

Clinicians' Fidelity to a Manual-Based Family Treatment as a Predictor of the One-Year Course of Bipolar Disorder

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This study assessed whether therapist adherence to the family focused treatment model¹ for patients with bipolar disorder and their relatives was associated with patient outcomes at one year after treatment entry. A total of 78 videotaped sessions of FFT consisting of 26 families with a member with bipolar disorder (3 sessions/family) were rated on fidelity using the Therapist Competence/Adherence Scale (TCAS; see Endnote 1, p. 130). Patients' outcomes (relapse status) were assessed using the Brief Psychiatric Rating

Scale (BPRS) and selected items from the Schedule of Affective Disorders and the Schizophrenia-Change (SADS-C) scale (measured at 3-month intervals for 12 months). Contrary to expectations, therapist fidelity was not related to overall outcome as assessed by the BPRS and the SADS-C. Among patients who did relapse, higher levels of cooperation among therapists predicted a later date for relapse than did lower levels of cooperation. Surprisingly, and in opposition to the study's hypotheses, patients who were hospitalized because of relapses had therapists who were rated as more competent in their ability to conduct the problem-solving module of FFT. Study implications are discussed.

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BIPOLAR illness is a psychiatric disorder characterized by severe mood swings and a relapse/remission course. Despite the chronicity of this illness, there is increasing evidence that interventions which involve patients and their family members are effective at prevent-

ing or decreasing the frequency of relapses (see Miklowitz, Simoneau, George, et al., 2000) and other severe mental disorders such as schizophrenia (see Falloon, Boyd, McGill, et al., 1985; Randolph, Eth, Glynn, et al., 1994). However few studies have examined whether the efficacy of these treatments depends on specific elements of the intervention and/or on how closely therapists comply with a systematic method of treatment.

The present study was designed to evaluate the relationship between clinicians' competence and adherence to a specific form of family treatment and outcome for patients with bipolar disorder. This treatment approach, entitled family focused treatment (FFT; Miklowitz & Goldstein, 1997), combines educational and social learning principles to improve family functioning and the course of illness for patients with bipolar disorder. The treatment was modeled after an approach developed by Falloon, Boyd, and McGill (1984) for working with families with a member with schizophrenia. However, the approach was modified by Goldstein and associates (see Goldstein & Miklowitz, 1994) and manualized by Miklowitz and Goldstein (1997) to meet the needs of families with a bipolar member.

In an earlier study using the same sample as in the present study, Weisman, Okazaki, Gregory, et al. (1998) developed the *Therapist Competence/Adherence Scale* (TCAS) to evaluate clinicians' fidelity to the FFT model in treating bipolar illness. This scale is based on a treatment manual developed by Miklowitz and Goldstein (1997). Results from the Weisman et al. (1998) study revealed that therapist competency and adherence to the treatment model could be reliably coded from videotaped sessions.

At the time of the Weisman et al. (1998) study, several patients had not yet completed their participation in the Family Management of Bipolar Disorder project,

so we were unable to examine whether adherence to the manual actually predicted one-year clinical outcomes of the disorder. In the present study we used the TCAS to assess whether therapists' fidelity to FFT was associated with a better course of illness for patients with bipolar illness. Although it is generally assumed that treatment fidelity is associated with better outcome, few studies have empirically evaluated this assumption (Svartberg & Stiles, 1992).

In this study we hypothesized that patients who relapsed within one year of entry into FFT had therapists who were rated as less competent/adherent on the TCAS, as compared with therapists of patients who do not relapse. We further hypothesized that, for those patients who did relapse, greater treatment competence/adherence would be associated with prolonged time to relapse and decreased likelihood of inpatient hospitalization.

METHOD

Participants

Study participants were drawn from a larger project (see Goldstein, Rea, & Miklowitz, 1996), which was designed to assess the efficacy of a psychoeducational intervention program used in conjunction with mood-stabilizing medications in the treatment of bipolar disorder. All patients and families were recruited from three inpatient psychiatric facilities serving Los Angeles County. To be eligible for study participation, all patients met the *Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition* (DSM-III-R; American Psychiatric Association, 1987) criteria for a manic episode and were hospitalized for an episode of mania at the time of study entry. Diagnoses were made based on the Present State Examination (PSE; Wing, Cooper, Sartorius, 1974) supplemented by selected items from the Structured Clinical

Interview for the DSM-III-R (SCID; Spitzer, Williams, Gibbon, & First, 1990) to assess manic symptoms. All patients were required to take mood-stabilizing medications during their participation in the study. At that time, patients were randomly assigned to either FFT or to individual case management.

Participants meeting criteria for the present study included 26 families that had been randomly assigned to FFT and completed the treatment. Patients in this sample ranged in age from 18 to 46 (mean = 27.19) and had an average of 2 years post-high school education. Sixty-four percent of patients resided with their relatives. Sixty-five percent of participants were Caucasian, 27% were African American, and 8% were Asian American. Relatives participating in the treatment included 12 mothers, 13 fathers, 5 spouses, a cousin, a grandmother, and one aunt; 66% of cases had only one relative participating in FFT and 34% had two or more relatives participating in the treatment.

Overview of Treatment

In the present study, therapists consisted of 13 clinicians trained in FFT. Treatment was led by pairs of clinicians and an attempt was made to pair therapists who were new to FFT with highly experienced FFT clinicians. Each family received approximately 21 FFT sessions over a period of roughly 9 months. Treatment was scheduled to occur weekly for the first 3 months, biweekly for the second 3 months, and once a month for the final 3 sessions. All sessions were videotaped.

FFT has three core components, each lasting between 2–9 sessions, depending on the individual needs of the family. The first segment is Psychoeducation. The primary objective of this phase is to encourage a thorough understanding of bipolar illness, including the nature, causes,

course, and treatment of the disorder. This segment is presented didactically using a series of handouts that outline the major concepts and factual information. Factors that increase risk of relapse (e.g., irregular sleeping patterns, drug use) and factors that protect against relapse (e.g., medication, family support) are reviewed, and a stress-vulnerability model of bipolar illness is presented. Readings are assigned as homework to facilitate the families' learning this material.

The second module is called Communication Training. The primary objective of this segment is to reduce family stress by improving family communication. Modeling and role-playing are used to teach communication techniques such as active listening, giving positive and negative feedback, and making positive requests for change in another's behavior. Families are given structured homework assignments that encourage the members to practice the communication techniques between sessions.

The third component of FFT is Problem Solving. The underlying rationale for this segment is that knowledge of the steps involved in solving problems, in combination with good communication skills, will reduce the familial tension that often develops in response to stressful life events. Families are presented with a series of steps to follow when solving conflicts, including defining problems as specifically as possible, brainstorming about solutions, evaluating each solution as to its pros and cons, choosing the best solutions, and implementing the solutions chosen. In this phase, a "relapse drill" is also conducted in which families use problem-solving techniques to develop a plan of action should the patient's symptoms return.²

Measures

Therapist fidelity ratings: The Therapist Competence/Adherence Scale (TCAS);

Weisman et al., 1998) was developed to assess therapists' fidelity to the three specific modules of FFT and several other "nonspecific" aspects of the treatment. The TCAS is 7-point scale (ranging from 1 = very poor adherence to 7 = excellent adherence) patterned after Harpin, McGill, and Falloon's (1983), Therapist Competency Rating Scale for Behavioral Family Therapy and Miklowitz's supplement to the Harpin et al. scale, Additional Items: Therapist Competency Scale (1990). The first category, education, has one item assessing competence in accurately conveying factual information about bipolar disorder in language understandable to the family. The second category, communication training, includes 3 items which evaluate competence in giving instructions and laying out the communication techniques, directing role plays, and giving family members feedback about their performance in carrying out the exercises. The third category includes one item assessing competence in directing brainstorming, evaluation of ideas, and implementation of solutions that occur in the problem-solving phase of treatment. The fourth category is entitled general skills and includes 6 items tapping areas such as ability to establish rapport, pacing and efficient use of time, and competence in assigning relevant homework assignments. The fifth category includes one item designed to evaluate co-therapists' skill at working together to provide a safe and effective therapeutic environment. A final category included one item to assess the level of difficulty each family posed in the session. The rating on this item was based on factors such as family members' ability to grasp and carry out the FFT exercises and their willingness to cooperate with the therapists.

Three raters, two Ph.D.-level psychologists (A.W. & S.O.), and one psychology graduate student (J.G.), all of whom were trained in FFT, rated one videotape per

family using the TCAS. The first videotaped session in each segment of FFT treatment (education, communication training, and problem solving) was rated for each of 26 families, yielding a total of 78 session ratings. All coders rated an equal number of the Psychoeducation, Communication Training, and Problem-Solving sessions. The two Ph.D.-level raters had also served as treating clinicians for one family each. In no case did the raters rate their own therapy sessions. All three raters were blind to patients' outcome data, which was obtained by a research assistant who was unaware of patients' psychosocial assignment group.

For each family, scores on family difficulty, therapist cooperation, and all six general items were based on the average rating across the three sessions. Scores on communication training, problem solving, and education for each family were based on the first session in which this segment of treatment occurred. To assess interrater reliability of the TCAS ratings, all coders rated 9 of the same videotaped sessions (3 of each treatment segment with 9 separate families). As published in Weisman et al. (1998), intraclass correlation coefficients for each of the 13 items on the TCAS ranged from .74 to .98.

Patient outcome: Patient outcome was assessed using the Brief Psychiatric Rating Scale (BPRS) and the Schedule of Affective Disorders and Schizophrenia-Change (SADS-C) scale administered every 3 months. Patients were placed in the relapse outcome category if they had an acute exacerbation of symptoms at any followup point during the one-year period of active treatment phase. Relapse was defined as a rating of 6 or 7 (on a 7-point scale ranging from 1 = not present to 7 = extremely severe) on the BPRS/SADS-C core symptoms of depression (depressed mood, loss of interest), or mania (hostility, elevated mood, grandiosity) or psychosis (unusual thought content, suspicious-

ness, hallucinations, conceptual disorganization) and at least two ancillary symptoms (suicidality, guilt, sleep disturbance, appetite disturbance, lack of energy, negative evaluation, discouragement, increased energy/activity). Whether or not patients who did relapse were hospitalized was also coded as a dichotomous (yes, no) variable.

RESULTS

Competence and Adherence

As indicated in a previous manuscript by the same group of authors (Weisman et al., 1998) mean competence ratings for clinicians in this project suggest that therapists had very good overall adherence to the FFT Manual. Therapists received greatest competence and adherence ratings in the areas of education (mean = 6.12; SD = .73) and rapport (mean = 6.05; SD = .75). In other words, clinicians were judged to have "very good" competence/adherence in imparting relevant information about bipolar illness and were rated as "very good" in interacting with patients in an empathic and warm manner. Clinicians also had very high ratings (mean = 5.92; SD = .70) in their overall command of the session. That is, therapists appeared skillful in directing the sessions and maintaining the focus on topics related to FFT.

Competence and adherence to FFT was rated lowest for the item "assigning homework to families." The mean score of 4.15 (SD = 1.14) reflects an overall rating of "competence" with respect to the use of homework assignments. However, this moderate-range rating suggests that therapists occasionally failed to give assignments when appropriate and/or did not fully explain the relevance of homework assignments to their therapy goals.

Patient Outcome

In examining patient outcome, we tested the hypothesis that greater therapist fidelity to the FFT manual would be associated with nonrelapsing status at one year into the study. A series of Bonferroni corrected *t*-tests (which adjust for number of comparisons) were conducted to compare therapist adherence/competence in each TCAS category for patient outcome groups (relapsed/did not relapse) as assessed every 3 months by the BPRS and SADS-C ratings. Results did not indicate any significant associations between therapist competence/adherence and patient outcome ($p > .05$ for all).³

In line with study hypotheses we did find, however, that for those patients who did relapse ($n = 11$; 42% of sample), having therapists who scored higher on the cooperation subscale was significantly associated with a later date of relapse ($r = .78, p < .05$).⁴ Finally, and in direct opposition to our third set of hypotheses, a Bonferroni corrected *t*-test indicated that therapists of patients who were hospitalized were rated as significantly more competent (mean = 5.57; SD = 1.40) in their ability to conduct the problem-solving module of treatment than were therapists of patients who were not hospitalized (mean = 3.25; SD = .50), $p < .05$.⁵

DISCUSSION

In this study, we assessed therapist competency and adherence to family-focused treatment as a predictor of the course of illness for patients with bipolar disorder. Surprisingly, our results did not indicate any significant associations between therapist competence/adherence and patient outcome. This puzzling finding may have occurred because of the rigorous training to conduct FFT required by this clinical trial. All treating clinicians were closely supervised throughout the intervention and relatively inexperienced

FFT therapists were working alongside of highly experienced clinicians. Indeed, our results suggest a high degree of both adherence and competence in conducting the family-based treatment. Standardized and rigorous FFT training of therapists may have resulted in a reduction in range of TCAS scores, which may have precluded observing the full association between treatment fidelity and patient outcome. Alternatively, the TCAS may not have captured minor variations in the ways that different pairs of clinicians administered FFT (e.g., amount or quality of telephone crisis intervention contact between sessions) but that may have been important in determining outcome.

As expected, we did find that, for patients who eventually relapsed during the treatment year, having therapists judged to be more cooperative with one another was associated with a later date of relapse (meaning that the patient had a longer period of wellness prior to relapse). It is perhaps not surprising that therapist pairs who work more effectively together and are in greater unison would be more successful at prolonging the time before symptomatic patients relapse. In another paper (still in preparation) reporting the comparative treatment effects of FFT in this sample of patients with bipolar disorder, Rea and colleagues have found that patients randomly assigned to FFT had fewer relapses than those randomly assigned to an individual case management therapy. Case management was matched for overall number of therapy sessions, and other important characteristics such as the requirement that all patients receive mood-stabilizing medications which were monitored by a project affiliated psychiatrist. Our findings in conjunction with those of Rea et al. suggest that, even in a chronic and remitting disorder such as bipolar illness, family therapy may be beneficial in decreasing the number of relapses or prolonging the time before they

occur, particularly when the treatment is conducted by therapy teams who are working cohesively and cooperatively.

In direct opposition to our expectations, we found that therapists of hospitalized patients were rated as significantly more competent in their ability to conduct the problem-solving module of treatment than were therapists of patients who were not hospitalized. This is a surprising and unexpected finding, especially in the light of recent results from Rea and colleagues. In their study (using the same FFT participants included in the present study), they observed that patients in family therapy, were less likely to be hospitalized during a 2-year followup period when contrasted with patients who received individual case management. Given the exorbitant cost and the disruption to patients' daily lives associated with inpatient hospitalizations, any treatment that reduces the need for inpatient stays would surely be beneficial. However, bipolar illness is episodic in nature and most patients do relapse at some point. Despite the best interventions, many require hospitalization.

Good problem-solving ability is an asset in any type of treatment. With respect to results from the present study, it is possible that therapist teams who were skilled at problem solving may have been better at identifying the need for hospitalization when patients did become symptomatic and begin to relapse. In their proficient communication of problem-solving techniques (e.g., brainstorming, evaluation of ideas, and implementation of those solutions designated to be the best), these therapists may have also been more skillful at convincing families with a relapsing relative that the best solution at the time was affording the patient of the extra care and monitoring available to him or her in the hospital. However, we should not assume that families do not want hospitalization. Because of their close proximity

and greater understanding of what is usual and atypical behavior for their relative, family members often recognize the need for hospitalization, even before professionals do. Consequently, our findings may suggest that therapists who are more competent in conducting problem solving are those who genuinely allow families to do their own evaluation of the situation, brainstorming, etc., rather than imposing the therapists' own assumptions and beliefs. Under these circumstances families may be more likely to implement hospitalization during a relapse.

An alternative explanation as to why greater skill at the problem-solving component of FFT was associated with greater likelihood of inpatient hospitalization may be that, since family therapy per se may be significantly more difficult when a relapsing patient is present (which, was the case in FFT except under unusual circumstances), or require more skill to adhere to the agenda, therapists working with families and a patient in the midst of a relapse may have had greater opportunity to use and demonstrate their problem-solving competency and adherence to the treatment manual. For example, key problem-solving techniques such as the *relapse drill*, *brainstorming* about symptom management solutions, and the selection of best solutions (e.g., hospitalization vs. home care) may be more accessible and relevant when dealing with relapsing patients. In other words, it may be easier to demonstrate problem-solving capacity when there is a concrete and important issue to address (e.g., coping with a relapsing patient), which lends itself to the specific steps outlined in the problem-solving segment of FFT.

As noted previously by Weisman et al. (1998), a limitation of this study is that we did not distinguish between adherence and competence despite the fact that they reflect somewhat different concepts. Adherence is generally defined as the extent

to which therapists use interventions and approaches prescribed or encouraged by a treatment. Competence is generally defined as the level of skill and judgment shown by clinicians in delivering the therapy (Waltz, Addis, Koerner, & Jacobson, 1993). In the present study, TCAS ratings were based on combined judgments regarding clinicians' overall fidelity to the techniques and strategies outlined in the FFT manual, as well as on their level of skill in carrying out specific and nonspecific aspects of the treatment. It is possible that, at times, therapists might be adherent without being particularly competent, or vice versa. An example given in the Weisman et al. (1998) study of was that of an experienced therapist who "chatted" a lot in sessions because she believed this to be necessary to maintain a therapeutic alliance with a client. This clinician may be judged as showing good judgment and competence, yet low adherence to the structure of FFT. In our current rating system we were unable to evaluate this possibility.

Our inability to establish a link between competence and adherence and outcome may also relate to our combining these constructs. For example good judgment and flexibility in altering treatment strategies to best meet the needs of individual families (competence) may be highly associated with better patient outcome, whereas strict adherence to the guidelines of a protocol (adherence) may not. Or the reverse may be true: rigorous adherence may be associated with better outcomes whereas flexibility and judgment may not be as predictive. Having a rating scale that does not allow us to differentiate between competence and adherence may have diminished our ability to predict outcome.

One conclusion that can be drawn from this study is that therapist competence and adherence may not, in fact, be particularly important for treatment outcome.

As noted by Rea et al. (2001), the combination of FFT and medication does appear to be beneficial in delaying relapse among patients with bipolar disorder. However, the mechanisms that underlie this success may have little or nothing to do with the specific components of FFT. It is possible that simply the support and security associated with having a treatment "team" that includes two empathic and knowledgeable therapists, along with other invested individuals (family and loved ones), may improve mental health irrespective of the type of family treatment provided. Future research is needed to pinpoint the specific elements that underlie the success of FFT and other related family interventions.

In summary, findings from our study indicate that greater cooperation by therapists may be associated with prolonging the time before patients with bipolar disorder experience a relapse. Our results may also suggest that good problem-solving ability may help therapists recognize the need for hospitalization when it does arise and communicate this convincingly to patients and their relatives. As stated earlier, families often recognize relapse in a loved one even prior to trained clinicians. Thus, good problem-solving skills may also better enable clinicians to see the merit of family members own, often realistic, assessment of their ill relative's mental status, and incorporate these perceptions into the treatment plan. Studies that include a range of therapists of varying degrees of experience and competencies are needed to assess further the role of fidelity to family treatment in patients' courses of illness. Furthermore, studies that assess competence and adherence as separate dimensions are necessary in order to examine how these overlapping but unique constructs may impact the outcome of family therapy.



ENDNOTES

- ¹ In the earlier Weisman, Okazaki, Gregory, et al., 1988 study, we referred to the intervention as Behavioral Family Management (BFM), and to the manual as the BFM-TCAS. In recent years, we changed the name of the intervention to Family Focused Treatment (FFT) to reflect more accurately the nature of this intervention, and we have eliminated the letters BFM from the name of the scale.
- ² A relapse drill is first introduced in the Psychoeducation session but is practiced here using the skills outlined in the Problem-Solving component of FFT.
- ³ Significance levels were not altered when less stringent *t*-tests were conducted.
- ⁴ Time to relapse was not significantly associated with any other dimension assessed by the TCAS ($p > .05$ for all).
- ⁵ No other relationships between therapist competence/adherence and rates of hospitalizations were found ($p > .05$ for all).

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