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Family Aided Community Treatment For The Treatment Of Early Psychosis: A Proof Of Concept Study

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This study was completed as part of the first author's dissertation.

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Abstract

Major psychotic disorders are one of the leading causes of disability worldwide. If these conditions are identified early and treatment promptly implemented, the prognosis is improved. This study examined the impact of a yearlong family aided community treatment (FACT) intervention upon psychiatric symptoms. Psychiatric symptom scores improved with the FACT intervention. Improved training on early recognition for mental health clinicians, implementation of a specific treatment model in community settings and policy around treatment funding allocation are implications of this study.

Keywords: major psychotic disorders, prodromal syndromes

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Schizophrenia has a prevalence rate of 1 in 100 people. Onset usually begins in late adolescence or early adulthood (APA, 2000). Symptoms include hallucinations, delusions, confused thinking, and a range of cognitive deficits (APA, 2000). In its acute phase, a person afflicted with schizophrenia becomes unable to discern what is real from what is not and may act on incorrect or inaccurate information about the environment. The young person often loses the ability to participate in school and work or even to take care of basic needs. Families may mistakenly attribute the cause of these changes in a loved one to antisocial behavior or drug use. Friends drop away quickly as these youth isolate or behave strangely.

The fact that schizophrenia begins during teenage and young adult years makes early intervention critical. The illness interferes with key developmental tasks, including forming an identity, finishing school and beginning employment, taking on adult roles and responsibilities, and forming intimate relationships. Psychosis can impede these developmental processes in ways that will affect a person for life. The stress can lead to family dissolution and even homelessness. Unable to tell what is safe from what is not or what is real from what is not, the person with schizophrenia is at risk of accidental death, injury, or suicide. It is common for psychosis to lead to arrest and legal charges (Sale & Melton, 2010).

Unfortunately, these experiences are common because many people with schizophrenia do not get the right help in the early stages of psychosis (Harrigan, McGorry, & Krstev, 2003). Treatment programs and providers are often untrained and

unprepared to provide appropriate support. Too often, a series of traumatizing crises and inappropriate care lead to an involuntary hospital commitment, entry into the federal disability system, or both (Edwards & McGorry, 2002). The longer it takes for a person to get appropriate help, the more challenging recovery becomes.

To address the problem that many people with schizophrenia do not get the right help in the early stages of psychosis, the State of Oregon implemented Early Assessment and Support Alliance (EASA) programs in 11 counties. These counties cover 60% of Oregon's population. The first year case rate for this program ran between $9,000 to $12,000 per annum. The year two case rate ran at two-thirds of the year one rate. These case rates were consistent with those reported by Mihalopoulos, Harris, Henry, Harrigan, and McGorry (2009).

A key thrust of EASA programming was providing a family aided community treatment (FACT) for this at-risk population. FACT is a combination of four distinct elements. These elements are: (a) psychoeducational multifamily groups, (b) assertive community treatment, (c) psychotropic medications, and (d) supported employment and education (McFarlane, Stastny, & Deakins, 1992; McFarlane, 2002). While theory and research backs each FACT element, the question whether FACT treatment package is effective is an open one. The present proof of concept study is a response to this open question.

The specific research question for this study was: "What is the impact of a family aided community treatment upon the psychiatric symptoms of people aged 12-25 with early psychosis?" Based upon the extant research on this topic, the null hypothesis (H_0)

was directional: A family aided community treatment will not improve psychiatric symptoms of people aged 12-25 with early psychosis.

Methods

Research Design

Archival data sets were analyzed using a single-group pre/post test design (Harris, et al. 2006). The analysis compared baseline and 12-month scores for the purpose of proof of concept of the FACT intervention (Eli Lilly and Company, n.d.).

Participants

Archival data were analyzed from 8 participants who received and completed 12 months of the FACT intervention. The mean age was 19.6 (*SD* = 3.28). Males comprised 75% of the participants. The sex difference is consistent with Hafner et al. (1993). The racial demographics included 75% White and 25% Hispanic, which is consistent with data from Brekke and Barrio (1997).

Participants were selected from referrals made to the Early Assessment and Support Alliance. Eligible referrals included residents, aged 12-25, of the Mid-Willamette Valley Region of Oregon. At initial referral the participants appeared to have early, low-intensity or low-frequency psychotic symptoms. If participants met the inclusion criteria (i.e., age, location, and level of symptoms), they and their families were asked if they would be interested in participating in a research study. If they agreed, they were asked to attend an orientation session, which covered the FACT intervention, informed consent, description of financial incentives provided, and scheduling of the Structured Interview for Prodromal Syndromes (SIPS). The final inclusion and exclusion criteria were determined by scores and syndromes of the SIPS. Inclusion criteria

consisted of participants who met criteria for a first episode psychosis. These participants presented with psychotic symptoms (at least one score of 6 on one of the positive symptom scales from the Structured Interview for Prodromal Syndromes (SIPS), with loss of insight, and treatment with anti-psychotic medication) for less than 30 days.

Included participants were offered the FACT intervention. At baseline the data set included 11 individuals who met criteria for inclusion. At the end of 12 months, 8 participants remained for final analysis (see Figure 1). There were no clinical or demographics differences between the participants who remained in the research and those who were not in the final analysis. The final age range for the participants who remained was 16-25. A two-tailed t-distribution test did not find significant differences in the Structured Interview for Prodromal Syndromes (SIPS) Positive, Negative, Disorganized, or General symptoms baseline scores between participants who dropped out and the participants who remained in the study.

Some potential participants were excluded because the purpose of this research project was to prevent the disabling effects of the *onset* of psychotic disorder. Those excluded met at least one of the following criteria: (a) a current diagnosis of a psychotic disorder at baseline, (b) a positive symptom score of 6 for over 30 days, (c) receiving anti-psychotic medication at a dosage appropriate to treat a psychotic illness for over 30 days, (d) a score lower than a 6 on any of the Positive symptoms scales, (e) aged less than 12 years or over 25, (f) an IQ less than 70 based on school records, (g) living outside the Mid-Willamette Valley region, (h) not an English speaker, and/or neither parent is an English speaker, (i) incarcerated, (j) psychotic symptoms due solely to acute psychoactive substance toxicity, or (k) clear organic etiology of psychotic symptoms.

Measures

Structured Interview for Prodromal Syndromes (SIPS). Participants received the SIPS at baseline and again at 12 months. The SIPS is a semi-structured diagnostic interview including five components: (a) the 19-point Scale of Prodromal Symptoms, (b) a version of the Global Assessment of Functioning with well-defined anchor points, (c) a Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR, 2000) schizotypal personality disorder checklist, (d) a family history of mental illness, and (e) a checklist for the Criteria of Prodromal Syndromes (Miller et al., 2002). The five components are used to determine if the person meets criteria of a Psychosis Risk Syndrome, indicating lower risk or a presence of psychotic symptoms (greater risk). SIPS questions include questions determined valid for predicting conversion to schizophrenia. For example, an item exploring unusual thought content asks the question, "Have you felt that you are not in control of your own ideas or thoughts?"

People who meet criteria for a prodromal syndrome have a positive, predictive value of conversion to psychosis related to schizophrenia: 43% at 6 months, 50% at 12 months, 62% at 18 months and 67% at 24 months. There was a significant relationship of diagnostic status at baseline to outcomes at 6 months and 12 months (Miller et al., 2002).

Independent research assistants who were blind to which participants received the FACT intervention conducted all interviews. Research assistants received regular inter-rater reliability checks by a Yale University certified rater expert in scoring the SIPS. SIPS raters who received training from a certified rater yielded an inter-rater reliability score of $k = .81$ (Miller et al., 2002). To maintain inter-rater reliability, research assistants were asked to score 10-videotaped SIPS interviews. Reliability was measured

by computing the intraclass correlation of raters' scores with criterion scores of experienced researcher trained by Dr. Tandy Miller, one of the developers of the Structured Interview for Prodromal Syndromes instrument. In a prior study using the SIPS, this format was used to establish reliability (McFarlane et al., 2010). The intraclass correlation was .81 for the positive symptom scale and .81 for the negative symptom scale.

The Structured Interview for Prodromal Syndromes 19 item instrument broken into four domains; positive (5 items), negative (6 items), disorganized (4 items) and general symptoms (4 items). Each item is rated on a seven point fully-anchored Likert scale. The end anchors are Absent (0) to Extreme (6). Any score in the positive symptoms domain between a 3 and 5 is indicative of sub-clinical psychosis, whereas a 6 is considered psychotic (Miller et al., 1999). For the purposes of this study, an average score of each domain was calculated at baseline and at the end of the study to determine improvement over the course of the treatment.

Positive and Negative Syndrome Scale (PANSS). Participants also received the Positive and Negative Syndrome Scale (PANSS). The PANSS is a 30-item researcher rated scale used to determine severity of positive and negative symptoms of psychosis, in addition to other excitatory, depressive, and cognitive psychiatric symptoms (PANSS Institute, 2015). Higher scores indicate a greater severity of psychiatric symptoms. PANSS construct, discriminative, convergent, and predictive validity is supported by longitudinal, multidimensional, and psycho-pharmacological research in people with acute and chronic schizophrenia. In two studies of 37 acute and 47 chronic people with schizophrenia, the criterion-related validity of the PANSS used for typological distinction

was supported (Kay, Opler, & Lindenmayer, 1988; Lindenmayer, Kay, & Opler, 1984). Studies specific to young people with schizophrenia found that high negative scores in the early presentation co-varied with: (a) lesser incidence of psychosis related to schizophrenia and (b) greater incidence of a psychosis related to a mood disorder (Kay & Opler, 1987; Lindenmayer, Kay, & Friedman, 1986).

For the present study, the Positive Symptom Subscale and Negative Symptom Subscale were used. Both subscales have seven items. Each item is scored on a seven-point scale. The range of the scores are as followed; 1 = absent, 2 = minimal, 3 = mild, 4 = moderate, 5 = moderate- severe, 6 = severe, and 7 = extreme (Kay, Flszbein, & Opfer, 1987). Similar to how the Structured Interview for Prodromal Symptoms, an average score of the positive and negative symptom subscale was calculated at baseline and at the end of the study to determine improvement over the course of the treatment.

Global Functioning Scale (GFS). Participants also received the Global Functioning Scale (GFS). The GFS produces a 10-item score measuring social and role functioning. Higher scores indicate higher functioning in each domain.

GFS studies on construct validity have found statistical significant correlations with the Strauss-Carpenter Outcome Scale. The Global Functioning Social Scale (Auther, Smith, & Cornblatt, 2006) of the GFS was correlated with the Strauss-Carpenter Outcome Social Contacts Scale ($r = .70$, $p < .001$). The Global Functioning Role Scale (Niendam, Bearden, Johnson, & Cannon, 2006) was correlated with the Strauss-Carpenter Outcome Work/School Functioning Scale ($r = .57$, $p < .001$). Researchers on the Global Functioning Scales also have found statistical significant correlations with the

Premorbid Adjustment Scale on the Global Functioning Social Scale with the Premorbid Adjustment Social Scale ($r = .49$, $p < .001$) and on the Global Functioning Role Scale with the Premorbid Adjustment Role Scale ($r = .68$, $p < .001$) (Cornblatt et al., 2007).

One study using 100 research clinicians at two different mental health research clinics found that GFS inter-rater reliability yielded .84 and .92 for the Social and Role functioning scores respectively (Cornblatt et al., 2007). The researcher who collected PANSS and GFS data did not undergo regular inter-rater reliability check as they did with the Structured Interview for Prodromal Syndromes. However, the positive and negative symptoms from the SIPS were used to score the PANSS so reliability is inferred.

For the purposes of this study, the scores from the Global Functioning: Social (GF: Social) and the Global Functioning: Role (GF: Role) subscales were employed. Each scale is a 0-10 scale, with higher scores indicating higher levels of functioning (Cornblatt et al., 2007). Each scale is scored via clinical opinion, similar to how the DSM-IV Global Assessment of Functioning Scale (GAF) is scored.

Treatment

Providers. Participants who were assigned to the FACT intervention were given appointments with a master's level clinician who was responsible for providing and coordinating the FACT intervention elements. These clinicians had Master's degrees in counseling, psychology, social work or occupational therapy.

Components. FACT is a manualized treatment comprised of four components (see McFarlane et al., 1992; McFarlane, 2002; McFarlane et al., 2010). These

components are: (a) psychoeducational multifamily groups, (b) assertive community treatment, (c) psychotropic medications, and (d) supported employment and education.

Psychoeducational multifamily groups. The multifamily group intervention had three part. These parts were: (1) joining with people and their families, (2) educational workshops, and (3) twice-monthly problem solving groups involving the person and their family (McFarlane, 2002).

Assertive community treatment. Assertive Community Treatment is a comprehensive, biopsychosocial intervention with the intended goal of improving community functioning with the mentally ill. Components of Assertive Community Treatment include in vivo teaching of coping and problem-solving skills, 24-hour availability to respond to crisis, a small caseload (1–10 people), and a multidisciplinary team approach. As described, the original intention of the Assertive Community Treatment model was to serve high-risk mentally ill populations. Recently, there has been an increased awareness of its potential with first-episode and at-risk populations (McFarlane et al., 2010).

Psychotropic medications. A board certified psychiatrist managed psychotropic medications. Persons were seen every one to three months depending on level of symptom severity. Medications were typically prescribed if symptoms indicated a conversion to psychosis or reached a level at which medications were indicated (McFarlane, 2002).

***Supported employment and education*.** Supported Employment is an evidenced-based, manualized treatment to support people with symptoms of mental illness return to or gain new employment. It involves an integration of employment and traditional

mental health services. Clinicians using the supported employment model must offer rapid job search of competitive employment emphasizing the person's preferences for work goals. The model also involves clinicians offering support while the person is employed and assisting with benefits planning. The model is implemented regardless of the person's level of symptoms or substance use. The only inclusion is a person's statement they want to work (Swanson & Becker, 2011).

Supported Education involves collaboration between clinician and educational institutions, and teaching skills relevant to the person's current level of education. A mental health clinician in collaboration with an occupational therapist completes this intervention. The occupational therapist is responsible for evaluating the person's functional and cognitive abilities and using that information to guide intervention.

Treatment Fidelity

All clinicians involved in implementing the FACT intervention received a weeklong training on the elements of the model. The delivery of each clinical service provided was documented using a secure web-based tracking program. Using measurements of services people received was found to be a reliable and valid predictor of outcomes with populations similar to the one used for this study (Cook et al., 2005). Treatment fidelity scales exist for FACT elements of multi-family group treatment and supported employment. Certified trainers monitored fidelity of these treatments on a monthly basis in collaboration with the clinicians that implemented these FACT interventions.

Clinical Significance

The term "clinically significant change" has typically been defines as the extent to which an intervention moves a person outside the range of the dysfunctional population or within the range of the functional population (Jacobson & Truax, 1991). For the SIPS, if any of the Positive Symptoms scales dropped from a baseline score of 6, the participant would no longer be considered psychotic, hence producing a clinically significant change (Miller et al., 2002).

Data Analysis Plan and Procedures

The data were obtained from the Early Detection and Intervention for the Prevention of Psychosis Program (EDIPPP) National Database (Robert Wood Johnson Foundation, 2014). To determine impact of the Family Aided Community Treatment (FACT) intervention, multiple repeated measures t-tests were used to compare the outcome variables of pre-test and post-test average positive and negative symptoms subscales scores of the Structured Interview for Prodromal Syndromes, The Positive and Negative Symptoms Scale, and the Global Functioning Scales. The post-tests were given at 12 months post baseline testing. An intent-to-treat approach was used to avoid the effects of treatment crossover inherent in the FACT model. This research design provided information about the potential effects of the FACT model rather than the effects of specific treatment within the model. The assumptions of a repeated measures t-test were met given the wide distributions of scores at baseline in all outcome variables.

Results

The hypothesis posited there would be an improvement in psychiatric symptoms of participants with early psychosis receiving the FACT intervention. The alternative hypothesis (H_1) was supported for all outcome variables except role functioning (see

Table 1). There was a change in average role functioning score indicating improvement but the change was not statistically significant. In almost every scale, the standard deviation was smaller post-intervention. This smaller standard deviation was another indicator that the FACT intervention produced change.

Discussion

Schizophrenia and major psychotic disorders are conditions with historically poor outcomes, both at a person and system level. These outcomes have produced a sense of entrenched pessimism among clinicians treating people with schizophrenia and major psychotic disorders. The present study indicates that using an intensive, multi-discipline treatment model with people in the very early stages of a major psychotic disorder can improve psychiatric symptoms and functioning.

Using a proof of concept design a with multiple repeated measures t-test, eight first-episode psychotic disorder participants engaged in the Family Aided Community Treatment (FACT) protocol in order to examine if psychiatric symptoms scale scores improved post-intervention. The alternative hypothesis was supported. The FACT intervention decreased psychiatric symptom scores in this population.

Beyond statistical significance, the intervention was clinically efficacious. The SIPS measure defines a person as psychotic when scored as a six on any item of the Positive Symptoms Scale. At baseline each individual had at least one score of six on at least one of the five Positive Symptoms Scale. At 12 months no participants had a single score of 6. This result, in combination with the statistical significant changes, implies that FACT intervention resulted in the participants moving from inside the diagnostic range of dysfunctional and psychotic to outside of that range.

This study had eight potential limitations that should be noted. First, the sample was composed of participants who were help-seeking and consented to a major research study. People with major psychotic disorders, specifically schizophrenia, often do not seek help (Amador, 2007; van Os, 2003) raising the question as to whether this study reflects a representative sample of people with the condition, who generally do not seek help. However, given this specific associated feature of the condition, the design and selection of participants for this study is an effective way to determine if the FACT model offers predictive validity. An essential component of the FACT model is assertive community treatment (ACT), which has proven outcomes indicating improved engagement in treatment among individuals with severe mental illness including those who do not seek help (Substance Abuse and Mental Health Services Administration, 2008).

The second limitation involves the history threat to internal validity. The use of multiple comparisons itself creates the chances of a Type I error. The history threat was present given it was possible an event outside of the treatment that occurred during the course of the participants' treatment resulted in the achieved results. Participants in this study did not enroll simultaneously, they were enrolled as they were referred and met criteria for the research. This reduces the likelihood of a history threat.

A third limitation centered on the possibility that the participants' outcomes would have been achieved as a natural course of their development (i.e., maturation). Baseline analysis of the participants found that they were a homogeneous group in terms of symptomology, age, gender and race. Also, the baseline demographics are consistent with persons who are diagnosed with psychosis. If maturation were present, persons

outside of this study with early psychosis would also have experienced a reduction in symptoms that has not been the case.

A fourth limitation involved a pre-posttest design threat to internal validity is the testing threat. Consideration of this treat involve the question: "Did the participants experience of being administered the SIPS at baseline prepare them for improved responses at 12-month administration of the SIPS?" To address this threat, the PANSS and SIPS were used in tandem. The PANSS is researcher rated and hence not a risk for a testing threat. The PANSS scores were similar in terms of level of psychosis to the SIPS both at baseline and at 12 months. The advantage of using the same two instruments measuring the same construct also reduces the risk of the instrumentation threat, which would imply the participants change in symptomology would be due to the alternative forms of the same tests intended to be equivalent but are not.

This study had a small number of participants lost to attrition (n = 3). No statisically significant clinical or demographics differences were found between participants who remained in the research and those who dropped out; this reduced the threat of attrition.

A seventh potential limitation could be the sample size (n = 8). Yet, it is important to note that the incidence of schizophrenia is 7 to 8 of 100,000 (Drake, Haley, Akhtar, & Lewis, 2000). The sample was pulled from a population of 630,000. The number of participants is consistent with an expected incidence rate. To investigate this limitation, power analysis was conducted to assess the importance of sample size on the t-test statistics. For the majority of scales, post-hoc power analysis supported the t-test

results. In all these analyses an alpha of .05 and a power of .90 were used. The only analysis that did not support the sample size was the Global Functioning Role Scale.

The eighth and final potential limitation that needs to be noted is the regression threat. Given that the all the participants had extreme scores at baseline and the sample was not randomized or large, regression cannot be ruled out. However, several participants' scores improved drastically. Four participants with average SIPS P scores of four or higher reduced their scores to less than one.

The results suggest some potential modifications in practice. It demonstrates that there are tools that can easily be used in clinical practice for identifying early symptoms of psychotic disorders and that if the conditions are caught early there is a treatment model that is effective in reducing psychiatric symptoms and improving functioning. The positive results of this study may encourage practitioners of all disciplines to engage people with early psychotic conditions in treatment with a sense of hope and optimism as opposed to the historical beliefs of hopelessness and pessimism. It may also improve social justice efforts to reduce discrimination and stigma associated with psychotic disorders, and advocate for appropriate and evidenced base treatment that reduces symptoms to the person, reduces costs to systems and improve overall delivery of services.

There are two specific implications of this study for researchers. First, given the overall strengths of the findings after 12 months a follow-up study would be to explore the effects of the intervention for longer periods would add to the nomothetical net in this area . It may be possible that role functioning requires a longer treatment dose for the impact to be at a significant level.

The second implication arises from the intent-to-treat approach to avoid the effects of treatment crossover inherent in the FACT model. This research design provided information about the potential effects of the FACT model rather than the effects of specific treatment within the model. Implications for further research would be to identify the active ingredients within the FACT model that could be randomized, such as participation in multifamily psychoeducation groups, supported employment and education and occupational therapy. Also, using the proof of concept model this study has established a dose response relationship that could be used as the basis for a decision to move forward with additional trials.

This study examined the impact of a yearlong family aided community treatment intervention upon psychiatric symptoms. Psychiatric symptom scores improved with the intervention. The positive findings from the study demonstrated that there are reliable and valid tools for identifying early symptoms of psychotic disorders and that if the conditions are caught early there is a treatment model that is potentially effective in reducing psychiatric symptoms and improving functioning. Hence, further research on this intervention package is warranted.

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Table 1

FACT intervention outcome variables: Inferential Statistics (*N* = 8)

Variables	M	SD	t	H_0 (one-tail)
SIPS P Scale	3.60	0.70	14.53	Reject
Pre	3.93	0.59		$p < .05$
Post	0.33	0.41		
SIPS N Scale	1.27	1.04	3.46	Reject
Pre	2.52	1.21		$p < .05$
Post	1.25	0.71		
SIPS D Scale	1.81	1.22	4.22	Reject
Pre	2.09	1.21		$p < .05$
Post	0.28	0.34		
SIPS G Scale	2.22	0.96	6.55	Reject
Pre	3.28	0.66		$p < .05$
Post	1.06	1.19		
PANSS P Scale	1.77	0.47	10.63	Reject
Pre	2.96	0.56		$p < .05$
Post	1.20	0.34		
PANSS N Scale	1.00	0.59	4.82	Reject
Pre	2.27	0.73		$p < .05$
Post	1.27	0.30		
GFS-Social	1.13	0.84	3.81	Reject
Pre	6.00	1.60		$p < .05$
Post	7.13	1.36		
GFS-Role	0.50	4.00	0.35	Do not Reject
Pre	4.13	2.26		$p > .05$
Post	4.63	3.29		