Published in final edited form as:

Psychiatry Res. 2009 July 30; 168(2): 94–101. doi:10.1016/j.psychres.2008.03.016.

The short term impact of generic versus individualized environmental supports on functional outcomes and target behaviors in schizophrenia

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Abstract

We examined the short-term efficacy of 2 treatments using environmental supports (e.g. signs, alarms, pill containers, checklists) to improve target behaviors in individuals with schizophrenia. 120 participants were randomized into one of 3 treatment groups 1) Cognitive Adaptation Training (CAT; a manual-driven set of environmental supports customized to individual cognitive impairments and behaviors and established and maintained in participants' homes on weekly 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; standard follow-up provided by a community mental health center). Global level of functional outcome and target behaviors including orientation, grooming and hygiene, and medication adherence were assessed at baseline and 3 months. Results of an analysis of covariance indicated that patients in both CAT and GES had better scores on global functional outcome at 3 months than those in TAU. Results of Chi Square analyses indicated that patients in CAT were more likely to improve on target behaviors including orientation, hygiene, and medication adherence than those in GES. Irrespective of treatment group, individuals who were high utilizers of environmental supports were more likely to improve on target behaviors than individuals who were low utilizers of supports.

Keywords

environmental supports; Cognitive Adaptation Training; schizophrenia; functional outcome

1. Introduction

Cognitive deficits in attention, memory, and executive functions are core features of schizophrenia that predict multiple domains of community outcome (Saykin et al., 1991; Gold

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and Harvey, 1993; Green 1996; Velligan et al., 1997; Velligan and Bow-Thomas, 1999; Velligan et al., 2000a). Environmental supports such as signs, checklists, provision of supplies, and the organization of belongings have been used to bypass cognitive impairments in an effort to improve functional outcomes for patients with schizophrenia. We have developed two different interventions utilizing environmental supports; Cognitive Adaptation Training and Generic Environmental Supports.

Cognitive Adaptation Training (CAT) is a manual-driven series of environmental supports (signs, checklists, supplies, organization of belongings) designed to bypass problems in attention, memory, and executive functions, cue and sequence appropriate behaviors, and discourage inappropriate behavior in the home environment (Velligan and Bow-Thomas, 2000; Velligan et al., 2000a, 2006b; Velligan et al., in press). CAT treatment plans are based upon the results of a comprehensive assessment of cognitive abilities, behavior, functional ability and the patient's environment. CAT supports are offered to the client during home visits on a weekly basis to address specific problems including poor hygiene, care of living quarters, medication adherence, and lack of social or leisure activities. The treatment is described in detail in a series of articles (Velligan et al., 2000b, 2002, 2006b; Maples and Velligan, in press; Velligan et al., in press) we found that schizophrenia patients who received CAT improved to a greater extent in terms of community functioning than those in control or treatment as usual groups (Velligan et al., 2000b, 2002, 2006b).

Generic Environmental Supports (Velligan et al., 2006b) is a generic set of environmental supports including hygiene supplies, pill containers and calendars offered to individuals at the time of their regular clinic visits. In GES, the client is expected to set up the supports on their own utilizing a tape recording of the therapist discussing with the patient where and how to use the supports in the home environment. We included in GES the supports that were used most often in CAT. Because CAT requires weekly home visits, we were aware that the cost of the treatment could be prohibitive for large, under-funded, understaffed community agencies which typically serve those with serious mental illnesses. GES was developed to address this issue.

Specific differences between CAT and GES are outlined below. CAT supports are established and maintained by a CAT trainer on weekly home visits whereas GES supports are expected to be set up by the patient, and are replaced monthly as needed at regular clinic appointments. In addition, CAT visits are conducted weekly for 9 months, while GES visits occur monthly with regular medication follow-up visits. CAT treatment is individualized based upon the results of a comprehensive assessment of cognitive performance, behavior, and adaptive functioning, whereas no specific testing is required for GES and all consumers in GES get the same kit of environmental supports. The number of targeted behaviors in CAT is larger based upon specific functional problems identified in the assessment process, while GES targets a smaller number of basic skills (Velligan et al., 2006b).

The effect of GES on functional outcomes has not been evaluated to date. However, preliminary data from the current study compared the rates of utilization of environmental supports in these two treatments. Results indicated that patients in CAT were more likely to use environmental supports than those in GES (Velligan et al., 2006b). Rates of utilization were approximately 80% for CAT about 45% for GES during the first 3 months of treatment.

While CAT has been found to improve global levels of functional outcome, we have no information on the efficacy of GES. Moreover, there is no published evidence that targeted behaviors such as grooming and hygiene improve with the use of environmental supports in either CAT or GES. Finally, there are no data examining the relationship between improvement in target behaviors and the utilization of supports.

The present study is a randomized, rater-blinded, clinical trial examining the efficacy of CAT, GES, and treatment as usual (TAU) for improving functional outcomes and target behaviors for individuals with schizophrenia. For the current paper, we examine the short term efficacy of these treatments from baseline to 3 months. Since CAT is labor intensive, it is important to show improvements early in treatment. In addition, we examine the relationship between utilization of supports and improvement in target behaviors. We hypothesized that both CAT and GES would have a greater impact upon global functional outcome than treatment as usual, that patients in CAT would be more likely to improve in global functioning and in targeted behaviors than those in GES, and that individuals who utilized supports to a high degree would be more likely to improve than those who did not use the supports to a high degree irrespective of treatment group.

2. Methods

2.1 Study Design

Participants were outpatients with schizophrenia or schizoaffective disorder who were receiving medication and routine follow-up care at community clinics. They received a baseline assessment and then were randomized to one of 3 treatment groups; 1) Cognitive Adaptation Training (CAT—individualized supports established on weekly visits in the clients' homes, 2) Generic Environmental Supports (GES—a generic group of environmental supports provided at a routine clinic visit, or 3) Treatment as Usual (TAU—no additional treatment beyond standard medication follow-up). Participants were reassessed after 3 months of treatment.

2.2 Subjects

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, and living in a stable 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.

Of 230 subjects who were approached for consent, 140 were consented, of these 120 were randomized. 19 dropped prior to participating in the baseline assessment and one dropped after baseline prior to being randomized. Of the 120 randomized patients, 113 had both baseline and 3 month follow-up data; 39 in Treatment as Usual, 38 in GES and 36 in CAT. Utilization data were available on 34 out of 36 CAT patients and 35 out of 38 GES patients. Problems with contacting patients by telephone or the lack of telephone service to the patients' homes prevented assessment of utilization for 5 individuals.

2.3 Treatment Groups

CAT—Cognitive Adaptation Training is a manual-driven series of compensatory strategies based upon neuropsychological, behavioral, and occupational therapy principals (Velligan et al., 2000b, 2002). Prior to participating in CAT, all patients receive comprehensive behavioral, neuropsychological, functional, and environmental assessments. These assessment procedures are described in detail elsewhere (Velligan et al., 2000b, 2002).

CAT treatment plans are based upon two dimensions: (1) level of apathy versus disinhibition, and (2) level of impairment in executive functions (the ability to plan and carry out goal-

directed activities). The development of CAT treatment plans are described by Velligan and Bow-Thomas (2000). 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 medication placed on the refrigerator, an alarm set to prompt leaving for an appointment). 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 taking of multiple doses of medication at the same time by placing pills in single dose containers, or remove old and outdated medications to be stored elsewhere. 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. Detailed progress notes listed all supports provided and their intended target behaviors.

Generic Environmental Supports—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 based upon 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 needed to require minimal training. Supports for GES include, an alarm clock, a watch, bus passes, 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).

The GES therapist offered the same set of supports to all participants 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 and/or use watches, alarms, 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 only, supports were dropped off at the client's home.

Utilization—on a monthly basis, a utilization researcher (UR) phoned each patient in CAT and GES. The UR used treatment notes, and store receipts to determine all supports provided during the preceding one month period for patients in CAT. For patients in GES, the UR used the original item list for the package and the GES therapist's notes regarding which items were supplied in the past month. For each monthly call, the UR asked the subject whether they had used each support over the past 7 days and exactly how the support was used. In an effort to prevent the subject from making his or her therapist “look good”, the subject was told at the beginning of each call that the information provided would not be shared with the CAT or GES therapist. Based upon the information provided, the utilization researcher categorized “use” as a dichotomous variable (yes or no), and also calculated a percentage of utilization based upon the intended use of the support. For example, if an item was intended to be used daily and it was used 4 out of 7 days, the percentage of utilization for the item would be 4 divided by 7 or 57%. A mean utilization score for each UR contact was generated by averaging the percentages for each item, and then the UR contacts for the 3-month period were averaged. These procedures are described in detail in a previous article. (Velligan et al., 2006b) We divided

participants in treatment into high and low utilizers of supports on the basis of the utilization percentage across the 3 month period. High utilizers had utilization scores of 75% or higher. This corresponds to cutoffs for medication treatment in which good adherence is typically defined as taking between 70 and 80% of prescribed medication (Velligan et al., 2006b).

2.4 Assessments

The primary outcome variable for the study was the Social and Occupational Functioning Scale (SOFAS) (American Psychiatric Association, 1994). This instrument assesses the overall level of function on a scale from 1 to 100 based upon social, school and work functioning. Symptoms are not considered in the rating. Higher scores indicate better adaptive function. The SOFAS score was based upon all information obtained during several hours of assessments conducted by blinded raters. Additional assessments were utilized to examine changes in specific target behaviors. The Brief Psychiatric Rating Scale-Expanded version (BPRS) rates a series of symptoms on a 7-point scale ranging from 1 (absent) to 7 extremely severe (Ventura et al., 1993). The Negative Symptom Assessment rates a series of negative symptom behaviors on a scale ranging from 1 (absent) to 6 (extremely severe) (Alphs et al., 1989). The Multnomah Community Ability Scale is a 17-item scale assessing a variety of domains of community adjustment (Barker et al., 1994). Higher scores reflect better community functioning. Item 14 on this scale assesses the regularity with which medication is taken. Ratings from these additional assessments were used to examine improvements in target behaviors.

Target behaviors—Target behaviors were identified from the GES treatment manual and specific items were chosen from the battery of assessments to represent each target behavior. Three primary behavioral targets were identified that were addressed regularly in CAT and addressed by more than one support in GES treatment. These included: Medication Adherence, Orientation & Scheduling, and Grooming & Hygiene. While a bookstore gift card is given to GES participants in an effort to promote leisure activity, and there is a checklist item that is intended to prompt social behavior, these areas of functioning are not well addressed in GES. Including these items in analyzing group effects between CAT and GES would favor the CAT group. The targeted behaviors investigated and the assessments and items utilized to determine improvement are listed in Table 1. Note that the interventions under Orientation & Scheduling address both these targets. However, the rating scale measures focus only on orientation.

Criteria utilized to classify subjects as “impaired” on each item at baseline were determined “a priori” as were the criteria utilized to classify “improvement versus non-improvement” at 3 months. Each criterion is listed in Table 1. Improvement versus non-improvement for each target was identified based upon the difference between the baseline score and the score received for that target at 3 months on structured assessments conducted by blinded raters. Only subjects scoring in the “impaired” range at baseline were included in the analysis for each target behavior. If a subject was not impaired, the area was not addressed by the CAT therapist. In addition, if a subject was not impaired, he or she would not be expected to use the supports included in the GES packet to address that problem. Each patient identified as improving on one or more specific target behaviors was identified as an improved patient for the purpose of data analysis.

2.5 Rater Training

All raters were research assistants who participated in a comprehensive rater training and quality assurance program conducted by the PI. Prior to rating participants in the study, each rater was required to reach a criterion of .80 intraclass correlation coefficient on a series of videotaped and live interviews for each of the rating instruments. Throughout the study, raters were observed by the study coordinator during subject assessments to evaluate and improve their skills for eliciting necessary information and scoring accurately. In addition, monthly

quality assurance meetings were held throughout the study to prevent rater drift. Procedures were modeled after those developed for the expanded version of the Brief Psychiatric Rating Scale (Ventura et al., 1993).

2.6 Data Analysis

Differences in functional outcome over time by group (CAT, GES, TAU) were assessed using analysis of covariance for mixed models. The baseline SOFAS score was used as the covariate, and the outcome was the score on the SOFAS at 3 months. For the active treatment groups CAT and GES, we examined differences by group in rates of utilization for overall use of supports with a t test. While a preliminary analysis was published on a subset of participants, this analysis was repeated on the completed sample and results are presented here. With respect to target behaviors, we used 2 X 2 chi square analyses to compare to proportions of patients considered high versus low utilizers of environmental supports and proportions of patients classified as improved versus not improved on specific target behaviors at 3 months. This analysis did not consider group assignment. We then examined the relationship between group assignment and improvement in a 2 X2 chi square analysis. These analyses were two-tailed and the level of significance was set at .05.

3. Results

3.1 Descriptive and Baseline data

Baseline characteristics of the sample appear in Table 2. There were no statistically significant differences between groups with respect to any of these variables at the time of initial assessment. There were no differences in demographic variables for subjects who dropped prior to 3 months versus those with 3 month data (all p's >0.33).

We conducted an analysis of covariance for mixed models on SOFAS scores by group (CAT, GES, TAU) following 3 months of treatment. Results illustrated in Figure 1 indicate a main effect of group ($F_{(2,108)} = 15.61$; $p < .0001$). Planned comparisons suggested that the CAT group differed significantly from the assessment only group and had a higher mean SOFAS score at 3 months taking into account baseline functioning ($t = 5.54$; $p < .0001$). In addition, patients in GES differed significantly from those in the control condition and had higher scores on the SOFAS at 3-months taking into account baseline functioning ($t = 3.05$; $p < .003$). There was a non-significant trend for the active treatment groups to differ from one another ($t = 2.24$; $p < .09$).

3.2. Utilization

Consistent with the previous report, results of a t-test indicated that participants in CAT used a higher proportion of supports than those in GES ($t = -5.7$; $p < .0001$). Rates of utilization were 83.3% and 49.8% in CAT and GES groups respectively. 22/34 CAT patients or 65% were high utilizers versus 8/38 or 21% of individuals in GES.

3.3 Target behaviors

Participants who were initially classified as impaired on any one of the three target behaviors were grouped as improved or not improved on the basis of the criteria for each target behavior provided in Table 1. The numbers of individuals meeting criteria for impairment appear in Table 2. More of those in CAT and TAU met criteria for initial impairment in these specific target behaviors than those in GES ($X^2 = 6.75$; $p < .03$). In addition, participants in CAT and GES were divided into high and low utilization groups based upon a cutoff score of 75% utilization of items provided. Results indicated that patients who utilized the supports to a greater degree irrespective of treatment group were more likely to be classified as improvers

on specific target behaviors than those who used the supports less frequently. Over 93% of high utilizers (14/15) improved on at least one targeted behavior versus only about 53% of low utilizers (9/17; $X^2=7.1$; $p<.007$). Among high utilizers, of the 12 patients impaired on medication adherence, 9 improved, of the 3 patients impaired on orientation 1 improved, of the 6 patients impaired on hygiene, 4 improved. In addition, patients in CAT (18/22; 63.0%) were more likely to improve on specific target behaviors than those in GES (6/13; 37.1%; $X^2=4.77$; $p<.03$).

4. Discussion

The results of the study provide evidence that CAT and GES improve global functional outcome for patients with schizophrenia in the short term. Significant gains in global functional outcome compared to standard treatment are observed as early as 3 months. Because CAT is fairly labor intensive, it is important that treatment gains in CAT are realized early. Surprisingly, treatment gains in GES which is a far less labor intensive treatment are also noted after 3 months. Whether these gains are maintained with longer term treatment will be examined in future analyses. This is the first study to demonstrate that CAT improves targeted behaviors such as orientation and hygiene. Fewer participants in GES were classified as improvers on target behaviors than were participants in CAT. This may have been due to the relative low rates of utilization in GES compared to CAT (Velligan et al., 2006b). This idea is supported by the fact that individuals who use environmental supports frequently as indicated are more likely to improve with respect to target behaviors than individuals who do not use supports regularly, irrespective of treatment group. The results support the notion that if environmental supports are utilized by patients, important functional improvements may be observed.

This is the first evidence that providing a generic set of environmental supports to patients may improve functional outcome. The effect of GES should be further investigated, particularly because the cost of GES treatment which does not involve comprehensive assessment and weekly home visits is far lower than that of CAT. Ways to improve levels of utilization of supports in GES need to be investigated.

Several methodological limitations should be kept in mind when reviewing these findings. Utilization researchers were aware of treatment group assignment when asking about the use of supports provided. We attempted to balance this by using data obtained by blinded raters to classify both impairment and improvement on target behaviors. A patient identified as an improver, could have improved on one to three of the target behaviors examined. The numbers of participants classified as impaired at baseline on individual target behaviors were not large enough to analyze these behaviors separately. Moreover target behaviors examined basic activities of daily living. Examining higher level behaviors for patients in CAT will be important in future studies. When examining improvements in specific target behaviors for patients starting in the "impaired" range, regression toward the mean may have accounted for some of the improvement in patients with high rates of utilization. However, it is unclear why regression to the mean would not be equally observed in patients with low rates of utilization. With respect to medication adherence, the rating used to classify patients is primarily based upon detailed self-report of pill taking behavior. While there are multiple problems with self-report data on medication adherence, patients who say they do not take medication regularly are typically accurate in their report. However, those who say they take medication regularly may overestimate their adherence (Velligan et al., 2003, 2006b). Data from another clinical trial examines the issue of medication adherence in CAT using more objective assessments of adherence including unannounced, in home pill counts and pharmacy records (Velligan et al., in press). Finally, this manuscript examined only the first 3 months of treatment. It is possible that the effect of environmental supports in a less intensive treatment such as GES would

decrease over time after the novelty of items wears off. This issue will be investigated in the larger study.

This study extends previous research on the use of environmental supports and opens new directions for future research. If the use of supports in GES could be improved, it is possible that this relatively inexpensive, clinic-based treatment could be more effective in improving functional outcomes. A novel treatment designed to train patients in the use of environmental supports in a clinic-based group format has shown some promising early results (Twamley et al., in press). In addition, to increasing the use of supports, it will be important to examine the maintenance and trajectory of improvements in functional outcomes in longer term studies.

Acknowledgements

This work was supported by a grant from the National Institute of Mental Health R01 MH61775. The author was supported during the writing of this manuscript by grants R01 MH62850 and R01 MH074047. We would like to thank the Center for Health Care Services staff and the study participants for their continued support of our research program.

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Fig. 1.
Social and Occupational Functioning Scale score.

Table 1

Target behaviors and improvement

Target Behavior	Assessments Items and Baseline Cutoff Score for Impairment	Criterion for Improvement
Medication Adherence (Higher scores=better adherence)	MCAS- Medication Adherence Item-A score of 1, 2 or 3 (never, seldom or sometimes takes medication) on a 5 point scale	Improvement of 1 point or greater on the 5-point scale.
Orientation (Lower scores=better orientation)	BPRS Disorientation Item- a score of greater than or equal to 5 (moderately severe impairment) NSA Temporal Disorientation Item- a score of greater than or equal to 4 (suggesting a moderate problem.)	Improvement of one point or more on the 7-point scale. Improvement of one point or more on the 6-point scale
Grooming & Hygiene (Lower scores=better grooming)	BPRS Self-Neglect Item- A score of greater than or equal to 5 NSA Poor Grooming Item-A score of 4 or greater	Improvement of 1 point or more on the 7-point scale. Improvement of 1 point or more on the 6-point scale.

Table 2

Baseline Characteristics by Treatment Group

	Treatment As Usual (n=39)	GES n = (38)	CAT n = (36)
% male	51.3	50.0	50.0
% Hispanic	36.0	42.1	41.7
% Non-Hispanic White	36.0	34.2	47.2
Age	40 (S.D. = 3.3)	42 (S.D.= 9.9)	41 (S.D.= 8.0)
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)
Social and Occupational Functioning Scale	45.6 (S.D. = 9.4)	46.3 (S.D. = 11.1)	44.1 (S.D. = 10.2)
Number Impaired on orientation	7	2	5
Number Impaired on hygiene	10	5	11
Number Impaired on medication adherence	14	10	17
Impaired on any target behavior	22	13	22