Family-Focused Treatment for Adolescents and Young Adults at High Risk for Psychosis: Results of a Randomized Trial

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Objective: Longitudinal studies have begun to clarify the phenotypic characteristics of adolescents and young adults at clinical high risk for psychosis. This 8-site randomized trial examined whether a 6-month program of family psychoeducation was effective in reducing the severity of attenuated positive and negative psychotic symptoms and enhancing functioning among individuals at high risk. **Method:** Adolescents and young adults (mean age 17.4 ± 4.1 years) with attenuated positive psychotic symptoms, brief and intermittent psychosis, or genetic risk with functional deterioration were randomly assigned to 18 sessions of family-focused therapy for individuals at clinical high risk (FFT-CHR) in 6 months or 3 sessions of family psychoeducation (enhanced care [EC]). FFT-CHR included psychoeducation about early signs of psychosis, stress management, communication training, and problem-solving skills training, whereas EC focused on symptom prevention. Independent evaluators assessed participants at baseline and 6 months on positive and negative symptoms and social-role functioning. **Results:** Of 129 participants, 102 (79.1%) were followed up at 6 months. Participants in FFT-CHR showed greater improvements in attenuated positive symptoms over 6 months than participants in EC ($F_{1,97} = 5.49$, $p = .02$). Negative symptoms improved independently of psychosocial treatments. Changes in psychosocial functioning depended on age: participants more than 19 years of age showed more role improvement in FFT-CHR, whereas participants between 16 and 19 years of age showed more role improvement in EC. The results were independent of concurrent pharmacotherapy. **Conclusion:** Interventions that focus on improving family relationships may have prophylactic efficacy in individuals at high risk for psychosis. Future studies should examine the specificity of effects of family intervention compared to individual therapy of the same duration and frequency. Clinical trial registration information—Prevention Trial of Family Focused Treatment in Youth at Risk for Psychosis; http://clinicaltrials.gov/; NCT01907282. J. Am. Acad. Child Adolesc. Psychiatry, 2014;53(8):848–858. **Key Words:** attenuated psychotic symptoms, schizophrenia, early warning signs, psychoeducation, family therapy

There has been increasing interest in the role of psychosocial interventions for adolescents and young adults who are at clinical high risk (CHR) for psychosis. Longitudinal studies have identified phenotypic precursors to psychosis that may narrow the populations for whom early interventions are applied, although false-positive prediction rates are high. About 35% of individuals with attenuated or intermittent psychosis symptoms, schizotypal personality disorder, or a family history of psychosis with recent functional deterioration develop an episode of psychosis over 2 to 3 years.[1] A meta-analysis of 2,500 persons at clinical high risk in 27 studies found a conversion rate of 18% in 6 months, 22% in 1 year, and 36% after 3 years.[2]

Intervention during the high-risk period may reduce subthreshold psychotic symptoms,

This article is discussed in an editorial by Dr. Randal G. Ross on page 833.

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enhance social and role functioning, and, over the long term, prevent or delay conversion to episodes of psychosis. Results from early intervention trials indicate that targeted medication strategies have short-term benefits on attenuated positive symptoms in individuals at clinical high risk.[3-7] A meta-analysis that included 4 randomized psychotherapy trials with participants at high risk concluded that cognitive behavioral therapy (CBT) was associated with a greater reduction in positive symptoms (standardized mean difference = −0.27) over 6 to 12 months compared to supportive therapy.[6] The effects of CBT and other psychosocial interventions on negative symptoms, functioning, and quality of life were nonsignificant across studies.[6]

We hypothesized that early psychosocial intervention would be strengthened by involving family members in treatment. First, individuals at high risk for psychosis are often adolescents living with their parents, and parental involvement may enhance the young person's access to mental health services. Second, the evolution of attenuated psychotic symptoms may be affected by family contextual variables. For example, levels of expressed emotion (i.e., criticism, hostility, or overprotectiveness) in parents were associated with the severity of attenuated psychotic symptoms in youth at clinical high risk over 6 months.[8] Levels of parental expressed emotion (EE) may escalate in reaction to the functional deterioration of an offspring with emerging psychosis but may also become a stressor for the offspring.[9,10]

This article reports results of the first multisite randomized trial of a family intervention for youth at high risk for psychosis. We tested an adaptation of family-focused therapy (FFT), a psychoeducational treatment found to be effective in stabilizing symptoms and delaying recurrences among adults with bipolar I or II disorder and youth with or at high risk for bipolar spectrum disorders.[11-13] The adaptation of FFT for individuals at clinical high risk for psychosis (FFT-CHR) emphasizes coping with stressors that may contribute to psychotic symptoms, behavioral activation to reduce negative symptoms and increase social engagement, and skills training to enhance interpersonal communication and problem solving.

This trial was conducted within the 8-site North American Prodrome Longitudinal Study, 2 (NAPLS-2).[14] FFT-CHR was administered in weekly and biweekly sessions over 6 months and compared to a brief (1-month) family educational intervention (enhanced care [EC]). We examined 2 hypotheses, as follows: first, compared to EC, FFT-CHR would be associated with decreases in subthreshold positive symptoms (primary outcome) and negative symptoms; and second, FFT-CHR would be associated with greater gains in psychosocial functioning (secondary outcome) over 6 months.

METHOD

Study Participants

All 8 research centers of the NAPLS-2 consortium (Emory University, Harvard University, University of Calgary, University of California Los Angeles, University of California San Diego, University of North Carolina, Yale University, and Zucker Hillside Hospital) contributed participants to the study. The study was approved by the human research review boards of all centers.

Between January 2010 and February 2012, participants who had consented for the NAPLS-2 naturalistic study and were living with or in frequent contact with significant others (parents, grandparents, spouses, or partners) were approached by a NAPLS-2 research assistant and invited to be evaluated for a randomized study of family intervention. Participants and at least 1 relative gave written informed assent or consent to participate following a full explanation of the procedures. Participants under age 18 signed an assent form that also required the permission signature of their parent.

Participants met the following eligibility criteria: age between 12 and 35 years; speaks and writes English; meets criteria for 1 of 3 prodromal syndromes as assessed by the Structured Interview for Prodromal Syndromes (SIPS)[15] and the Scale of Prodromal Symptoms (SOPS)[16]: attenuated positive symptoms with worsening in the past year; brief intermittent psychosis; or genetic risk and deterioration, defined as a 30% or greater decline in Global Assessment of Functioning (GAF)[17] scores in the past year, plus either a diagnosis of schizotypal personality disorder or a first-degree relative with psychosis. Participants were excluded if they met current *DSM-IV-TR* criteria for schizophrenia or schizoaffective disorder, pervasive developmental disorders, substance use disorders, or neurological disorders based on the Structured Clinical Interview for *DSM-IV* Axis I Disorders, Patient Version (SCID-P).[18,19]

Study participants who were geographically dispersed were given the opportunity to participate in FFT via secure videoconference; 2 families accepted this option. Further information regarding recruitment strategies in NAPLS-2 can be found elsewhere.[14,20]

Procedures: Outcome Assessments

Before the random assignments (baseline) and at 6-month follow-up, independent evaluators (IEs) who