Indian Journal of Behavioural Sciences
An Official Journal of **Central Psychiatric Society**
(Indian Psychiatric Society-Central Zone)

ORIGINAL ARTICLE
e-ISSN: 2455-6599 | p-ISSN: 2319-2062
doi: 10.55229/ijbs2022.0306

The Feasibility and Effectiveness of Home-based Cognitive Remediation in Clinically Stable Schizophrenia Patients attending a North Indian Tertiary Care Institution

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ARTICLE INFO

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Dates:
Received: 01-02-2022
Accepted: 07-03-2022
Published: 05-05-2022

Keywords:
Cognitive remediation, Disability, Home-based, Quality of life, Schizophrenia.

How to Cite:
Moun V, Tripathi A, Dalal PK, et al. The Feasibility and Effectiveness of Home-based Cognitive Remediation in Clinically Stable Schizophrenia Patients attending a North Indian Tertiary Care Institution. Indian Journal of Behavioural Sciences. 2022;25(1): 25-34. doi: 10.55229/ijbs2022.0306

Abstract

Background: Cognitive deficits are one of the core symptoms of Schizophrenia that compromises real-world functioning, adversely impacts rehabilitation, and negatively influence the quality of life. Studies evaluating interventions for cognitive remediation in Schizophrenia are scarce in India. This study aimed to evaluate the effectiveness of the add-on home-based cognitive remediation strategy in schizophrenia in comparison to the schizophrenic patients receiving treatment as usual.

Methods: The research was carried out in a North Indian tertiary care teaching hospital. Clinically stable patients diagnosed with schizophrenia were randomly assigned to study and control groups. The control group had received treatment as usual, whereas the study group had received 8 weeks of home-based manual-based cognitive remediation in addition to the treatment as usual. Assessment of psychopathology, cognitive functioning, disability, and quality of life was done at baseline, completion at 8 weeks and 16 weeks follow up.

Results: A total of 186 patients with schizophrenia were screened based on selection criteria. 74 patients were included in the study. During the intervention, 17 patients were dropped out, making the sample size of the study group to be 28 and the control group to be 29. At the baseline, the socio-demographic, as well as clinical variables, were comparable. After cognitive remediation intervention, the study group had better cognitive functioning, less disability, and better quality of life in comparison to the control group. The benefits were sustained in the study group at the end of two-month follow-up period. The effect size of home-based cognitive remediation was found to be moderate (Cohen's d 0.4 to 0.69) at the end of the intervention.

Conclusion: Home-based cognitive remediation is a feasible and effective strategy of intervention in patients with schizophrenia which has at least a short-lasting effect and it is also useful in limiting the disability and improving the quality of life.

Introduction

Schizophrenia is a chronic and debilitating psychiatric illness that includes cognitive deficits as one of its core symptoms, along with positive and

negative symptoms.[1,2] The third meeting of the Cognitive Neuroscience Treatment Research to Improve Cognition in Schizophrenia (CNTRICS) project concluded that schizophrenia had been strongly linked with impairment in multiple domains of cognition, including attention, working memory, perception, executive functioning, long-term memory, and social cognition.[3-5] Various meta-analyses have also reported that individuals with schizophrenia have a significant reduction in different cognitive domains when compared to normal subjects.[6,7]

Cognitive deficit are one of the major impediments to complete recovery from schizophrenia[8] and predicts the poor functional outcome of the treatment.[9-12] In an Indian cohort of patients with schizophrenia, it was found that approximately 45% patients with first episode schizophrenia with illness duration less than two years, more than 50% deficit in cognitive functions present,[13] which indicated that cognitive deficits are severe, impairing and common, even in the early course of the disease. Cognitive symptoms, being more persistent over time than positive symptoms and more resistant to the available conventional treatment, tend to influences quality of life as well.[14] Furthermore, cognitive impairment appears to be linked to negative symptoms of schizophrenia, which can affect patients' social and vocational functioning as well as make caregivers' lives more difficult by increasing the burden of care.[15] As a result, improving neurocognitive deficiencies has been identified as a critical therapy aim in schizophrenia, with the potential to enhance a variety of areas of patients' lives.

Though there is some evidence that atypical antipsychotic drugs may improve certain aspects of cognitive performance,[16-18] they do not eliminate cognitive deficits[19] and can have damaging effects on cognition as well. As a result, a number of researchers have looked into non-pharmacological treatments such as cognitive remediation to treat people with schizophrenia improve their residual cognitive and functional deficiencies.

Recent decades have witnessed significant progress in the development of cognitive remediation initiatives in developed countries, such as computer-assisted cognitive training, but such programs are difficult to adopt successfully on a large scale in developing countries due to a scarcity of availability of such applications. Also, various factors including socio-cultural factors, educational standards, living standards of the patient population, budget restrictions as well as limitation of mental health resources limit the utility of existing cognitive remediation training to the majority of the population. Thus, there arises the need for an affordable, feasible, and acceptable cognitive training program that can be facilitated by non-specialist health professionals using inexpensive resources. Studies were done in low and middle-income countries (LAMIC) also highlighted the need for a cost-effective cognitive remediation program.[20] Hegde *et al*., (2012), attempted home-based cognitive remediation in Indian population with schizophrenia (first episode) by administering a two-month cognitive training program intensively.[21] This study revealed significant improvement in the cognitive functioning (in the domains of divided attention, conceptualization, planning and set-shifting ability) in the group, who received cognitive remediation in addition to treatment as usual versus those who received treatment as usual alone.[21]

Thus, a home-based cognitive training program was envisaged for patients with schizophrenia, hoping that such a therapy would help not only in improving the cognition in such patients but also improve their quality of life and limit the disability incurred due to the illness. The aim of the study is to evaluate the effectiveness of a home-based cognitive remediation strategy in schizophrenia in comparison to schizophrenic patients receiving treatment as usual. In this replicative study, we adopted the intervention model and study design of Hegde *et al*., (2012)[21] in a relatively larger North Indian population with schizophrenia irrespective of the duration of their illness.

Materials and Methods

Sample

The study sample was recruited from adult psychiatry outpatients of a tertiary care hospital of North India. The sample included 74 patients who have been diagnosed with schizophrenia (by the consultant in

charge) according to ICD-10 DCR diagnostic criteria. To be included in the study, the patient needs to be clinically stable on the same antipsychotic medications for at least 3 months and have a reliable caregiver. In our study, the operational definition of term "Clinically stable" was kept as patients who score <70 in positive and negative symptom scale (PANSS) at the time of recruitment, with a score of <4 on items of delusions, hallucinations, grandiosity, suspiciousness/persecution, conceptual disorganization, hostility, unusual thought content. Patients were included if they spoke Hindi well, had good vision and hearing, and had at least an eighth-grade education. Patients with severe Extrapyramidal side effects, an Intelligence Quotient below the 25th percentile on Standard Progressive Matrices, a serious medical or surgical condition, a current or previous history of organic mental disorder, and those involved in any psychosocial intervention programme or who had received electroconvulsive therapy in the previous 6 months were all excluded. The research protocol was approved by the institutional ethics committee, and patients and caregivers signed written informed consent forms.

Design of Study

A randomised controlled design was adopted in the research. Using the random allocation approach, the investigator assigned patients (who met the inclusion and exclusion criteria) to either the treatment or control groups.

Intervention

The treatment group received a 2 months home-based cognitive training program (adopted from the study of Hegde *et al*., 2012)[21] along with treatment as usual (included psycho-education and drug treatment) from outpatients. The control group received only treatment as usual.

Home-Based Cognitive Training Program: Core cognitive domains commonly affected in schizophrenia i.e., attention, mental speed, verbal fluency, and executive functions like working memory, response inhibition, planning, set-shifting ability, and abstraction were targeted in the cognitive training program (Table 1).

The tasks in training program were given every two weeks in a booklet form in four successive sessions. In each set, the numbers of tasks to be carried out each day were designated. First set was given after the baseline assessment. Remaining three sets were given subsequently at an interval of two weeks each. Work was assigned for 6 days per week with 1 day off. The clinic sessions lasted for 60–90 minutes in which samples of cognitive training tasks were discussed and demonstrated. The patients were asked to complete one sample of each type of training task in front of the investigator first before giving it for home. Review of the performance of the tasks given in previous session were done before giving the next set of exercises. The task difficulty was increased gradually along with the progress of the training program. The patients performed the tasks in the home settings, with a minimum level of monitoring by the caregivers. Completion of at least two-thirds of the tasks given for each session was considered as adequate compliance. Motivation and encouragement for greater participation were given in each session. Equal attention was paid to all patients whether performing well or not. The role of the caregiver during therapy was to be supportive,

Table 1: Description of the home-based cognitive training program[#]

Cognitive training task (week of administration)	*Frequency and numbers of tasks done per week*	*Cognitive training task description*	*Targeted cognitive domain*
Number connection task (1–25; 1–50; 1–70); Number and alphabet connection task (1–13 and 13 Hindi alphabets; 1–13 and 13 English alphabets; 1–25 and 25 English alphabets). (week 1–4)	Thrice a week; 2 tasks per day.	To connect randomly placed numbers serially. Difficulty level was increased by changing placements and increasing the total numbers to be connected. Gradually alphabets (Hindi & English) were added which were to be connected alternatively with numbers serially. The task difficulty was increased at 5 levels.	Attention

Cognitive training task (week of administration)	*Frequency and numbers of tasks done per week*	*Cognitive training task description*	*Targeted cognitive domain*
Design coloring task (week 1–4)	Daily; 1 task per day	To colour different geometric designs and pictures using colour pencils. Symmetry, sharpness, appropriate colour selection and uniformity in colour filling was emphasized. The task difficulty was increased at 6 levels by increasing complexity of design structure.	Response Inhibition
Alphabet-symbol substitution task; Alphabet-alphabet substitution task (week 1–6)	Thrice a week; 2 tasks per day.	To write symbols below the corresponding English alphabets by matching from the reference column given on the top of the task. Task difficulty was increased at 8 levels by increasing number of columns, adding alphabets to which no symbols were designated and subsequently substituting alphabets with alphabets.	Mental speed
Grain sorting task (week 1–6)	Daily; 1 task per day	The task involved sorting of grains from the mixture of grains. The task was given at six difficulty levels. Task difficulty was increased by increasing the types of grains and decreasing the size of grains to be sorted out.	Mental speed
Maze Solving task (1–8 weeks)	Daily; 1 task per day	To trace the way out in the given maze beginning from the start point without breaching the boundary line of the blind alleys. Tasks were given at four difficulty levels by the complexity of maze.	Planning
Short essay writing (1–8 weeks)	Thrice a week; 1 task per day	To write a short essay (maximum 500 words) on a given topic. The topics were related to day to day activities and common social issues. The task difficulty was increased at four levels by increasing reconditeness of the topic.	Planning
Alphabet cancellation task; Number cancellation task (3–8 weeks)	Thrice a week; 2 tasks per day	To cancel specific letters and numbers in given sets of rows of randomly arranged alphabets and numbers. The task was given at twelve levels of difficulty. Increase in task difficulty was achieved by increasing the sets of rows of alphabets and numbers to be cancelled and using mixtures of alphabets and numbers in different combinations.	Sustained attention, set-shifting ability
Jumbled words (5–8 weeks)	Daily; 1 task per day	To rearrange jumbled words to make a meaningful sentence. The task was given at four levels of difficulty. Difficulty level was increased by increasing complexity and length of sentences.	Working memory (executive function)
Categorization task (5–8 weeks)	Daily; 1 task per day	To arrange words into different categories according to some common characteristic shared. Task was given at four levels of difficulty. Difficulty level was increased by introducing more similar categories.	Abstraction
Proverb illustration (7–8 weeks)	Thrice a week; 1 task per day	To illustrate a given proverb by writing the meaning of the proverb with an example. The task was given at 2 levels of difficulty	Abstraction

[#]The home-based cognitive training program has been adopted from the original work of Hegde *et al*., (2012).[21]

but not to get over-involved or be punitive. In case of any confusion or difficulty, the therapist could be contacted for clarifications and help. Attempts were made to get the tasks completed in time. However, a maximum window period of up to two weeks was allowed in case of inadequate compliance in the whole period of study. Further non-compliance would lead to the drop-out of the patient. A window period of +2 days was given for attending follow-up sessions.

The patients/caregivers were given prior information about the session timings via telephone calls 3 days in advance. A reminder call was given the day before. Most of the sessions were conducted by the investigator preferably on weekends. Weekends were chosen as it suited the patients, their caregivers, and the investigator alike. The patients in the control groups were also called every 2 weeks, similar to the study group, and sessions of psycho-education were given for 45 to 60 minutes each time. Patients taking benzodiazepines were instructed not to take benzodiazepines at least 8 hours prior to the assessments.

Assessment of Patients

Baseline assessment: The following standardised tools were applied in the study by the primary investigator. PANSS was utilized to rate psychopathology of schizophrenia, WHO-Disability Assessment Schedule (WHODAS) 2.0[22] for disability, Brief Assessment of Cognition in Schizophrenia (BACS)[23] for cognition and WHO-Quality of Life Scale-Brief version (WHOQOL-BREF)[24] was used for quality-of-life assessment. All these tools were well validated tools and widely used in previous research.
Assessment on subsequent visits: BACS, PANSS, WHODAS 2.0, and WHOQOL-BREF were applied during the follow-up assessments. The follow up assessment was done after two months of the baseline assessment i.e., at the completion of the intervention (post-assessment), and subsequently at 2 months of post- assessment (4 months follow-up since baseline assessment).

One of the co-authors (AT) had carried out the assessments of the patients, immediately post-intervention and in the subsequent follow-up period, while the first author (VM) conducted the cognitive training sessions. Though the assessor (AT) was unaware of the allocations of patients in study and control groups, complete blinding was not possible due to the nature of the study.

Treatment Adherence (Home-based Cognitive Retraining Program)

The 2 months home-based cognitive training programme was completed by 28 of the 36 patients who were included in the therapy group [Figure 1]. A minimum of two-thirds of the training programme was completed by all patients. The short essay writing job and the proverb illustration work were the least adhered to and finished tasks. [Figure 1]

Statistical Analysis

Data were summarized as mean ± SD. Groups were compared by independent samples Student t test. Categorical groups were compared by chi-square ($\chi 2$) test. A two-sided ($\alpha = 2$) $p < 0.05$ was considered statistically significant. The level of improvement due to treatment was measured using effect sizes (Cohen's d). For statistical analysis, the Statistical Package for Social Sciences (SPSS) version 15.0 (25) was used.

Results

In our study, a total of 186 patients were screened, of which 112 were excluded. Remaining 74 patients were randomly allocated to the study arm and control arm. A total of 17 patients were dropped out (8 from the study group and 9 from the control group) between recruitment and completion of the study, with a dropout rate of 22.97%. At the completion of study, 28 patients retained in the study group and 29 in the control group. Data of these patients were analysed in the study. The mean age of the patients in study group and control group were 29.79 ± 6.5 years and 29.48 ± 5.7 years respectively. The mean years of education of the patients in study group

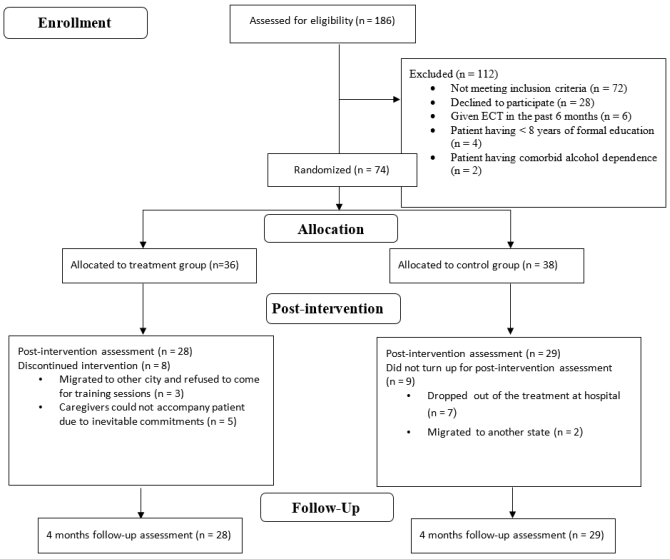

Figure 1: Flowchart of patients recruited in the study

and control group were 12.79 ± 3.39 years and 13.21 ± 2.90 years, respectively. The difference in age and years of education among the study and control group were not statistically significant. In both study and control group, most of the patients were male, unmarried and from urban background. There was no difference in socio-demographic variables like – gender, marital status, occupation, domicile and income among the study and control group.

At the baseline assessment, there was no significant difference in the mean scores on PANSS ($p = 0.903$), BACS sub-items ($p = 0.312$ to 0.989), WHO-DAS 2.0 ($p = 0.879$) and WHO-QOL- BREF ($p = 0.697$).

Effect of Intervention on Patients-Cognitive Functions, Disability, Quality of Life and Psychopathology

On evaluating the difference between mean changes of both the groups (Table 2) in the outcome measure of cognition, it was seen that the study group performed significantly better than the control group at follow up-2 ($p < 0.05$) i.e., 2 months after discontinuation of cognitive training. Thus, it can be stated that the effect of home-based cognitive training in improving cognition was sustained for at least two months after discontinuation of therapy.

On evaluating the difference between mean changes of both the groups in the outcome measure of disability and quality of life, it was seen that the study group had statistically significant improvement at second follow up ($p < 0.01$).

Effect of cognitive training on digit sequencing was small (Cohen's d = 0.2–0.5) while all other domains assessed on BACS had moderate effect of cognitive training (Cohen's d=0.5–0.8) (Table 3).

Discussion

This research used restorative tactics based on neuronal plasticity with the goal of addressing a specific deficit by aiming to repair the underlying impaired function by embracing the brain's ability to develop and repair itself throughout one's life.[26-28] Bottom-up and top-down approaches are used in restorative remediation procedures. Bottom-up techniques begin with fundamental neurocognitive skills such as attention and progress to more complicated skills such as problem solving. Top-down strategies, on the other hand, make use of more complex skills in order to improve certain neurocognitive domains.[29] In this study the bottom-up approach was employed.

In the current work, BACS was used. BACS is a sensitive battery to measure cognitive impairments in patients with schizophrenia with high completion

Table 2: Comparison of changes in clinical variables between study and control group from baseline to second follow-up

Variable	*Mean change in study group between baseline and 2nd follow-up* Δ_{2_s} *Mean(S.D.)*	*Mean change in control group between baseline and 2nd follow-up* Δ_{2_c} *Mean(S.D.)*	*t value*	*p value*
BACS				
Verbal memory	1.64 (3.55)	.07 (1.31)	2.20	.034
Digit sequencing	.64 (1.34)	-.07 (1.28)	2.05	.045
Token motor	2.71 (5.31)	-.07 (1.96)	2.60	.013
Verbal fluency	.82 (1.51)	.07 (1.19)	2.08	.043
Symbol coding	.70 (1.54)	-.03 (1.24)	2.02	.048
Tower of London	1.82 (4.00)	-.03 (1.32)	2.33	.026
WHODAS 2.0 score	-2.60 (3.95)	-.06 (.52)	-3.37	.002
WHOQOL-BREF score	3.79 (6.77)	.10 (.31)	2.87	.008
PANSS				
Positive score	.07 (.26)	-.03 (.19)	-.61	.54
Negative score	-.2 (.79)	-.10 (.31)	-.70	.492
General psychopathology score	-.21 (.57)	-.07 (.26)	-1.24	.224
Total score	-.50 (1.35)	-.17 (.38)	-1.24	.225

Table 3: Effect Size (Cohen's d) of cognitive training (at end of intervention)

Variable	*Mean change in study group at the end of intervention* Δ_{1_s} *Mean (S.D.)*	*Mean change in control group at the end of intervention* Δ_{1_c} *Mean (S.D.)*	*Cohen's d*	*Range*
BACS				
Verbal memory	1.68 (3.63)	.03 (1.35)	0.5	-0.8-.99
Digit sequencing	.61 (.99)	.17 (.47)	0.4	-.05-.91
Token motor	2.64 (5.79)	.07 (.65)	0.64	-1.5-.88
Verbal fluency	.75 (1.24)	.03 (.87)	0.69	.23-1.0
Symbol coding	.68 (1.06)	.07 (.96)	0.6	.22-.96
Tower of London	1.96 (4.26)	.03 (.87)	0.64	.64-.96

rates and high reliability, requiring lesser time in comparison to standard tests.[30,31] Furthermore, we used the WHO-QOL BREF, which assessed a person's quality of life and widened the scope of insights gained on the overall impact of the illness on the patient's life as well as the impact of our intervention on it.[32]

Since, in developing nations such as India, family is typically the most important and, at times, the sole support system for the patient. In addition, family substantially influences decisions about when, where, and how to get help, the type of therapy (medical or nonmedical), the need to continue treatment, and other issues including employment and marriage. In such a context, enlisting the assistance of a family member to supervise cognitive training might be beneficial and cost-effective.[33]

Our study sample included patients stable on same treatment for at least 3 months and stability was found to occur both early and late in the course of illness. Around 54% patients in study and 62% in control group were stable on the same antipsychotic medications for >6 to 12 months. As a result, it's unlikely that medications contributed to improvements in cognition and psychopathology because any medication impact would have peaked before the study began. Further, it has been observed that stable patients are most likely to benefit from cognitive remediation.[34] Stable patients are also likely to accept and co-operate more in cognitive remediation training.

When mean changes from baseline to follow up were compared between the study and control groups, cognitive dysfunction, as measured by BACS, showed statistically significant improvement ($p < 0.05$) in all domains assessed, namely verbal memory, working memory, motor speed, verbal fluency, attention, speed information processing, and executive functioning. Effect size (Cohen's d) was also calculated to measure the extent of improvement due to treatment at the end of intervention which revealed moderate effect size (Cohen's d = 0.5–0.8) for all the domains of BACS except digit sequencing which had small effect size (Cohen's d = 0.2–0.5). Possible reasons for lack of differential improvement in different cognitive domains could be type of cognitive tasks used in the cognitive training which covered specifically each of these domains, and contextualisation of the cognitive task by making clear practical usefulness of each of the training tasks and their connection to real life situations. Earlier, Indian studies measured the neurocognitive performance among the patients with first episode schizophrenia,[13,21] and the effect size of home-based cognitive retraining to be large despite small sample size.[21] Thus, cognitive training was able to improve cognition at the end of the therapy and its effect was sustained for at least two months after completion of the cognitive training intervention.

Several variables could have contributed to the improvements seen across several cognitive domains. To begin, cognitive functions were targeted using a bottom-up approach in which basic neurocognitive skills were addressed initially, followed by more complicated skills later in the remediation programme. In the first phase of the retraining programme, basic cognitive skills like attention and mental speed were targeted, followed by higher-order cognitive functions like abstraction and set-shifting ability later on. Second, the tasks in the programme were organised in increasing complexity order, which facilitated learning without overtaxing the patient's thinking.

Thirdly, improvements in executive processes may have influenced other aspects of cognition, such as motor speed, verbal memory, and verbal fluency. Fourth, the fact that the patient was made to feel less "patient-like" by making him/her competent for performing out cognitive training at home with limited caregiver involvement may have increased intrinsic motivation. Furthermore, the progressive increase in the complexity of training assignments would have aided the patient's drive to complete the tasks. Motivation, according to Medalia and Choi (2009), mediates adherence to cognitive rehabilitation programmes as well as improvements in cognitive skills. Training tasks also had a component of entertainment i.e. colouring task, maze etc. which may have further increased involvement of the patients.[35] These findings corroborate findings of previous studies showing improvements in different areas of cognition by cognitive training.[36-38]

In the assessment of the disability (as per WHODAS 2.0), on comparison of two groups at follow-up the study group showed statistically significant improvement ($p < .05$) than the control group. Improvement in cognitive domains like attention, verbal memory, executive functioning, working memory, motor speed could have played a role in the improvement observed on WHODAS, which has items assessing cognitive abilities like learning new tasks and concentrating for ten minutes. Further, improved cognition could have helped patients in dealing with their day-to-day work and household responsibilities which are some of the items assessed on WHODAS 2.0.

The outcome measure of quality of life as assessed by WHOQOL-BREF, showed statistically significant improvement in the study group when compared to control group at follow-ups. This improvement could be explained by improvement in different cognitive areas like working memory, attention, motor speed, verbal fluency, processing speed and executive functioning which affect patient's day to day life functioning and thus may be responsible for subjective feeling of improvement in quality of life by the patient. Processing speed has also been shown as one of the most important cognitive factors that predicts Quality of Life.[39]

Limitations of the Study

The sample size was small and was drawn from clinical population attending tertiary care psychiatric facility. Thus, the results can't be generalised to the rest of patients' population. No active attention comparator was used in study design, as per current research recommendations in cognitive remediation studies. Control group received only medications and psycho-education. The investigator was not completely blind to allocation. We could not assess influence of intervention on real life functioning, vocational success, self-esteem, and independent living of the patients. Long-term follow up outcomes were not studied, as it was a time bound study.

Conclusion and Recommendations

Cognitive symptoms in schizophrenia are persistent and disabling, and they create effects on the lives of both patients and caregivers. Current medications, while beneficial, are unable to totally alleviate these symptoms, therefore role of non-pharmacological measures such as cognitive remediation therapy becomes critical. The findings of our study reflected the effect home based cognitive remediation could have on various executive functions as well as its overall effect on the quality of life. More such studies are required to substantiate these results so that such therapies can be used more often in the treatment of those with prominent cognitive symptoms, thus attempting to offer them a better quality of life. Another, findings of this study were home based cognitive retraining is feasible and caregivers can easily ensure the monitoring at home setting without any expert assistance. As homebased cognitive remediation is an effective intervention in schizophrenia by improving quality of life and limiting disability, the patients and their caregivers may be educated about the cognitive stimulation strategies to practice in the home setting for betterment of the patients.

Acknowledgements

We sincerely acknowledge the guidance of Dr. Shantala Hegde, Additional Professor and Clinical

Consultant (Neuropsychology), DBT/ Wellcome Trust India Alliance CPH, National Institute of Mental Health and Neurosciences, Hosur Road, Bangalore, Karnataka, India.

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