

Patient Functioning and Family Burden in a Controlled, Real-World Trial of Family Psychoeducation for Schizophrenia

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Objective: This study explored the effectiveness of a psychoeducational family intervention for schizophrenia on patients' personal and social functioning as well as on relatives' burden and perceived support.

Methods: Thirty-four mental health professionals from 17 public mental health centers in Italy selected 71 families of consumers with schizophrenia. Forty-two families were randomly assigned to a group that received the intervention for six months, and 29 families were assigned to a waiting list for six months. At baseline and six months later, validated tools were used to assess patients' clinical status, personal and social functioning, and social network as well as relatives' burden, social resources, and perception of professional support. **Results:** In the intervention group the number of patients with poor or very poor global personal and social functioning decreased significantly, from 17 (47 percent) at baseline to nine (25 percent) at follow-up. A significant improvement was found for the intervention group in patients' social relationships, interests in obtaining a job, maintenance of social interests, and management of social conflicts. Twenty-seven patients (74 percent) reported that their social relationships had improved during the six-month period. For both the intervention and control groups, family burden significantly improved. Relatives' social contacts and perception of professional support significantly increased only in the intervention group. **Conclusions:** The results suggest that a psychoeducational family intervention may have a significant impact on functional outcomes of schizophrenia when provided to patients and caregivers in real-world settings. (*Psychiatric Services* 57:1784–1791, 2006)

Several studies conducted since the 1980s have demonstrated the efficacy of psychoeducational family interventions for the treatment of schizophrenia. For pa-

tients whose families received these interventions, the relapse rate at one year ranged from 6 to 12 percent, compared with 41 to 53 percent for patients who received routine care

(1–3). At two years the relapse rates were 17 to 40 percent for the intervention groups, compared with 66 to 83 percent for the control groups. Recent meta-analyses have shown that among patients with schizophrenia whose families receive psychoeducational interventions, relapse rates are reduced fourfold at one year and twofold in the subsequent year, compared with rates for patients who receive usual care (4,5). In addition, research findings are consistent with the possibility that these interventions reduce the disability of patients with schizophrenia (6–8) and ameliorate family burden (9–11).

Differences in clinical outcome between usual treatment for schizophrenia and treatment that includes psychoeducational interventions are so impressive that, as pointed out by McFarlane and colleagues (2), “they are some of the most substantial and consistent empirical effects achieved by any treatment in the mental health field.” Even though a large number of randomized controlled trials have examined the effectiveness of psychoeducational interventions, very few studies have looked at the impact on clinical and social outcomes of patients with schizophrenia of psychoeducational interventions provided in real-world settings by ordinary staff (7,12–15). Therefore, it is not clear to what extent these interventions are able to

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ameliorate patients' disability (6,8, 16) when they are provided in clinical settings or to what extent the interventions are able to reduce the burden of care and improve the relationships between service users, their families, and mental health service providers (17).

Psychoeducational family interventions are rarely available in routine care. About 10 percent of the families of American patients with schizophrenia and between 0 and 15 percent of their European counterparts receive these interventions in clinical practice (18–20). In Italy mental health care is strongly community oriented. Although 80 percent of families of service recipients with schizophrenia have regular contact with the local mental health service, only 8 percent of these families receive a psychoeducational intervention (21). The reasons for the lack of availability of these interventions in clinical settings have been only partly clarified (2,22).

From 2003 to 2004 the Department of Psychiatry of the University of Naples SUN coordinated a national program to implement psychoeducational interventions in Italian mental health centers and explore their effectiveness. The program, promoted by the National Institute of Health and an association of consumers' families, included two main phases. The first phase explored the impact of a modular staff training program in a psychoeducational intervention and the use of the intervention in routine care (19). Forty-six mental health professionals from 23 mental health centers participated in the training phase, which was completed by 38 professionals. In the second phase of the program, participants selected 71 families of consumers with schizophrenia: 42 families were randomly assigned to a group that would receive the intervention for six months, and 29 families were assigned to a waiting list for six months.

In this article we present the results of the second phase, which was aimed at exploring the impact of the intervention on patients' personal and social functioning and relatives' burden and perceived support.

Methods

Design

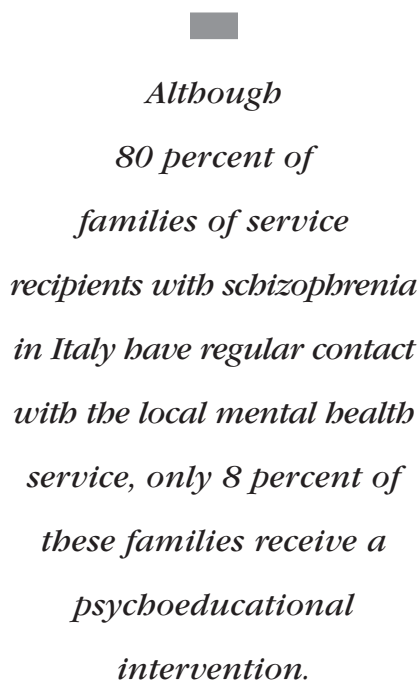
The study, which was approved by the Ethical Committee of Italy's National Institute of Health, was carried out in 17 public mental health centers between 2003 and 2004. At each center two professionals (one psychiatrist or psychologist and one nurse, social worker, or rehabilitator) completed a formal training program in the family psychoeducational intervention developed by Falloon (6). The intervention consists of four components: assessment of individual and family

sions in the use of the Brief Psychiatric Rating Scale (BPRS) (23) and the Social Network Questionnaire (SNQ) (20), and the other professionals were trained in the use of the Assessment of Disability (AD) (21), the Family Problems Questionnaire (FPQ) (20), and the SNQ. The training sessions on the BPRS and AD included description of each interview and the principles of rating; presentation of taped interviews and discussion of participants' ratings; and presentation of a further set of taped interviews that were independently rated by participants, on which exact agreement among raters was calculated by using Cohen's kappa coefficient.

In the intervals between the training modules, participants were invited to select for the intervention five patients with a *DSM-IV* diagnosis of schizophrenia who were clinically stable, in treatment with the local center for at least the previous six months, and living with at least one adult relative. Eligible families and patients were asked for their consent to participate in the study. They were informed that they would be randomly assigned either to receive the intervention immediately or to a waiting list to receive the intervention six months later. At each center three families were assigned to the intervention group and two families were assigned to the waiting list by means of a computerized random procedure performed by the coordinating center in Naples.

After completing the basic training course, professionals started the intervention with the first group of families. Professionals were instructed to carry out at least three one-hour sessions a month for each family for six months. The frequency and location of the sessions were decided on the basis of each family's needs and the professionals' working time and caseloads.

At baseline and six months later, patients' clinical status and personal and social functioning were assessed by the BPRS and the AD, respectively. Patients' and relatives' social resources were evaluated by the SNQ. The burden of care was assessed for each family member by the FPQ. Information about inter-



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needs; information sessions with consumers and their relatives about clinical aspects of schizophrenia, its treatments and early signs of relapse; communication skills training; and problem-solving skills training. The training program included three monthly modules of two and a half days each. In the year after the training course, participants attended four supervision meetings and each month they received by phone tutorial support on family work.

Participants were also trained in the use of the assessment instruments selected for the study. Psychiatrists and psychologists attended training ses-

Table 1

Baseline sociodemographic and clinical characteristics of patients with schizophrenia assigned to a psychoeducational family intervention or a control group

Characteristic	Intervention group (N=42)		Control group (N=29)	
	N	%	N	%
Demographic				
Male	29	69	24	83
Age (M±SD)	36.9±8.2		34.1±7.8	
Single marital status	39	93	27	93
Education				
No degree	5	12	4	14
Primary school degree	3	7	7	24
Secondary school degree	12	29	8	27
High school or professional degree	22	52	10	35
Employed ^a	9	21	1	4
Relatives living in the same household (M±SD)	2.1±.8		2.3±1.1	
Clinical				
Age at onset of illness (M±SD)	21.7± 6.0		21.9±6.5	
Lifetime voluntary hospital admissions (M±SD)	2.2±3.3		2.4±2.9	
Lifetime compulsory admissions (M±SD)	1.0±2.1		.7±.9	
Months in treatment at the mental health center (M±SD)	91.7±75.6		86.0±72.0	
Suicide attempts	9	21	10	36
Brief Psychiatric Rating Scale score (M±SD) ^b				
Depressive-anxiety symptoms	2.6±1.1		2.6±1.0	
Negative symptoms	2.4±1.0		2.7±1.2	
Mania-hostility symptoms	2.1±.9		2.3±.8	
Positive symptoms	2.4±1.1		2.6±1.1	
Assessment of Disability global score (M±SD) ^c	3.5±.9		3.7±.9	

^a Significant between-group difference ($p < .05$)

^b Possible scores range from 1, absent, to 7, very severe.

^c Possible scores range from 1, excellent functioning, to 6, very severe disability.

ventions provided by the mental health centers to the patients and their families in the previous six months were collected by the Pattern of Care Schedule (PCS) (21).

Instruments

The BPRS is a semistructured interview that assesses patients' psychopathological status. It contains 24 items grouped on the basis of factor analysis (23) in four subscales: positive symptoms, negative symptoms, mania-hostility symptoms, and depression-anxiety symptoms. Each item is rated on a 7-point scale from 1, absent, to 7, very severe. The AD is a semistructured interview derived from the Disability Assessment Schedule (24), which explores personal and social functioning. Components of personal function-

ing are poor or excessive self-care, underactivity, and psychomotor slowness or acceleration. The social functioning components are social withdrawal or overinvolvement, participation in household activities, affective and sexual relationships with a spouse or partner, parental role, conflicts in social and interpersonal relationships, work ability for employed persons or interest in getting a job for unemployed persons, interests and information about local events, and behavior during emergencies involving the patient in the previous month. A global evaluation item is also included. Each item is rated on a 6-point scale from 1, excellent functioning, to 6, very severe disability. Cohen's kappa coefficient was higher than .79 for seven BPRS items (29 percent of the items), be-

tween .79 and .50 for 12 BPRS items (50 percent) and 11 AD items (64 percent), and lower than .50 for five BPRS items (21 percent) and six AD items (36 percent).

The FPQ is a self-administered questionnaire containing 34 items that cover five aspects of a family's situation: practical burden (Cronbach's $\alpha = .88$), psychological burden ($\alpha = .74$), support received from professionals and members of the social network in emergencies concerning the patient ($\alpha = .72$), the relative's positive attitude toward the patient ($\alpha = .61$), and the relative's criticism of the patient's behavior ($\alpha = .24$). The items are rated on a 4-point scale from 1, never, to 4, always. The test-retest reliability of the questionnaire ranged from .50 and 1 (Cohen's kappa) for 27 of the items (79 percent) (20).

The SNQ is a 15-item self-administered tool exploring four dimensions of the respondents' social relationships: quality and frequency of social contacts ($\alpha = .68$), practical social support ($\alpha = .75$), emotional support ($\alpha = .66$), and quality of an intimate supportive relationship ($\alpha = .56$). The items are rated on a 4-point scale from 1, never, to 4, always. The test-retest reliability of the questionnaire ranged between .50 and 1 (Cohen's kappa) for ten of the items (69 percent) (20).

The PCS collects information on pharmacological, sociorehabilitative, and psychotherapeutic interventions received by the patient and on the professional support provided to the family in the previous six months. Compliance with the interventions was rated on a 3-point scale from 1, regular compliance for more than 50 percent of time in the reference period, to 3, irregular compliance for most of the time in that period.

Statistical analysis

At baseline the intervention and control groups were compared with respect to patients' clinical variables and families' sociodemographic characteristics by chi square tests and analysis of variance as appropriate. In each group *t* tests were used to compare baseline and follow-up scores for patients' clinical status,

personal and social functioning, and social network as well as for relatives' burden, social network, and professional support. Differences in these variables between the two groups at follow-up were tested by analysis of variance. Differences between baseline and follow-up scores on the BPRS subscales and items on the AD, SNQ, and FPQ were further explored by the Wilcoxon test for paired data. The statistical significance was set at .05. Data analysis was performed by using the SPSS package, version 11.5.

Results

Sample description

The 34 professionals from 17 public mental health centers (14 psychiatrists, ten nurses, three psychologists, four rehabilitators, and three social workers) selected 71 families of consumers with schizophrenia, of which 42 were randomly allocated to the intervention group and 29 were assigned to the control group.

Patients' sociodemographic and clinical characteristics at baseline are reported in Table 1. For both groups of patients, the average score on the BPRS subscales corresponded to a mild level of symptoms and the AD global score corresponded to moderate-marked impairment in social and occupational functioning.

In the six months before the study, 11 patients in the intervention group (26 percent) had attended information sessions on schizophrenia and psychotropic drugs, 12 (29 percent) had received individual psychotherapy, and 22 (52 percent) had participated in a rehabilitative program. The respective figures for the control group were nine (31 percent), eight (28 percent), and 16 (55 percent). All patients were taking antipsychotic drugs.

Patients' relatives were mostly parents or siblings. As shown in Table 2 in one-third of cases they were currently employed. In the six months before the study, 45 relatives (59 percent) in the intervention group and 30 relatives (60 percent) in the control group had attended supportive meetings with professionals, and 18 (24 percent) and 21 (42 percent), respectively, had participated in infor-

Table 2

Characteristics of relatives of patients with schizophrenia assigned to a psychoeducational family intervention or a control group

Characteristic	Intervention group (N=76)		Control group (N=50)	
	N	%	N	%
Male	27	35	22	44
Age (M±SD)	56.3±16.5		56.8±16.0	
Single marital status	17	22	5	10
Education				
No degree	27	36	16	32
Primary school degree	17	22	10	20
Secondary school degree	15	20	15	30
High school or professional degree	14	18	6	12
University degree	3	4	3	6
Employed	23	31	17	35
Relationship to the patient				
Spouse	4	5	2	4
Parent	54	71	40	80
Son	2	3	2	4
Sibling	15	20	4	8
Other	1	1	2	4
Daily hours in contact with the patient (M±SD)	8.1±3.5		8.4±4.8	

mation sessions on schizophrenia and drug treatment.

The only statistically significant difference at baseline between the two patient groups was in employment status—nine patients in the intervention group (21 percent) were employed, compared with one patient (4 percent) in the control group ($\chi^2=4.5$, $df=1$, $p<.05$).

Attrition rate

In the intervention group six of the 42 families (14 percent) left the study. In three cases relatives cited lack of time or interest, in one case a family member experienced a psychotic breakdown, in another case the family believed that the treatment was too demanding for the patient, and in another case the patient died from a physical illness. The families who dropped out differed from the other families only in regard to patients' mean±SD score on the BPRS mania-hostility subscale, which was significantly higher for those who dropped out (2.9 ± 1.5 compared with $2.0\pm.7$; $F=6.5$, $df=1$ and 40, $p<.02$).

In the control group three of the 29 families (10 percent) refused the six-month evaluation. In two cases the families moved to other geographic

areas, and in one case the patient refused despite having previously agreed to the follow-up assessment. The families who did not participate in the follow-up differed from those who did in the number of hours of close contact with the patient, which was higher among the families who did not participate (13.8 ± 6.2 compared with 7.7 ± 4.2 hours; $F=10.1$, $df=1$ and 48, $p<.003$).

Outcome measures at six months

Thirty-six patients in the intervention group completed the 18 sessions required over the six-month period. In the control group, 26 patients were reassessed at six months. Medication dosages for these groups during the study period were as follows: haloperidol, 12 patients in the intervention group (33 percent) and four in the control group (15 percent) (mean dosages of 4.2 ± 2.5 and 3.8 ± 1.6 mg); for risperidone the respective figures were eight (22 percent) and seven (27 percent) (3.2 ± 2.3 and 4.1 ± 1.4 mg); for olanzapine, eight (22 percent) and four (15 percent) (19.4 ± 8.6 and 12.5 ± 6.4 mg); for clozapine, six (17 percent) and four (15 percent) (300 ± 151.6 and 337.5 ± 205.6 mg); for fluphenazine, three (8 percent) and

Table 3

Symptoms, levels of disability, and social networks at baseline and six-month follow-up of patients with schizophrenia assigned to a psychoeducation family intervention or a control group

Measure and subscale	Intervention (N=36)				Control (N=26)			
	Baseline		6-month follow-up		Baseline		6-month follow-up	
	M	SD	M	SD	M	SD	M	SD
Brief Psychiatric Rating Scale (M±SD score) ^a								
Depressive-anxiety symptoms	2.6	1.1	2.4	.9	2.6	1.0	2.4	.9
Negative symptoms	2.5	.9	2.2	1.0	2.6	1.1	2.5	1.3
Mania-hostility symptoms	2.0	.7	1.9	.6	2.2	.7	2.0	1.0
Positive symptoms	2.4	1.0	2.1	1.0	2.5	1.1	2.3	.9
Assessment of disability (M±SD score) ^b								
Poor self-care ^c	2.5	.7	2.3	.7	2.8	1.1	2.8	1.0
Underactivity	3.1	1.0	2.9	.7	3.2	1.0	2.8	1.1
Slowness	2.5	.8	2.5	.7	2.7	1.0	2.5	.6
Social withdrawal ^d	3.2	.8	2.9	.8	3.0	1.0	2.9	.9
Participation in household activities ^e	2.9	.9	2.6	.8	3.5	1.2	3.1	1.2
Affective and sexual relationships	4.1	.8	3.9	.9	3.8	1.1	3.7	1.0
Friction in social and interpersonal relationships ^d	2.8	.8	2.4	.6	2.4	.7	2.4	.7
Interest in getting a job or studying ^f	3.7	1.2	3.2	1.1	4.3	1.1	3.9	1.3
Interests and information about local events ^d	2.8	.8	2.5	.8	3.0	.9	2.7	.6
Patient's behaviour in emergencies ^g	2.4	.8	2.7	.9	3.0	.9	2.9	.9
Global score ^h	3.5	.9	3.0	.8	3.7	.9	3.4	1.0
Social Network Questionnaire (M±SD score) ⁱ								
Social contacts	2.0	.7	2.0	.6	2.2	.6	2.3	.6
Practical support ^d	3.0	.8	3.3	.7	3.0	.8	3.1	.8
Psychological support	2.2	.8	2.5	.6	2.3	.6	2.5	.5

^a Possible scores range from 1, absent, to 7, very severe.

^b Possible scores range from 1, excellent functioning, to 6, very severe disability.

^c Significant between-group difference ($p < .05$) at follow-up

^d Significant difference ($p < .05$) at follow-up for the intervention group

^e Significant difference ($p < .05$) at follow-up for the control group

^f Significant difference ($p < .005$) at follow-up for the intervention group

^g Significant between-group difference ($p < .01$) at follow-up

^h Significant difference ($p < .001$) at follow-up for the intervention group

ⁱ Possible scores range from 1, never, to 4, always.

three (12 percent) ($1.0 \pm .2$ and 2.2 ± 2.4 mg); and for quetiapine, three (8 percent) and one (4 percent) (533.3 ± 230.9 and 800.0 mg). In the control group three patients (11 percent) received chlorpromazine (31.7 ± 16.1 mg) and one patient (4 percent) was treated with perphenazine (5.0 mg).

In regard to psychological interventions, nine patients in the intervention group (25 percent) and three in the control group (12 percent) received individual psychotherapy; for group therapy, the respective figures were four (11 percent) and two (8 percent). In addition, ten patients in the intervention group (28 percent) and nine in the control group (35 percent) received social skills training; the respective figures were 14 (39 percent) and six (23 percent) for participation in a socialization group.

Compliance with interventions was rated regular for 31 patients in the intervention group (94 percent) and 23 in the control group (96 percent).

At follow-up, compared with patients in the control group, those in the intervention group demonstrated lower levels of disability in self-care ($F = 5.4$, $df = 1$ and 60 , $p < .05$) and in behavior in emergencies ($F = 7.1$, $df = 1$ and 57 , $p < .01$). In the intervention group, a statistically significant improvement was found in global levels of disability, as well as in social withdrawal, interest in getting a job or studying, social interests, and management of friction in social and interpersonal conflicts (Table 3).

In the intervention group, 17 patients (47 percent of those followed up) had poor or very poor global functioning at baseline, compared with

nine (25 percent) at follow-up ($z = -3.3$, $p < .001$). Social withdrawal was either moderate or severe for 13 patients (36 percent) in the intervention group at baseline, compared with seven (19 percent) at follow-up ($z = -2.1$, $p < .03$). Difficulties in managing friction in social and interpersonal relationships were noted for seven patients (19 percent) in the intervention group at baseline and for two (5 percent) at follow-up ($z = -2.4$, $p < .01$). Difficulties in maintaining interests were found for 23 patients (64 percent) in the intervention group at baseline and for 14 (39 percent) at follow-up ($z = -2.0$, $p < .05$).

In the intervention group, 27 patients (75 percent) stated at follow-up that their social relationships had improved during the previous six months, whereas at baseline 21 pa-

Table 4

Burden, social network, and professional support at baseline and six-month follow-up among relatives of patients with schizophrenia assigned to a psychoeducation family intervention or a control group

Subscale ^a	Intervention group (N=57)				Control group (N=43)			
	Baseline		6-month follow-up		Baseline		6-month follow-up	
	M	SD	M	SD	M	SD	M	SD
Objective burden ^{b,c}	1.9	.7	1.8	.6	2.0	.7	1.7	.6
Subjective burden ^{d,e}	2.4	.6	2.2	.6	2.2	.6	2.0	.5
Practical social support ^c	2.9	.8	3.0	.7	2.6	.8	2.9	.8
Affective social support	2.4	.7	2.5	.6	2.5	.7	2.5	.6
Social contacts ^b	2.2	.6	2.4	.5	2.4	.7	2.4	.6
Social help in the patient's emergencies ^b	2.1	.8	2.3	.8	2.5	.8	2.5	.8
Professional support ^f	2.9	.5	3.2	.5	2.8	.7	3.0	.6

^a Measured by the Family Problems Questionnaire. Possible scores range from 1, never, to 4, always.

^b Significant difference ($p < .05$) at follow-up for the intervention group

^c Significant difference ($p < .05$) at follow-up for the control group

^d Significant difference ($p < .005$) at follow-up for the intervention group

^e Significant difference ($p < .01$) at follow-up for the control group

^f Significant difference ($p < .001$) at follow-up for the intervention group

tients (58 percent) reported such improvement ($z = -2.1$, $p < .03$). In addition, 29 patients in the intervention group (82 percent) felt that they had someone to take care of them in case of illness at follow-up, compared with 23 patients (63 percent) at baseline ($z = -3.07$, $p < .002$).

In the control group, the only statistically significant improvement in patients' personal or social functioning was in participation in household activities, which was very poor for six patients (23 percent) at baseline and for four (15 percent) at follow-up ($z = -2.0$, $p < .05$).

Family burden, social network, and professional support

Fifty-seven relatives in the intervention group completed the 18 sessions required over the six-month period. In the control group, 43 relatives were reassessed at six months. As shown in Table 4, at follow-up the average level of family burden significantly improved in both the intervention and control groups. In the intervention group, 29 relatives (51 percent) reported having had to always or often neglect their own hobbies at baseline, compared with 12 (21 percent) at six months ($z = -2.6$, $p < .01$). Twenty-six relatives (46 percent) in the intervention group reported cry-

ing and feeling depressed at baseline, compared with 16 (28 percent) at follow-up ($z = -2.5$, $p < .02$), and 32 (56 percent) reported being worried about the future of other family members at baseline, compared with 22 (39 percent) at follow-up ($z = -2.4$, $p < .02$). Twelve relatives (21 percent) in the intervention group reported at baseline feeling embarrassed when they were in public places with the patient, and five (9 percent) reported such feeling at six months ($z = -3.4$; $p < .001$).

In the control group 14 relatives (32 percent) reported at baseline that they had to neglect their own hobbies, compared with 12 (28 percent) at follow-up ($z = -2.0$, $p < .05$), and ten (23 percent) reported having to neglect their job activities at baseline, compared with three (7 percent) at follow-up ($z = -3.0$, $p < .003$). Fifteen relatives in the control group (35 percent) felt unable to bear the situation any longer at baseline, compared with nine (21 percent) at follow-up ($z = -2.1$, $p < .04$), and 20 (47 percent) reported worrying about the future of other family members at baseline, compared with 13 (30 percent) at follow-up ($z = -2.6$, $p < .008$).

Relatives' social contacts and perceived help in emergencies involving the patient significantly improved in

the intervention group. At follow-up 25 relatives (44 percent) stated that they had been contacted by relatives and friends, compared with 15 (26 percent) at baseline ($z = -2.9$, $p < .003$), and 31 (54 percent) reported that they could rely on friends in critical situations at follow-up, compared with 22 (39 percent) at baseline ($z = -2.4$, $p < .02$). Moreover, 25 relatives (44 percent) reported a significant improvement in social relationships in the previous six months at follow-up, compared with ten (18 percent) at baseline ($z = -2.3$, $p < .02$).

In the control group practical social support significantly improved over the six-month period. In particular, 23 relatives (53 percent) stated at follow-up that they could rely on someone for demands, compared with 16 (37 percent) at baseline ($z = -2.8$, $p < .005$).

Relatives' perception of the level of professional support significantly increased only in the intervention group. In particular, 53 relatives (93 percent) stated at follow-up that they had received information by professionals on how to cope with patients' disturbing behavior, compared with 37 (65 percent) at baseline ($z = -4.4$, $p < .001$). Twenty-four (42 percent) felt confident about receiving professional help in case of emergencies,

compared with 16 (28 percent) at baseline ($z=-2.5$, $p<.01$), and 53 (93 percent) reported a high level of professional help provided to the patient by psychiatrists at follow-up, compared with 48 (84 percent) at baseline ($z=-2.0$, $p<.04$).

Discussion

This is the first controlled trial in a routine clinical setting of a psychoeducational family intervention for schizophrenia carried out in Italy. An important feature of the study was the random allocation of the families to an intervention or a control group. The adoption of a waiting list led to a condition similar to clinical routine and ensured that all recruited families received the intervention in a reasonable period.

The intervention was implemented by two professionals at each center who had limited expertise in behavioral family interventions (19), which reflects the limited resources currently available in Italy to implement evidence-based treatments in clinical settings. Such limitations make it very difficult to train a majority of mental health professionals in these interventions. The high level of staff attendance suggests that a modular training program could facilitate the dissemination of psychoeducational intervention in routine clinical settings when the professional resources are scarce.

The inclusion criteria—a *DSM-IV* diagnosis of schizophrenia and cohabitation with one adult relative—permitted recruitment of a broad sample. In addition, patients with co-occurring conditions, such as alcohol or drug abuse and physical illness, were not excluded. Thus the sample was representative of the heterogeneity of patients with schizophrenia in Italy (21).

The study focused on the impact of the intervention on functional outcomes of schizophrenia, in particular patient's personal and social functioning and social network. Such a focus addresses a frequently emphasized weakness of clinical trials involving patients with schizophrenia, which often use relapse as the outcome variable, whereas consumers and their families are more concerned about

such issues as housing, employment, and social relationships (25–28).

The well-validated assessment tools were administered by the same professionals who provided the intervention. In real-world trials, this is not regarded as detrimental, because it guarantees a condition more similar to clinical routine, where professionals are expected to evaluate their own clinical work (26,27). It should also be noted that most of the instruments used in the study were self-administered.

The main limitations of the study are the small sample and the relatively brief period of follow-up, which has prevented us from assessing the impact of the intervention on other outcome variables, such as return to work or achievement of independent life goals. The most impressive result of the study is the significant reduction in levels of personal and social disability among the patients, especially in interests and social relationships. This result, in line with those reported in randomized controlled trials by Montero and colleagues (8) and Falloon (6), may be at least partly related to the identification of individual goals that could reasonably be achieved in a few months, which in most cases concerned social activities; the focus on communication skills in family sessions; and the active involvement of family members in the management of the patient's disorder. As pointed out by Liberman and Liberman (29), psychoeducational family interventions can be regarded as rehabilitative because they provide all family members, including the patient, with knowledge, skills, and support to function better in daily life and to achieve their own personal goals.

A significant improvement was observed in family burden in both the intervention and control groups. This improvement is in contrast with data reported by Mueser and colleagues (1), Canive and associates (30), and McDonnell and coauthors (31), who found no reduction of burden in treated families compared with families in the control groups. The previous findings may be a result of special attention paid to families' needs by professionals in both the intervention

and control groups as well as to the expectations about forthcoming treatment among families in the control group. Understanding the impact of the intervention on family burden and social resources will require long-term investigations.

In the intervention group the percentage of relatives who reported feeling embarrassed when they were in public places with the patient decreased significantly, from 21 to 8 percent at follow-up. This finding suggests a specific effect of the intervention on stigma perceived by the relatives, which may be related to improvement in the patient's competence and to information provided to relatives about the clinical characteristics and outcome of schizophrenia.

Another interesting finding is the significant increase in relatives' perception of professional support only among families who received the intervention. This finding reflects improvement in relationships with consumers and their families reported by the professionals, which is considered among the main advantages of the use of the psychoeducational intervention (15,19).

Conclusions

The results of this study suggest that psychoeducational interventions may have a significant impact on functional outcomes of schizophrenia, even when they are provided to patients and caregivers recruited in a real-world service setting. Further studies are needed to address additional issues, such as the long-term effects of psychoeducational interventions on the quality of life of persons with schizophrenia and their relatives.

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References

- Mueser KT, Sengupta A, Schooler NR, et al: Family treatment and medication dosage reduction in schizophrenia: effects on patient social functioning, family attitudes, and burden. *Journal of Consulting and Clinical Psychology* 69:3–12, 2001
- McFarlane WR, Dixon L, Lukens E, et al: Family psychoeducation and schizophrenia: a review of the literature. *Journal of Marital and Family Therapy* 29:223–245, 2003
- Falloon IRH: Family interventions for mental disorders: efficacy and effectiveness. *World Psychiatry* 2:20–28, 2003
- Pekkala E, Merinder L: Psychoeducation for schizophrenia. *Cochrane Database Systematic Review*, 2002
- Pharoah FM, Rathbone J, Mari JJ, et al: Family intervention for schizophrenia. *Cochrane Database Systematic Review*, 2003
- Falloon IRH: Family Management of Schizophrenia: A Controlled Study of Clinical, Social, Family and Economic Benefits. Baltimore, John Hopkins University Press, 1985
- Barrowclough C, Tarrier N, Lewis S, et al: Randomized controlled effectiveness trial of a needs-based psychosocial intervention service for carers of people with schizophrenia. *British Journal of Psychiatry* 174:505–511, 1999
- Montero I, Asencio A, Hernandez I, et al: Two strategies for family intervention in schizophrenia: a randomized trial in a Mediterranean environment. *Schizophrenia Bulletin* 27:661–670, 2001
- Stam H, Cuijpers P: Effects of family interventions on burden of relatives of psychiatric patients in the Netherlands: a pilot study. *Community Mental Health Journal* 37:179–187, 2001
- Berglund N, Vahlne JO, Edman A: Family intervention in schizophrenia: impact on family burden and attitude. *Social Psychiatry and Psychiatric Epidemiology* 38:116–121, 2003
- Hazel NA, McDonell MG, Short RA: Impact of multiple-family groups for outpatients with schizophrenia on caregivers' distress and resources. *Psychiatric Services* 55:35–41, 2004
- Cardin VA, McGill CW, Falloon IRH: An economic analysis: costs, benefits, and effectiveness, in *Family Management of Schizophrenia: A Controlled Study of Clinical, Social, Family and Economic Benefits*. Edited by Falloon IRH. Baltimore, John Hopkins University Press, 1985
- Rund BR, Moe L, Sollien T, et al: The Psychosis Project: outcome and cost-effectiveness of a psychoeducational programme for schizophrenic adolescents. *Acta Psychiatrica Scandinavica* 89:211–218, 1994
- Mak KY, Wong MC, Ma LK, et al: A cost-effectiveness study of a community-based family management rehabilitation programme for schizophrenic outpatients in Hong Kong: a six-month report. *Hong Kong Journal of Psychiatry* 7:26–35, 1997
- Magliano L, Fiorillo A, Fadden G, et al: Effectiveness of a psychoeducational intervention for families of patients with schizophrenia: results of a study funded by the European Commission. *World Psychiatry* 4:45–49, 2005
- Hornung WP, Feldmann R, Klingberg S, et al: Long-term effects of a psychoeducational psychotherapeutic intervention for schizophrenic outpatients and their key-persons: results of a five-year follow-up. *European Archives of Psychiatry and Clinical Neurosciences* 249:162–167, 1999
- Lehman AF: The role of mental health service research in promoting effective treatment for adults with schizophrenia. *Journal of Mental Health Policy and Economics* 1:199–204, 1998
- Dixon L, Lyles A, Scott J, et al: Services to families of adults with schizophrenia: from treatment recommendations to dissemination. *Psychiatric Services* 50:233–238, 1999
- Magliano L, Fiorillo A, Malangone C, et al: Implementing psychoeducational interventions in Italy for patients with schizophrenia and their families. *Psychiatric Services* 57:266–269, 2006
- Magliano L, Fadden G, Madianos M, et al: Burden on the families of patients with schizophrenia: results of the BIOMED I study. *Social Psychiatry and Psychiatric Epidemiology* 33:405–412, 1998
- Magliano L, Marasco C, Fiorillo A, et al: The impact of professional and social support on the burden of families of patients with schizophrenia in Italy. *Acta Psychiatrica Scandinavica* 106:1–9, 2002
- Dixon L: Providing services to families of persons with schizophrenia: present and future. *Journal of Mental Health Policy and Economics* 2:3–8, 1999
- Lukoff D, Nuechterlein KH, Ventura J: Manual for the expanded Brief Psychiatric Rating Scale (BPRS). *Schizophrenia Bulletin* 12:594–601, 1986
- WHO Psychiatric Disability Assessment Schedule (DAS). Geneva, World Health Organization, 1988
- Cochrane AL: Effectiveness and Efficiency: Random Reflection on Health Services. London, Nuffield Provincial Hospital Trusts, London, 1972
- Roland M, Torgerson DJ: Understanding controlled trials: what are pragmatic trials? *British Medical Journal* 317:1075, 1998
- Haynes B: Can it work? Does it work? Is it worth it? *British Medical Journal* 319:652–653, 1999
- Hotopf M: The pragmatic randomised controlled trial. *Advances in Psychiatric Treatment* 8:326–333, 2002
- Liberman DB, Liberman RP: Involving families in rehabilitation through behavioural family management. *Psychiatric Services* 54:633–635, 2003
- Canive JM, Sanz-Fuentenebro J, Vasquez C, et al: Family psychoeducational support groups in Spain: parents' distress and burden at nine-month follow-up. *Annals of Clinical Psychiatry* 8:71–79, 1996
- McDonell MG, Short RA, Berry CM, et al: Burden in schizophrenia caregivers: impact of family psychoeducation and awareness of patient suicidality. *Family Process* 42:91–103, 2003