.04 (0.90)	1.70 (0.70)	0.118
Orientation at follow-up assessment	1.55 (0.67)	2.03 (0.89)	0.036
P (intragroup)	0.002	0.001	
Word Recognition at baseline assessment	4.48 (1.48)	4.17 (1.38)	0.417
Word Recognition at follow-up assessment	3.68 (1.64)	4.37 (1.27)	0.097
P (intragroup)	0.001	0.561	
Remembering test instructions at baseline assessment	2.63 (0.69)	2.40 (0.72)	0.226
Remembering test instructions at follow-up assessment	2.36 (0.66)	2.47 (0.63)	0.570
P (intragroup)	0.001	0.161	
Comprehension at baseline assessment	2.00 (0.78)	1.93 (0.74)	0.743
Comprehension at follow-up assessment	1.86 (0.71)	1.97 (0.76)	0.623
P (intragroup)	0.329	0.326	
Word finding difficulty at baseline assessment	1.91 (0.92)	2.17 (0.91)	0.942
Word finding difficulty at follow-up assessment	1.91 (0.92)	2.10 (0.92)	0.464
P (intragroup)	No change	0.326	
Spoken language ability at baseline assessment	2.48 (0.58)	2.43 (0.57)	0.753
Spoken language ability at follow-up assessment	2.32 (0.57)	2.47 (0.57)	0.358
P (intragroup)	0.162	0.326	
Concentration/distractibility at baseline assessment	2.59 (0.64)	2.57 (0.63)	0.877
Concentration/distractibility at follow-up assessment	2.50 (0.67)	2.57 (0.63)	0.715
P (intragroup)	0.162	No change	
Total score			
Total score at baseline assessment	32.33 (7.80)	30.33 (6.83)	0.306
Total score at follow-up assessment	27.64 (7.27)	31.53 (7.17)	0.060
P (intragroup)	0.001	0.509	

differences in cognitive performance of various subtypes of dementia.

The neurocognitive outcome, as per the MoCA scale showed there was no statistically significant difference between the groups at baseline assessment. The mean total MoCA score improved significantly in the CST group from 16.15 to 18.27 while in the control group, there was a statistically significant decrease (from 16.30 to 14.83). No previous studies have used the MoCA scale to assess the neurocognitive outcome in CST patients. The authors have previously utilized other cognitive scales that tested similar cognitive domains and have reported significant improvements in attention, memory, and learning in patients administered CST, which is consistent with our observation also. Breuil *et al*.[8] (1994) found improvements in memory and learning after 10 CST sessions over five weeks, as assessed using the word list memory test. We used an alternative version of MoCA to prevent practice effects. The inter-rater variability assessments were done beforehand to prevent inter-rater variability errors.

The mean total ADAS-Cog score in the CST group improved significantly at the follow-up assessment (from 32.33 to 27.64). This is consistent with the observation by Spector

Table 3: Comparison of scores on the IADL scale between the two groups ($n=57$)

	Mean (SD)		*P*
	CST group ($n=27$)	Control group ($n=30$)	
Ability to use the telephone at baseline assessment	2.26 (1.02)	2.10 (0.88)	0.531
Ability to use the telephone at follow-up assessment	2.09 (.92)	2.27 (1.01)	0.524
P (intragroup)	0.329	0.023	
Shopping at baseline assessment	2.52 (0.75)	2.40 (0.67)	0.533
Shopping at follow-up assessment	2.27 (0.55)	2.53 (0.78)	0.185
P (intragroup)	0.162	0.043	
Food preparation at baseline assessment	2.63 (0.97)	2.57 (0.86)	0.795
Food preparation at follow-up assessment	2.45 (0.86)	2.67 (0.96)	0.414
P (intragroup)	0.329	0.083	
Housekeeping at baseline assessment	2.67 (1.39)	2.57 (1.28)	0.778
Housekeeping at follow-up assessment	2.36 (1.25)	2.70 (1.42)	0.380
P (intragroup)	0.329	0.043	
Laundry at baseline assessment	1.96 (0.81)	1.77 (0.63)	0.307
Laundry at follow-up assessment	1.68 (0.57)	1.97 (0.81)	0.163
P (intragroup)	0.042	0.012	
Mode of transport at baseline assessment	2.67 (0.87)	2.50 (1.01)	0.573
Mode of transport at follow-up assessment	2.36 (1.00)	2.67 (1.21)	0.344
P (intragroup)	0.083	0.023	
Responsibility for medication at baseline assessment	2.07 (1.21)	1.90 (0.76)	0.424
Responsibility for medication at follow-up assessment	1.77 (0.75)	2.10 (0.88)	0.167
P (intragroup)	0.042	0.012	
Ability to handle finances at baseline assessment	2.41 (0.50)	2.23 (0.43)	0.164
Ability to handle finances at follow-up assessment	2.23 (0.43)	2.43 (0.50)	0.128
P (intragroup)	0.162	0.012	

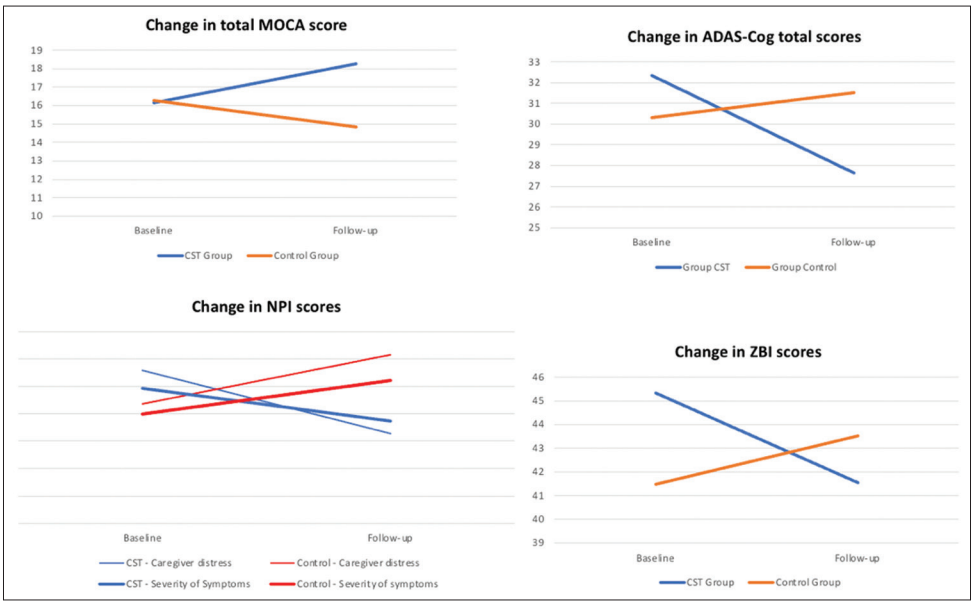

Figure 2: Showing changes in the respective scales between cognitive stimulation therapy (CST) and control groups at eight weeks

et al.[4] (2003), who did the first randomized controlled trial on CST among 201 people with dementia and reported generalized improvement in cognition using the ADAS-Cog scale. The mean total improvement is also consistent with the outcome reported by Aguirre *et al*.[9] in 2012. In the subgroup analysis of ADAS-Cog, word recall, commands, constructional praxis naming, orientation, word recognition, and remembering test instructions showed a statistically significant improvement over the follow-up period in the CST group. In contrast, ideational praxis, comprehension, word finding, spoken language, and

Table 4: Comparison of scores on the Neuropsychiatric Inventory Questionnaire for the severity of symptoms for the patient between the two groups

Severity grading	Mean (SD)		*P*
	CST group (*n*=27)	Control group (*n*=30)	
Delusions at baseline assessment	0.26 (0.71)	0.13 (0.43)	0.418
Delusions at follow-up assessment	0.24 (0.47)	0.20 (0.66)	0.702
P	0.910	0.161	
Hallucinations at baseline assessment	0.41 (0.75)	0.30 (0.65)	0.564
Hallucinations at follow-up assessment	0.38 (0.63)	0.33 (0.76)	0.762
P	0.882	0.326	
Agitation/aggression at baseline assessment	0.59 (0.75)	0.57 (0.77)	0.898
Agitation/aggression at follow-up assessment	0.59 (0.73)	0.73 (1.01)	0.579
P	1.000	0.023	
Depression/dysphoria at baseline assessment	0.44 (0.70)	0.33 (0.61)	0.523
Depression/dysphoria at follow-up assessment	0.27 (0.46)	0.50 (0.73)	0.205
P	0.162	0.023	
Anxiety at baseline assessment	1.04 (0.71)	0.97 (0.72)	0.711
Anxiety at follow-up assessment	0.77 (0.61)	1.13 (0.82)	0.088
P	0.042	0.023	
Elation/euphoria at baseline assessment	0.0	0.0	1.000
Elation/euphoria at follow-up assessment	0.0	0.0	1.000
P	1.000	1.000	
Apathy/indifference at baseline assessment	0.26 (0.45)	0.23 (0.43)	0.824
Apathy/indifference at follow-up assessment	0.18 (0.39)	0.30 (0.60)	0.423
P	0.161	0.161	
Disinhibition at baseline assessment	0.41 (0.80)	0.37 (0.76)	0.845
Disinhibition at follow-up assessment	0.41 (0.80)	0.40 (0.81)	0.968
P	1.000	0.326	
Irritability/lability at baseline assessment	1.04 (0.65)	1.00 (0.91)	0.414
Irritability/lability at follow-up assessment	0.82 (0.59)	1.13 (0.78)	0.117
P	0.162	0.006	
Motor disturbance at baseline assessment	0.04 (0.19)	0.03 (0.18)	0.941
Motor disturbance at follow-up assessment	0.0	0.10 (0.40)	0.251
P	0.329	0.161	
Night-time behaviors at baseline assessment	0.44 (0.80)	0.17 (0.38)	0.095
Night-time behaviors at follow-up assessment	0.32 (0.78)	0.23 (0.63)	0.660
P	0.161	0.573	
Appetite at baseline assessment	0.0	0.0	1.000
Appetite at follow-up assessment	0.0	0.0	1.000
P	1.000	1.000	
NPI patient severity at baseline assessment	4.93 (3.75)	4.00 (2.99)	0.305
NPI patient severity at follow-up assessment	3.73 (2.68)	5.21 (6.68)	0.118
P (intragroup)	0.004	0.001	

concentration did not show any improvement. Spector *et al*.[4] and Hall *et al*.[10] observed statistically significant improvement in all the components of language function as assessed by MoCA or ADAS-Cog scale. This can be explained by the mode of delivery of CST, as virtual CST delivery might not be as efficient enough as face-to-face group interaction in terms of processing syntax, and facilitating verbal recall by creating new semantic links.

In our study, the control group showed a trend towards worsening daily activity over two months follow-up on assessment using the IADL scale. However, the CST group did not show a significant worsening of any ADL outcomes. Previous studies have documented a consistent benefit in ADL outcomes in CST patients.[11]

From the comparison of the mean total NPI scale for the severity of symptoms for the patient in the two groups, it was observed that there was a statistically significant decrease in the severity of BPSD symptoms in the CST group while there was a significant increase in the mean total NPI severity score in the control group. A similar observation was made from the NPI scale for caregiver distress. Orrell *et al*. 2014[11] demonstrated improved NPI outcomes in maintenance CST groups at 3 and

Table 5: Comparison of scores on the Neuropsychiatric Inventory Questionnaire for caregiver distress between the two groups (*n*=57)

Care-giver distress grading according to the respective symptoms	Mean (SD)		*P*
	CST group (*n*=27)	Control group (*n*=30)	
Delusions at baseline assessment	0.33 (0.96)	0.17 (0.59)	0.429
Delusions at follow-up assessment	0.14 (0.47)	0.30 (0.95)	0.462
P	0.929	0.103	
Hallucinations at baseline assessment	0.44 (1.01)	0.30 (0.84)	0.558
Hallucinations at follow-up assessment	0.27 (0.77)	0.40 (1.04)	0.629
P	0.790	0.083	
Agitation/aggression at baseline assessment	0.74 (1.09)	0.73 (1.14)	0.980
Agitation/aggression at follow-up assessment	0.71 (0.84)	1.37 (1.10)	0.212
P	0.329	0.017	
Depression/dysphoria at baseline assessment	0.41 (0.69)	0.30 (0.60)	0.532
Depression/dysphoria at follow-up assessment	0.18 (0.39)	0.53 (0.78)	0.057
P	0.011	0.006	
Anxiety at baseline assessment	1.19 (1.04)	0.97 (0.72)	0.458
Anxiety at follow-up assessment	0.71 (0.84)	1.37 (1.10)	0.027
P	0.010	0.003	
Elation/euphoria at baseline assessment	0.0	0.0	1.000
Elation/euphoria at follow-up assessment	0.0	0.0	1.000
P	1.000	1.000	
Apathy/indifference at baseline assessment	0.15 (0.36)	0.13 (0.35)	0.875
Apathy/indifference at follow-up assessment	0.05 (0.21)	0.23 (0.57)	0.147
P	0.083	0.083	
Disinhibition at baseline assessment	0.44 (0.89)	0.37 (0.76)	0.724
Disinhibition at follow-up assessment	0.36 (0.73)	0.53 (1.11)	0.534
P	0.329	0.057	
Irritability/lability at baseline assessment	1.07 (0.92)	1.00 (0.91)	0.414
Irritability/lability at follow-up assessment	0.73 (0.70)	1.30 (0.99)	0.024
P	0.010	0.005	
Motor disturbance at baseline assessment	0.07 (0.38)	0.13 (0.51)	0.941
Motor disturbance at follow-up assessment	0.0	0.07 (0.36)	0.397
P	0.329	0.329	
Night-time behaviors at baseline assessment	0.74 (1.29)	0.23 (0.63)	0.095
Night-time behaviors at follow-up assessment	0.32 (0.78)	0.23 (0.63)	0.665
P	0.011	1.000	
Appetite at baseline assessment	0.0	0.0	1.000
Appetite at follow-up assessment	0.0	0.0	1.000
P	1.000	1.000	
NPI caregiver distress at baseline assessment	5.59 (4.85)	4.37 (3.71)	0.285
NPI caregiver distress at follow-up assessment	3.27 (2.78)	6.14 (4.42)	0.010
P (intragroup)	0.001	0.001	

6 months follow-up. They, however, did not report a subgroup analysis of all items of the NPI scale.

Mean total ZBI scores did not show a significant difference between the two groups in baseline assessment but on follow-up assessment the mean total ZBI score decreased significantly in the CST group, exhibiting less caregiver burden in dementia patients post-CST intervention. No previous studies utilized ZBI scores for the assessment of caregiver burden.

Although there are significant improvements in specific areas of cognitive abilities in the CST group, the control group at follow-up assessments had been found to have poor performance in several cognitive domains as per most of the cognitive scales used in our study. The natural history of the disease elucidates the majority of dementias are progressive and irreversible, and it is not unusual to have a deterioration of cognitive skills at two month follow-up. As the study was undertaken during the lockdown phase with the COVID-19 surge the elderly dementia patients as well as their caregivers in the intervention arm had a chance to socially interact with each other along with the medical personnel delivering CST continuously throughout the two months study period which could also have a beneficial effect on their cognition in addition to the effect directly related to the cognitive stimulation tasks

Table 6: Comparison of scores on the Zarit Burden Inventory (ZBI) scale between the two groups ($n=57$)

	Mean (SD)		*P*
	CST group ($n=27$)	Control group ($n=30$)	
ZBI at baseline assessment	45.33 (16.66)	41.47 (13.99)	0.345
ZBI at follow-up assessment	41.55 (15.65)	43.53 (12.66)	0.598
P (intragroup)	0.001	0.002	

used in CST intervention. On the other hand, in the control arm, elderly dementia patients didn't have the opportunity to socially interact, which may also have contributed to their rapid cognitive worsening over two months of follow-up. Drug compliance and efficacy of medications in the control group were not taken into consideration in our study which can also be a factor for the worsening parameters.

We can't comment on whether the benefits of CST will tend to last longer or is just a short-term effect. It will require a larger study sample with longer follow-up time as well as dementia subcategorization. The effects of CST on advanced dementia have also not been studied in our study.

Our study findings align with existing scientific literature from developed countries or high-income settings. The acceptability and feasibility of CST for cultural adaptation in LMICs like India has been done earlier. However, this is the first study to explore the wider application of CST intervention in India for its effectiveness as well as for exploring the other beneficial effects in terms of BPSD and ADL outcomes of dementia and caregiver burden following the intervention. Assessment tools used in our study are specifically validated for use in dementia patients. Our study has also tested the applicability of virtual delivery of CST in a pandemic-affected and low-cost setting. In the future, it may emerge as a unique mode of delivery of CST in dementia patients.

The ongoing COVID-19 pandemic was a tough challenge to conduct the study. As the study subjects were elderly dementia patients with multiple comorbidities, the attrition rate was high. Many caregivers of the study participants withdrew consent subsequently after the initial agreement, and few did not report for follow-up assessments. The study was conducted with a substantially decreased sample size which was a major limitation of our study. As virtual CST was given for all sessions, participants who did not have a smartphone or internet-enabled device had to be excluded, which can also be a source of bias. Multi-centric studies incorporating patients with severe dementia and a longer follow-up period need to be conducted so the sustained benefits of CST, if any, can be opined.

Conclusion

This study proved that CST has a significant impact on cognitive outcomes in dementia and independence in performing daily activities. The study also shows that CST has a significant impact on BPSD outcomes of dementia both in terms of severity of neuropsychiatric symptoms as well as caregiver distress pertaining to the neuropsychiatric symptoms of dementia. Based on the outcome analysis looking into the significant improvements in specific areas of cognitive abilities in the CST group, it can be concluded that CST has a definite role in the management of dementia and it can emerge as an early treatment option for mild to moderate dementia in near future. However, whether the improvements in cognition attained immediately after completion of all CST sessions will be sustained for months after or not needs further research.

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Declaration of patient consent

We hereby certify that we have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients 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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Nil.

Conflicts of interest

There are no conflicts of interest.

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