

The effects of psychoeducational family intervention on coping strategies of relatives of patients with bipolar I disorder: results from a controlled, real-world, multicentric study

Gaia Sampogna,¹ Mario Luciano,¹ Valeria Del Vecchio,¹ Claudio Malangone,^{1,2} Corrado De Rosa,¹ Vincenzo Giallonardo,¹ Giuseppina Borriello,¹ Benedetta Poci,¹ Micaela Savorani,¹ Luca Steardo Jr,¹ Debora Lampis,³ Franco Veltro,⁴ Francesco Bartoli,⁵ Francesco Bardicchia,⁶ Anna Maria Moroni,⁷ Giusy Ciampini,⁸ Emanuele Orlandi,⁹ Silvia Ferrari,¹⁰ Silvia Biondi,¹¹ Sonia Iapichino,^{11,12} Enrico Pompili,¹³ Massimiliano Piselli,¹⁴ Alfonso Tortorella,¹⁵ Giuseppe Carrà,^{5,16} Andrea Fiorillo¹

¹Department of Psychiatry, University of Campania "Luigi Vanvitelli", Naples, ²Mental Health Centre of Ravello, Mental Health Unit, Ravello, ³Mental Health Centre of Lanusei, Mental Health Unit, Lanusei, ⁴Mental Health Department of Campobasso, Campobasso, ⁵Department of Medicine and Surgery, University of Milano Bicocca, Monza, ⁶Mental Health Centre of Grosseto, Mental Health Unit, Grosseto, ⁷Niguarda Hospital, Department of Psychiatry, Milan, ⁸Mental Health Centre of Lanciano, Mental Health Unit, Lanciano, ⁹Mental Health Centre of Sassuolo, Mental Health Unit, Sassuolo, ¹⁰University of Modena and Reggio Emilia, Department of Psychiatry, Reggio Emilia, ¹¹Mental Health Centre of Montecatini, Mental Health Unit, Montecatini, ¹²Auditor Psychiatrist, for the activities of Clinical Risk Management and safety of treatments, Tuscany Region, ¹³Mental Health Centre of Rome, Mental Health Unit, Rome, ¹⁴Mental Health Centre of Foligno, Mental Health Unit, Foligno, ¹⁵Department of Medicine, Section of Psychiatry, University of Perugia, Perugia, Italy; ¹⁶Division of Psychiatry, University College of London, London, UK

Correspondence: Gaia Sampogna
Department of Psychiatry, University of Campania "Luigi Vanvitelli", Largo Madonna delle Grazie, 80138 Naples, Italy
Tel/fax +39 081 566 6531
Email gaia.sampogna@unicampania.it

Background: Psychoeducational family intervention (PFI) has been proven to be effective in improving the levels of family burden and patients' personal functioning in schizophrenia and bipolar disorders (BDs). Less is known about the impact of PFI on relatives' coping strategies in BD.

Methods: A multicenter, controlled, outpatient trial funded by the Italian Ministry of Health and coordinated by the Department of Psychiatry of the University of Campania "Luigi Vanvitelli" has been conducted in patients with bipolar I disorder (BD-I) and their key relatives consecutively recruited in 11 randomly selected Italian community mental health centers. We aim to test the hypothesis that PFI improves problem-oriented coping strategies in relatives of BD-I patients compared to the Treatment As Usual (TAU) group.

Results: The final sample was constituted of 123 patients and 139 relatives. At baseline assessment (T0), the vast majority of relatives already adopted problem-oriented coping strategies more frequently than the emotion-focused ones. At the end of the intervention, relatives receiving PFI reported a higher endorsement of adaptive coping strategies, such as "maintenance of social interests" (odds ratio [OR]=0.309, CI=0.04–0.57; $p=0.023$), "positive communication with the patient" (OR=0.295, CI=0.13–0.46; $p=0.001$), and "searching for information" (OR=0.443, CI=0.12–0.76; $p=0.007$), compared to TAU relatives, after controlling for several confounders. As regards the emotion-focused coping strategies, relatives receiving the experimental intervention less frequently reported to adopt "resignation" (OR=–0.380, CI=–0.68 to –0.08; $p=0.014$) and "coercion" (OR=–0.268, CI=–0.46 to –0.08; $p=0.006$) strategies, compared to TAU relatives.

Conclusion: PFI is effective in improving the adaptive coping strategies of relatives of BD-I patients, but further studies are needed for evaluating the long-term benefits of this intervention.

Keywords: coping strategies, family burden, psychoeducation family intervention, bipolar disorder, social functioning

Introduction

Following the seminal work with families of people with bipolar disorders (BDs) by Miklowitz et al¹ and Miklowitz and Goldstein,² it became clear that relatives have an extreme need to be supported in managing their family member's illness and to learn adaptive strategies to cope with the situation.³ In particular, Miklowitz and Chung found that relatives – following a mood episode – are usually very anxious about the risk of a new mood episode; sometimes, they decide to stop working or change the daily routine in order to take care of their ill relative.⁴ These caregivers seem to have

an emotional overinvolvement similar to that of family members of patients with schizophrenia,^{5,6} reporting high levels of subjective and objective burden, restrictions in social life, a high risk to develop depressive or anxiety symptoms, financial and working difficulties, general global health problems, and a reduced quality of life.⁷⁻¹² Moreover, caregivers often report feelings of powerlessness, hopelessness, and inability to change the situation.^{13,14}

Relatives develop different strategies to deal with patients' symptoms and behaviors, which are defined "coping strategies". Lazarus and Folkman¹⁵ identified two patterns of relatives' coping strategies: problem- and emotion-focused strategies. The former refers to the adaptive efforts to impact on stressful situations by using problem-solving and other cognitive personal resources (such as seeking for information about the disorder, using positive communication skills with the patient, finding support from friends, engaging in leisure activities).¹⁶ The latter can be defined as the emotional reactions to patient's behaviors or symptoms and include avoidance, collusion, resignation, and coercion.¹⁴

A significant association between relatives' coping strategies and the long-term outcome of BD patients has been found. In particular, when relatives adopt effective coping strategies to deal with patients' disturbing behaviors, patients can feel less stigmatized and stressed and report a reduced rate of relapses and hospitalization.¹⁷ Moreover, coping strategies are closely linked with the level of family functioning, emotional involvement, and severity of patients' clinical status;¹³ and the adoption of adaptive coping strategies can reduce the levels of family burden.^{14,18,19}

According to several studies^{20,21} and international guidelines,^{22,23} the optimal management of BD patients should include the provision of psychoeducational family interventions (PFIs), in order to improve long-term clinical and functional outcomes of patients and their relatives.^{14,17-19,24}

Jönsson et al¹⁴ showed that relatives of BD patients receiving an educational intervention improve their coping strategies, and these results were confirmed in two other studies also.^{25,26} However, these findings came from clinical trials with a small sample size and were not implemented in real-world settings. Moreover, the PFI, according to the Falloon model,²⁷ has been proven to be effective in improving adaptive coping strategies (such as positive communication and seeking for information) in relatives of patients with schizophrenia,²⁸ but it has never been tested in relatives of BD patients.

Within a multicenter study funded by the Italian Ministry of Health and coordinated by the University of Campania "Luigi Vanvitelli" on the evaluation of the efficacy of PFI

for families of bipolar I disorder (BD-I) patients in the real-world setting, we aim to test the hypothesis that PFI is effective in improving problem-oriented coping strategies in a sample of relatives of BD-I patients compared to the Treatment As Usual (TAU) group.

Methods

This study is based on the secondary analyses of data collected in a multicenter, controlled, outpatient trial conducted in BD-I patients and their key relatives consecutively recruited in 11 randomly selected Italian community mental health centers. Eleven mental health centers were selected by using a randomization procedure performed by a statistician from the Coordinating Center.^{29,30}

Patients' inclusion and exclusion criteria

Inclusion criteria for patients were the following: 1) age between 18 and 65 years; 2) diagnosis of BD-I according to the *Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (Text Revision)* criteria;³¹ 3) on the caseload of the local mental health center for at least 6 months, with a minimum of one contact per month in the last 12 months; 4) at least one affective episode in the past 3 years; 5) living with at least one relative; and 6) providing informed consent to participate in the study and to involve their relatives.

All patients who agreed to participate were asked for their permission to contact and involve their key relative(s). For each patient, one or more key relatives could be recruited. Key relatives were defined as those spending the highest number of hours in contact with the patient during the last year.³²

Relatives' inclusion criteria were: 1) age between 18 and 70 years, and 2) absence of any disabling physical or mental disorder.

Recruitment

According to the study's protocol, each participating center was expected to recruit at least 16 families of BD patients.

Patients and their key relatives who agreed to participate in the study were consecutively allocated to the experimental group (up to eight families per center), or to a waiting list, receiving the intervention at the end of the study (TAU).^{29,30} A consecutive recruitment procedure was adopted for reducing the contamination between subjects in the study centers.

Description of the experimental intervention

The experimental intervention is based on the PFI developed by Ian Falloon in 1985 for patients affected by schizophrenia and their relatives.²⁷

The intervention consists of three or four informative sessions, at least four communication skills sessions, and two or three problem-solving sessions. Sessions take place three times a month for a period ranging from 4 to 6 months (about 18 sessions in total). Each session lasts about 90 minutes. Site and frequency of sessions are adapted to families' needs and mental health professionals' duties and workloads.

The Falloon intervention has been adapted to BD-I by our research group with the following methodology: 1) analysis of scientific literature; 2) evaluation of available handbooks and manuals on psychoeducational approaches for BD-I;³³⁻³⁷ and 3) focus groups with research researchers and clinical experts and with users and carers, in order to identify the most relevant components to be included in the intervention.

The intervention was discontinued if the following occurred: 1) patients or relatives were unable to attend more than five psychoeducational sessions; or 2) patients were hospitalized or had any affective relapse during the intervention; or 3) patients or relatives withdrew their consent. In both groups, patients continued to receive the treatment usually provided in their center.

Outcome measure

Herein, we address a new research question on the efficacy of the PFI – according to the Falloon model²⁷ – in improving relatives' coping strategies.

The main outcome measure was the score in the Family Coping Questionnaire³⁸ (FCQ). The FCQ is a self-administered questionnaire consisting of 34 items, which has shown a good reliability and external validity. Each item is rated on a 4-level scale, from 1 (never) to 4 (always). The items can be grouped into the following 11 subscales: seeking for information on patient's illness (two items, Cronbach's alpha value=0.66, eg, "I tried to ask for guidance on how to behave toward S"); positive communication toward the patient (six items, Cronbach's alpha value=0.55, eg, "Whenever S appeared nervous or anxious, I tried to have him/her sit down and tell me what was wrong, and I tried to be reassuring"); relatives' maintenance of social interests (six items, Cronbach's alpha value=0.77, eg, "I had time to think of my own needs or interests"); patient's involvement in social activities (three items, Cronbach's alpha value=0.49, eg, "I tried to get S interested in something that might prove pleasant for him/her"); talking with friends about the patient's condition (one item, "I tried to discuss problems related to S's situation with my friends"), coercion (five items, Cronbach's alpha value=0.52, eg, "When he/she spoke nonsensically, I shouted to him/her to cut the nonsense"), avoidance (two items, Cronbach's alpha value=0.66,

eg, "I avoided staying alone in S's company"), resignation (three items, Cronbach's alpha value=0.69, eg, "I felt that I had no energy left to respond and that I was just waiting for events to happen"); use of alcohol and drugs (one item, "I had to drink or take drugs to forget about S's situation"); collusion (four items, Cronbach's alpha value=0.60, eg, "When S said something strange, I agreed with him/her"); and search for spiritual help (one item, "I have prayed or asked for spiritual help because of S's situation"). A higher score is indicative of a stronger endorsement of each coping strategy. The FCQ has been widely used for the assessment of coping strategies among relatives of people with severe mental disorders, such as schizophrenia,³⁸ and recently in families of people with eating disorders.^{39,40}

Assessment tools

Patients' clinical status was assessed with the 24-items Brief Psychiatric Rating Scale (BPRS);⁴¹ for the purposes of this study, we used the BPRS depressive-anxiety and manic/hostility subscales.

Patients' social functioning was assessed by the Disability Assessment Schedule,⁴² with higher scores indicating a worse social functioning.

Pharmacologic treatment was considered adequate if at least one mood stabilizer or one antipsychotic drug was prescribed to patients, according to the National Institute for Health and Care Excellence guidelines for the treatment of BD.²² Pharmacologic treatment was maintained stable as much as possible in the two groups over the intervention period.

This trial was conceived as a "real-world" study, and there was no possibility to include another active intervention as a comparator besides TAU. According to the study protocol, a waiting list was added in order to minimize the burden for mental health professionals and to guarantee that all relatives and patients would receive the intervention.⁴³⁻⁴⁶

Patients' clinical and sociodemographic characteristics, as well as relatives' sociodemographic characteristics at the baseline were recorded by ad hoc schedules.

In both groups, patients continued to receive the treatment usually provided in their center.

Patients and relatives were assessed prior to the beginning of the intervention (T0 assessment) and at the end of the intervention (T1 assessment).

Ethical approval

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. All patients and relatives received detailed information on the study and

provided written informed consent. The protocol was submitted to and approved by the Ethical Committee of the University of Campania “Luigi Vanvitelli”.

Statistical analyses

Per-protocol analysis – including only those patients who completed the treatment originally allocated to – was implemented in order to evaluate the effects of treatments in the real-world setting. Making an imputation of the missing values would be out of interest of a real-world study.

Frequency counts and descriptive analyses were performed, as appropriate. Baseline differences in socio-demographic and clinical characteristics were tested using χ^2 or Student's *t*-test, as appropriate. In each group, the impact of the experimental intervention and of TAU on relatives' coping strategies was explored by Student's *t*-test for paired samples. Moreover, in order to reduce type 1 error, bootstrap calculation with 1,000 bootstrap replications was implemented and 95% CI values of bootstrap were reported.

Correlations between coping strategies and relatives' sociodemographic characteristics, as well as between coping strategies and patients' clinical characteristics were explored using the Spearman correlation.

In order to test the efficacy of the experimental intervention on coping strategies, linear regression models were implemented, using the mean score of the FCQ subscales as outcome measures. In particular, the mean score of each FCQ subscale (eg, FCQ – collusion) was used as a continuous variable, and having received or not the experimental intervention was entered as the main predictor (considered as binary variable “Yes vs No”). Each regression model was controlled for patients' clinical and sociodemographic variables (ie, patient's age, gender, years of school, duration of illness, mean scores of BPRS subscales at baseline, Disability Assessment Schedule global score at baseline) and relatives' sociodemographic characteristics (ie, age, gender, type of relationship with the patient, years of cohabiting with the patient, daily hours spent in contact with the patient, being part of the same nuclear family) identified from the relevant literature in the field.¹⁶ Data analysis was performed using SPSS statistical software, version 18.0;⁴⁷ a two-tailed alpha level of significance was set at $p < 0.05$.

Results

Recruitment process and attrition rate

One center out of the 11 involved did not run the intervention after training of mental health professionals. The remaining 10 centers were expected to recruit up to 16 patients with BD-I and their key relatives. Of the

143 contacted families, six refused due to lack of time or current family conflicts. Of the remaining 137 families, 70 were consecutively allocated to the experimental group and 67 to the control group.

In the experimental group, 10 families dropped out during the intervention phases, with a retention rate of 93% (final study sample of 60 families). In the control group, four families dropped out during the study, with a retention rate of 94% (final study sample of 63 families).

Final sample

The final sample consisted of 123 patients and 139 relatives, of whom 60 patients and 72 relatives were allocated to the experimental group and 63 patients and 67 relatives to the control group. Sixty-eight relatives out of 139 (49%) reported to have children. Also, 45.6% of them were underage and were not included in the study. Patients' and relatives' sociodemographic characteristics as well as patients' clinical features are reported in Table 1.

Description of coping strategies

The most frequently adopted coping strategy was positive communication with the patient (3.1 ± 0.6), followed by patients' involvement in social activities (3.0 ± 0.7), maintenance of social interests (2.6 ± 0.8), and seeking for information (2.3 ± 1.0). Emotion-focused coping strategies, such as collusion (2.1 ± 0.4), coercion (2.0 ± 0.6), resignation (2.0 ± 0.9), and spiritual help (2.0 ± 1.1), were less frequently adopted. At baseline, no statistically significant difference in coping strategies was found between the two groups (Table 1).

According to the correlation analyses (Table 2), patients' involvement in social activities was positively associated with a higher educational level of relatives ($\rho = 0.183$, $p = 0.031$) and better psychosocial functioning of patients ($\rho = -0.359$, $p = 0.0001$). Maintenance of social interests was positively associated with relatives' level of education ($\rho = 0.297$, $p = 0.0001$) and patients' social functioning ($\rho = -0.358$, $p = 0.0001$), and negatively correlated with patients' depressive symptoms ($\rho = -0.187$, $p = 0.021$). Seeking for information was associated with worse social functioning of the patients ($\rho = 0.479$, $p = 0.0001$), while talking with friends was associated with a better level of patients' social functioning ($\rho = -0.253$, $p = 0.0001$).

Collusion was positively associated with relatives' older age ($\rho = 0.328$, $p = 0.0001$), a lower level of education ($\rho = -0.172$, $p = 0.042$), and more years of cohabiting with the patient ($\rho = 0.171$, $p = 0.045$). Coercion, avoidance, and resignation were more frequently adopted by relatives of patients

Table 1 Sociodemographic and clinical characteristics of the sample

	Patients group				Relatives group			
	Experimental group (n=60)	Treatment as usual group (n=67)	t/ χ^2	p-value	Experimental group (n=72)	Treatment as usual group (n=67)	t/ χ^2	p-value
Gender, F, % (n)	56.7 (34)	65.1 (41)	0.471	0.392	56.9 (41)	59.7 (40)	0.044	0.430
Age, M (SD)	50.0 (10.3)	48.6 (12.2)	0.975	0.458	50.9 (12.9)	52.7 (13.8)	0.734	0.780
Marital status, married, yes, % (n)	66.7 (40)	54.0 (34)	0.960	0.239	68.1 (49)	70.1 (47)	0.196	0.652
Level of education, high school, % (n)	46.7 (28)	41.3 (26)	1.969	0.121	36.9 (31)	40.0 (28)	1.594	0.486
Relationship with the patient, % (n)			NA				3.612	0.194
Parent	–	–			22.5 (16)	32.8 (22)		
Spouse/partner	–	–			54.9 (39)	43.3 (29)		
Son/daughter	–	–			9.9 (7)	16.4 (11)		
Sibling	–	–			11.3 (8)	4.5 (3)		
Other relative	–	–			1.4 (1)	3.0 (2)		
Employed, yes, % (n)	43.3 (26)	31.7 (20)	1.050	0.327	55.7 (39)	49.2 (31)	1.317	0.633
Number of family members, M (SD)	3.4 (1.0)	3.2 (1.1)	–0.732	0.761	–	–	NA	
Daily hours spent with the patient in the last 2 months, M (SD)	–	–	NA		6.6 (3.4)	6.7 (3.4)	1.245	0.455
Years of cohabiting with the patient, M (SD)	–	–	NA		24.6 (12.2)	27.9 (11.5)	1.586	0.760
Duration of illness, years, M (SD)	14.1 (10.0)	16.0 (6.7)	1.099	0.598	–	–	NA	
Months in charge at the MHC, M (SD)	73.2 (69.0)	103.5 (75.3)	2.326	0.032	–	–	NA	
No. of voluntary admissions lifetime, M (SD)	2.7 (4.1)	3.0 (3.4)	0.430	0.743	–	–	NA	
No. of involuntary admissions lifetime, M (SD)	0.7 (2.0)	1.5 (4.2)	1.345	0.299	–	–	NA	
Suicide attempts, yes, % (n)	23.7 (14)	23.8 (15)	0.008	0.983	–	–	NA	
BPRS, manic/hostility symptoms, M (SD)	1.3 (0.5)	1.3 (0.5)	0.584	0.348	–	–	NA	
BPRS, depression/anxiety symptoms, M (SD)	2.0 (0.7)	2.1 (0.8)	0.516	0.176	–	–	NA	
DAS global score, M (SD)	2.9 (1.0)	2.8 (1.0)	0.425	0.371	–	–	NA	
Antipsychotics, yes, % (n)	61.7 (37)	57.1 (36)	0.001	0.267	–	–	NA	
Mood stabilizers, yes, % (n)	86.7 (52)	85.7 (54)	0.143	0.588	–	–	NA	
Antidepressants, yes, % (n)	41.7 (25)	34.9 (22)	2.049	0.741	–	–	NA	
FCQ – positive communication, M (SD)	–	–	NA		3.1 (0.6)	3.1 (0.6)	0.787	0.722
FCQ – patient's involvement in social activities, M (SD)	–	–	NA		3.0 (0.7)	3.0 (0.7)	0.490	0.395
FCQ – relatives' maintenance of social interests, M (SD)	–	–	NA		2.7 (1.0)	2.5 (0.8)	0.074	0.210
FCQ – seeking for information, M (SD)	–	–	NA		2.4 (1.0)	2.3 (0.9)	0.771	0.349
FCQ – collusion, M (SD)	–	–	NA		2.1 (0.3)	2.1 (0.4)	0.520	0.501
FCQ – spiritual help, M (SD)	–	–	NA		2.1 (1.1)	2.0 (1.2)	0.714	0.129
FCQ – talking with friends about patient's condition, M (SD)	–	–	NA		2.1 (1.0)	1.9 (1.0)	0.271	0.379
FCQ – resignation, M (SD)	–	–	NA		2.0 (0.9)	2.0 (0.9)	0.783	0.901
FCQ – coercion, M (SD)	–	–	NA		2.0 (0.5)	2.0 (0.6)	0.481	0.559
FCQ – avoidance, M (SD)	–	–	NA		1.4 (0.7)	1.3 (0.6)	0.676	0.495
FCQ – use of alcohol and drugs, M (SD)	–	–	NA		1.1 (0.3)	1.2 (0.6)	0.075	0.741

Notes: Mean score of each subscale is reported; score ranges from 1 (never) to 4 (always) with higher score indicating higher endorsement of each strategy. Significant p-values have been highlighted in bold characters.

Abbreviations: BPRS, Brief Psychiatric Rating Scale; DAS, Disability Assessment Schedule; FCQ, Family Coping Questionnaire; M, mean score; SD, standard deviation; MHC, mental health center; NA, not applicable.

with higher levels of symptoms of the two BPRS subscales and with worse social functioning (Table 2).

Efficacy of the PFI

At the end of the intervention, the *t*-test for independent samples along with 95% CI bootstrap highlighted that relatives in the experimental group endorsed, more frequently, a positive communication strategy compared with those in the TAU

group, with a mean difference of 0.35 (95% CI: 0.47–0.24; $p=0.001$). Moreover, relatives receiving the PFI reported a higher endorsement of seeking for information (mean difference: 0.42, 95% CI: 0.66–0.18; $p=0.001$), maintenance of social interests (mean difference: 0.25, 95% CI: 0.47–0.05; $p=0.020$), and patient's social involvement (mean difference: 0.20, 95% CI: 0.38–0.04; $p=0.032$), compared with relatives from the control group. As regards the emotion-focused

Table 2 Correlation analyses

	Relatives' sociodemographic characteristics							
	Age		Years of education		Daily hours spent with the patient		Years spent with the patient in the same household	
	ρ	<i>p</i> -value	ρ	<i>p</i> -value	ρ	<i>p</i> -value	ρ	<i>p</i> -value
FCQ – coercion	-0.044	0.611	-0.056	0.514	0.087	0.311	-0.062	0.470
FCQ – collusion	0.328	0.000	-0.172	0.042	-0.002	0.980	0.171	0.045
FCQ – avoidance	-0.054	0.530	0.028	0.746	0.029	0.650	-0.046	0.589
FCQ – resignation	0.132	0.124	-0.148	0.083	0.208	0.014	0.176	0.333
FCQ – spiritual help	0.173	0.043	-0.265	0.002	0.196	0.021	0.183	0.031
FCQ – use of alcohol and drugs	0.001	0.992	0.070	0.416	-0.021	0.808	-0.062	0.466
FCQ – patient's involvement in social activities	-0.135	0.116	0.183	0.031	0.107	0.208	0.021	0.804
FCQ – positive communication	-0.107	0.212	0.114	0.183	0.040	0.640	-0.059	0.493
FCQ – relatives' maintenance of social interests	-0.148	0.084	0.297	0.000	-0.471	0.000	-0.056	0.513
FCQ – seeking for information	0.021	0.805	0.004	0.959	0.048	0.572	0.028	0.747
FCQ – talking with friends about patient's condition	-0.077	0.367	-0.022	0.795	-0.066	0.441	0.058	0.495

Notes: Mean score of each subscale is reported; score ranges from 1 (never) to 4 (always), with higher score indicating higher endorsement of each strategy. Significant *p*-values have been highlighted in bold characters.

Abbreviations: ρ , rho coefficient; FCQ, Family Coping Questionnaire.

strategies, relatives from the PFI group reported a significant reduction in collusion (mean difference: -0.16, 95% CI: -0.06 to -0.25; $p=0.001$), resignation (mean difference: -0.41, 95% CI: -0.18 to -0.63; $p=0.001$), avoidance (mean difference: -0.15, 95% CI: -0.01 to -0.29; $p=0.035$), and coercion (mean difference: -0.29, 95% CI: -0.17 to -0.41; $p=0.001$), compared with relatives from the TAU group (Table 3).

When considering *t*-test for paired samples, we found that only positive communication (mean difference: 0.19, 95% CI: 0.07–0.33; $p=0.006$) and seeking for information (mean difference: 0.27, 95% CI: 0.05–0.49; $p=0.028$) strategies significantly improved over time in relatives receiving the experimental intervention. As regards the emotion-focused strategies, only collusion (mean difference: -0.19, 95% CI: 0.09–0.29; $p=0.000$), resignation (mean difference: -0.32, 95% CI: -0.50 to -0.13; $p=0.001$), and avoidance (mean difference: -0.17, 95% CI: -0.27 to -0.06; $p=0.004$) were reduced over time in relatives receiving the PFI (Table 3).

Linear regression models

Regarding the impact of the intervention on relatives' coping strategies, family members receiving the experimental intervention reported higher score in the “maintenance of social interests” subscale (odds ratio [OR]=0.309, CI=0.04–0.57; $p=0.023$), “positive communication” subscale (OR=0.295, CI=0.13–0.46; $p=0.001$), and the “searching for information” subscale (OR=0.443, CI=0.12–0.76; $p=0.007$), after controlling for confounders (Table 4). As regards the

emotion-focused coping strategies, relatives receiving the experimental intervention reported lower scores in “resignation” (OR=-0.380, CI=-0.68 to -0.08; $p=0.014$), “coercion” (OR=-0.268, CI=-0.46 to -0.08; $p=0.006$), and “use of alcohol and drugs” subscales (OR=-0.182, CI=-0.33 to -0.04; $p=0.014$), after controlling for confounders (Table 5).

Discussion

The main novelty of our findings is related to the evaluation of the efficacy of the PFI according to the Falloon model in improving coping strategies of relatives of patients with BD-I. In fact, the Falloon model has been found to be one of the most effective psychosocial interventions for improving the family burden and coping strategies of relatives of patients with schizophrenia,^{32,48–51} but until now, no data are available on the efficacy of this model in families of people with BD-I. The majority of trials on PFI for BD have shown a positive impact on relapse prevention, symptom reduction,^{9,37–39} and patients' functioning.²⁹ Relatives' coping strategies have been less frequently considered as an outcome measure, despite the evidence clearly showing that high levels of family instability and maladaptive coping strategies can have a negative impact on the long-term outcome of the disorder.¹³

The main findings of our study are the following: 1) relatives of patients with BD tend to adopt, more frequently, problem-oriented coping strategies, such as positive communication, patients' involvement in social activities, maintenance of social interest, and seeking for information, than emotion-focused ones such as collusion, coercion,

Patients' sociodemographic characteristics													
Age		Years of education		Months in charge at the MHC		Duration of illness (years)		BPRS depressive symptoms		BPRS manic symptoms		DAS global score	
ρ	<i>p</i> -value	ρ	<i>p</i> -value	ρ	<i>p</i> -value	ρ	<i>p</i> -value	ρ	<i>p</i> -value	ρ	<i>p</i> -value	ρ	<i>p</i> -value
-0.115	0.203	0.050	0.531	-0.001	0.824	-0.031	0.910	0.184	0.016	0.256	0.003	0.181	0.035
-0.122	0.084	0.141	0.181	-0.153	0.280	-0.131	0.230	0.014	0.708	-0.030	0.775	0.136	0.609
-0.117	0.507	0.132	0.324	-0.035	0.096	-0.198	0.873	0.184	0.033	0.162	0.050	0.294	0.001
-0.094	0.268	0.077	0.140	0.074	0.296	-0.097	0.463	0.437	0.000	0.179	0.206	0.625	0.000
-0.092	0.357	-0.067	0.002	0.115	0.549	0.047	0.536	0.170	0.115	0.016	0.794	0.180	0.012
-0.063	0.687	0.153	0.299	-0.005	0.796	0.007	0.898	-0.034	0.796	0.080	0.112	-0.016	0.874
0.172	0.075	0.028	0.136	0.106	0.907	-0.035	0.272	0.364	0.000	0.014	0.624	-0.359	0.000
-0.043	0.891	-0.001	0.799	0.234	0.912	-0.009	0.023	0.186	0.056	-0.035	0.779	0.150	0.177
0.004	0.942	0.132	0.239	0.034	0.811	-0.004	0.642	-0.187	0.021	-0.119	0.193	-0.358	0.000
-0.066	0.593	0.075	0.727	0.043	0.856	-0.149	0.887	0.288	0.000	-0.041	0.868	0.479	0.000
-0.033	0.811	-0.028	0.460	0.012	0.545	-0.059	0.758	0.139	0.167	0.083	0.278	-0.253	0.000

resignation, and spiritual help; 2) relatives' coping strategies are strongly correlated with patients' symptoms severity and psychosocial functioning; and 3) relatives receiving PFI show a significant reduction in the adoption of emotion-focused strategies and an increase in problem-oriented ones.

The primary hypothesis that the experimental intervention is effective in improving adaptive coping strategies was thus confirmed. In particular, family members receiving the experimental intervention reported an improvement in the adoption of problem-oriented coping strategies with a reduction of the emotion-focused ones. This positive and encouraging finding is in line with studies promoted by Ruffolo et al⁵² and by Jönsson et al,¹⁴ who documented that the provision of a family psychoeducational intervention is associated with a change in the pattern of coping styles over time and with a reduction of emotion-focused coping strategies in relatives of patients with BD. Also, Perlick et al²⁵ found that, after providing a family-focused treatment, the reduction in the adoption of emotion-focused coping strategies is associated with an improvement in patients' clinical status. Moreover, in our study, the PFI has been conducted in a real-world setting, which further emphasizes the promising role of such an intervention in clinical practice. However, the improvements found should also be interpreted in the light of global improvement in the levels of family burden and patients' personal functioning (as observed in our previous study).²⁹

In our sample, the findings that relatives of patients with BD adopt, more frequently, problem-oriented coping strategies deserve some further explanations. First, in our sample,

patients were recruited in a stable phase of their disorder since PFI is better provided during patients' remission in order to increase patients' adherence to treatment sessions.²¹ Such methodological choice may have an impact on the coping strategies adopted since family members may have already developed some resiliency factors (such as adaptive coping strategies) which could benefit from reinforcement by the PFI sessions.^{53,54} In fact, as van der Voort et al¹⁰ observed, caregivers' difficulties coping with patients' behaviors are associated with a high number of relapses and hospitalizations, and with symptoms' severity. As reported by Goossens et al,¹³ relatives tend to adopt more primitive coping reactions (such as avoidance) and to less frequently seek support from the social network when patients have more severe symptoms.⁵⁵ This is confirmed by our findings that relatives' coping strategies strongly correlate with patients' severity of illness and psychosocial functioning. In particular, relatives adopted, more frequently, emotion-focused coping strategies when patients had high scores of BPRS subscales and worse social functioning. In fact, when patients have continuous symptoms and a progressive worsening in social functioning, relatives can perceive the situation as not amenable to change, and thus may more easily avoid the situation, feel resigned, or not be able to bear the situation any longer.¹⁶ The episodic pattern of BD can influence the adoption of relatives' coping strategies, since family members can learn from their previous experience what to do and seem to get used to dealing with the situation, with a consequent reduction in the levels of perceived distress.^{13,56}

Table 3 Differences in coping strategies adopted by relatives allocated to the experimental and TAU groups (N=139)

	Group T0				TI				Paired samples					
	Mean (SD)	Independent t-test	Mean diff	95% CI bootstrap	Bootstrap p-value	Mean (SD)	t-test	Mean diff	95% CI bootstrap	Bootstrap p-value	t-test	Mean diff	95% CI bootstrap	Bootstrap p-value
Collusion	Exp 2.1 (0.3) TAU 2.1 (0.4)	0.64	0.04	-0.08 to 0.17	0.520	1.2 (0.4) 2.1 (0.4)	3.32	-0.16	-0.06 to -0.25	0.001	3.91	-0.19	0.09-0.29	0.000
Patient's involvement in social activities	Exp 2.9 (0.7) TAU 3 (0.7)	0.69	0.08	-0.17 to 0.32	0.490	3.1 (0.7) 2.9 (0.8)	-2.26	-0.20	-0.38 to -0.04	0.032	1.49	0.14	-0.04 to 0.32	0.142
Resignation	Exp 2.0 (0.9) TAU 1.9 (0.9)	-0.28	-0.04	-0.33 to 0.23	0.783	1.7 (0.8) 2.1 (1)	3.55	-0.41	0.18-0.63	0.001	-3.48	-0.32	-0.50 to -0.13	0.001
Avoidance	Exp 1.4 (0.7) TAU 1.3 (0.6)	-0.42	-0.05	-0.24 to 0.17	0.676	1.2 (0.5) 1.4 (0.6)	2.08	-0.15	0.01-0.29	0.035	-2.98	-0.17	-0.27 to -0.06	0.004
Coercion	Exp 1.9 (0.5) TAU 2.0 (0.5)	0.71	0.07	-0.12 to 0.24	0.481	1.9 (0.4) 2.2 (0.5)	4.62	-0.29	0.17-0.41	0.001	0.37	0.03	-0.13 to 0.22	0.711
Relatives' maintenance of social interests	Exp 2.7 (0.7) TAU 2.5 (0.8)	-1.80	-0.24	-0.52 to 0.03	0.074	2.8 (0.7) 2.5 (0.9)	-2.53	-0.25	-0.47 to -0.05	0.020	1.4	0.09	-0.16 to 0.04	0.364
Positive communication	Exp 3.1 (0.5) TAU 3.1 (0.6)	-0.27	-0.03	-0.23 to 0.16	0.797	3.3 (0.4) 2.9 (0.5)	-5.82	-0.35	-0.47 to -0.24	0.001	2.84	0.19	0.07-0.33	0.006
Seek for information	Exp 2.4 (1.0) TAU 2.3 (0.9)	-0.30	-0.05	-0.36 to 0.24	0.771	2.6 (0.9) 2.2 (0.9)	-3.63	-0.42	-0.66 to -0.18	0.001	2.24	0.27	0.05-0.49	0.028
Use of alcohol and drugs	Exp 1.1 (0.3) TAU 1.2 (0.6)	1.80	0.14	0.01-0.31	0.083	1.0 (0.2) 1.2 (0.5)	-0.16	0.08-0.25	0.899	-1.10	-0.13	-0.35 to 0.10	0.275	
Talking with friends about patient's condition	Exp 2.1 (0.9) TAU 1.9 (1)	-1.11	-0.19	-0.52 to 0.14	0.271	1.9 (0.9) 1.9 (0.9)	-0.01	-0.22 to 0.22	0.961	-0.241	-0.01	-0.13 to 0.09	0.810	
Spiritual help	Exp 2.0 (1.1) TAU 1.9 (1.2)	-0.37	-0.07	-0.43 to 0.31	0.714	1.9 (1.1) 1.9 (1.1)	0.03	-0.24 to 0.32	0.832	-1.01	-0.12	-0.31 to 0.12	0.317	
											0.08	0.01	-0.23 to 0.23	0.935

Notes: T0= baseline assessment; T1= 6 months assessment. Bootstrap p-value based on 1,000 bootstrap replications. Mean difference = TAU mean - experimental mean. Mean difference² = experimental mean T1 - experimental mean T0 or TAU mean T1-TAU mean T0. Mean score at each subscale is reported; score ranges from 1 (never) to 4 (always), with higher score indicating higher endorsement of each strategy. Significant p-values have been highlighted in bold characters.

Abbreviations: Exp, experimental group; FCQ, Family Coping Questionnaire; TAU, Treatment As Usual group; T0, baseline assessment; T1, end of the intervention assessment; diff, difference.

Table 4 Impact of the experimental intervention on the problem-oriented coping strategies

	Patients' social involvement		Relatives' maintenance of social interests		Positive communication		Searching for information		Talking with friends	
	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value
Experimental treatment	0.157 (-0.08 to 0.40)	0.199	0.309 (0.04-0.57)	0.023	0.295 (0.13-0.46)	0.001	0.443 (0.12-0.76)	0.007	-0.011 (-0.35 to 0.32)	0.948
Patient's gender, male	-0.123 (-0.43 to 0.18)	0.426	0.147 (-0.19 to 0.48)	0.386	-0.117 (-0.33 to 0.10)	0.281	-0.141 (-0.55 to 0.27)	0.493	0.254 (-0.17 to 0.68)	0.240
Relative's gender, male	-0.145 (-0.45 to 0.16)	0.344	0.126 (-0.21 to 0.46)	0.453	-0.115 (-0.33 to 0.09)	0.280	-0.151 (-0.55 to 0.25)	0.457	0.099 (-0.52 to 0.32)	0.642
Relationship with patients, ref. cat.: other										
Parent	0.57 (-1.02 to 1.14)	0.917	-0.451 (-1.064 to 0.73)	0.452	0.655 (-0.10 to 10.41)	0.088	-0.193 (-10.63 to 10.24)	0.791	-0.661 (-20.17 to 0.84)	0.386
Partner	0.310 (-0.55 to 10.16)	0.475	-0.767 (-10.70 to 0.17)	0.108	0.605 (0.01-10.20)	0.047	-0.196 (-10.33 to 0.94)	0.734	-0.376 (-10.57 to 0.81)	0.533
Son	0.157 (-0.78 to 10.10)	0.742	-0.139 (-10.17 to 0.89)	0.791	0.321 (-0.34-0.98)	0.335	-0.307 (-10.56 to 0.95)	0.629	0.007 (-10.30 to 10.32)	0.992
Sibling	0.333 (-0.64 to 10.31)	0.501	-0.123 (-10.19 to 0.95)	0.820	0.619 (-0.06 to 10.30)	0.075	-0.062 (-10.40 to 10.20)	0.925	-0.030 (-10.39 to 10.33)	0.965
Duration of the illness	-0.004 (-0.02 to 0.01)	0.632	0.006 (-0.01 to 0.02)	0.491	-0.002 (-0.01 to 0.01)	0.655	-0.009 (-0.03 to 0.01)	0.367	0.005 (-0.01 to 0.02)	0.633
Months in charge	-0.000 (-0.01 to 0.01)	0.673	0.000 (-0.01 to 0.01)	0.778	-0.000 (-0.01 to 0.01)	0.484	0.000 (-0.01 to 0.01)	0.760	0.000 (-0.01 to 0.01)	0.835
Daily hours with the patient	0.020 (-0.01 to 0.06)	0.290	-0.052 (-0.09 to -0.01)	0.015	0.024 (0.00-0.05)	0.071	-0.039 (-0.09 to 0.01)	0.130	-0.034 (-0.01 to 0.02)	0.207
Patient's age	0.002 (-0.02 to 0.02)	0.821	0.001 (-0.02 to 0.02)	0.955	0.000 (-0.01 to 0.01)	0.944	0.006 (-0.02 to 0.03)	0.643	-0.018 (-0.05 to 0.01)	0.205
Relative's age	-0.008 (-0.02 to 0.01)	0.409	-0.002 (-0.02 to 0.01)	0.823	-0.017 (-0.03 to -0.01)	0.008	0.000 (-0.02 to 0.02)	0.993	0.009 (-0.01 to 0.03)	0.500
Relative's years of schooling	0.074 (0.04-0.39)	0.105	0.207 (-0.02 to 0.44)	0.080	0.048 (-0.10 to 0.19)	0.522	-0.075 (-0.36 to 0.21)	0.601	0.066 (-0.23 to 0.36)	0.660
Years spent in the same household	-0.005 (-0.02 to 0.01)	0.451	0.001 (-0.01 to 0.01)	0.910	-0.001 (-0.01 to 0.01)	0.887	0.004 (-0.01 to 0.02)	0.622	0.012 (-0.01 to 0.03)	0.210
BPRS, depressive symptoms, baseline	0.231 (0.02-0.44)	0.028	-0.029 (-0.25 to 0.20)	0.798	0.050 (-0.09 to 0.19)	0.491	0.001 (-0.27 to 0.27)	0.994	0.109 (-0.18 to 0.39)	0.455
BPRS, manic symptoms, baseline	0.048 (-0.21 to 0.31)	0.716	0.101 (-0.18 to 0.39)	0.483	-0.102 (-0.28 to 0.08)	0.267	-0.165 (-0.51 to 0.18)	0.349	0.134 (-0.23 to 0.50)	0.466
DAS, global score	0.049 (-0.11 to 0.21)	0.544	-0.134 (-0.31 to 0.04)	0.131	0.049 (-0.06 to 0.16)	0.386	0.382 (0.17-0.59)	0.001	0.171 (-0.05 to 0.39)	0.129

Note: Significant p-values have been highlighted in bold characters.

Abbreviations: BPRS, Brief Psychiatric Rating Scale; DAS, Disability Assessment Schedule; OR, odds ratio; CI, confidence intervals; ref. cat., reference category.

Table 5 Impact of the experimental intervention on the emotion-focused coping strategies

	Collusion		Resignation		Avoidance	
	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value
Experimental treatment	-0.116 (-0.25 to 0.02)	0.086	-0.380 (-0.68 to -0.08)	0.014	-0.185 (-0.39 to 0.01)	0.070
Patient's gender, male	0.005 (-0.16 to 0.17)	0.956	-0.336 (-0.72 to 0.04)	0.083	-0.214 (-0.47 to 0.04)	0.098
Relative's gender, male	0.048 (-0.12 to 0.21)	0.566	-0.317 (-0.69 to 0.06)	0.098	-0.151 (-0.40 to 0.10)	0.236
Relationship with patients, ref. cat.: other						
Parent	0.261 (-0.33 to 0.85)	0.386	-0.435 (-10.78 to 0.91)	0.523	0.335 (-10.23 to 0.56)	0.462
Partner	0.072 (-0.40 to 0.54)	0.761	-0.112 (-10.78 to 0.95)	0.835	-0.267 (-0.98 to 0.44)	0.457
Son	0.112 (-0.41 to 0.63)	0.670	-0.208 (-10.38 to 0.96)	0.726	-0.727 (-10.51 to 0.05)	0.068
Sibling	0.093 (-0.44 to 0.63)	0.732	-0.574 (-10.79 to 0.64)	0.352	-0.334 (-10.14 to 0.49)	0.417
Duration of the illness	-0.005 (-0.01 to 0.00)	0.269	-0.002 (-0.02 to 0.01)	0.836	0.001 (-0.01 to 0.01)	0.901
Months in charge	0.000 (-0.00 to 0.00)	0.705	0.001 (-0.01 to 0.01)	0.286	0.001 (-0.01 to 0.01)	0.247
Daily hours spent with the patient	-0.003 (-0.02 to 0.02)	0.806	0.021 (-0.03 to 0.07)	0.374	0.002 (-0.03 to 0.03)	0.910
Patient's age	0.004 (-0.01 to 0.01)	0.448	-0.008 (-0.03 to 0.01)	0.515	0.001 (-0.01 to 0.01)	0.895
Relative's age	0.004 (-0.01 to 0.01)	0.410	-0.003 (-0.03 to 0.02)	0.772	-0.014 (-0.03 to 0.00)	0.063
Relative's years of schooling	0.085 (-0.03 to 0.20)	0.149	-0.232 (-0.49 to 0.03)	0.084	0.046 (-0.13 to 0.22)	0.607
Years spent in the same household	0.007 (-0.00 to 0.01)	0.068	0.006 (-0.01 to 0.02)	0.452	0.007 (-0.00 to 0.01)	0.210
BPRS, depressive symptoms, baseline	-0.027 (-0.14 to 0.09)	0.632	0.137 (-0.12 to 0.39)	0.290	0.036 (-0.13 to 0.21)	0.679
BPRS, manic symptoms, baseline	0.031 (-0.11 to 0.17)	0.673	-0.212 (-0.54 to 0.11)	0.196	0.008 (-0.21 to 0.22)	0.942
DAS, global score	0.073 (-0.01 to 0.16)	0.102	0.321 (0.12 to 0.52)	0.002	0.090 (-0.04 to 0.22)	0.178

Notes: Mean score at each subscale is reported; score ranges from 1 (never) to 4 (always), with higher score indicating higher endorsement of each strategy. Significant p-values have been highlighted in bold characters.

Abbreviations: BPRS, Brief Psychiatric Rating Scale; DAS, Disability Assessment Schedule; OR, odds ratio.

Several sociodemographic characteristics were correlated with relatives' coping strategies. In particular, we found that emotion-focused coping strategies are more frequently adopted by relatives who are older, with a low educational level, and when they have more years of cohabitation with the patient. This finding could be due to the fact that relatives' coping strategies change over time, from adaptive to maladaptive, when the contact or cohabitation with patients increases. Similar results have also been found in relatives of patients with schizophrenia^{32,57} or eating disorders.^{39,40} Interestingly, among problem-oriented coping strategies, only seeking for information was frequently adopted when patients had a worse psychosocial functioning. This probably reflects the relative's need to have appropriate information on how to deal with the patient's disability, and suggests the importance of providing relatives with adequate information about the disorder and what to do in case of patients' disturbing behaviors.⁵²

We found that the effect of the intervention was independent from several patients' and relatives' sociodemographic and clinical characteristics, contradicting the hypothesis that psychoeducation is effective only when patients or relatives are younger, and with a short duration of illness.^{14,58}

This study has several strengths that are already acknowledged, and some limitations. The first is that relatives' coping strategies have been evaluated through a single self-reported questionnaire. However, the FCQ is a well-known

questionnaire with good psychometric properties, which has been used in previous studies involving relatives of patients with severe mental disorders.³⁸⁻⁴⁰ The second limitation is that patients' symptoms were tested with the BPRS, instead of more specific tools for affective symptoms. However, this choice was due to the fact that the BPRS is a very well-known, easy-to-use, and reliable instrument that can be adopted in ordinary settings by mental health professionals with a relatively short period of training. The third limitation of the study is the lack of randomization of patients and the relatively small sample size. This was intended as a "real-world" study, and the efficacy of the experimental intervention was tested in the routine care of Italian mental health centers. However, the purposive sampling and the per-protocol analysis adopted may have biased the results, but the sample representativeness has been preserved by the random selection of the participating centers. Moreover, in order to enhance fidelity to real-world settings, per-protocol methodology was adopted, and the imputation of missing data would not have been appropriate for this study. Another possible limitation is the exclusion of underage children and not-cohabiting close relatives from the intervention. This choice may have limited the generalizability of the results, since quite often, BD patients live with their underage children. However, this choice was due to the fact that we aimed to explore the effect of the PFI on adult relatives, and we aim to analyze the effect of BD on underage

Coercion		Use of alcohol and drugs		Seeking for spiritual help	
OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value
-0.268 (-0.46 to -0.08)	0.002	-0.182 (-0.33 to -0.04)	0.014	-0.002 (-0.38 to 0.38)	0.994
-0.220 (-0.46 to 0.02)	0.071	-0.085 (-0.27 to 0.10)	0.355	-0.164 (-0.65 to 0.32)	0.505
-0.201 (-0.44 to 0.03)	0.094	0.039 (-0.14 to 0.21)	0.667	-0.498 (-0.98 to -0.02)	0.042
-0.173 (-10.02 to 0.67)	0.685	0.466 (-0.18 to 10.11)	0.154	0.110 (-10.61 to 10.83)	0.899
0.015 (-0.65 to 0.68)	0.966	0.288 (-0.22 to 0.80)	0.265	0.210 (-10.15 to 10.57)	0.760
0.017 (-0.72 to 0.75)	0.963	-0.049 (-0.51 to 0.61)	0.864	-0.104 (-10.60 to 10.39)	0.891
-0.144 (-0.91 to 0.62)	0.710	0.298 (-0.28 to 0.88)	0.313	-0.156 (-10.70 to 10.40)	0.842
0.003 (-0.01 to 0.01)	0.654	0.002 (-0.01 to 0.01)	0.702	0.018 (-0.01 to 0.04)	0.119
0.000 (-0.01 to 0.01)	0.775	-0.001 (-0.01 to 0.01)	0.236	-0.001 (-0.01 to 0.01)	0.718
0.009 (-0.02 to 0.03)	0.538	0.002 (-0.02 to 0.02)	0.874	0.023 (-0.04 to 0.08)	0.453
-0.008 (-0.02 to 0.01)	0.302	0.006 (-0.01 to 0.01)	0.301	-0.013 (-0.04 to 0.02)	0.419
0.005 (-0.01 to 0.01)	0.468	-0.010 (-0.02 to 0.00)	0.070	-0.010 (-0.04 to 0.02)	0.507
-0.051 (-0.22 to 0.11)	0.544	-0.056 (-0.18 to 0.07)	0.381	-0.352 (-0.69 to -0.02)	0.040
-0.002 (-0.01 to 0.01)	0.764	-0.002 (-0.01 to 0.01)	0.657	0.016 (-0.00 to 0.04)	0.119
0.040 (-0.12 to 0.20)	0.621	-0.065 (-0.19 to 0.06)	0.298	0.135 (-0.19 to 0.46)	0.413
-0.008 (-0.21 to 0.19)	0.934	0.047 (-0.11 to 0.20)	0.553	-0.151 (-0.56 to 0.26)	0.472
0.009 (-0.11 to 0.13)	0.883	0.053 (-0.04 to 0.15)	0.269	0.078 (-0.17 to 0.33)	0.540

children in future studies. Moreover, the main aim of this study was to evaluate the efficacy of the PFI according to the Falloon model in coping strategies of those relatives cohabiting with the patient.

Future perspective and conclusion

PFI is effective in improving problem-oriented coping strategies in family members of patients with BD. This is a very relevant issue since adaptive coping strategies are essential for improving the level of family functioning and, consequently, to improve the long-term course of patients with BD. These findings further support the importance to routinely provide PFI to patients and family members.

Further steps should be focused on the assessment of the level of satisfaction of users and carers with these kinds of interventions. In fact, as recently pointed out in a survey carried out with all the categories of stakeholders involved in mental health, there is the need to include users' perspective in research studies⁵⁹⁻⁶² and to promote shared decision making⁶³⁻⁶⁹ in order to develop a more person-centered approach.⁷⁰⁻⁷² Finally, long-term studies can help to evaluate the stability of adaptive coping strategies over time, since these can change as the illness progresses.

Acknowledgment

The research project has been funded by the Italian Ministry of Health (registration number: 9556/2009).

Author contributions

AF designed the study and wrote the protocol. AF, VDV, ML, CDR, and CM organized the training and supervision for mental health professionals and coordinated the activities with participating mental health centers. GS, ML, and AT managed the literature searches and analyses. FB, GC, SI, DL, AM, FB, FV, LS, SF, SB, MP, EP, VG, and GB recruited patients and key relatives, carried out the intervention in their center, and coordinated the study in their center. GS, ML, and GC undertook the statistical analyses. ML, GS, VDV, AT, and AF wrote the first draft of the manuscript. All authors contributed toward data analysis, drafting and revising the paper and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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