

# Intervention for Adolescents With Early-Onset Psychosis and Their Families: a Randomized Controlled Trial

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**Objective:** The present study aims to assess the efficacy of a structured psychoeducational group intervention for adolescents with early-onset psychosis and their families. The intervention was implemented in parallel in 2 separate groups by focusing specifically on problem-solving strategies and structured psychosis-related information to manage daily life difficulties associated with the disease, to mitigate crises and to prevent relapses. **Method:** We performed a 9-month, randomized, rater-blinded clinical trial involving 55 adolescent patients with early-onset psychosis and either or both of their parents. A psychoeducational problem-solving group intervention ( $n = 27$ ) was compared with a nonstructured group intervention ( $n = 28$ ). The primary outcomes were number of hospitalizations, days of hospitalization, and visits to the emergency department. The secondary outcome measures were clinical variables and family environment. **Results:** Assessments were performed before and after the intervention. At the end of the group intervention, 15% of patients in the psychoeducational group and 39% patients in the nonstructured group had visited the emergency department ( $\chi^2 = 3.62$ ,  $df = 1$ ,  $p = .039$ ). The improvement in negative symptoms was more pronounced in the psychoeducational group (12.84 [7.87]) than in the nonstructured group (15.81 [6.37]) ( $p = .039$ ). **Conclusion:** A parallel psychoeducational group intervention providing written instructions in a structured manner could help adolescents with early-onset psychosis and their parents to manage crises by implementing problem-solving strategies within the family, thus reducing the number of visits to the emergency department. Negative symptoms improved in adolescents in the psychoeducational group. *J. Am. Acad. Child Adolesc. Psychiatry*, 2014; ■(■):■-■. **Key Words:** psychosis, families, group therapy, psychoeducation

Psychoeducational programs are among the most widely studied psychosocial interventions for psychotic disorders. These programs are systematic and didactic, and consist of psychotherapeutic interventions aimed at providing information about the disease in question to patients and their relatives to foster coping skills and understanding.<sup>1</sup>

**S**tudies in adult populations with schizophrenia have shown that psychoeducational interventions can reduce the probability of relapse, number of hospitalizations, and symptom severity.<sup>2,3</sup> They can also improve social and occupational functioning and increase adherence to treatment.<sup>4,5</sup> Additional benefits include reduced

family burden, improved coping skills, and recognition and understanding of psychosis as a disease.<sup>2,6,7</sup> In accordance with the stress-vulnerability model, environmental factors such as family interactions can play an important role in the continuity of the disorder.<sup>8-10</sup> Hence, family psychoeducational programs are aimed at influencing the environment in which the patient lives,<sup>11</sup> by reducing anxiety and increasing family members' self-confidence and ability to react constructively to behavioral disturbances and the patient's symptoms. This result has been confirmed in recent studies that show that the relapse rate can be reduced by approximately 20% if the parents of patients with schizophrenia are included in the treatment.<sup>2</sup> Strenuous efforts to engage families in the prevention of relapses are

justified, because 80% to 90% of patients are living with their parents when they are referred for treatment.<sup>12</sup>

To our knowledge, only 1 study<sup>13</sup> has assessed the efficacy of a psychoeducational treatment program in adolescents with psychosis, although it was not a randomized controlled trial. Furthermore, despite the fact that some programs offer psychoeducational approaches for young adults with a first episode of psychosis that include parents as an important complement in the program,<sup>14,15</sup> none of them includes a specific age range for adolescents. Other studies evaluate the efficacy of a family-focused psychoeducational approach for adolescents with mood disorders who frequently have accompanying psychotic features.<sup>16-19</sup> Our study aimed to examine the efficacy of a parallel, structured, and specific psychoeducational group intervention (PE) for adolescent patients and their families by comparing it with a nonstructured group intervention (NS).

To the best of our knowledge, this is the first randomized controlled trial to compare a PE intervention with an NS intervention in adolescents with early-onset psychosis. We hypothesized that patients in the PE group would have fewer hospitalizations, days in hospital, and visits

to the emergency department. We also hypothesized that these patients would have better clinical outcomes and more favorably perceived family environments.

## METHOD

### Study Design and Procedure

We performed a randomized, rater-blinded, outpatient trial. Participants were randomly allocated to PE or NS as an add-on intervention to treatment as usual, using a computer-generated sequence.

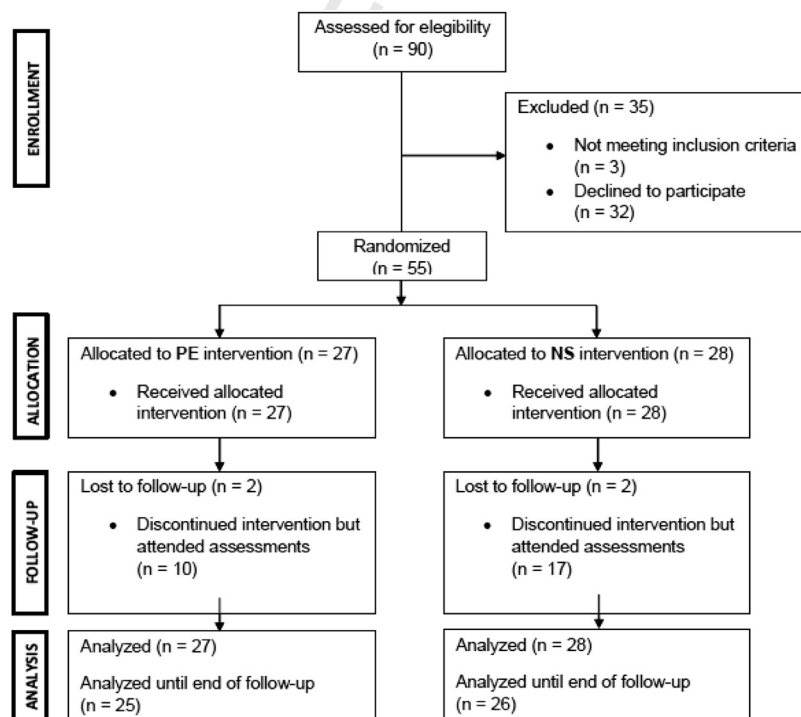
The group treatment was conducted once every 15 days at the outpatient clinic of the Child and Adolescent Psychiatry Department of Hospital General Universitario Gregorio Marañón, Madrid, Spain. After complete explanation of the study, written informed consent was obtained from all patients and their parents or legal guardians. The study was approved by the research and ethics committee of Hospital General Universitario Gregorio Marañón.

### Study Participants

The program was offered to 90 participants (Figure 1). They were adolescent outpatients diagnosed with early-onset psychosis and accompanied by 1 or both parents.

The inclusion criterion for patients was the presence of at least 1 positive psychotic symptom (delusions or hallucinations) before age 18 years and 1 of the

**FIGURE 1** Study flow chart. Note: NS = nonstructured group; PE = psychoeducational group.



following diagnoses from the *DSM-IV*: schizophrenia, schizoaffective disorder, schizophreniform disorder, bipolar disorder, major depressive disorder with psychotic features, brief psychotic disorder, or psychosis not otherwise specified.

Patients were between 14 and 18 years of age and lived at home with either or both parents, caregivers, or legal guardians.

The exclusion criteria were patient's drug abuse or dependence at the time of the intervention (drug use was not an exclusion criterion), the presence of any neurological developmental disorder and inability to engage in conversation or read in Spanish that might interfere with the progress of group treatment.

Of the 55 patients enrolled in the program, 48 had a first episode of psychosis (6 of them had never been admitted to hospital) and 7 had had previous episodes (1 hospitalization [ $n = 1$ ], 2 hospitalizations [ $n = 3$ ], and 3 hospitalizations [ $n = 3$ ]).

#### Assessment and Measurement Instruments

Assessments were conducted blindly by psychiatrists experienced in child and adolescent psychiatric disorders. Participants and their families were assessed before and after treatment. Baseline assessments were made within a maximum of 1 month before the intervention, and post-treatment assessment within 1 month after the intervention. In the case of patients who discontinued treatment, the post-treatment assessments were made approximately 9 months after the baseline assessment. Patient diagnoses were made according to *DSM-IV* criteria following the Spanish version of a semi-structured interview for children and parents, the Schedule for Affective Disorders and Schizophrenia for School-Age Children—Present and Lifetime version) (K-SADS PL).<sup>20,21</sup>

Clinical evaluations were performed by applying the Spanish version of the Positive and Negative Syndrome Scale (PANSS).<sup>22,23</sup> The level of functioning was measured using the Children's Global Assessment of Functioning Scale (C-GAS).<sup>24,25</sup> Interrater reliability for the scales was determined using the intraclass correlation coefficient, which was greater than 0.80. Adherence to treatment was appraised by analyzing levels of antipsychotic medication in venous blood using high-performance liquid chromatography.<sup>26</sup> The overall family psychological climate was assessed using the Family Environment Scale (FES),<sup>27</sup> both with patients and with their relatives. This self-administered questionnaire is a 90-true/false-item inventory that evaluates various characteristics of the family environment clustered in 10 different categories: cohesion, expressiveness, conflict, independence, achievement orientation, intellectual-cultural orientation, active-recreational orientation, moral-religious emphasis, organization, and control.

Finally, our main outcome measures were obtained through a specifically developed questionnaire to record

the number of hospital admissions, the total number of days of psychiatric hospitalization, and the number of visits to the emergency department. The questionnaire was administered to both parents and adolescents. Independent corroboration of the data collected was carried out using medical records.

#### Programa de Intervención en Psicosis Adolescente (PIENSA) Program

Our program seeks to help patients and their families to create an environment that fulfills the particular needs of patients with early-onset psychosis in order to improve the disease course by modifying patient and family response to the usual stressors. Given the age of the participants and the fact that 1 of the developmental challenges that adolescents have to face as they mature is differentiation from their parents, we decided to run 2 simultaneous and parallel groups: 1 group for parents and the other for adolescents in each of our 2 proposed clinical interventions.<sup>28</sup>

*Psychoeducational Intervention.* The PE is an adaptation to our environment and population (adolescents diagnosed with early-onset psychosis and receiving treatment in the Spanish National Health System) of the Psychoeducational Model and Multi-Family Treatment (MFT) from McFarlane *et al.*<sup>29</sup> The adaptation was developed by 3 of the authors (A.R.-S., M.M., and M.M.). Our PE consisted of 2 consecutive phases: the initiation/alliance phase and the group phase (following the MFT format). The initiation phase consists of 3 individual sessions of 50 minutes each in which the group leaders interview families and adolescents separately. Once participants have completed the initiation phase, they are invited to join 2 separate groups, one for patients and the other for parents. The group phase consists of 12 sessions of 90 minutes each, once every 15 days. PE sessions are structured, and the patients and their families receive written material adapted for the adolescents in the PE modality. The material is composed of 12 chapters, 3 of which address medication, side effects, and crisis management. Both contents and group structure were the same in the adolescents and parents' version of the program. Groups specifically focused on problem-solving strategies to manage daily life difficulties associated with the disease to mitigate crises and to prevent relapses. After the session ended, both the adolescents and the parents were asked to put the psychoeducational approach into practice together (M. Mayoral, M. Moreno, O. Robles, R. Lozano, unpublished, 2012).

*Nonstructured Intervention.* The NS also has an initiation phase (3 separate individual sessions for parents and adolescents) and 12 group sessions occurring every 15 days. Facilitators did not follow a preset model but used a supportive group approach that connected persons facing similar challenges, thus enabling members to share experiences and advice (for example, on medication and side effects). No written

material was provided to parents or adolescents. Both the PE and NS group interventions complemented current individual psychiatric management and psychopharmacological treatment.

### Therapists

To control for therapist effects such as gender, personal characteristics, training, and experience, the same therapists delivered both group interventions, depending on whether the groups were patient groups or parent groups. Therefore, there were 2 therapists for the patient groups (both of them delivered the PE and NS group interventions) and 2 different therapists for the parent groups. All group sessions were video recorded, and all therapists were then supervised in weekly clinical review meetings by an experienced external supervisor (A.R.-S.) to assess their clinical competence and their degree of adherence to the therapeutic model. Fidelity to treatment was assessed with an adherence questionnaire with 22 items on a 5-point Likert-type scale (1–5). The highest score was 110; therapists scored above 91, and the average was 102.9.<sup>28</sup>

### Data Analysis

Data were analyzed on an intention-to-treat basis, according to which all patients were analyzed in the treatment groups to which they were randomly allocated, regardless of whether they had completely followed the scheduled design. The samples then included both treatment completers and treatment noncompleters. Statistical analysis was made using SPSS version 20.0 for Windows. The baseline characteristics of the sample were compared using the Pearson  $\chi^2$  test for categorical variables such as sex, ethnicity, and diagnosis. Quantitative variables were analyzed using non-parametric tests (Mann–Whitney and Wilcoxon) because

our data did not fulfill the general linear model assumptions (normality and homoscedasticity).

Group differences were assessed using the Mann–Whitney test for the intergroup analysis and the Wilcoxon test for the intragroup analysis. The Pearson  $\chi^2$  test was used for categorical variables such as hospitalization and visits to the emergency department. Effect sizes were also calculated to quantify the effect of the intervention between groups.

## RESULTS

### Sociodemographic and Clinical Variables

We found no statistically significant differences between the PE and NS groups regarding sociodemographic, diagnostic, or clinical variables at baseline (Table 1).

### Group Intervention Compliance

No statistically significant differences were observed between the 2 study groups with respect to the number of participants completing treatment ( $n = 17$  [63.3%], in the PE group versus  $n = 11$  [39.3%] in the NS group;  $\chi^2 = 3.08$ ,  $df = 1$ ,  $p = .079$ ).

No significant differences were observed between the 2 groups in the mean number of therapy sessions received by patients (7.37 [4.7] in the PE group versus 6.75 [4.94] in the NS group) or by parents (8.93 [4.07] in the PE group versus 6.86 [4.82] in the NS group).

### Adherence to Pharmacological Treatment

No differences were observed between the groups regarding antipsychotic medication measured in chlorpromazine (CPZ) equivalents<sup>30</sup> at baseline

**TABLE 1** Sociodemographic, Diagnostic, and Clinical Data at Baseline

| Characteristic                                   | PE                | NS              | p Value |
|--|-------------------|-----------------|---------|
| Age, y, mean (SD)                                | 16.4 (1.34)       | 16.5 (1.45)     | .88     |
| Male sex   | 16.0 (59.3)       | 18.0 (64.3)     | .70     |
| White ethnicity                                  | 25.0 (92.6)       | 24.0 (85.7)     | .14     |
| Diagnosis  |                   |                 |         |
| Schizophrenia spectrum psychosis                 | 9.0 (33.3)        | 12.0 (42.9)     | .46     |
| Affective psychosis                              | 7.0 (25.9)        | 9.0 (32.1)      | .52     |
| Other psychosis                                  | 11.0 (40.7)       | 7.0 (25.0)      | .21     |
| Neuroleptic dosage in CPZ equivalents, mean (SD) | 1107.67 (4007.11) | 345.28 (506.16) | .39     |
| Risperidone                                      | 11.0 (40.7)       | 11.0 (39.3)     |         |
| Quetiapine                                       | 6.0 (22.2)        | 5.0 (17.9)      |         |
| Aripiprazole                                     | 5.0 (18.5)        | 5.0 (17.9)      |         |
| Olanzapine                                       | 2.0 (7.4)         | 5.0 (17.9)      |         |
| Clozapine  | 0.0               | 1.0 (3.6)       |         |
| No antipsychotic treatment                       | 1.0 (3.7)         | 1.0 (3.6)       |         |

Note: Values are expressed as n (%) unless otherwise indicated. CPZ = chlorpromazine; NS = nonstructured intervention; PE = psychoeducational intervention.

(Table 1) or after treatment (PE, 234.28 [367.49]; NS, 1805.24 [7538.59];  $p = .622$ ).

Intragroup analyses revealed a significant decrease in the dosage of antipsychotics (CPZ equivalents) during the treatment phase in the PE group ( $z = -2.109, p = .035$ ). In the NS group, the antipsychotic dosage remained stable ( $z = -1.067, p = .286$ ).

According to the results of high-performance liquid chromatography, at baseline, 17 patients in the PE adolescent group (63%) were taking their medication as prescribed and 9 (33.3%) were not. One patient was not prescribed antipsychotic medication. In the NS group, 14 patients (50%) were taking their medication as prescribed, and 6 patients (21.4%) were not; in 7 cases (25%), the sample could not be extracted; and in 1 case (3.6%), the patient was not prescribed antipsychotic medication.

After the intervention, 14 of the 25 patients in the PE group (51.9%) were taking their medication as prescribed and 1 (3.7%) was not. The sample was not processed in 7 cases (25.9%), and 3 patients (11.1%) were not taking antipsychotic medication. In the NS group, 12 of the 26 patients (42.9%) were taking their medication as prescribed, 1 (3.6%) was not, 11 case samples (39.3%) were not processed, and 2 patients (7.1%) were not taking antipsychotic medication. No differences were recorded between the 2 groups either at baseline or after the intervention.

### Symptoms and Functional Outcomes

We observed statistically significant differences between the 2 groups in the negative subscale of the PANSS. The PE group showed a greater reduction in negative symptoms after treatment than did the NS group (Table 2). A medium effect size for improvement in negative symptoms was observed ( $r' = 0.41$ ). There were no differences between the groups in regard to the other PANSS scores (Table 2). The 2 groups improved in positive symptoms and functioning after the intervention. However, only the PE group improved in negative symptoms after the intervention.

### Effects on Relapse

No differences were found between the groups for baseline data in terms of the number of hospitalizations, days of hospitalization, or number of visits to the emergency department. Patients in the PE group had fewer visits to the emergency department ( $\chi^2 = 3.62, df = 1, p = .039$ ) in the post-treatment assessment. A medium effect size was observed ( $r' = 0.42$ ).

Similarly, a trend toward significance was observed regarding differences between the 2 study groups in the number of post-treatment hospital admissions: 11% of patients were admitted in the PE group compared with 32% of the patients in the support group ( $\chi^2 = 4.24, df = 1, p = .057$ ). No differences were observed

**TABLE 2** Symptoms and Functional Outcomes

|                | Pretreatment  | Posttreatment | <i>p</i> Value                | Difference Between PE and NS ( <i>p</i> Value) |
|----------------|---------------|---------------|-------------------------------|--|
| PANSS Positive |               |               |                               | .163 <sup>b</sup>                              |
| PE             | 14.77 (8.22)  | 10.72 (14.33) | <b>.022</b> <sup>a,*,§</sup>  |  |
| NS             | 16.92 (9.10)  | 11.77 (3.93)  | <b>.006</b> <sup>a,*,§</sup>  |  |
| PANSS Negative |               |               |                               | <b>.039</b> <sup>b,*,§</sup>                   |
| PE             | 16.55 (7.27)  | 12.84 (7.87)  | <b>.013</b> <sup>a,*,§</sup>  |  |
| NS             | 17.03 (7.42)  | 15.81 (6.37)  | .254 <sup>a</sup>             |  |
| PANSS Total    |               |               |                               | .264 <sup>b</sup>                              |
| PE             | 61.85 (23.37) | 50.29 (19.28) | <b>.026</b> <sup>a,*,§</sup>  |  |
| NS             | 69.00 (27.71) | 55.35 (17.39) | <b>.009</b> <sup>a,*,  </sup> |  |
| GAF            |               |               |                               | .163 <sup>b</sup>                              |
| PE             | 64.37 (18.79) | 73.92 (14.33) | <b>.039</b> <sup>a,*,§</sup>  |  |
| NS             | 58.46 (19.02) | 66.31 (15.23) | <b>.034</b> <sup>a,*,§</sup>  |  |

Note: Boldface *p* values indicate significance. GAF = Global Assessment of Functioning; NS = nonstructured intervention; PANSS = Positive and Negative Syndrome Scale; PE = psychoeducational intervention.

<sup>a</sup>Wilcoxon test.

<sup>b</sup>Mann-Whitney test.

\* $p < .05$ .

§ $p \leq .05$ .

|| $p \leq 0.01$ .

in the number of days of hospitalization between the 2 groups after the intervention ( $p = .142$ ) (Table 3).

### Family Environment

The patients' ratings of their family environment before and after the intervention are summarized in Table 4. We observed differences between the 2 study groups in the FES subscale "active-recreational orientation," which evaluates participation in social activities. The recreational orientation score for adolescents in the PE group increased after the PE.

No differences were observed between the 2 study groups in parents' ratings of their family environment either at baseline or after the intervention.

## DISCUSSION

The present study shows that the short-term outcome of early onset-psychosis was improved by implementing a comprehensive psychoeducational program early in the course of the disease. Our results shows that patients enrolled in the PE group had fewer visits to the emergency department, a reduction in the number and intensity of negative symptoms, and more active-recreational involvement than patients in the NS group.

### Relapse Prevention

Naturalistic long-term follow-up studies have shown that the early course of psychosis is characterized by relapses. Up to 80% of patients with first-episode psychosis experience a relapse within 5 years of remission of the initial episode.<sup>31-34</sup>

**TABLE 3** Outcome of Relapse

| Relapse                           | Posttreatment |              |                            |
|-----------------------------------|---------------|--------------|----------------------------|
|                                   | PE (n = 25)   | NS (n = 26)  | p Value                    |
| Patients hospitalized, n (%)      | 3 (11.1)      | 9 (32.1)     | .057 <sup>a</sup>          |
| Days hospitalized, mean (SD)      | 4.08 (13.03)  | 7.42 (13.64) | .142 <sup>b</sup>          |
| Patients visited ED visits, n (%) | 4 (14.8)      | 11 (39.3)    | <b>.039<sup>a,*†</sup></b> |

Note: Boldface p value indicates significance. ED = emergency department; NS = nonstructured intervention; PE = psychoeducational intervention.

<sup>a</sup> $\chi^2$  test.  
<sup>b</sup>Mann-Whitney test.  
<sup>\*</sup> $p < .05$ .  
<sup>†</sup> $p \leq .005$ .

Recurrent episodes are associated with higher costs in terms of personal and family suffering, resource consumption, and economics. Relapses were related to poor prognosis<sup>35,36</sup> and are likely to interfere with the social and vocational development of young persons.<sup>3</sup> Therefore, early intervention for first episode psychosis has a major emphasis on reducing the number and severity of relapses.

A recent meta-analysis on the efficacy of available interventions for the prevention of relapse in young persons who experienced a first episode of psychosis observed that specialized programs for this condition were more effective in preventing relapse than was treatment as usual.<sup>37</sup> Such programs usually take the form of assertive outreach programs (cognitive behavior therapy, medication, family support) that include a combination of interventions in which family psychoeducational groups are a fundamental component.<sup>15,38</sup> It is precisely the combination of specific elements that makes them more effective (higher intensity of treatment than 1 intervention alone). However, when studies compared the efficacy of 2 isolated modalities of intervention (without being integrated into a broader treatment package) in relapse prevention, no differences were found,<sup>39,40</sup> although, overall, psychological interventions are more effective than treatment as usual.

In our study, patients who participated in the PE group had fewer visits to the emergency department than patients in the NS group; this observation is relevant in terms of relapse prevention. The PE might reduce the number of contacts with the emergency services through improved problem-solving strategies within the family, as it was specifically designed to empower families in conflict resolution to face crisis situations more efficiently. With regard to the implications of the use of written material in the results, it is important to bear in mind that, in the PE group, the psychoeducational material included 3 chapters about medication, side effects, and crisis management; these topics were then discussed in the problem-solving strategy groups. The NS group had the opportunity to ask questions about any topic that they considered important during the group sessions. In fact, some participants in the NS group demanded more information about these issues. In contrast to PE group therapy, the information in the NS group was transmitted differently, according to the demands of participants and did not follow a written guide, as in the case of the PE group. This

TABLE 4 Patients' Perceptions of Family Environment

|     | Pretreatment: FES, Mean (SD) |               |                   | Posttreatment: FES, Mean (SD) |               |                             |
|-----|------------------------------|---------------|-------------------|-------------------------------|---------------|-----------------------------|
|     | PE                           | NS            | p Value           | PE                            | NS            | P Value                     |
| C   | 44.35 (7.57)                 | 41.74 (10.20) | .519 <sup>a</sup> | 44.50 (7.27)                  | 43.00 (9.50)  | .687 <sup>a</sup>           |
| EX  | 49.35 (9.73)                 | 48.17 (9.95)  | .638 <sup>a</sup> | 49.13 (8.99)                  | 46.41 (9.73)  | .389 <sup>a</sup>           |
| CON | 52.52 (7.32)                 | 55.61 (10.34) | .276 <sup>a</sup> | 51.13 (7.59)                  | 54.11 (9.82)  | .352 <sup>a</sup>           |
| IND | 46.13 (9.72)                 | 44.35 (10.18) | .623 <sup>a</sup> | 47.44 (8.54)                  | 49.00 (6.59)  | .618 <sup>a</sup>           |
| AO  | 45.48 (9.10)                 | 50.09 (6.61)  | .051 <sup>a</sup> | 47.27 (5.95)                  | 49.59 (8.41)  | .535 <sup>a</sup>           |
| ICO | 49.43 (10.21)                | 46.43 (9.35)  | .321 <sup>a</sup> | 48.81 (12.75)                 | 49.76 (8.18)  | .584 <sup>a</sup>           |
| ARO | 55.57 (8.14)                 | 55.09 (7.89)  | .713 <sup>a</sup> | 61.43 (7.37)                  | 55.76 (7.36)  | <b>.035<sup>a,b,*</sup></b> |
| MRE | 45.09 (8.11)                 | 48.13 (8.07)  | .320 <sup>a</sup> | 47.75 (6.71)                  | 45.76 (10.45) | .336 <sup>a</sup>           |
| ORG | 47.52 (10.59)                | 46.83 (11.62) | .982 <sup>a</sup> | 50.56 (8.39)                  | 47.29 (10.28) | .463 <sup>a</sup>           |
| CTL | 50.52 (8.19)                 | 51.74 (7.82)  | .582 <sup>a</sup> | 49.31 (7.63)                  | 52.88 (7.44)  | .191 <sup>a</sup>           |

Note: Boldface p value indicates significance. AO = achievement orientation; ARO = active-recreational orientation; C = cohesion; CON = conflict; CTL = control; EX = expressiveness; FES = Family Environment Scale; ICO = intellectual-cultural orientation; IND = independence; MRE = moral-religious emphasis; NS = nonstructured intervention; ORG = organization; PE = psychoeducational intervention.

<sup>a</sup>Mann-Whitney test.  
\*p ≤ .05.

difference might be related to the number of visits to the emergency department, with more patients in the NS visiting the emergency department because of poorer understanding of medication side effects.

The number of visits to the emergency department is 1 way to measure relapse, even when the patient is not hospitalized. However, hospitalization is more expensive than visits to the emergency department, and can increase personal and family suffering and resource use. We did not find statistically significant differences between the PE and NS groups during follow-up because of the small sample size and because the NS group intervention was also a psychological intervention. In addition, frequent monitoring in the NS group could have acted as a protective factor; nevertheless, it is important to highlight that the number of patients hospitalized was nearly triple that of the NS group (11.1% versus 32.1%).

#### Negative Symptoms

Negative symptoms are associated with relapse, poor social and occupational functioning, cognitive impairment, lower subjective quality of life, and poor long-term prognosis.<sup>41,42</sup> The decrease in the number and intensity of negative symptoms in patients in the PE group suggests that structured psychotherapeutic interventions could help to reduce symptoms that are refractory to pharmacological treatments. Other studies that evaluated structured interventions such as cognitive behavioral therapy for first-episode psychosis<sup>43</sup>

and multiple-family groups in patients with schizophrenia<sup>44</sup> replicate this hypothesis.

#### Family Environment

Adolescents with mental illness may have altered developmental skills, such as increased difficulty socializing with friends, attending school, and/or pursuing vocational goals. In an exploratory analysis, we obtained differences in "active-recreational orientation" in PE patients only after the intervention. This finding should be interpreted with caution, but could indicate that adolescents develop their ability to become involved in social activities while they are undergoing the PE intervention. We were not able to demonstrate differences in the parents' perception of the family environment between the 2 study groups after the intervention. The first direct exposure to symptoms of mental illness may be difficult for families to grasp, and a longer assessment period is necessary before transformations can be detected in the family environment.

#### Treatment Adherence

Client engagement can be 1 of the biggest challenges in group programs. The first stage of the disease is difficult for both parents and adolescents, and the denial that they often feel may adversely affect adherence to treatment.

No differences were found between the 2 study groups with respect to the number of participants completing treatment. However, 60% of the NS group dropped out before finishing group therapy, compared with 37% of the PE group. A potential explanation is that the PE approach

provides participants with a clear framework (structure and consultation material) that could help them to improve their commitment to treatment and contain their extreme emotions without “acting out” on them. Families may have dropped out because of the adolescents’ lack of autonomy, which made it difficult for them to attend the sessions without their parents in a city as large as Madrid, where transfers from home to hospital are usually long and expensive. Some families do not have sufficient economic resources, and most of the parents had to be at work when the sessions were scheduled. The fact that parents attended, on average, 1.5 more sessions than adolescents could be because parents have a higher demand for treatment.

Antipsychotic medication is an important component of treatment. Adherence to prescribed medication was good at baseline and after the intervention in both groups.

This is a pilot study and subject to several limitations. First, the indicators used to assess relapse prevention, such as number of admissions or quantitative symptom scales, might not be as comprehensive as the global impact on psychosocial functioning that a group intervention can produce. Future studies should address this matter by including coping skills or well-being questionnaires. It would be interesting to conduct qualitative research regarding the above-mentioned issues. Second, we performed a short-term follow-up assessment. Data on the long-term effects of the intervention are necessary. Third, not considering Axis II pathology is also a limitation of the study. Fourth, the lack of control for the use of cannabis in adolescents might constitute a limitation. Finally, the small sample size may have precluded finding more significant differences between the groups (with trends toward better outcomes in the PE group).

In conclusion, the PIENSA program is a comprehensive pioneer intervention and pilot study in Spain. It centers on problem-solving strategies for adolescents and their families, and is therefore interesting in terms of research and of its suitability for clinical practice. The present study

shows that a comprehensive PE might help adolescent patients and their families to manage crises, to improve negative symptoms, and to increase patient involvement in social activities. Such an intervention would be of the utmost importance in clinical practice, as it precedes social and functional recovery. &

Accepted March 7, 2014.

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This work was supported by the Spanish Ministry of Economy and Competitiveness, Instituto de Salud Carlos III, CIBERSAM, the Madrid Regional Government (S2010/BMD-2422 AGES), the European Union Structural Funds, Fundación Alicia Koplowitz, Fundación Mutua Madrileña, and a predoctoral fellowship award from Gobierno de La Rioja, Spain (A.C.).

The authors thank all participants in this study: the adolescents, families, and the team members of the Programa de Intervención en Psicosis Adolescente (PIENSA) program. We are grateful to Mario Alvarez-Jimenez, PhD, with Orygen Youth Health Research Centre, University of Melbourne, Australia, for advice on an earlier version of this manuscript and to Manuel Desco, PhD, Universidad Carlos III, Hospital General Universitario Gregorio Marañón (HGUGM), and CIBERSAM, for advice on data analysis.

Disclosure: Dr. Calvo has received a predoctoral fellowship award from Gobierno de La Rioja, Spain, and a grant for short-term placements from the Instituto de Investigación Sanitaria Gregorio Marañón, (IISGM). Dr. Rapado-Castro has received a Sara Borrell Health Research Fellowship from the Institute of Health Carlos III, Spanish Ministry of Economy and Competitiveness, an Alicia Koplowitz research grant, and a short-term fellowship from the Alicia Koplowitz Foundation. Dr. C. Moreno has served as a consultant to Janssen. Ms. Sánchez-Gutiérrez has received a Health Research Predoctoral Fellowship grant (PFIS) and a grant for short-term placements, both from Institute of Health Carlos III, Spanish Ministry of Economy and Competitiveness. Dr. Arango has served as a consultant to or has received honoraria from AstraZeneca, Bristol-Myers Squibb, Janssen-Cilag, Lundbeck, Otsuka, Pfizer, Roche, Servier, and Schering-Plough. Drs. M. Moreno, Ruiz-Sancho, and Mayoral report no biomedical financial interests or potential conflicts of interest.

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<http://dx.doi.org/10.1016/j.jaac.2014.04.004>

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