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The Effectiveness of Family-Focused Therapy on Family Functioning in Individuals with Bipolar Disorder: A Randomized Controlled Trial

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Abstract

Introduction: Bipolar disorder profoundly disrupts interpersonal relationships and family cohesion. This study aimed to evaluate the effectiveness of Family-Focused Therapy in improving family functioning among individuals with bipolar disorder.

Method: A randomized clinical trial with a pretest-posttest control group design and a three-month follow-up was conducted. The study population consisted of individuals aged 25–45 years diagnosed with bipolar disorder in Sari during 2025. Thirty participants, along with one self-selected family member, were recruited through convenience sampling and randomly assigned to experimental and control groups (n=15 per group). The experimental group underwent ten 90-minute sessions of an abbreviated adaptation of Family-Focused Therapy, while the control group received no additional psychosocial intervention (treatment as usual, consisting of pharmacotherapy only) during this period. Data were collected using the Family Assessment Device, which was completed by both the patient and one family member to reflect a family perspective (scores were averaged or jointly reported as appropriate). Data were analyzed via repeated measures analysis of variance in SPSS version 26.

Results: The experimental group showed significant reductions in Family Assessment Device scores (indicating improved family functioning, since higher scores reflect poorer functioning) from pretest to posttest and at the three-month follow-up ($P<0.01$). These improvements were sustained, with no significant differences between posttest and follow-up scores.

Conclusion: Family-focused therapy was associated with improvements in family functioning in individuals with bipolar disorder in this sample. This modality can be considered as an adjunctive psychosocial intervention to promote familial outcomes and systemic stability.

Keywords: Bipolar Disorder, Family Therapy, Family Relations, Treatment Outcome, Psychotherapy

Introduction

Bipolar disorder is a chronic and severe psychiatric condition characterized by recurrent and fluctuating episodes of mania, hypomania, and depression [1]. These profound shifts in mood and energy levels lead to significant impairments across social, occupational, and interpersonal domains of life. Individuals diagnosed with bipolar disorder often struggle with emotional dysregulation and cognitive deficits that complicate their daily functioning and long-term stability [2]. Beyond the clinical symptoms, the unpredictable nature of the disorder creates a persistent state of psychological distress and instability for the affected person [3]. Research indicates that patients with bipolar disorder face high risks of comorbid conditions, including substance abuse and anxiety disorders, which further exacerbate their clinical prognosis [4]. Moreover, the pervasive social stigma associated with bipolar disorder often leads to social withdrawal and reduced adherence to essential pharmacological treatments [5]. Given these complexities, the management of bipolar disorder necessitates a comprehensive strategy that extends beyond biological interventions to address the socio-emotional and environmental context of the individual [6].

Family functioning serves as a critical environmental determinant that influences the clinical course and recovery trajectory of bipolar disorder [6]. The presence of a family member with bipolar disorder often imposes a substantial emotional, psychological, and financial burden on the entire household, a phenomenon frequently described as caregiver burden. High levels of "Expressed Emotion"—characterized by criticism, hostility, or emotional over-involvement—within the family environment are significantly correlated with higher rates of relapse and increased severity of symptoms [7]. According to the McMaster model of family functioning, essential dimensions such as problem-solving, communication, clarity of roles, and affective responsiveness are often severely compromised in these households [8]. Dysfunctional family dynamics can hinder the recovery of the individual with bipolar disorder and negatively impact the psychological well-being and systemic health of other family members. Therefore, the family unit is not merely a background support system but a dynamic and influential environment that can either facilitate stability or trigger recurrence in bipolar disorder [9].

Family-Focused Therapy (FFT) is an evidence-based psychosocial intervention developed primarily for individuals with bipolar disorder and their families, adapted from earlier family therapy models [10]. This therapeutic modality integrates comprehensive psychoeducation, communication enhancement training, and structured problem-solving skills to help families navigate the unique challenges posed by the disorder [11, 12]. Previous empirical studies have consistently demonstrated that FFT, when utilized as an adjunct to pharmacological treatment, is associated with a significant reduction in the duration of depressive episodes and decreased risk of clinical relapse [13, 14]. For instance, Waraan et al. [15] have shown that this intervention effectively reduces suicidal ideation and enhances the overall functional recovery of patients. Furthermore, evidence suggests that FFT is highly effective in lowering expressed emotion and improving interpersonal communication patterns within the family unit [16]. Despite the proven efficacy of this approach in various clinical settings globally, there remains a critical need to evaluate its impact on holistic family functioning metrics within diverse cultural and geographical contexts to ensure its broad applicability.

Although the clinical benefits of FFT are well-documented, many healthcare settings continue to rely predominantly on pharmacological interventions. Enhancing family functioning is essential for ensuring long-term remission and preventing the breakdown of vital social support networks. In the specific context of the healthcare infrastructure in Sari, there is a notable scarcity of controlled clinical trials examining the impact of this systemic intervention on family dynamics. Most prior FFT trials have emphasized relapse prevention and symptom reduction, with fewer specifically targeting holistic family functioning metrics as the primary outcome. Addressing this empirical gap is crucial for developing localized and culturally sensitive therapeutic protocols that address the unique needs of these families. Consequently, the present study was conducted to evaluate the effectiveness of FFT on family functioning in individuals with bipolar disorder. It was hypothesized that participation in FFT would be associated with greater improvements in family functioning compared to treatment as usual.

Method

The present study employed a randomized clinical trial with a pretest-posttest control group design and a three-month follow-up period.

The statistical population encompassed all individuals aged 25 to 45 years diagnosed with bipolar disorder who referred to Zare Psychiatric Hospital, psychological clinics, and specialized psychiatric offices in Sari, Iran, during 2025. A sample of thirty individuals with bipolar disorder, each accompanied by one self-selected family member, was recruited through convenience sampling based on the inclusion and exclusion criteria. Participants were then randomly allocated using block randomization (blocks of four, generated via a random number table) into two groups: the experimental group (n=15) and the control group (n=15).

Inclusion criteria involved a definitive diagnosis of bipolar disorder by a psychiatrist based on the DSM-5, being within the age range of 25 to 45 years, stable pharmacotherapy (no planned medication changes during the study period), and a willingness of at least one primary family member (e.g., spouse, parent, or sibling living with or closely involved with the patient) to participate consistently across all assessment points. Exclusion criteria included the presence of comorbid psychotic disorders, substance abuse, or missing more than two intervention sessions. The same family member completed the Family Assessment Device (FAD) at pretest, posttest, and follow-up. Ethical considerations were strictly observed; all participants provided informed written consent, and they were assured of the confidentiality of their personal data and their right to withdraw from the study at any time.

The sample size was calculated using G*Power software (version 3.1). For repeated measures ANOVA (within-between interaction), we assumed a medium effect size of f = 0.25 (equivalent to partial $\eta^2 \approx 0.0588$, based on Cohen's conventions and similar psychosocial intervention studies in bipolar disorder), alpha=0.05, power=0.80, number of groups=2, number of measurements = 3 (pretest, posttest, follow-up), and a nonsphericity correction $\varepsilon=1$ (conservative assumption). The correlation among repeated measures was set to 0.5 (a common default for psychological outcomes). This yielded a total required sample size of approximately 30–34 participants (15–17 per group) to achieve the desired power. The final sample of 30 (15 per group) was selected based on these calculations, adjusted for feasibility in this single-center pilot trial and expected minimal attrition in the local setting.

The tools used in this study were as follows:

The Family Assessment Device (FAD): This 60-item self-report questionnaire was utilized to evaluate family functioning based on the McMaster Model. The device assesses seven dimensions: Problem Solving, Communication, Roles, Affective Responsiveness, Affective Involvement, Behavior Control, and General Functioning. Each item is scored on a four-point Likert scale, ranging from 1 (Strongly Agree) to 4 (Strongly Disagree). Higher scores in each subscale indicate poorer family functioning, while lower scores represent healthier dynamics [17]. In international studies, the instrument has demonstrated high internal consistency, with Cronbach's alpha coefficients ranging from 0.72 to 0.92 [18]. In Persian-validated versions, the reliability was reported at 0.85 [19], and in the current study, the Cronbach's alpha for the total scale was calculated at 0.88, confirming its high reliability for this population.

The research procedure commenced after obtaining the necessary ethical approvals and coordinating with the clinical centers. Initially, both the experimental and control groups completed the pretest assessment. The experimental group then participated in ten 90-minute sessions of an abbreviated adaptation of FFT, conducted weekly. During this period, the control group remained on treatment as usual (pharmacotherapy only, with no additional psychosocial intervention; post-study access to FFT was offered to waiting-list participants). Immediately following the conclusion of the sessions, a posttest was administered to both groups. To evaluate the stability of the therapeutic effects, a follow-up assessment was conducted three months after the posttest. To ensure the integrity of the data collection process, all questionnaires were administered under the supervision of the researcher. The therapist was not blinded to group allocation due to the nature of the active intervention but adhered strictly to the standardized protocol to minimize bias.

The therapeutic intervention followed an abbreviated adaptation of the standardized FFTprotocol developed by Miklowitz et al. [20]. This intervention is a psychoeducational and behavioral approach designed to improve the family environment. The treatment consisted of ten 90-minute sessions held weekly. A summary of the objectives and content of each session is presented in Table 1.

The collected data were analyzed using descriptive statistics (mean and standard deviation) and inferential statistics. Specifically, repeated measures analysis of variance was employed to compare the scores across the three phases (pretest, posttest, and follow-up) and between the two groups using SPSS version 26. The significance level was set at $P<0.05$.

Table 1. Summary of FFT Sessions for Individuals with Bipolar Disorder

Session	Title	Brief Description of Content
1	Introduction & Engagement	Orientation to the treatment program, establishing rapport with the family, and assessing the family's understanding of the illness.
2	Psychoeducation (I)	Discussing the symptoms, etiology, and biological nature of bipolar disorder to reduce family guilt and stigma.
3	Psychoeducation (II)	Explaining the importance of medication adherence and identifying the impact of stress on the course of bipolar disorder.
4	Relapse Prevention	Teaching the family to identify early "prodromal" symptoms and developing a collaborative crisis management plan.
5	Communication Skills (I)	Introduction to communication enhancement training, focusing on the skill of "Active Listening" within the family.
6	Communication Skills (II)	Training family members on how to deliver "Positive Feedback" and "Constructive Requests for Change" to reduce hostility.
7	Communication Skills (III)	Focused practice on expressing negative feelings effectively without escalating conflict or expressed emotion.
8	Problem-Solving (I)	Teaching a structured approach to identifying family problems and generating multiple potential solutions through brainstorming.
9	Problem-Solving (II)	Selecting a specific solution, evaluating its pros and cons, and planning the implementation of the chosen strategy.
10	Review & Termination	Reviewing the skills acquired during the program, discussing future challenges, and officially concluding the therapeutic process.

Results

The participants had a mean age of 34.2 years (SD=5.8; range=25–45 years). The sample consisted of 18 males (60%) and 12 females (40%). No significant differences were observed between the experimental and control groups in terms of age ($P=0.678$), gender distribution ($P=0.689$), or baseline Family Assessment Device subscale and total scores ($P>0.05$), confirming baseline equivalence across groups.

As shown in Table 2, the experimental group exhibited substantial reductions in mean scores on all Family Assessment Device subscales and the total family functioning score from pretest to posttest, with these reductions largely maintained at the three-month follow-up (indicating improvements in family functioning, as higher scores reflect poorer functioning). In contrast, the control group displayed minimal changes across the three assessment phases, with mean scores remaining relatively stable and indicative of persistent dysfunctional patterns (Figure 1).

Table 2. Descriptive Statistics for Family Assessment Device Subscales and Total Score across Measurement Phases in Experimental and Control Groups

Variable	Group	Pre-test	Post-test	Follow-up
		Mean ± SD	Mean ± SD	Mean ± SD
Problem solving	Experimental	16.38±2.28	11.80±2.26	11.67±2.33
	Control	16.60±2.26	16.46±2.29	16.39±2.35
Communication	Experimental	19.42±1.60	15.48±1.56	15.41±1.55
	Control	19.52±1.51	19.32±1.88	19.26±2.06
Roles	Experimental	24.10±2.92	18.14±2.79	18.01±2.73
	Control	24.33±2.13	24.18±2.08	24.11±2.10
Affective responsiveness	Experimental	14.86±3.93	10.65±1.98	10.52±1.95
	Control	14.84±3.98	14.77±4.02	14.70±4.07
Affective involvement	Experimental	17.77±2.63	13.91±2.85	13.84±2.56
	Control	17.83±3.11	17.71±3.14	17.64±3.19
Behavior control	Experimental	22.77±1.49	18.51±1.36	18.45±1.43
	Control	22.87±1.23	22.75±1.41	22.69±1.58
General functioning	Experimental	30.44±4.01	21.20±2.68	21.13±2.60
	Control	30.61±4.37	30.49±4.45	30.42±4.51
Family functioning (total)	Experimental	145.74±14.89	110.93±10.04	110.26±10.12
	Control	146.60±11.55	146.32±11.95	146.05±12.06

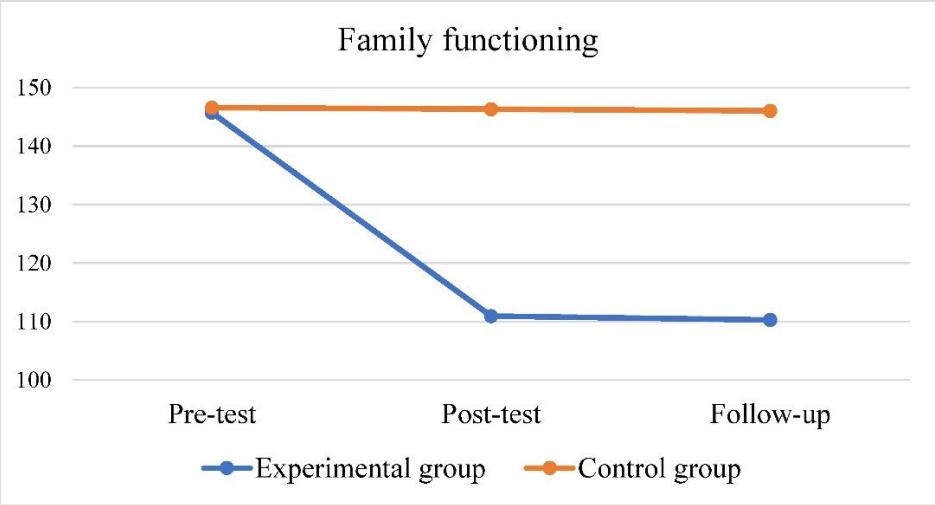

Figure 1. Changes in mean Family Assessment Device total scores from pretest to posttest and follow-up by group (experimental vs. control).

Prior to conducting the primary inferential analyses, the assumptions underlying repeated measures analysis of variance were examined. Normality of the data was assessed using the Shapiro-Wilk test, which indicated no significant deviations from a normal distribution across subscales and measurement phases ($P>0.05$). Levene's test confirmed homogeneity of variances between groups at pretest ($P>0.05$); homogeneity was similarly non-significant at posttest and follow-up ($P>0.05$).

Repeated measures analysis of variance revealed significant main effects of group, time, and group-by-time interaction for all subscales and the total score. The significant interaction effects indicate that reductions over time were predominantly attributable to the experimental group. Effect sizes (partial η^2) were moderate to large, ranging from 0.18 to 0.59, underscoring the clinical meaningfulness of the observed changes, particularly in the domains of Roles ($\eta^2=0.50$) and General Functioning ($\eta^2=0.59$) (Table 3).

Post-hoc pairwise comparisons with Bonferroni adjustment demonstrated statistically significant reductions in all subscale scores and the total family functioning score from pretest to posttest ($P<0.01$) and from pretest to follow-up ($P\leq0.001$) in the experimental group. Importantly, no significant differences were found between posttest and follow-up scores across all variables, indicating that the observed improvements associated with FFT were sustained over the three-month follow-up period (Table 4).

Table 3. Results of Repeated Measures Analysis of Variance for Family Assessment Device Subscales

Variable	Source	SS	df	MS	F	P	η^2
Problem solving	Group	230.53	1	230.53	15.79	0.001	0.36
	Time	91.06	1	91.06	17.24	0.001	0.38
	Time × Group	75.89	1	75.89	14.37	0.001	0.34
Communication	Group	151.74	1	151.74	15.68	0.001	0.36
	Time	68.57	1	68.57	37.63	0.001	0.50
	Time × Group	52.60	1	52.60	21.20	0.001	0.43
Roles	Group	382.05	1	382.05	34.86	0.001	0.56
	Time	149.95	1	149.95	32.57	0.001	0.54
	Time × Group	129.18	1	129.18	28.13	0.001	0.50
Affective responsiveness	Group	171.12	1	171.12	5.96	0.020	0.18
	Time	74.98	1	74.98	14.49	0.001	0.34
	Time × Group	66.31	1	66.31	12.81	0.001	0.31
Affective involvement	Group	146.88	1	146.88	6.06	0.001	0.18
	Time	63.65	1	63.65	8.66	0.001	0.24
	Time × Group	52.64	1	52.64	7.16	0.001	0.20
Behavior control	Group	184.45	1	184.45	16.33	0.001	0.37
	Time	75.89	1	75.89	22.45	0.001	0.46
	Time × Group	64.33	1	64.33	19.04	0.001	0.41
General functioning	Group	878.59	1	878.59	22.54	0.001	0.45
	Time	338.56	1	338.56	42.99	0.001	0.51
	Time × Group	312.47	1	312.47	39.68	0.001	0.59

Table 4. Post-hoc Pairwise Comparisons (Bonferroni-adjusted) for Significant Time Effects in the Experimental Group

Variables	Phases		Mean difference	SE	P
Problem solving	Pre-test	Post-test	2.36	0.58	0.01
	Pre-test	Follow-up	2.45	0.59	0.001
	Post-test	Follow-up	0.10	0.07	0.260
Communication	Pre-test	Post-test	2.07	0.39	0.001
	Pre-test	Follow-up	2.14	0.41	0.001
	Post-test	Follow-up	0.09	0.08	0.999
Roles	Pre-test	Post-test	3.06	0.56	0.001
	Pre-test	Follow-up	3.16	0.55	0.001
	Post-test	Follow-up	0.11	0.11	0.999
Affective responsiveness	Pre-test	Post-test	2.14	0.61	0.001
	Pre-test	Follow-up	2.24	0.59	0.001
	Post-test	Follow-up	0.13	0.12	0.756
Affective involvement	Pre-test	Post-test	1.99	0.70	0.001
	Pre-test	Follow-up	2.06	0.70	0.001
	Post-test	Follow-up	0.07	0.07	0.999
Behavior control	Pre-test	Post-test	2.19	0.46	0.001
	Pre-test	Follow-up	2.25	0.48	0.001
	Post-test	Follow-up	0.06	0.05	0.507
General functioning	Pre-test	Post-test	4.68	0.72	0.001
	Pre-test	Follow-up	4.75	0.73	0.001
	Post-test	Follow-up	0.07	0.07	0.999

Discussion

The present study found that an abbreviated adaptation of FFT was associated with significant reductions in Family Assessment Device scores (indicating improved family functioning) in the overall family functioning and its various subscales, including problem-solving, communication, and affective responsiveness. These reductions remained stable during the three-month follow-up period, suggesting short-term maintenance of gains in this Iranian sample.

The significant reductions in family functioning scores can be attributed to the multifaceted nature of FFT. By integrating psychoeducation with behavioral skills training, this intervention addresses the core environmental stressors that often exacerbate the symptoms of bipolar disorder [16]. In households where bipolar disorder is present, family members frequently experience high levels of distress, which can manifest as "Expressed Emotion" [21]. FFT directly targets these maladaptive interaction patterns by teaching family members how to communicate more effectively and solve problems collaboratively [22]. When families understand the biological basis of bipolar disorder, their tendency to blame the patient decreases, leading to a more supportive and less critical home environment [23].

The findings of this research are consistent with several previous studies in the field of psychosocial interventions. For instance, the results align with the findings of Miklowitz et al. [23], who demonstrated that FFT significantly enhances the quality of interpersonal relationships and

reduces the risk of symptomatic recurrence by improving the family's emotional climate. Similarly, our results are congruent with the study conducted by Yosefi Tabas et al. [10], which highlighted that structured family interventions lead to substantial improvements in the functioning and coping mechanisms of caregivers and patients alike. By empowering families with specific tools to manage the complexities of bipolar disorder, FFT fosters a sense of systemic efficacy and stability [26].

The improvement in the "Communication" and "Problem-Solving" subscales in this study is particularly noteworthy. These skills are essential for navigating the crisis periods associated with manic or depressive episodes. FFT provides a structured framework where family members can practice active listening and constructive feedback, which reduces the likelihood of high-conflict interactions [27]. As the family becomes more adept at managing external and internal stressors, the overall functioning of the unit may improve, creating a potential "buffer effect" that protects the individual with bipolar disorder from environmental triggers of relapse [22].

Furthermore, the stability of the results during the three-month follow-up period indicates that the skills acquired during FFT may have been internalized by the family members. Unlike purely pharmacological approaches that primarily target the patient's biology, this psychosocial intervention targets family interactions. By changing the way family members interact and support one another, the therapy may help establish new patterns of behavior that persist in the short term. This potential systemic change is crucial for the long-term management of a chronic condition like bipolar disorder.

Despite the positive findings, this study has certain limitations. The use of convenience sampling and the relatively small sample size (n=15 per group) may limit the generalizability of the results to all individuals with bipolar disorder. The three-month follow-up provides evidence of short-term sustainability, but longer-term follow-up (e.g., 1–2 years) is needed to confirm durability, as some studies of FFT show varying maintenance of effects over extended periods, with benefits sometimes emerging or strengthening after the active treatment phase. Additionally, the reliance on self-report measures for assessing family functioning could introduce social desirability bias. The involvement of only one family member limits representation of the full family system. Convenience sampling from one city (Sari) severely restricts external validity. The abbreviated (10-session) format, while feasible in this setting, may not fully capture the effects observed in longer standard protocols (e.g., 21 sessions over 9 months). Future research should consider larger, multi-center samples, extended follow-up periods (e.g., 12–24 months), inclusion of symptom relapse rates and clinical outcomes, and objective behavioral observations to further validate these findings.

Conclusion

In conclusion, this randomized controlled trial provides preliminary evidence that an abbreviated adaptation of FFT, as an adjunctive intervention to pharmacotherapy, was associated with improvements in family functioning — as measured by reductions in Family Assessment Device scores — among individuals with bipolar disorder in this Iranian sample. By addressing systemic dynamics, enhancing communication skills, and providing comprehensive psychoeducation, this approach may contribute to fostering a more supportive and stable home environment in the short term. The observed short-term improvements and their stability over the three-month follow-up period highlight the potential clinical utility of involving family members in the treatment process of bipolar disorder. Consequently, integrating FFT into standard psychiatric care in similar settings should be further explored as a means to reduce familial distress and support the overall functional recovery of affected individuals. Future research directions include conducting larger multicenter trials, implementing extended follow-up periods, assessing the impact on symptom relapse rates and clinical outcomes, and incorporating perspectives from multiple family members to better capture the full family system.

Conflict of Interest

The authors declare no conflicts of interest.

Ethical Approval

Approval was obtained from the Ethics Committee of Islamic Azad University, Sari Branch, Iran (Approval Code: IR.IAU.SARI.REC.1403.389). The trial was also registered with the Iranian Registry of Clinical Trials (IRCT20250429065529N1). All participants provided written informed consent prior to enrollment, and confidentiality of personal data was strictly maintained throughout the study.

Declaration of Generative AI and AI-Assisted Technologies

No generative AI or AI-assisted technologies were employed by the authors during the preparation of this manuscript, encompassing the writing process, generation of figures, data analysis, or any other component of the research and publication.

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