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A pilot study of functional Cognitive Behavioral Therapy (fCBT) for schizophrenia

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Abstract

Background: The feasibility and preliminary efficacy of a novel cognitive behavioral treatment for decreasing psychotic symptoms and improving social functioning was evaluated in a pilot study. This represents the first treatment outcome study of CBT for psychosis with a manualized, active comparison condition.
Methods: Thirty outpatients with schizophrenia or schizoaffective disorder, depressed type with residual psychotic symptoms were randomly assigned to either 16 weekly sessions of functional cognitive behavioral therapy (fCBT) or psychoeducation (PE) with assessments conducted at baseline and post-treatment by blind evaluators.
Results: Attrition was only 7% and did not differ between fCBT and PE, indicating good tolerability of both treatments. For this sample with persistent symptoms, between groups effects were not significantly different, but within group effect sizes indicated greater treatment benefit for fCBT on positive symptoms, particularly for the PSYRATS voices subscale.
Conclusion: The results suggest that fCBT is well tolerated and holds promise for reducing persistent positive symptoms.

Keywords: Schizophrenia; Therapy; Cognitive-behavioral therapy

1. Introduction

The need for improved treatment of schizophrenia is underscored by high rates of residual positive symptoms in medication-treated individuals (Kane and Marder, 1993; Pantelis and Barnes, 1996; Wiersma et al., 1998), suboptimal medication adherence in the majority of patients (Fenton et al., 1997), and the burden to patients and caregivers of subjective distress, legal problems, financial costs, and impaired social functioning (Bustillo et al., 1999; Kane and McGlashan, 1995). Awareness of these issues has led

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to a surge of interest in cognitive-behavioral interventions for schizophrenia in Europe, and more recently in North America (Cather et al., in press). Typically, these interventions have been tested as an adjunct to pharmacotherapy and case management.

To date, at least eight randomized, controlled trials of cognitive behavioral therapy for treatment refractory psychotic symptoms in schizophrenia outpatients have been published, excluding studies with patients early in the course of illness as well as those which combine cognitive behavioral therapy with other stand-alone interventions such as motivational interviewing or social skills training (Durham et al., 2003; Gumley et al., 2003; Kuipers et al., 1997; Rector et al., 2003; Sensky et al., 2000; Tarrier et al., 1993, 1998; Turkington et al., 2002). Most of these studies have demonstrated advantages of CBT over control conditions for symptom reduction with treatment gains maintained up to 18-months post-treatment (Gould et al., 2001; Pilling et al., 2002).

Although a meta-analysis of early studies of CBT for psychosis found large treatment effect sizes (Gould et al., 2001), many of these studies were characterized by one or more of the following limitations, including the absence of blind evaluations, relatively high attrition rates, selection biases that may have prohibited the generalizability of findings to more severely ill individuals, a failure to control for time with the therapist in the comparison condition, and a lack of standardization of pharmacotherapy treatments (Drury et al., 1996a,b; Garety et al., 1994; Milton et al., 1978). Recent studies have addressed some of these methodological issues, including the role of non-specific effects of therapy by employing supportive therapy as the control condition (Durham et al., 2003; Gumley et al., 2003; Lewis et al., 2002; Rector et al., 2003; Sensky et al., 2000; Tarrier et al., 1998).

Meta-analyses suggest CBT is effective at reducing symptoms, although there has been wide variation in the reported effect sizes. One reason for this is that the strength of the control conditions has varied across studies. Although supportive therapy has been used as a control intervention in several CBT studies, it has not been structured and guided by a manual. Manual-based control interventions provide a more rigorous and valid comparison treatment than non-manualized control interventions by standardizing the material and thereby minimizing the effects of individual therapist factors on outcome (Cris-Christoph et al., 1991).

For the present study we examined the efficacy of CBT compared to a manual-based psychoeducational program. As noted by Penn et al. (in press), active, supportive comparison conditions have shown to have a modest benefit for individuals with schizophrenia, perhaps by providing a comfortable situation for discussing problems with a concerned, helpful person. The psychoeducational (PE) program studied here incorporated supportive elements of therapy in a manualized intervention delivered by experienced cognitive-behavioral therapists who spent an equivalent amount of time with participants. Accordingly, this study provides a preliminary test of whether the specific elements of fCBT offer additional benefits other than a structured format, psychoeducation, and supportive interactions.

Impaired functioning is a hallmark of schizophrenia and there is a growing recognition of the need to measure the effect of interventions not only on symptoms, but also on functional outcomes. Existing approaches have modified CBT interventions for anxiety and depressive disorders for psychosis and have sought to increase insight or recognition by the patient of psychotic symptoms (Chadwick et al., 1996; Fowler et al., 1995; Nelson, 1997; Perris, 1989). The treatment employed in this study, functional cognitive-behavioral therapy (fCBT), represents a novel, manualized approach to CBT for residual psychotic symptoms in two important ways (Cather et al., unpublished manuscript; Cather et al., in press).[1] First, fCBT was developed to target only symptoms that interfere with progress toward functional goals. This approach was designed to enhance client motivation to work on symptom reduction. Furthermore, because fCBT does not rely on improving insight as a mediator of change in psychotic symptoms, it was anticipated that it would have broader applicability than traditional cognitive-behavioral approaches to psychosis. Secondly, fCBT was designed to target improved functioning as an explicit outcome of treatment. Specifically, fCBT incorporates goal-setting and problem-solving in the areas of

[1] The fCBT manual is available from the lead author.

social, personal care, or occupational functioning into treatment with the explicit aim of improving functioning in these areas.

In summary, the current pilot study sought to accomplish two goals. The primary aim of the study was to assess the feasibility of a new method of CBT for psychotic symptoms, fCBT. The second goal was to assess whether fCBT confers greater benefit than a structured psychoeducational intervention for both psychotic symptoms and social functioning.

2. Methods

2.1. Design

We used a randomized controlled design to compare the efficacy of fCBT to a structured psychoeducational (PE) program for treating residual psychotic symptoms. Participants were stratified by severity of symptoms (PANSS cut off score of <63) and gender and randomized to receive either fCBT or PE by an independent member of the research team. Both treatments consisted of weekly 1-h individual sessions for a total of 16 weeks. Assessments were conducted at baseline and post-treatment (week 16) by interviewers who were blind to treatment condition.

2.2. Participants

A total of 30 individuals with schizophrenia or schizoaffective disorder, depressed type were enrolled in the study. Participants were recruited from two sites in Boston, the Massachusetts General Hospital Schizophrenia Program outpatient clinic and the Boston Veterans Administration outpatient clinic (n=18), and the Schizophrenia Treatment and Evaluation Program at the University of North Carolina at Chapel Hill (n=12). Inclusion criteria were: 18–65 years of age, English speaking, treated with olanzapine for at least 6 months and at a stable dose for at least 30 days, and exhibiting residual psychotic symptoms as defined by two ratings of 'mild' or one rating of 'moderate' on "psychosis" items of the Positive and Negative Syndrome Scale (PANSS; Kay et al., 1987). Exclusion criteria were known or suspected organic brain disorder, substance use disorder in the past 3 months, a conceptual disorganization rating on the PANSS of 'moderate' or higher, or previous exposure to the study treatments.

Eligible patients were identified by staff psychiatrists and referred to one of the principal investigators for consent. After providing informed consent, study staff confirmed eligibility criteria with the Structured Clinical Interview for DSM-IV (SCID-IV; First et al., 1996), chart review, and consultation with the treating psychiatrist. Following the baseline interview, participants were randomly assigned to fCBT or PE.

2.3. Assessment measures

2.3.1. Schizophrenia symptom severity

The PANSS is a structured clinical interview consisting of 30 items designed to assess severity of symptoms over the past week on a 7-point scale (Kay et al., 1987). Raters were trained to an inter-rater agreement of 80% on a series of videotapes for which "gold standard" consensus ratings had been determined by a group of experienced raters. PANSS subscales corresponding to the factor structure described by (White et al., 1997) were used to measure negative symptoms (i.e., blunted affect, lack of spontaneity, emotional withdrawal, poor rapport, passive/apathetic social withdrawal, motor retardation, mannerisms and posturing), positive symptoms (i.e., delusions, hallucinations, unusual thought content, grandiosity), and dysphoric mood (i.e., depression, tension, anxiety, guilt, somatic concern).

More detailed information on hallucinations and delusions was collected with the Psychotic Rating Scales (PSYRATS; Haddock et al., 1999). The PSYRATS consists of 17 items that focus on auditory hallucinations and delusions experienced over the past week. This scale rates features such as frequency, intensity, and interference of hallucinations and delusions on a 4-point scale, and yields a total score, and scores on hallucination and delusion subscales. Higher scores on the PSYRATS are indicative of more severe and less controllable symptoms.

2.3.2. Social functioning

The Social Functioning Scale (SFS; Birchwood et al., 1990) measures social and occupational functioning of individuals with schizophrenia. The SFS is comprised of 74 items that are rated by the respondent on likert and frequency scales with higher scores

indicating better functioning. Although the scale was designed to assess functioning over the past 3 months, for this study the past week was used as the timeframe of assessment in order to be consistent with the other outcomes. There are seven subscales of the SFS: (1) *social engagement/withdrawal*; (2) *interpersonal communication*; (3) *independence-performance*, frequency of performing activities of daily living (ADLs) without help; (4) *independence-competence*, ability to perform ADLs; (5) *recreation*, frequency of engagement in nonsocial leisure activities; (6) *prosocial*, frequency of participation in social activities; and (7) *employment*. The subscale and total scores on the SFS were used as indices of social functioning.

2.4. Treatments

2.4.1. Functional Cognitive Behavioral Therapy (fCBT)

fCBT is a 16-session, weekly individual treatment for residual psychotic symptoms in schizophrenia. FCBT comprises several modules, including education, coping skills, cognitive restructuring, behavioral experiments and goal-setting. Early in treatment, the therapist seeks to identify ways in which symptoms are interfering with functioning or causing distress. Patients are taught skills for managing persistent positive symptoms that interfere with accomplishing certain activities or goals; only symptoms that interfere with goal attainment or role functioning are targeted. This approach allows the therapist to maintain a consistent focus on improving the patient's sense of well-being and achievement of meaningful personal goals, while narrowing treatment targets. For example, rather than discussing hallucinations or delusions as "real or unreal" or "rational or distorted," fCBT focuses on whether psychotic symptoms and responses to these symptoms block attainment of specific goals. This approach helps ensure that therapists always have a context for challenging maladaptive responses to symptoms.

To acquaint patients with the style and content of therapy, an introductory videotape is used in the first session. The videotape presents general information on schizophrenia and its treatment with fCBT, and provides brief, simulated therapy vignettes. For example, the active role of the therapist, the collaborative nature of the therapeutic relationship, the focus on the connection between thoughts, behaviors, and present difficulties, the development of written materials during the session, and the assignment of homework are each exemplified in the videotape.

Beginning in the second session, and continuing through session five, the client is engaged in developing a list of functional goals and the symptoms that interfere with attaining them. The content of sessions 6–16 is determined by the selection of particular treatment targets based on the therapist's case formulation. Each module involves targeting a symptom or behavior believed to be interfering with functionality. The specific interventions (e.g., coping skill training, behavioral experiments, cognitive restructuring, increasing activity level, etc.) include those typically used in current CBT interventions (Chadwick et al., 1996; Fowler et al., 1995; Kingdon and Turkington, 1994; Nelson, 1997).

2.4.2. Psychoeducation (PE)

Team Solutions is a psychoeducational intervention developed and sponsored by Eli Lilly and Company to teach patients about schizophrenia and the principles of its management. The program, which is not medication-specific, includes a video, patient workbook and instructor's manual and was delivered in an individual format. The program is organized into 10 modules including, promoting understanding of the illness and of symptoms of schizophrenia, identifying members of the treatment team and their roles, learning about medication and side effects, preventing relapse, and coping with symptoms. The philosophy of Team Solutions is rooted in promoting 'reintegration', which corresponds largely to improved functioning through education about symptoms and strategies for symptom management. One of the investigators (CC) was formally trained in the implementation of Team Solutions and authorized to train therapists in its use. For the purposes of this study, the videotape was reviewed in session one and each of the 10 modules were taught over 1–2 sessions. In the event that all of the material was covered prior to session 16, the patient and therapist collaboratively decided on modules for review over the remaining sessions. Sessions involved an introduction to the material in

the module, review, and in-session completion of the corresponding patient workbook.

2.5. Therapists

Treatment was delivered by nine therapists with an average of 7.8 years (SD=4.77) of experience conducting cognitive-behavioral therapy. Weekly supervision meetings were held to discuss cases and ensure protocol adherence.

2.6. Statistical analyses

Due to the preliminary nature of the study and small sample size, we examined the magnitude of effect sizes for between- and within-group comparisons, and complemented these analyses with traditional significance testing. Consistent with previous research in the area (Kuipers et al., 1997), we also compared, using a Fisher's exact test, the proportion of patients who achieved a clinically significant reduction of positive symptoms, which was defined as a 20% reduction in PANSS positive factor score from pre- to post-treatment.

3. Results

3.1. Sample characteristics

Demographic characteristics and baseline measures are presented in Table 1. Sixty-one percent of the participants had a diagnosis of schizophrenia and 39% had a diagnosis of schizoaffective disorder, depressive type. Participants had a mean age of 40.4 years (SD=11.96) and were ill for an average of 18 years (SD=13.1). Participants were more likely to be male (57.1%), Caucasian (67.9%), and had a mean education level of 13.7 years (SD=1.89). Participants from the Boston sites were older, less educated, had a

Table 1
Sample characteristics, total sample

Variable	MGH (n=16)	UNC (n=12)	Total sample (n=28)
Age, M (SD)**	45.88 (10.20)	33.08 (10.34)	40.4 (11.96)
Gender, % female (n)*	25 (4)	66.7 (8)	42.9 (12)
Ethnicity, % (n)			
White, non-Hispanic	68.7 (11)	66.7 (8)	67.9 (19)
Hispanic	6.3 (1)	0 (0)	3.6 (1)
Black	25 (4)	33.3 (4)	28.5 (8)
Education, M (SD)**	13.07 (1.49)	14.58 (2.07)	13.7 (1.9)
Years of illness, M (SD)***	24.88 (11.48)	8.83 (9.12)	18 (13.1)
Diagnosis, % (n)			
Schizophrenia	62.5 (10)	58.3 (7)	60.7 (17)
Schizoaffective disorder	37.5 (6)	41.7 (5)	39.3 (11)
Olanzapine dose, M (SD)	21.67 (7.72)	16.39 (9.45)	19.69 (8.61)
Additional neuroleptic, % (n)	31.3 (5)	37.5 (3)	33.3 (8)
Number of Sessions, M (SD)	14.33 (2.55)	15.83 (0.58)	15 (2.06)
PANSS negative factor, M (SD)*	15.94 (4.97)	12.17 (3.86)	14.3 (4.8)
PANSS positive factor, M (SD)	13.88 (4.43)	13.08 (3.03)	13.5 (3.8)
PANSS dysphoric factor, M (SD)	14.44 (4.99)	13.33 (2.77)	14 (4.2)
PANSS total, M (SD)	55.25 (14.09)	45.49 (7.83)	51.1 (12.6)
PSYRATS-voices, M (SD)	25.19 (11.34)	16.33 (12.62)	21.4 (12.5)
PSYRATS-delusions, M (SD)	12.56 (6.48)	10.92 (5.00)	11.9 (5.9)
PSYRATS-total, M (SD)	37.69 (12.21)	24.42 (13.87)	33.3 (13.7)
Auditory hallucinations, % Yes (n)	87.5 (14)	83.3 (10)	85.7 (24)
Social functioning scale, M (SD)	115.61 (24.58)	131.64 (18.86)	118.5 (21.5)

* $p<0.05$.
** $p<0.01$.
*** $p<0.001$.

longer history of illness and more severe negative symptoms than the North Carolina participants (see Table 1). However, there were no site differences on any of the symptom measures for which there were significant within group effects.

Doses of olanzapine ranged from 5 to 40 mg, with a mean daily dose of 19.7 (8.6) mg; 33% of the sample was taking another antipsychotic in addition to olanzapine. There were no differences between treatment groups at baseline in any of the symptom measures.

3.2. Treatment participation

The number of sessions received over the 16-week period of treatment ranged from 9 to 16, with a mean completion rate of 75% for all 16 sessions. Of the participants who completed the baseline assessment, two participants (1 in fCBT and 1 in PE) received fewer than four sessions and were considered drop-outs and excluded from the analyses. Attrition rates did not differ significantly between the fCBT (6%) and PE (7%) groups.

3.3. Evaluation of treatment efficacy

Table 2 provides a summary of mean differences and effect sizes associated with the primary outcome measures from pre- to post-treatment. Although the interaction terms did not reach the $p<0.05$ significance level in this small study, differential effects of treatment, favoring fCBT, were suggested for the PSYRATS-total, PSYRATS-Voices, and the SFS by effect sizes in the small to medium range according to Cohen's (1988) standards ($0.3<d<0.5$). Examination of within group t-tests indicated a significant reduction in PSYRATS total score ($t(13)=2.64$, $p<0.05$), and PSYRATS voices ($t(13)=2.87$, $p<0.05$) for the fCBT condition. There were no significant pre-post differences in the PE condition on any of the symptom measures and no significant within treatment effects were observed for either condition on either the SFS total or subscale scores. Differential treatment effects on the SFS appeared to be driven by a worsening in social functioning in the PE group (reflecting an effect size of $d=0.36$), whereas no substantial change was evident in the fCBT group. Both treatment groups improved on the PANSS positive factor, with only a slight advantage indicated for fCBT relative to PE, reflecting an effect size in the small range ($d=0.16$). According to within group t-tests, significant improvement in PANSS positive scores occurred only in the fCBT group ($t(14)=3.33$, $p<0.01$). In a further test of the CBT model, we examined whether improvements in positive symptoms were associated with improvements in social functioning by looking at

Table 2
Means (standard deviations) and effect sizes for outcome variables for each treatment group before and after intervention

Variables	fCBT				PE				Interaction effect size
	Pre-tx (n=15)[a]	Post-tx (n=15)	t-value	fCBT effect size	Pre-tx (n=13)	Post-tx (n=13)	t-value	PE effect size	
PANSS positive factor	13.80 (4.26)	10.93 (2.55)	3.33**	0.67	13.23 (3.44)	11.08 (3.73)	1.42	0.63	0.16
PANSS negative factor	14.33 (5.34)	14.87 (4.97)	−0.64	−0.10	14.31 (4.40)	14.92 (5.72)	−0.58	−0.14	0.02
PANSS dysphoric factor	14.27 (3.86)	13.13 (4.47)	0.24	0.29	13.62 (4.61)	12.38 (4.23)	0.62	0.27	−0.02
PSYRATS-total	33.22 (10.90)	28.58 (14.18)	2.64*	0.43	31.08 (14.68)	31.34 (17.13)	−0.05	−0.02	0.36
PSYRATS-voices	21.79 (10.59)	18.11 (11.36)	2.87*	0.35	19.46 (13.91)	20.52 (12.57)	−0.23	−0.08	0.41
PSYRATS-del	11.54 (4.75)	10.69 (6.49)	0.77	0.18	11.46 (6.74)	10.15 (7.48)	0.60	0.19	−0.08
SFS	132.07 (17.99)	129.88 (24.91)	0.47	0.12	114.27 (25.18)	105.21 (25.57)	1.27	0.36	0.32

t-values associated with within subject comparisons.

[a] ns vary somewhat because some scales are only applicable to individuals who endorse particular symptoms (e.g., hallucinations).

* $p<0.05$.

** $p<0.01$.

associations between change scores on the PSYRATS voices subscale and change scores on the subscales of the SFS. We found that reductions in voices as measured by the PSYRATS from baseline to post-treatment was associated with increased functioning on the independence-performance ($r=-0.61$, $p<0.05$) and recreation subscales of the SFS ($r=-0.56$, $p<0.05$) from baseline to post-treatment for the fCBT condition only.

3.4. Clinical significance of symptom changes

Sixty percent of subjects who received fCBT showed a clinically significant reduction in positive symptoms (i.e., a 20% reduction in PANSS positive factor), compared to only 31% of subjects who received PE (Fisher's Exact Test $p=0.12$, ns). This corresponds to a large effect size ($d=0.74$).

4. Discussion

This pilot study had two aims: (1) to evaluate the feasibility of a new cognitive-behavioral approach for persistent psychotic symptoms in schizophrenia (fCBT) and (2) to evaluate whether fCBT had a greater impact on symptoms and social functioning than psychoeducation (PE). The high rate of retention in therapy by fCBT (94%) supports the feasibility of the program in this population. We did not find significant between-group differences on symptom reduction, indicating no significant benefit of fCBT over PE. Within-group effect sizes, however, suggest an advantage for fCBT relative to PE for reducing positive symptoms, particularly auditory hallucinations. Our study was the first investigation of cognitive-behavioral treatment of persistent psychotic symptoms to employ an active, manualized treatment control group. The use of an active rather than passive control intervention created a more stringent comparison for fCBT, which may have further reduced power to detect the hypothesized changes.

Contrary to expectations, fCBT did not significantly improve social functioning, although there was a relationship between decreased auditory hallucinations and improvement in functioning for recipients of fCBT. Specifically, decreased PSYRATS voices scores from baseline to post-treatment were associated with increased engagement in ADLs and recreational activities from pre- to post-treatment, suggesting functional benefits of symptom reduction in the fCBT group. Prior studies of cognitive behavioral treatment of persistent positive symptoms have found that significant improvements often occur following termination of the treatment (Gould et al., 2001; Gumley et al., 2003; Pilling et al., 2002; Sensky et al., 2000), suggesting that core skills taught in treatment may be consolidated over time in the absence of ongoing therapy. It is possible that differences between fCBT and PE in social functioning would emerge after treatment termination. Second, social functioning was assessed over the past week, rather than the past 3 months as recommended by the developers of the instrument (Birchwood et al., 1990). This briefer time interval may have introduced error into the measure of social functioning, making it more difficult to detect treatment effects. Third, it is possible that fCBT needs to be strengthened in order to improve social functioning, perhaps by addressing either general neurocognitive deficits or deficits in social cognition (Penn et al., in press; Pinkham et al., 2003).

This study has a number of strengths, which include a randomized design, a stringent manualized comparison condition, standardization of pharmacotherapy, and evaluations that were blind to treatment assignment. Limitations of the study included the small sample size and the lack of long-term follow-up assessments. These limitations notwithstanding, the results of this study support the feasibility of the fCBT treatment, and suggest possible benefits for positive symptoms. Further research on fCBT is warranted to evaluate its long-term effects on psychotic symptoms and functioning.

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