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Comparing the Efficacy of Interventions that use environmental supports to Improve Outcomes in Patients with Schizophrenia

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Abstract

We examined the efficacy of 2 treatments using environmental supports (e.g. signs, alarms, pill containers, checklists) to improve functional outcomes in individuals with schizophrenia. 120 participants were randomized into one of 3 treatment groups 1) Cognitive Adaptation Training (CAT; supports customized to individual cognitive impairments and behaviors and maintained on weekly home visits 2) Generic Environmental Supports (GES; a generic set of supports given to patients at a routine clinic visit and replaced on a monthly basis) and 3) treatment as usual (TAU). Functional outcomes, positive symptoms and motivation were assessed at baseline, 3, 6, 9, 18 and 24 months. After 9 months of intensive treatment with CAT, visits were decreased from weekly to monthly to examine whether treatment gains could be maintained. Results of a mixed effects regression model with repeated measures indicated a significant main effect of group (CAT>GES>TAU) with non-significant time and group by time interactions. Post-hoc analyses indicated that while individuals in CAT remained significantly better than those in TAU when treatment frequency was reduced, gains in CAT decreased to the level of those seen in GES. While group differences for positive symptoms were not significant, motivation improved in CAT and GES relative to TAU. The highest intensity treatment produced the best outcomes with respect to functioning. However, some improvements were seen with a relatively inexpensive, clinic-based treatment using a package of generic environmental supports.

Keywords

functional outcomes; Cognitive Adaptation Training; environmental supports; schizophrenia

1. Introduction

Schizophrenia is characterized by significant impairments in cognitive functioning that are related to the ability to perform basic activities of daily living and to social and role functioning (Gold and Harvey, 1993; Green et al., 1996; Saykin et al., 1991; Velligan et al., 1997). While environmental supports such as signs, checklists, alarms, and the organization of belongings

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have been used to bypass cognitive impairments in individuals with head injuries and mental retardation for many years and have been found to improve medication adherence in individuals with psychosis, (Benedict, 1989; Boczkowski et al. 1985; Epstein and Cluss, 1982; Sohlberg et al., 1993; Zygmunt et al., 2002), the comprehensive use of environmental supports has only recently been applied in a systematic manner in the rehabilitation of individuals with schizophrenia (Velligan et al., 2007).

Cognitive Adaptation Training (CAT) is a manual-driven series of environmental supports used to bypass deficits in cognitive functioning and improve community adaptation for individuals with schizophrenia (Maples and Velligan, in press; Velligan et al., 2000). CAT is customized for each individual based upon a comprehensive assessment of cognition, behavior and environment. Supports are established and maintained on weekly home visits. The treatment is described in detail in a series of articles (Maples & Velligan, in press; Velligan and Bow-Thomas, 2000; Velligan et al., 2000). In several randomized trials we compared CAT to treatment as usual and to a control condition in which individuals received weekly home visits and environmental changes that were unrelated to cognition. We found that individuals with schizophrenia who received 9 months of CAT treatment were hospitalized less often, had better adherence to medication, and improved to a greater extent in terms of community functioning and symptomatology than those in the other treatment groups (Velligan et al., 2000, 2007). In a small study of patients who were frequent users of high intensity services (e.g. crisis, hospital), we found CAT to be more effective in improving outcomes at a lower cost than Assertive Community Treatment, perhaps because aspects of the treatment (supports) were present in CAT in the absence of the treatment provider (Korell et al., 2002).

While CAT has been shown to be effective, it is somewhat labor intensive due to the need for weekly home visits. There is a great need to develop less labor intensive treatments using environmental supports to cue and sequence adaptive behavior (Velligan et al., 2006).

With this goal in mind, our research group has developed two strategies to reduce the costs of using environmental supports. First, we developed a treatment called Generic Environmental Supports. GES is a clinic-based treatment that provides a generic set of environmental supports such as calendars and pill containers to individuals at the time of their regular clinic visits. In GES, clients set up the supports on their own utilizing a tape recording made on a routine clinic visit where client discusses with their caseworker where and how to use the supports in the home environment. Supports are replaced monthly as needed. A previous article outlines the differences between CAT and GES (Velligan et al., 2006). Giving supports to clients at clinic visits is one way in which overburdened delivery systems that serve individuals with severe mental illness may attempt to provide "CAT" treatment at low cost. It is important to determine whether in home, customized treatment with supports is necessary for effectiveness or whether the same results could be achieved with lower cost models.

Another strategy to reduce the costs associated with CAT is to reduce the frequency of treatment visits after an initial treatment period. A decrease in the frequency of visits would free CAT therapist/trainers to take on new cases. In a recent study, we found that while gains in medication adherence remained when CAT home visits were stopped, functional gains were not maintained after 6 months (Velligan et al., 2006). Recent work by Brekke and colleagues (2007) indicates that individuals with severe mental illness have higher rates of improvement with more frequent rehabilitation visits and that more frequent visits may be compensating for some of the rate-limiting effects of cognitive deficits. Given these findings, it is important to examine whether treatment gains established in CAT can be maintained (possibly by environmental supports) when the frequency of visits is decreased.

In this study, we compare the efficacy of CAT and GES to standard treatment as usual (TAU) and investigate whether gains in CAT can be maintained when treatment frequency in CAT is reduced from weekly to monthly. We hypothesized that 1) patients in both CAT and GES would have better functional outcomes and lower levels of positive symptomatology and amotivation than patients in an assessment only condition, 2) patients in CAT would do better with respect to these outcomes than those in GES and 3) gains for patients in CAT would be maintained over a one-year period when the intensity of treatment was reduced.

2. Method

2.1 Subjects

Participants were outpatients recruited for an NIMH-funded trial examining the efficacy of environmental supports for improving outcomes in schizophrenia. Of 120 randomized, 113 had a baseline and at least one follow-up assessment and comprised the intent to treat sample for data analysis. See Figure 1 for a description of patient flow.

Subjects were identified through chart reviews by research staff credentialed at participating sites. In accordance with HIPAA requirements, a waiver was obtained through the university's institutional review board to allow research staff privileged at participating clinics to review basic diagnostic and demographic data and identify eligible individuals for study participation. After obtaining consent of the treating physician, research staff approached eligible individuals for participation. The researcher explained the study to prospective participants and answered any questions relating to participation. All participants signed a written consent form approved by the University's Institutional Review Board.

Subjects met the following inclusion criteria: Diagnosis of schizophrenia/schizoaffective disorder according to the Structured Clinical Interview for DSM-IV, between 18 and 60 years of age, receiving treatment with an atypical antipsychotic medication other than clozapine, no hospitalizations within the past 3 months, having a stable living environment for the past 3 months. Subjects were excluded if substance abuse interfered with their study participation (e.g. assessment or treatment), if they had a documented history of significant head trauma, seizure disorder, neurological disorder or mental retardation, if they were currently being seen by an Assertive Community Treatment Team, if they had a history of violence in the past one year period, or if they had a score on the Social and Occupational Functioning Scale greater than 80 indicating a high level of adaptive functioning.

57 subjects were male and 56 were female. 45 were Hispanic, 44 were Non-Hispanic White, 24 were African-American, or from other or mixed ethnic groups. Mean age of participants was 41.0 (S.D. = 9.1).

2.2 Design

Following a baseline assessment, subjects in standard medication and case management were randomly assigned to one of three treatments 1) CAT, 2) GES or 3) treatment as usual (TAU). The treatment period lasted for 24 months. In CAT, after an initial 9 months of weekly home visits, visits were decreased in frequency from weekly to monthly from months 9–12 and participants were seen monthly through 24 months. Assessments were conducted at baseline and 3, 6, 9, 18 and 24 months follow-up.

2.3 Treatment Groups

2.3.1. CAT—Cognitive Adaptation Training is a manual-driven series of compensatory strategies based upon neuropsychological, behavioral, and occupational therapy principals (Velligan et al., 2000). Prior to participating in CAT, all patients receive comprehensive

behavioral, neuropsychological, functional, and environmental assessments. These assessment procedures described in detail elsewhere, form the basis for the treatment plan (Velligan et al., 2006; Maples & Velligan, in press).

CAT treatment plans are customized for each person's level of apathy versus disinhibition and each individual's level of impairment in executive functions (the ability to plan and carry out goal-directed activities (Velligan et al., 2006). Behaviors characterized by apathy can be altered by providing prompting and cueing to initiate each step in a sequenced task. For example, CAT therapists may provide checklists for tasks which involve complex behavioral sequencing or place signs and equipment for daily activities directly in front of the patient (e.g., a checklist for cleaning the kitchen). Individuals who exhibit disinhibited behaviors respond well to the removal of distracting stimuli and behavioral triggers and to redirection. For example, a CAT therapist may help to discourage wearing clothing that is inappropriate for the weather by working with the individual to place such items in a container under the bed. Individuals with mixed behavior (apathy and disinhibition) are offered a combination of these strategies.

Individuals with greater degrees of executive impairment are provided a greater level of structure and assistance and more obvious environmental cues (larger, brighter, more proximally placed). Individuals with less impairment in executive function can perform instrumental skills adequately with less structure, and more subtle cues. These general plans are adapted for individual strengths or limitations in other cognitive areas. Interventions are explained, maintained and altered as necessary by brief (30 minute) weekly visits from a CAT trainer. After 9 months, treatment was decreased during months 9–12 from every week, to every other week and then to monthly. All patients were seen monthly from month 12–24.

2.3.2. GES—General Environmental Supports (GES) is a manual-driven series of environmental supports offered to patients at their regular clinic visit. The GES package was designed using the supports that were most frequently used and described as most helpful by clients in the CAT program. In addition, supports selected for the GES package were those that required minimal training to use. Supports for GES included, an alarm clock, a watch, bus passes (in marked envelopes for specific destinations), a checklist of everyday activities (e.g. taking medication, showering), hygiene products (e.g. shampoo, toothpaste), pill containers, reminder signs (e.g. "Did I take my medication?"), and a bookstore gift card (for leisure activities (Velligan et al., 2006)).

In the present study, GES therapists offered the same supports to all subjects and provided instructions on how to use each item. The GES therapist discussed with the client where to place signs to get maximum benefit, and how to set use watches, alarms, bus passes and pill containers. The session was audio taped and the client was given both the tape and the tape-recorder to replay the instructions any time. Once monthly, the therapist called the client and asked if the client needed any replacement supplies. If supplies were needed, the client picked them up from the clinic. For some patients, for the purposes of the study, supports were dropped off at the client's home.

2.4 Assessments

Symptom and functional assessments were administered by Bachelor's, (n=4) and Master's level (n=5) psychologists required to reach a criterion of .80 intraclass correlation coefficient on a combination of video recorded and live interviews for each assessment prior to making ratings. In addition, all raters were observed in assessment interviews at regular intervals throughout the trial to ensure standardized and competent administration of all scales. Regular meetings were held to prevent rater/scorer drift as recommended by Ventura et al., (1993).

Adaptive Functioning—The primary outcome variable for the study was the Social and Occupational Functioning Scale (SOFAS) (DSM-IV; APA, 1998). This instrument assesses the overall level of function on a scale from 1 to 100 based upon social, school and work functioning. Higher scores indicate better adaptive function. The SOFAS score was based upon all information obtained during several hours of assessments conducted by blinded raters.

As a secondary measure of adaptive functioning we utilized scores on the Multnomah Community Ability Scale (MCAS). The MCAS is a 17-item scale assessing a variety of domains of community adjustment following a lengthy interview with the participant. Higher scores reflect better community functioning.

Positive symptomatology was assessed using the Psychosis Factor from the Brief Psychiatric Rating Scale-Expanded version (BPRS) which rates psychosis symptoms on a 7-point scale ranging from 1 (absent) to 7 extremely severe. Motivation (a subscale of the Negative Symptom Assessment; Alphas et al., 1989) was utilized to examine the effect of treatment on motivational difficulties and participation in activities. Previous studies demonstrated improvements on the motivation difficulties subscale with CAT in comparison to an active control and treatment as usual (Velligan et al. 2006). The motivation subscale is composed of items assessing grooming, interests, engagement in activities, and sense of purpose. Lower scores indicate fewer motivational problems.

2.5 Treatment Blinds

In an effort to maintain treatment blinds, all subjects and collaterals were asked at the beginning of each assessment neither to divulge information about any visits made by staff of the research project nor to refer to any items they may have received as part of the study. If blinds were broken, alternative raters blind to group assignment completed the remaining assessments

2.6 Data Analysis

We examined distributions for normality and homogeneity of variance and used transformations where necessary to meet the assumptions of the statistical models. The primary outcome variable was the score from the social and occupational functioning scale. Secondary variables were a more detailed measure of functional outcome (MCAS) and measures of positive and negative symptoms. We examined group differences in functional outcomes (SOFAS score and MCAS) and symptomatology (BPRS positive symptom score NSA motivation over time (3, 6, 9, 18, 24 months) by treatment group (CAT, PharmCAT, Treatment as Usual) using mixed effects regression with repeated measures (SAS PROC MIXED; Cary Institute 1990). A random subject effect was included modeling intercept, linear and quadratic trend components. Baseline scores were used as covariates in the model. Group differences were tested by estimating group means at each of the assessment points from the model using an overall F test and pair-wise t tests at points of interest. Graphs of outcome variables depict lines generated from random regression model estimates and include the common baseline (covariate).

A priori power calculations were based upon the results obtained from pilot data for both functional and positive symptom measures (Velligan et al., 2002). In the pilot study, large effect sizes (greater than or equal to .8) were found between CAT and TAU for both types of measures. Therefore, in the current study, we estimated the power of detecting similar large effect size differences as significant using a two-sided alpha of .01 with a final sample size of 40 per group to be between .80 and .96 (Lipsey, 1990).

To investigate whether statistically significant effects were clinically meaningful, effect sizes were calculated for the primary outcome utilizing the standard deviation for the outcome

variable in the control group pooled over time. This standard deviation represents an estimate of the population standard deviation in a treatment as usual condition.

3. Results

Baseline characteristics for the three treatment groups are presented in Table 1. There were no statistically significant differences between groups with respect to any of these demographic or clinical variables at the time of initial assessment. There were no differences in baseline variables for subjects making it to randomization versus those who dropped prior to randomization (all p 's >0.33).

The numbers of subjects participating at each assessment point were as follows: baseline $n=113$; 3 month $n=112$, 6 month $n=109$, 9 month $n=108$, 12 month $n=89$ and 15 month $n=65$. Based upon results of a proportional hazards regression model, differences between groups with respect to drop out rates were not statistically significant $X^2(2)=1.01$; $p<.60$). By the end of 24 months, 31%, 37% and 17% of participants dropped out of TAU, GES, and CAT respectively.

3.1 Functional Outcomes

Results of a mixed effects regression model examining treatment group differences over time on SOFAS scores indicated a main effect for group with non-significant time and treatment by time effects. See Figure 2. Planned comparisons suggested that the CAT group differed significantly from TAU and from GES. GES also differed significantly from TAU. An inspection of means indicates the best functioning for participants in CAT, followed by those in GES, followed by those in TAU. Averaged across the time points, the effect sizes for CAT and GES compared to treatment as usual were 1.10 and .73 respectively. According to Cohen's conventions, (Cohen, 1988) these are large and medium to large treatment effects respectfully.

Results of a mixed models analysis of change scores (baseline to each follow-up time) indicated that TAU scores worsened significantly and CAT scores improved significantly from baseline to 3 months and that differences for both groups from baseline remained significant throughout follow-up. This indicates that both an improvement in CAT which was seen early and maintained and a worsening in TAU contributed to the significant group effect.

While there was no significant treatment by time interaction, we were interested in determining whether functional gains made in CAT treatment persisted when the frequency of treatment was reduced from weekly to monthly. The overall F test would not be sensitive to changes at the specific time point of interest. As illustrated in Figure 2, SOFAS scores for participants in CAT decreased from the end of intensive treatment, while scores during the same time period increased for individuals in GES and TAU. Therefore, we used a specific post-hoc analysis comparing the trend lines for treatment groups from months 9 to 18. Results indicated that the trend for CAT was significantly different than the trend for the other two treatment groups in which no changes were made to the treatments ($P<.03$). While this analysis is post-hoc, results suggest that gains made by patients in CAT may be reduced once the frequency of visits is decreased. However, functional outcomes for individuals in CAT remain better than for those in TAU.

As a secondary measure of functional outcome, we examined scores on the MCAS over time by treatment group. Results of a mixed effects regression model indicated a non significant trend for a main effect of group, with non-significant effects of time and treatment by time ($F(2, 106)=2.85$; $p<.06$; ($F(4, 88.7)=.78$; $p<.55$; and $F(8, 125)=1.51$; $p<.17$; respectively). Planned comparisons suggested that only the CAT group differed significantly from treatment

as usual ($t = -2.66$; $p < .02$ CAT). CAT and GES were not significantly different. However, a specific test of the linear hypothesis $CAT > GES > TAU$ was significant ($P < .01$).

3.2 Symptomatology

Results of a mixed effects regression model examining the psychosis factor from the BPRS over time by treatment group indicated no statistically significant effects for group, time or group by time (all p 's $> .17$). Results of a mixed effects regression model examining the motivation factor from the NSA over time by treatment group indicated a significant main effect of group with no significant effects of time or group by time. Planned comparisons indicated that both CAT and GES differed significantly from TAU. The active treatments were not significantly different from one another. Results are illustrated in Figure 3.

4. Discussion

This is the first randomized, double blind trial to examine the efficacy of CAT and 2 methods for decreasing the intensity of this treatment. Data from both a global measure and from a more detailed community adjustment scale are consistent with previous studies indicating that CAT improves functional outcomes (Velligan et al., 2000, 2007). There is some evidence that treatment gains in CAT on a global measure of functional outcome may be reduced when visit frequency is decreased from weekly to monthly. While these data are post-hoc and must be interpreted with caution in the context of a non-significant treatment group by time interaction, they are suggestive that more intensive treatment may be needed to maintain some of the gains achieved in CAT for some individuals. Results suggest that the largest effects on functional outcomes are found with the most intensive, individualized treatment. However, these functional improvements may not always represent learned behavior but rather, may be maintained by cueing from environmental supports and the reinforcement of weekly home visits.

It is important to note that both a significant improvement for individuals in CAT from the common baseline to the 3 month follow-up which was sustained through out the study and a significant worsening for individuals in TAU from the common baseline were responsible for the overall significant group effect. It is unclear why individuals in TAU worsened with respect to functional outcomes. It may be that with low intensity treatment in the public sector some individuals have difficulty maintaining a stable functional status.

This is the first study to suggest that improvement or less deterioration in functional outcome for patients with schizophrenia may be possible with a clinic-based treatment that provides a generic set of environmental supports. The impact of GES on functional outcome was less robust than that of CAT as evidenced by a smaller effect size in comparison to treatment as usual for a global measure of functional outcome (SOFAS) and no significant differences from treatment as usual on a more detailed measure of community adjustment (MCAS). Previous research indicates that only about 45% of the supports provided in GES are utilized by participants (Velligan et al., 2006). It may be that customizing supports based on comprehensive assessment at treatment initiation as in CAT, and delivering supports in a clinic setting as in GES would allow greater benefits for GES without the costs associated with weekly home visits.

This is the second large scale study to find no significant effect of CAT on positive symptoms. Data do not support original findings that patients in CAT had lower levels of positive symptomatology (Velligan et al., 2000, 2007). In stable outpatients with a mean level of positive symptomatology in the mild range at baseline, it may be difficult to demonstrate improvements in positive symptoms.

In agreement with previous studies, environmental supports designed to cue appropriate behaviors were associated with improvements in the motivation factor of the Negative Symptom Assessment. Both CAT and GES improved the motivation factor relative to TAU. This suggests that participants in CAT and GES may be responding to environmental cues with greater participation and interest in activities.

The study results must be interpreted in the context of its methodological limitations. Participants in the study had been ill on average for more than a decade. The extent to which these techniques would be helpful to individuals with a more recent onset of schizophrenia should be examined in future research. Negative symptoms on the NSA were rated irrespective of their origin. The extent to which improvements in motivation as assessed by the NSA reflect improvements in predominantly primary negative symptoms (Carpenter, 1996) or secondary negative symptoms (those caused by factors other than schizophrenia such as medication side effects, depression, and withdrawal due to disorganization or paranoia) is unclear (Arango et al., 2004).

Based upon the results of this study, the use of environmental supports in CAT and GES can improve functional outcomes and motivation. It will be important to investigate individual differences that may lead specific patients to benefit from CAT or GES. There may be a subset of individuals who can maintain gains with CAT treatment when intensity is reduced. Future research will be needed to identify characteristics that may lead to maintenance of functional gains in CAT when treatment frequency is reduced. It may be that combining the comprehensive assessment in CAT with the clinic-delivery of GES would produce a hybrid that will help patients improve functional outcomes at a reasonable cost. Moreover, it is important to note that clinicians for GES treatment contacted clients monthly to determine which supports needed to be replaced. It is unclear if GES would have a similar effect if clinic appointments were spaced farther apart than monthly. In some settings, clients may be seen only once every 3 months. Monthly maintenance may be important in the effects of GES. These issues will be investigated in future studies. It would also be important to examine CAT in comparison to skill building approaches for initial treatment effects and maintenance of treatment gains.

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Figure 1.
Patient flow

Figure 2.

Social and Occupational Functioning Scale Scores Over Time by Treatment Group

Main Effect of Group $F(2,106) = 22.61$; $p < .0001$

Main Effect of Time: $F(2,296) = 0.12$; $p < .98$

Treatment Group X Time: $F(4,166) = 1.12$; $p < .35$

CAT vs. TAU and GES $t = -6.57$; $p < .0001$ and $t = -2.20$; $p < .03$; respectively GES vs. TAU ($t = -4.41$; $p < .0001$)

Figure 3.

Motivational Difficulties Subscale from the Negative Symptom Assessment Over Time by Treatment Group

Main Effect of Group $F(2,104) = 5.41$; $p < .0058$;

Main Effect of Time $F(4, 291) = 0.41$; $p < .81$;

Treatment Group by Time Interaction $F(8,318) = 1.17$; $p < .32$.

CAT vs TAU $t(1,103) = 2.14$ $p < .04$

GES vs TAU $t(1,105) = 3.22$; $p < .002$

CAT vs TAU $F(1,105) = 1.04$ $p > .30$

Table 1

Baseline characteristics by Treatment Group

	Treatment as Usual (n=39)	GES n = (38)	CAT n = (36)
% male	48.72	50.00	50.00
% Hispanic	35.90	42.11	41.67
% Non-Hispanic White	35.90	34.21	47.22
Age	40 (S.D. = 9.3)	42 (S.D.= 9.9)	41 (S.D.= 7.8)
Education	11.7 (S.D. = 1.8)	12.2 (S.D.=1.7)	12.6 (S.D.= 1.8)
BPRS Psychosis Factor	2.8 (S.D. = 1.4)	2.7 (S.D. = 1.4)	2.8 (S. D. = 1.2)
NSA Motivation Factor	14.6 (S.D. = 3.7)	14.3 (S.D. = 4.1)	14.1 (S.D. = 4.3)