A Pilot Fidelity Study of Listen-Empathize-Agree-Partner (LEAP) with Assertive Community Treatment (ACT) Mental Health Clinicians

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ABSTRACT

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The primary objective of this study was to examine clinicians’ fidelity to a promising new clinical intervention known as Listen-Empathize-Agree-Partner (LEAP) that addresses issues of poor insight, therapeutic alliance, and treatment adherence prevalent in the schizophrenia population. A secondary purpose of this study was to assess the factor structure and psychometric properties of a measure developed to examine the core principles of the LEAP method. Forty-eight mental health clinicians working in Assertive Community Treatment (ACT) programs randomized into intervention and control groups were assessed for fidelity to the LEAP method via the LEAP Fidelity Measure (LFM), a self-report instrument. Results revealed a three-factor structure of this measure which were labeled “Reflective Listening, Delaying and Opining,” “Partnering on Shared Goals,” and “Client-Centered Listening and Empathizing.” Multivariate Analyses of Variance indicated that clinicians who were trained in LEAP had significantly higher levels of fidelity to the “Reflective Listening, Delaying and Opining” and “Partnering on Shared Goals” components than clinicians who were not trained in this method. There were no significant differences between the groups on the “Client-Centered Listening and Empathizing” component. Analyses did not reveal significant gender differences or effects
based on years of general and specific ACT clinical experience between the two groups. However, in a *post hoc* analysis, a modest correlation between gender and fidelity to the “Client-Centered Listening and Empathizing” component showed that male clinicians tended to report higher fidelity to this specific set of interventions when compared to their female counterparts. These results are discussed within the context of feasibility in training and implementing LEAP in real-world community mental health clinical settings. Additionally, limitations of this study and implications for future research are discussed.
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Chapter I
INTRODUCTION

Over the past decade, the Listen-Empathize-Agree-Partner (LEAP) program has been taught to tens of thousands of mental health practitioners worldwide to address the clinical challenges associated with limited insight, poor therapeutic alliance, and treatment non-adherence often observed in individuals diagnosed with schizophrenia (Amador, 2012). Despite the program’s popularity and high positive ratings from participants, no assessment of trainee fidelity to the program has ever been conducted. The importance of establishing and maintaining fidelity to treatment protocols has been emphasized in the psychotherapeutic intervention literature for decades (Bellg, et al., 2004; Eysenck, 1952; Kernberg, 1976; Moncher & Prinz, 1991; Shapiro & Shapiro, 1983; VandenBos, 1980). However, similar to existing research on the LEAP program, few studies of clinical interventions have adequately addressed issues of treatment fidelity (for review, see Borrelli et al., 2005; Naleppa & Cagle, 2010).

Schizophrenia is a severe and persistent mental illness that is associated with high personal, familial and societal costs (for review, see Harrison et al., 2001; Velligan, Lam, Ereshefsky, & Miller, 2003). Despite evidence suggesting that poor insight into illness (Amador & Kronengold, 2004; McEvoy, 2004), limited therapeutic alliance (Frank & Gunderson, 1990; Prince, 2007; Tattan & Tarrier, 2000), and low treatment adherence (Davis et al., 2003; Svarstad, Shireman, & Sweeney, 2001; Velligan et al., 2003, 2008) lead to detrimental outcomes among individuals with schizophrenia, the paucity of
research devoted to developing and evaluating specific psychotherapeutic interventions aimed at improving these aspects of the illness is alarming.

LEAP (Amador, 2000, 2007, 2010) is a psychotherapeutic intervention comprised of communication strategies designed to strengthen the therapeutic alliance and improve treatment adherence by addressing problems of poor insight associated with this population. Research suggests that lack of insight into illness is highly prevalent among individuals diagnosed with schizophrenia (Amador & Paul-Odouard, 2000; Amador & Kronengold, 2004) with rates ranging from 29-59% (Cernovsky, Landmark, Merskey, & Husni, 2004; Freudenreich, Deckersbach, & Goff, 2004; Larøi et al., 2000). Regarding treatment outcomes, acknowledging and addressing issues of poor insight is critical in this population as lack of awareness into illness has been found to be among the best predictors of treatment non-adherence among individuals with schizophrenia (Amador & Kronengold, 2004).

Poor insight has also been found to be significantly related to low therapeutic alliance in this population (Misdrahi, Petit, Blanc, Bayle, & Llorca, 2012; Wittorf et al., 2009). Research suggests that individuals with poor awareness into their illness have difficulty engaging in a positive therapeutic relationship (Johnson, Penn, Bauer, Meyer, & Evans, 2007). This finding is particularly alarming as research has consistently indicated that the relationship between patient and therapist is primarily responsible for change in the process of therapeutic treatment (Henry, Strupp, Schacht, & Gaston, 1994; Martin et al., 2000; Safran, Goldfried, & Muran, 1995). Consequently, low therapeutic alliance has been found to be associated with treatment non-adherence (for review, see Velligan, Lam, Ereshefsky, & Miller, 2003) and is predictive of poor outcomes among individuals
diagnosed with schizophrenia (Horvath & Luborsky, 1993; Horvath, 1994; Martin et al., 2000).

Due to the poor adherence to treatment demonstrated in the schizophrenia population, another goal of LEAP is to improve treatment adherence. The literature on adherence rates suggests that up to 60% of individuals diagnosed with schizophrenia are non-adherent to prescribed medications (Dolder, Lacro, Leckband, & Jeste, 2003; Gilmer et al., 2004; Velligan et al., 2003) and research also reveals high rates of disengagement from psychotherapeutic and psychosocial interventions in this population (Drake, 2009; Marshall & Lockwood, 2010; Marshall, Lockwood, & Green 2010). Taken together, non-adherence and intermittent adherence to treatment is associated with symptom relapse, rehospitalization, and high cost of treatment among individuals with schizophrenia (Davis et al., 2003; Velligan et al., 2003, 2008; Weiden et al., 1995).

As schizophrenia poses specific challenges to treatment and prognosis due to the poor insight, low therapeutic alliance, and treatment non-adherence associated with this diagnosis, psychotherapeutic approaches, such as LEAP, that aim to address these particular areas of the illness should be examined. LEAP incorporates components of motivational enhancement, cognitive-behavioral and client-centered therapies and provides communication tools that serve as an adjunctive intervention to other forms of psychotherapy and psychosocial education (Amador, 2000, 2007, 2010, 2012). The primary goal of LEAP is to develop a trusting and accepting environment that enables the practitioner to become more persuasive in his or her treatment recommendations to the patient. LEAP interventions are particularly suited for comprehensive treatment models, such as Assertive
Community Treatment (ACT), that serve individuals at high risk for repeated psychiatric crises, treatment non-adherence and service disengagement.

ACT is an evidence-based treatment framework that supports patients with Severe and Persistent Mental Illness (SPMI), such as schizophrenia, by providing intensive outpatient treatment ‘in vivo’ in their community of choice, including the patient’s home, local mental health clinic, or hospital setting (Marshall & Lockwood, 2010). The program facilitates psychiatric recovery and stability, as well as increased daily functioning and quality of life across various contexts (e.g., home, school, work, community) and relationships (e.g., peers, family). Due to the serious costs of chronic mental illness, the importance of using evidence-based approaches to improve patient outcomes is further underscored.

The extant research on issues of treatment fidelity conclude that not only do fidelity studies promote important methodological benefits to psychotherapy research, enhanced clinician fidelity to treatment protocols is critical for the successful evaluation of research-based clinical interventions as it is otherwise impossible to examine the effectiveness of a given treatment or to make valid comparisons between treatments (Borrelli et al., 2002, 2005; Mowbray, Holter, Teague, & Bybee, 2003). Despite the emerging focus on establishing empirically-supported treatments in psychotherapy research, the literature indicates that few studies adequately address clinician fidelity to treatments (Borrelli et al., 2002; Naleppa & Cagle, 2010). As such, researchers argue that establishing treatment fidelity is necessary to the development and dissemination of innovative, credible, and clinically-applicable interventions and programs for chronically mentally ill individuals (Bellg et al., 2004; Naleppa & Cagle, 2010).
Based on this literature, addressing issues of insight deficits, low therapeutic alliance, and limited treatment adherence among individuals diagnosed with schizophrenia is a clinical problem that needs to be addressed. As such, LEAP, comprised of psychotherapeutic techniques developed to specifically address these clinical challenges, will be presented as a promising adjunctive intervention that is the focus of this study. Based on the research arguing that fidelity assessments are critical in evaluating the effectiveness of clinical interventions, the primary purpose of this investigation is to assess clinicians’ fidelity to communication strategies that represent core components of LEAP. Clinician gender, years of general clinical experience, and years of specific clinical experience within the ACT program are evaluated as potential moderator variables. A secondary purpose of this study is to examine the factor structure of a measure developed to assess core principles of LEAP in an attempt to identify and compare differences between groups based on the principal components of this intervention.

Review of the Literature

In this chapter, the research literature related to insight into illness, therapeutic alliance, and treatment adherence associated with schizophrenia will be reviewed. Promising research on a clinical intervention known as LEAP will be presented as a psychotherapeutic approach that specifically addresses poor insight, low therapeutic alliance, and treatment non-adherence in this population. The applicability of LEAP principles to the ACT program, a treatment approach that has been empirically-validated as an effective intervention structure for individuals with chronic mental illness, will be
discussed. Furthermore, the literature arguing the importance of fidelity assessments to the effective development and dissemination of clinical interventions will be reviewed. The rationale and scientific value of the present study will be discussed in light of this literature.

*Insight Into Illness*

The current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR; American Psychiatric Association, 2000) cites scientific consensus that lack of insight into mental illness is a prevalent feature of schizophrenia and is a manifestation of the illness itself, rather than a coping strategy. At the time of its publication, the DSM-IV-TR revision chairpersons and experts reviewed approximately two hundred empirical studies (personal communication, Xavier Amador, co-chair of DSM-IV-TR Schizophrenia and Related Disorders section). In the decade prior to the publication of the last edition of the DSM, the extant literature on insight in this disorder had increased about twenty-fold. This was due, in large part, to increased agreement on terminology and phenomenology making comparison between studies and replications possible. For example, Amador, Strauss, Yale, and Gorman (1991) proposed a comprehensive and multidimensional definition of insight, stating that insight encompasses current and retrospective awareness of: (1) having a mental disorder, (2) the effects of medication, (3) the psychosocial consequences of mental disorder, and (4) the specific signs and symptoms associated with a given mental disorder. The authors further distinguish between *unawareness of illness*, which reflects a failure to acknowledge the presence of specific deficits, signs, or symptoms of illness when confronted with them, and *incorrect attribution*, which reflects
the expressed belief that a specific deficit, sign, or symptom of illness does not stem from mental dysfunction, as distinct dimensions of insight. Research suggests that insight into illness can be modality-specific rather than global, meaning that one can be aware of some aspects of their illness while lacking insight into others (Amador et al., 1994; Rosen, Mukherjee, Olarte, Varia, & Cardenas, 1982; Tremeau et al., 1997).

Research indicates that unawareness of illness is prevalent in a large proportion of people with schizophrenia (Amador & Paul-Odouard, 2000; Amador & Kronengold, 2004). The International Pilot Study of Schizophrenia (1973), a multi-national study conducted by the World Health Organization, found that 81% of 811 patients denied that they had a mental illness. A second international study involving more chronically-ill patients with schizophrenia (Wilson, Ban, & Guy, 1986) reported that 89% of 768 patients denied they had an illness. In both studies, insight was defined as present if there was “some awareness of mental illness” and absent if “mental illness was vigorously denied.”

More recent literature has also documented high rates of insight deficits in patients with schizophrenia. In a comprehensive study assessing insight into illness among patients with schizophrenia, schizoaffective disorder, and mood disorders with psychosis, Amador et al. (1994) found that 57.4% of patients with schizophrenia (n = 221) exhibited moderate to severe unawareness of having a mental disorder, 31.5% had severe unawareness of the social consequences of mental disorder, and 21.7% had severe unawareness of the efficacy of medication. The authors reported a range of 27.8% to 57.6% on unawareness of specific signs and symptoms associated with mental illness. Similarly, Sevy, Nathanson, Visweswaraiyah, and Amador (2004) reported that among 96 patients diagnosed with schizophrenia, 32.7% of patients lacked awareness of illness, 18.4% lacked awareness for
treatment response, 41.8% lacked awareness for social consequences, and 58.2% lacked awareness for symptoms. Other researchers found rates of unawareness of mental illness ranging from 29% to 59% in schizophrenia samples (Cernovsky, Landmark, Merskey, & Husni, 2004; Freudenreich, Deckersbach, & Goff, 2004; Larøi et al., 2000; Young, Davila, & Scher, 1993).

Research investigating varying levels of illness unawareness among psychotic patients has yielded significant results. In a study of insight involving 87 outpatients diagnosed with schizophrenia (n = 54) and schizoaffective disorder (n = 33), Dickerson, Boronow, Ringel, and Parente (1997) found that 49.5% of patients were at least moderately impaired, while 25% of patients had severe deficits in illness awareness. In a study of early-onset schizophrenia (n = 264), schizoaffective (n = 40), and schizoprophreniform (n = 231) disorder patients, Keshavan, Rabinowitz, DeSmedt, Harvey, and Schooler (2004) reported rates of 12% with no impairment, 12.4% with minimal impairment, 20.9% with mild impairment, 31.4% with moderate impairment, 13.7% with moderate to severe impairment, 9.4% with severe impairment, and 0.6% with extreme impairment in awareness of illness. Thus, these researchers found that 76% of these patients exhibited mild to severe levels of insight deficits regarding their mental illness. Furthermore, in a study of first-episode schizophrenia (n = 30) and schizoaffective disorder (n = 5) inpatients, Shad, Muddasani, Prasad, Sweeney, and Keshavan (2004) found that prior to pharmacological treatment, 51.4% had good insight, 17.1% had partial insight, and 31.4% had poor insight.

Although patients diagnosed with other psychiatric disorders, such as schizoaffective disorder, bipolar disorder, and major depressive disorder, may also exhibit
lack of insight into mental illness, research suggests that self-awareness deficits appear to be more severe and pervasive in those diagnosed with schizophrenia (Amador et al., 1994; Pini, Cassano, Dell’Osso, & Amador, 2001). Moreover, Carpenter, Bartko, Carpenter, and Strauss (1976) not only found poor insight to be a prevalent symptom of schizophrenia but also reported that it was a significant discriminating factor between schizophrenia and other psychotic disorders. There is also evidence suggesting that schizophrenic individuals with the deficit syndrome, characterized by primary enduring negative symptoms (i.e., affective flattening, alogia, or avolition), exhibit significantly lower levels of insight compared to non-deficit schizophrenia patients (Amador et al., 1994; Ratakonda, Gorman, Yale, & Amador, 1998).

In the psychoanalytic literature, deficits of insight into mental illness have been studied historically using subjective interpretation of case studies concluding that poor insight results from unconscious psychological defenses or conscious coping strategies (e.g. Levy, McGlashan, & Carpenter, 1975; Semrad, 1966; Van Putten, Crumpotm, & Yale, 1976). Although few studies have investigated the direct relationship between defensiveness and insight in schizophrenia (Kasapis, 1996; Nelson, 1997), there have been consistent findings characterizing lack of insight into illness as a prevalent symptom of schizophrenia resulting from organic brain dysfunctions rather than psychological processes (APA, 2000; Prigatano & Schachter, 1991; Amador & David, 2004). Many have argued that insight deficit in schizophrenia bears a strong resemblance to anosognosia related to neurological disorders such as stroke and other brain disorders (APA, 2000). When patients with schizophrenia and associated poor insight are compared to those with neurological disorders with anosognosia, both groups of patients exhibit similar
characteristics, including gross lack of awareness of illness persisting despite evidence to the contrary, confabulations to explain behaviors or observations that contradict their belief of not being ill, and a compulsion to prove this belief (Amador & Paul-Odouard, 2000; Flashman, 2004). Additionally, there is growing evidence linking lower levels of insight to neuropsychological dysfunctions, particularly in frontal lobe functioning (Larøi et al., 2000; Morgan & David, 2004; Shad et al., 2004; Young et al., 1993). Thus, research establishing associations between deficits in insight, enduring negative symptoms (deficit syndrome), and particular neuropsychological deficits have informed neuro-cognitive conceptualizations of illness unawareness in schizophrenia.

Importantly, deficits in insight into illness have been reported to significantly influence treatment outcomes in schizophrenia (Amador & Kronengold, 2004; McEvoy, 2004). Poor insight has been found to be among the best predictors of non-adherence and partial adherence to medications (Amador & Kronengold, 2004), with acknowledgement of illness (Bartko, Herczeg, & Zador, 1988; Kemp & David, 1996; Smith et al., 1999; Weiden et al., 1991) and advantages of medications (Buchanan, 1992; McEvoy, Appelbaum, Apperson, Geller, & Freter, 1989; McEvoy et al., 1993) being significantly related to treatment adherence and avoidance of re-hospitalization. Furthermore, research indicates that poor insight into illness is also associated with low therapeutic alliance in this population (Kemp & David; 1996; Misdrahi, Petit, Blanc, Bayle, & Llorca, 2012; Wittorf et al., 2009). For example, Johnson and colleagues (2007) found that level of insight predicted quality of therapeutic alliance among individuals with schizophrenia, suggesting that those with poor insight had difficulty engaging in a working alliance.
Therapeutic Alliance

Researchers and practitioners of psychotherapy have asserted that the therapeutic alliance – broadly defined as an open, trusting, and collaborative relationship between a patient and clinician – is an essential component of the therapeutic process of change. The concept of the alliance originated in early psychoanalytic theories (e.g., Freud, 1912; 1913) and was expanded by Carl Rogers’ Client-Centered Therapy (Farber, 2007; Rogers, 1957; Rogers & Wood, 1974). Although differences exist in conceptualizations of the therapeutic alliance, most theoretical definitions include three common themes: (1) the collaborative nature of the relationship, (2) affective attachment between patient and therapist, and (3) mutually agreed-upon objectives for treatment (Bordin, 1979; Gaston, 1990; Horvath & Symonds, 1991).

Within a historical context, Freud (1912; 1913) theorized that a positive therapeutic attachment creates an environment of safety and trust allowing the patient an opportunity to reflect on past experiences and to associate the analyst with significant figures from the past. Although a positive attachment is an important aspect of analysis, it is not viewed as a “real” relationship between the analyst and patient as the attachment is based on the patient’s projections of qualities defining past relationships onto the analyst, a process understood as transference. As such, the primary task in psychoanalysis is to derive interpretations regarding the various forms of transference that arise within the therapeutic relationship. Within this theoretical framework, the alliance is not viewed as an agent of therapeutic change in and of itself.

In 1951, the publication of Carl Rogers’ book, *Client-centered Therapy*, not only directed attention towards therapists’ contributions to the process of change, but also
suggested that the therapeutic relationship in itself may serve a healing function. To create a therapeutic environment that facilitates change, Rogers emphasized the use of a non-directive style of listening and empathy that promotes affective regulation. Through the use of empathy, the therapist responds to the client in a nurturing and accepting manner that enables the client to modulate their affective experiences and to internalize the therapist’s validating stance (Fosha, 2001; Watson, 2007). This process is facilitated through the therapist’s communication of warmth and caring as well as affective authenticity and genuineness, what Rogers (1951, 1957) called unconditional positive regard and congruence, respectively.

Rogers proposed three hypotheses regarding the therapeutic conditions that facilitate change (1951, 1957). First, he suggested that empathy, congruence and unconditional positive regard, viewed as the therapist’s contributions to developing a therapeutic alliance, are “necessary and sufficient conditions” of therapeutic change (Rogers, 1957, p. 87). Rogers made the theoretical argument, for the first time, that the relationship that the therapist provides the patient, rather than techniques applied within this context, is the agent of therapeutic change. Second, Rogers argued that these conditions supplied by the therapist are responsible for change regardless of the therapist’s theoretical orientation. Again, this hypothesis underscored the importance of the therapeutic relationship and also implied that the therapist’s most valuable contribution to the process of therapy is interpersonal rather than technical. Third, Rogers suggested that the client-centered approach was distinctive as the therapist was responsible for providing these transformational relationship conditions. The implication of this hypothesis is that the patient will grow under these benevolent conditions and that therapeutic change hinges
on the therapist’s ability to create an environment that allows the patient to access and
enhance his or her growth potential.

Unique to his time, Carl Rogers insisted upon empirical validation of his theoretical
hypotheses and to identify the essential aspects that facilitate change in therapy (Farber,
2007; Horvath, 2000; Watson, 2007). Results of numerous studies on his original theories
are generally supportive of his contention that a positive therapeutic alliance is associated
with favorable patient outcomes (for review, see Horvath & Symonds, 1991). However,
contrary to Rogers’ assertion, research suggests that the patient’s perception of empathy,
congruence and unconditional positive regard in the therapeutic relationship was more
predictive of outcome rather than objective measurements of these conditions (Farber &
Lane, 2002; Mitchell, Bozart, & Krauft, 1977).

In his presidential address to the Annual Conference of the Society for
Psychotherapy Research in 1975, Edward Bordin presented a reformulation of the concept
of the therapeutic alliance (Bordin, 1976). He altered the psychodynamic framework by
suggesting that the alliance was primarily a conscious relationship in the present rather
than predominantly informed by unresolved past relationships. He supported Rogers’
(1951, 1957) claim that the therapeutic alliance was fundamental to all helping processes.
However, in contrast to Rogers’ contention that the therapist was the sole provider of the
“necessary and sufficient conditions” of change, Bordin’s concept of the alliance entailed
agreements and collaboration between the therapist and the patient. Bordin’s (1976, 1994)
conceptualization of the alliance incorporates three associated components: (1) Bonds,
referring to interpersonal attachments (i.e., liking, trusting, etc.), (2) Tasks, defined as
agreements or consensus between the therapist and patient with respect to the primary
focus of therapy, and (3) Goals, involving consensus regarding the short- and long-term expectations between the therapist and patient. Bordin’s reformulation of the client-centered approach redirected attention onto the therapeutic alliance. This attention also generated extensive research investigating the relationship between the alliance and treatment outcomes.

The therapeutic alliance has become central to contemporary conceptualizations of the therapeutic process primarily due to the consistent finding that the quality of the therapeutic alliance is related to subsequent therapeutic outcomes (for review, see Horvath & Symonds, 1991). Researchers have investigated the effectiveness of psychotherapy across theoretical orientation that has yielded consistent evidence that psychotherapies are generally effective independent of the therapist’s theoretical perspective (Lambert & Bergin, 1994; Martin, Garske, & Davis, 2000). Many researchers consider the therapeutic alliance to be a common factor across therapy modalities accounting for positive treatment outcomes (Henry, Strupp, Schacht, & Gaston, 1994; Martin et al., 2000; Safran, Goldfried, & Muran, 1995), and Farber (2007) has evaluated the enduring and pervasive contributions of the client-centered approach to the field of psychotherapy.

The quality of the therapeutic alliance has also been consistently associated with treatment outcomes in individuals diagnosed with schizophrenia (Horvath & Luborsky, 1993; Horvath, 1994; Martin et al., 2000). A stronger therapeutic alliance has been associated with reduced symptom severity and higher community functioning (Neale & Rosenheck, 1995; Olfson, Glick, & Mechanic, 1993), higher medication and treatment adherence (Frank & Gunderson, 1990; Corriss et al., 1999; Olfson et al., 2000), increased goal attainment (Gehrs & Goering, 1994), better quality of life (Solomon, Draine, &
Delaney, 1995), and higher global patient functioning (Neale & Rosenheck, 1995; Svensson & Hansson, 1999a). Moreover, the absence of a positive alliance with a therapist predicted worse patient outcomes, including increased symptom severity and lower overall quality of life (Tattan & Tarrier, 2000). Furthermore, negative symptoms associated with schizophrenia, including blunted affect, emotional withdrawal, and a detached interpersonal style, have been found to significantly predict poorer alliance in psychotic (Couture et al., 2006) and non-psychotic samples (Hersoug, Monsen, Havik, & Hogeland, 2002; Kivlighan, 1998; Saunders, 2001). In a comprehensive study of predictors of treatment outcomes in schizophrenia, Frank and Gunderson (1990) found that patients with schizophrenia who developed a strong therapeutic alliance with a therapist within the first 6 months of treatment evidenced significantly lower treatment drop-out rates even when multiple pretreatment characteristics, including social and vocational functioning and severity of cognitive disorganization, were controlled for. Patients in this study who reported low alliance ratings showed a treatment drop-out rate of 72%.

Although the impact of lack of insight into illness and quality of therapeutic alliance on treatment outcomes in individuals with schizophrenia have been established independently, the influence of insight on the therapeutic alliance has rarely been studied (Wittorf et al., 2009). Kemp and David (1996) asserted that poor insight into illness is associated with decreased participation in treatment, suggesting that patients with poor insight may experience difficulty engaging in a therapeutic alliance. Johnson, Penn, Bauer, Meyer, & Evans (2007) supported this assertion when they found that higher baseline levels of insight predicted stronger group alliance at the mid-point of group therapy among patients with schizophrenia-spectrum disorders.
Despite emerging evidence suggesting that insight into illness affects the quality of the therapeutic alliance, few studies to date have investigated the impact of both insight and alliance on treatment outcomes in individuals with schizophrenia (Prince, 2007). One study (Prince, 2007) found an inverse relationship between awareness of illness and therapeutic alliance in relation to the number of inpatient hospitalizations among patients with schizophrenia. These results suggest that a higher number of hospitalizations was significantly related to increased levels of insight and decreased therapeutic engagement and alliance in a schizophrenic sample. Furthermore, Chadwick (2001) found that although therapeutic alliance and insight into illness significantly influenced medication adherence in patients with schizophrenia, no significant interaction effects were found.

In sum, research indicates that poor insight into illness and low therapeutic alliance are generally associated with poor treatment outcomes among individuals diagnosed with schizophrenia. As such, the specific contributions of these aspects of illness to treatment adherence, or non-adherence, should be evaluated.

**Treatment Adherence**

The primary form of treatment for schizophrenia is pharmacological intervention that targets symptoms associated with the illness and reduces relapse rates (Ayuso-Gutiérrez & del Rio Vega, 1997; Davis, Chen, & Glick, 2003). Despite the benefits afforded by neuroleptic medications, poor adherence to medications is a limitation common in the treatment of schizophrenia (Fenton, Blyler, & Heinssen, 1997; Hogarty & Ulrich, 1998). Medication adherence relates to “the extent to which the patient’s behavior corresponds with advice given by their physicians” (Keith & Kane, 2003, p. 1308).
Although researchers have often used the term “non-compliance” to describe patient’s low follow-up rates to pharmacological treatment, Velligan and colleagues (2006) recommend changing our terms to “non-adherence” or “non-concordance” to promote the notion that medical treatment is a collaborative enterprise between patient and physician.

Medication non-adherence is one of the strongest predictors of relapse and re-hospitalization in schizophrenia. Research suggests that up to 60% of individuals diagnosed with schizophrenia are non-adherent to prescribed medications (Dolder, Lacro, Leckband, & Jeste, 2003; Fenton, Blyler & Heinssen, 1997; Gilmer et al., 2004; Sullivan, Wells, Morgenstern, & Leake, 1995; Velligan, Lam, Ereshefsky, & Miller, 2003; Weiden et al., 1995). In a summary of studies on medication adherence rates, McEvoy (2004) reported that approximately 50% of patients with schizophrenia take medications as prescribed with little or no supervision, 35% of patients adhere to medications if supervised, and 15% of patients avoid taking medications under any circumstance. Poor adherence to medications has been associated with re-hospitalization, impediments to treatment progress, and high cost of treatment among individuals with schizophrenia (Davis et al., 2003; Svarstad, Shireman, & Sweeney, 2001; Velligan et al., 2003, 2008; Weiden et al., 1995).

Furthermore, several researchers have reported that schizophrenia patients who receive intermittent treatment at the onset of symptoms have less favorable outcomes compared to those who receive long-term and consistent treatment (Ayuso-Gutiérrez & del RioVega, 1997; Carpenter et al., 1990; Herz et al., 1991; Schooler et al., 1997). Weiden and Glazer (1997) found that among 64 “revolving door” patients (patients with frequent hospitalizations), non-adherence to medications accounted for 50% of the re-
hospitalizations. In one study (Wyatt et al., 1995), inconsistent adherence to medications was associated with a two-fold increase in the number of inpatient admissions and a four-fold increase in total duration of hospitalization. Thus, at a monthly relapse rate of 3.5% for patients with good adherence to oral antipsychotic medications versus 11% for those with poor adherence, approximately 40% of good adherence patients would relapse within one year compared to nearly 100% for poor adherence patients (Csernansky & Schuchart, 2002). It should be noted that even if non- or partial-adherence does not result in hospitalization, poor adherence to treatment can compromise symptom control and undermine overall adjustment among individuals with schizophrenia (Masand & Narasimhan, 2006). Despite recent advances in pharmacological treatments, second-generation antipsychotic medications with increased efficacy and improved side effect profiles have not substantially improved rates of medication adherence in schizophrenia (Dolder et al., 2003; Velligan et al., 2003).

Some researchers have suggested that perhaps the persistent and pervasive nature of schizophrenia contributes to partial or complete non-adherence to medications. The negative symptoms associated with schizophrenia have been found to reduce motivation and drive (Schmand et al., 1994), and cognitive deficits adversely affecting attention and memory make it difficult to adhere to medication regimens (Sharma & Antonova, 2003). Treatment-related factors, including the delayed onset of the therapeutic effects of most psychiatric medications (Oehl, Hummer, & Fleischhacker, 2000), complicated medication regimens (Greenberg, 1984; Oehl et al., 2000), and the therapeutic alliance with the physician (Frank & Gunderson, 1990; Corriss et al., 1999; Olfson et al., 2000) have been shown to affect medication adherence in this population. In addition, environmental
factors have been established, including supervision (Parkes, Brown & Monck, 1982), family supportiveness (Buchanan, 1992; Young, Zonana, & Shepler, 1986), high expressed emotion in the family (Oehl et al., 2000; Tamminga & Schulz, 1991), and family attitude toward psychiatric treatment (Oehl et al. 2000). Velligan and colleagues (2006) have asserted that although adherence rates are poor across a variety of medical and mental illnesses, the consequences of medication non-adherence in schizophrenia can be devastating due to the high personal, familial and societal costs associated with the disorder.

Although pharmacological treatment is an essential aspect of treatment for schizophrenia, little evidence suggests that antipsychotic medication alone significantly improves global functioning (Amminger et al., 1999; Baum & Walker, 1995; Halford & Hayes, 1995; Macdonald, Jackson, Hayes, Baglioni, & Madden, 1998). Although pharmacotherapy is effective in the treatment of acute symptoms of schizophrenia, medications alone do little to alleviate residual cognitive and social deficits associated with the disorder (Mueser, Bellack, Douglas, & Morrison, 1991). There is growing evidence that optimal treatment for schizophrenia also encompasses psychological strategies (Altamura et al., 2000; Amminger et al., 1999; Tarrier et al., 1993).

Although psychotherapeutic interventions are varied, most approaches geared toward individuals with psychosis include goals such as reducing the disability and distress associated with residual symptoms, reducing emotional concerns, and promoting an understanding of the illness to decrease rates of relapse (Penn et al., 2004). Researchers have investigated the impact of engagement in psychotherapy with treatment outcomes in schizophrenia and have found that psychological interventions are associated with
improved symptom control, quality of life, maintenance in the community, and psychosocial integration (Altamura et al., 2000; Amminger et al., 1999; Kuipers et al., 1998). A number of studies have suggested that psychological interventions can be effective in reducing the intensity of psychotic symptoms, such as hallucinations and delusions, among patients with schizophrenia (Dickerson, 2000; Gould, Mueser, Bolton, Mays, & Goff, 2001; Tarrier et al., 1999; Sensky et al., 2000). In a study involving acutely psychotic patients, Drury, Birchwood and Cochrane (2000) found that cognitive behavior therapy adjunctive to antipsychotic medication resulted in a significantly faster and more complete recovery from the psychotic episode. Thus, research suggests that psychotherapeutic interventions are important adjunctive strategies that can improve outcomes for patients diagnosed with schizophrenia.

Tarrier and colleagues (1993) purport that due to the pervasive nature of schizophrenia, a treatment approach involving pharmacological and psychological interventions is necessary to improve the patient’s level of functioning and quality of life. Furthermore, as the majority of patients with schizophrenia require long-term treatment due to the chronic nature of the illness, greater stability can be achieved through comprehensive intervention strategies focusing on psychoeducation, support, and the patient’s view of the illness to promote and enhance treatment progress (Altamura et al., 2000; Tarrier et al., 1993).

Despite the serious outcomes associated with medication non-adherence in schizophrenia, the paucity of research devoted to devising and evaluating specific interventions aimed at improving treatment adherence is surprising. The use of psychoeducational techniques in increasing treatment adherence in schizophrenia has been
examined. Psychoeducation is a widely used intervention focused primarily on increasing patient’s knowledge regarding schizophrenia, encompassing information about symptoms, treatment and medications, with the goal of increasing understanding and promoting adherence. Several studies have evaluated the effectiveness of individual and group psychoeducational interventions in increasing medication adherence, however, there is little evidence to suggest that psychoeducation alone is an effective means of increasing adherence to medication (Atkinson, Coia, Gilmour, & Harper, 1996; Gray, 2000; Smith, Birchwood, & Haddrell, 1992). In a randomized controlled trial of 44 patients with schizophrenia taking clozapine, Gray (2000) found that although three sessions of structured individual patient education improved patients’ understanding of their treatment, there was no effect on enhancing adherence to medications. Two independent meta-analyses (Dolder et al., 2003; Zygmunt, Olfson, Boyer, & Mechanic, 2002) concluded that psychoeducational interventions were the least successful at improving medication adherence in schizophrenia. Thus, the literature on psychoeducation suggests that while educational interventions may improve patients’ understanding of pharmacological treatment, this understanding does not improve adherence to medications. However, both meta-analyses also concluded that interventions incorporating aspects of cognitive and motivational enhancement therapies were the most promising in addressing treatment non-adherence in schizophrenia.

Given the strong association between treatment adherence and outcomes for individuals with schizophrenia, cognitive therapies incorporating motivational interviewing (MI) have been evaluated as therapeutic interventions that may affect adherence rates. MI has been proposed as an intervention to address a variety of problems,
including substance abuse (Baker et al., 2002; Barrowclough et al., 2001; Graeber, Moyers, Griffith, Guajardo, & Tonigan, 2003), goal identification (Corrigan, McCracken, & Holmes, 2001), and insight and treatment adherence (Rüsch & Corrigan, 2002), in addition to medication adherence among individuals with schizophrenia (Kemp, Hayward, Applewhaite, Everitt, & David, 1996; Kemp, Kirov, Hayward, Everitt, & David, 1998; O’Donnell et al., 2003). Originally based in substance abuse research, MI is an intervention that uses Prochaska and colleagues’ (Prochaska, DiClemente, & Norcross, 1992) stages to address issues of motivation for change collaboratively with the patient. This model of change is conceptualized as a step-wise phenomenon in which individuals proceed through distinct stages (i.e. precontemplation, contemplation, preparation, action, maintenance, and relapse) to achieve meaningful behavior change (Arkowitz & Miller, 2008). MI emphasizes the importance of motivation as a contextual factor rather than a personality trait, and reduces the role of confrontation when addressing resistance to change (Miller & Rollnick, 1991). In this model, effective change occurs when an intervention matches the patient’s particular stage of change rather than a “one-size-fits-all” approach. Thus, failure to pursue aftercare treatment is not viewed as a sign of resistance or character pathology, but rather as representative of an effort to change at an earlier stage (Swanson, Pantalon, & Cohen, 1999). Furthermore, collaboration is an important aspect of MI as the therapist and patient focus solely on goals that are mutually agreed upon and are often generated by the patient. MI encourages patients to weigh the risks and benefits of change, uses an empathic response to the exploration of ambivalence regarding illness and treatment, and promotes the patient’s self-efficacy regarding change (McCracken & Corrigan, 2008). Research has demonstrated that MI helps patients clarify
goals, explore obstacles to treatment and make commitments to change (Miller & Rollnick, 1991).

When using MI to address medication adherence, the four basic principles (express empathy, develop discrepancy, roll with resistance, and support self-efficacy; Miller & Rollnick, 2002) create an atmosphere of acceptance and attentive listening, which is conducive to a collaborative relationship. The accepting relationship provides a context in which the patient can voice and explore his or her ambivalence toward treatment and medications. Within the frame of MI, the therapist does not attempt to persuade the patient to accept a diagnosis, rather, the patient is encouraged to contemplate how particular behaviors (such as not taking medications) might help achieve or interfere with their self-identified goals (McCracken & Corrigan, 2008). Rüsch and Corrigan (2002) suggest that this approach helps patients overcome any cognitive deficits associated with their illness by focusing on concrete problems and personal goals rather than abstract concepts. Furthermore, by accepting ambivalence as a part of change, rather than a form of resistance, patients’ self-efficacy can be bolstered through the decision-making process.

There have been few controlled randomized studies that specifically evaluate the effectiveness of MI in improving adherence to pharmacological treatment in schizophrenia. Kemp and colleagues (Kemp et al., 1996, 1998) used the principles of MI to develop what they call ‘Compliance Therapy.’ Unlike broader based cognitive therapies that focus primarily on patient’s affect and symptom status, compliance therapy was developed as a short-term intervention with the primary goal of improving medication adherence following hospital discharge (Kemp et al., 1996). As in other cognitive therapy approaches, compliance therapy occurs in phases. In the first phase, the patient’s
psychiatric history is reviewed. In the next phase, the patient’s ambivalence toward treatment is explored. This phase is followed by a focus on medications as a useful strategy in improving the patient’s quality of life.

In Kemp and colleagues’ (1996) study, the compliance therapy intervention (n = 39) consisted of four to six 20- to 60-minute sessions conducted twice weekly. The control group (n = 35) received supportive counseling for a similar number and duration of sessions. The authors found that individuals who received compliance therapy had significantly higher medication adherence rates than those who were in the control group. They also reported that the compliance therapy group achieved significant secondary outcomes, including improved insight, better attitudes toward treatment and longer time to inpatient admission. Furthermore, these differences were maintained at 3-, 6-, and 18-month follow-up intervals. However, in a similar study, O’Donnell and colleagues (2003) were unable to replicate the findings that Kemp et al. reported. The authors reported that the power of the study may have been insufficient to detect a difference between the two experimental groups.

In another clinical trial, Gray and colleagues (Gray et al., 2006) conducted a single-blind, multi-center, randomized controlled trial of the effectiveness of compliance therapy on 409 outpatient and inpatient individuals with schizophrenia. Participants in the compliance therapy group received eight weekly sessions lasting an average of 30-50 minutes. The control group received the same number of sessions addressing didactic health education specifically excluding any compliance therapy skills or techniques. The authors reported no significant difference between the intervention and control groups at follow-up. Moreover, exploratory post hoc analyses on a subgroup of less treatment-
adherent participants also yielded non-significant results in relation to medication adherence. Gray et al. suggest that sample selection bias may account for the non-significant results as a large proportion of patients initially referred to the trial were excluded from the study. It should be noted that analyses on participant attrition indicate that the individuals who dropped out of the trial tended to have histories of longer inpatient hospitalizations ($p = .022$) than those who completed the trial. As such, the authors suggest that their sample may have been biased towards a subsample of more cooperative and treatment-adherent participants who were unlikely to benefit significantly from compliance therapy. Based on the inconsistent results of these studies, it is unclear whether the evidence suggests that compliance therapy effectively improves medication adherence in schizophrenia.

Based on the research literature that indicates that poor insight into illness, low therapeutic alliance, and treatment non-adherence are factors contributing to poor outcomes in individuals diagnosed with schizophrenia, therapeutic interventions, such as LEAP, should be explored as promising approaches that address specific clinical issues associated with this population.

*Listen-Empathize-Agree-Partner*

Listen-Empathize-Agree-Partner (LEAP; Amador, 2000, 2007, 2010; Paillot, Goetz, & Amador, 2009) is an intervention comprised of communication strategies designed to strengthen therapeutic alliance with the ultimate aim of improving treatment adherence. Based on Medication Adherence and Insight Therapy (MAIT; Amador & Beck, 2001), LEAP incorporates motivational enhancement, cognitive behavioral and
patient-centered therapy approaches and provides communication tools that serve as an adjunctive intervention to support therapeutic goals.

In his review of the empirical status of Carl Rogers’ “necessary and sufficient conditions” (empathy, congruence and unconditional positive regard) for therapeutic change and the enduring contributions of the client-centered approach to the field of psychotherapy, Farber (2007) suggests that although difficult to define and measure, empathy may be the most central feature of the client-centered approach. Furthermore, Bohart and colleagues (Bohart, Elliott, Greenberg, & Watson, 2002) suggest that empathy may lead to positive outcomes by increasing patient satisfaction in therapy which, in turn, increases patients’ adherence to therapists’ interventions and treatment recommendations. They also suggest that empathy may provide a corrective emotional experience and allows the patient to feel respected and understood within the context of therapy. Lastly, these authors propose that empathy influences outcomes by promoting patients’ exploration of feelings, facilitating emotional reprocessing, and mobilizing efforts to change. Aligned with the client-centered approach, LEAP acknowledges the importance of empathy, genuineness, and positive regard, as well as the influence of the therapeutic alliance on patient outcomes.

Core characteristics of LEAP include reflective listening, respect for the patient’s perspective and choices, reality testing only at the patient’s request, and an empathic stance. In LEAP, practitioners listen carefully to the patient’s point of view and accurately reflect their understanding without commenting, disagreeing or arguing. This approach is focused on reducing the patient’s resistance to talking about their illness and to help the practitioner gain a better understanding of the patient’s experiences, including their hopes
and expectations. To further enhance the patient’s experience of being heard and understood, the practitioner empathizes with the experiences that the patient shares. LEAP places particular emphasis on empathizing with any feelings that are associated with the patient’s delusions without commenting on the content of the delusions. This approach aims to validate the feelings elicited by the delusions, and thereby validating the patient’s experiences, without reality testing. Also, LEAP aims to achieve collaboration through establishing mutually agreed-upon goals between the practitioner and patient. Special emphasis is placed on acknowledging the personal choices of the patient and respecting that the patient is responsible for the decisions they make in life. When discussing choices, it is important for the practitioner to maintain a neutral stance by helping the patient consider the positive and negative consequences of their decisions. Through this process, the patient and practitioner partner in fulfilling the mutual goals. The ultimate goal of LEAP is to develop a trusting and accepting environment that enables the clinician or practitioner to become more persuasive in his or her treatment recommendations to the patient (Amador, 2007).

The effectiveness of LEAP in enhancing treatment adherence in schizophrenia has been examined in a single-blind, randomized controlled trial by Paillot, Goetz and Amador (2009). In their study, 54 pre-discharge inpatients receiving long-acting injectable antipsychotic medications (either typical or atypical) were assigned to either the experimental or control group. Those in the experimental group received 14 weeks of LEAP, consisting of weekly sessions lasting approximately one hour. The control group received a similar number of sessions of client-centered supportive psychotherapy. The authors reported that the participants in the LEAP group had significantly better adherence
to medications than the control group. Furthermore, they reported significant secondary outcomes for the LEAP group, including improvements in motivation to take medication, insight into the achieved effects of medication, attitudes toward treatment, and insight regarding their illness. Although the authors state that additional studies of LEAP as a clinical intervention are necessary, the results of their study suggest that LEAP appears to be a promising intervention aimed at improving medication adherence in schizophrenia.

Based on extant literature, the Schizophrenia Patient Outcomes Research Team (PORT; Dixon et al., 2010) concluded that “there is insufficient evidence to recommend any specific intervention to promote adherence to antipsychotic medications among persons with schizophrenia” (p. 61). Furthermore, commenting on the scant literature on clinical interventions that specifically target medication non-adherence in schizophrenia, Nosé, Barbui, Gray, and Tansella (2003) concluded that “experimental studies have to address the effectiveness of educational strategies, psychotherapeutic programs and specific service policies in large samples of patients recruited in many different settings and followed in the long term” (p. 204) and that patients with schizophrenia should be considered separate from those with other psychiatric diagnoses. However, Zygmunt and colleagues (2002) concluded that among existing interventions that target medication non-adherence in schizophrenia, interventions based on principles of motivational interviewing and models of community care such as Assertive Community Treatment are the most promising.
Assertive Community Treatment

Given the significant personal, familial and societal costs associated with chronic mental illness and schizophrenia, in particular, the importance of identifying and examining treatment modalities and contexts that improve patient outcomes is emphasized. The 2010 Cochrane Review (Marshall & Lockwood, 2010; Marshall, Lockwood & Green, 2010) concluded that Assertive Community Treatment (ACT) is an effective evidence-based treatment framework for individuals with severe mental illness for treatment non-adherence or for repeated psychiatric crises requiring a range of clinical, rehabilitation, and social services. Evidence-based practices are defined as “interventions for which there is consistent scientific evidence showing that they improve patient outcomes” (Drake et al., 2001, p. 179). Despite the extensive evidence for efficacious and effective mental health interventions, research suggests that the majority of individuals with severe mental illness do not routinely receive such interventions (Drake et al., 2001; Leff, Thornicroft, Coxhead, & Crawford, 1994). Due to the serious personal, familial, and societal costs of severe mental illness, the importance of using evidence-based approaches to improve patient outcomes is further emphasized.

ACT is a widely-used, intense and comprehensive mental health program model that serves patients with severe mental illness who do not readily benefit from clinic-based services, but who are at high risk for psychiatric hospitalization (Bond, Drake, Mueser, & Latimer, 2001). ACT was developed in the 1970s by Stein and Test (1980) as a community alternative to psychiatric hospitalization. In the ACT model, a multi-disciplinary team of mental health professionals provide intensive services to patients with
severe mental illness. ACT uses a holistic approach toward treatment that encompasses treatment, housing, finances, and other factors that impact patients’ quality of life.

Although ACT has been modified since it was initially developed, there is widespread agreement among researchers on most of the critical ingredients of the model (McGrew & Bond, 1995). ACT is composed of a group of mental health professionals representing various disciplines, including psychiatrists, psychologists, social workers, nurses, rehabilitation counselors, and substance abuse counselors. Although the overall social service system is fragmented, often requiring patients to navigate various agencies and programs to receive necessary treatment, ACT possesses the structure and the resources to address issues related to treatment, rehabilitation, substance use, practical assistance, social services, and family services tailored to the needs of the patient. ACT clinicians meet daily to discuss issues related to patient care, including treatment plans, rehabilitation efforts, and problem solving. The supportive organizational structure of the ACT program has also been shown to reduce burn-out among team members when compared to standard case management programs (Boyer & Bond, 1999). In addition, low patient-staff ratios are an essential component of the ACT program that ensures adequate individualization of services for patients, particularly as the literature suggests that caseloads that are too large results in ineffective case management services (Björkman & Hansson, 2000; King, Le Bas & Spooner, 2000). Although the 10:1 ratio has been frequently used a benchmark, ACT also takes into consideration caseload characteristics that may alter the ratio (Bond et al., 2001).

ACT programs aim to strengthen patients’ abilities to adapt well in the community as well as to bolster patients’ support networks (Dixon et al., 2010). ACT clinicians make
the majority of their contacts with patients and others involved in their treatment in home and community settings, rather than in clinics or offices. Stein and Test hypothesized that \textit{in vivo} interactions with patients would be a more accurate means to assess patient functioning and a more natural way to teach effective skills. Home visits also facilitate rapid access to services, including delivery of medications and crisis intervention. Furthermore, ACT clinicians utilize home visits as a means of ‘assertive outreach’ in continued efforts towards engagement of reluctant or uncooperative patients (Marshall & Lockwood, 2010; Marshall, Lockwood, & Green 2010). Increasing and maintaining medication adherence is a major priority of the ACT program. ACT clinicians emphasize the importance of accurate assessment regarding diagnosis and symptom reduction, choice of medications incorporating appropriate dosages and duration of treatment, and management of adverse side effects in accordance with evidence-based practice guidelines (Buchanan et al., 2010). In addition to treatment management, ACT clinicians focus on a wide range of issues related to everyday living, including housing, finances, and shopping, specifically targeting problem areas for patients. Incorporating all of these elements, ACT can be summarized as an intensive model of care providing treatment, rehabilitation and case management for individuals with severe and persistent mental illness (Bond et al., 2001).

Although ACT is often misunderstood as a type of case management, there are two key differences between these treatment approaches (Marshall & Lockwood, 2010; Marshall, Lockwood, & Green 2010). First, ACT emphasizes teamwork and team responsibility in regards to patient care (Essock & Kontos, 1995). In other words, ACT teams work together to provide services to a shared caseload of patients. In contrast, the
case management model emphasizes professional autonomy and individual responsibility in patient care. Second, ACT adheres to a specified model of treatment (see above) whereas case management is guided by general theoretical concepts (Ellison et al., 1995).

There is general consensus that not all patients with severe mental illness require the intense level of care that ACT programs provide. Currently, most ACT programs target a subset of individuals in this population who do not respond well to less-intensive treatment modalities and are frequent users of emergency psychiatric services (Bond et al., 2001). Admission criteria for ACT teams typically include frequent prior psychiatric inpatient hospitalizations or long-term hospitalizations, co-occurring substance use disorders, homelessness, as well as involvement in the legal system (Bond & Salyers, 2004).

ACT has been extensively researched as a comprehensive treatment model for individuals with severe mental illness. Results of randomized controlled trials of ACT have most consistently found that ACT programs contribute to lower rates of psychiatric hospitalizations and homelessness compared to standard care (Bustillo, Lauriello, Horan & Keith, 2001; Coldwell & Bender, 2007; Marshall & Lockwood, 2010; Marshall, Lockwood, & Green 2010; Morse et al., 2006; Nelson, Aubry & Lafrance, 2007). Other controlled studies have documented significant differences between ACT programs relative to standard care in reduced duration of inpatient hospitalization (Burns & Santos, 1995; Bush, Langford, Rosen & Gott, 1990; Dekker et al., 2002; Essock & Kontos, 1995; Lehman, Dixon, Kernan, DeForge, & Postrado, 1997; Marshall & Lockwood, 2010; Marshall, Lockwood, & Green 2010; Rosenheck & Neale, 1998; Stein & Test, 1980; Ziguras & Stuart, 2000), use of fewer emergency services and more outpatient services
(Lehman, Dixon, Kernan, DeForge, & Postrado, 1997; Lehman et al., 1999; Scott & Dixon, 1995; Morse Calsyn, Allen, Tempelhoff, & Smith, 1992; Sytema, Wunderink, Bloemers, Roorda, & Wiersma, 2007), decreased symptomatology (Stein & Test, 1980; Morse et al., 1997; Wolff et al., 1997; Hamernik & Pakenham, 1999; Fekete et al., 1998), longer duration in stable community housing (Nelson et al., 2007; Essock & Kontos, 1995; Morse et al., 2006; Stein & Test, 1980; Ziguras & Stuart, 2000), greater rates of employment (Marshall & Lockwood, 2010; Marshall, Lockwood, & Green, 2010), and greater patient and family satisfaction with services (Burns & Santos, 1995; Ziguras & Stuart, 2000; Marshall & Lockwood, 2010; Marshall, Lockwood, & Green, 2010; Morse et al., 1992; 1997). Notably, ACT interventions appear to be most effective in populations with high rates of hospitalization (Burns et al., 2007).

Furthermore, based on Marshall and Lockwood’s (2010a) extensive Cochrane Review meta-analysis, severely and persistently mentally ill (SPMI) individuals enrolled in ACT versus standard community care and hospital-based rehabilitation programs were more likely to maintain contact with clinicians, were less likely to have psychiatric hospital admissions, and spent less time in hospitals. The review also found that ACT was superior to standard care in regards to housing, employment, and patient satisfaction. These results are particularly interesting as there was no difference in mental status or social functioning between the ACT and community care individuals.

There is evidence that ACT programs significantly improve medication adherence among SPMI individuals (Stein & Test, 1980; Bush et al., 1990; Ford et al., 1995; Sands & Cnaan, 1994). In a randomized controlled study of the effectiveness of ACT, Stein and Test (1980) assigned 130 patients with severe mental illness (50% with schizophrenia) to
either the ACT intervention group or to standard care. The authors reported significantly higher rates of medication adherence in the ACT group as well as lower rates of hospitalization. In another randomized controlled study of ACT, Bush and colleagues (1990) assigned 28 patients (86% with schizophrenia) to either the ACT intervention group or to standard case management. The authors reported that patients in the ACT group had significantly higher rates of medication adherence as well as general adherence to their treatment plans. Furthermore, results also showed that individuals in the ACT group had lower rates of hospitalization and shorter duration of inpatient stays. In addition, in Sands and Cnann’s (1994) randomized controlled study of ACT versus intensive case management, the authors found that patients assigned to the ACT group had significantly higher rates of medication adherence.

As a result of extensive research evaluating ACT programs in improving outcomes for SPMI patients, ACT has been widely recognized as an evidence-based treatment framework (Bond & Salyers, 2004; Dixon et al., 2010; Drake et al., 2001; Marshall & Lockwood, 2010; Marshall, Lockwood, & Green 2010; Phillips et al., 2001). The dissemination of ACT as an effective treatment approach for the SPMI population has been supported by governmental reports (Surgeon General, 2000), expert consensus panels (Dixon et al., 2010), and advocacy groups such as the National Alliance for the Mentally Ill (NAMI; Allness & Knoedler, 2003). Based on this literature and the patient population served by ACT, interventions that address issues related to poor insight into illness, low therapeutic alliance, and treatment non-adherence, such as LEAP, should be examined. Furthermore, the extent to which clinicians working within this framework are able to learn and accurately implement effective new interventions should be evaluated.
Fidelity Studies of Psychological Interventions

Demonstrating the efficacy and effectiveness of clinical interventions is a critical component of psychological research. As such, intervention research encompassing outcome studies, clinical trials and feasibility studies are essential in establishing scientifically-validated, practice-based approaches. Fidelity to treatment, also known as treatment integrity, refers to the extent to which a clinical intervention was implemented as intended (Vermilyea, Barlow, & O’Brien, 1984; Yeaton & Sechrest, 1981). Establishing treatment fidelity requires accurate description, measurement, and implementation of the mechanism of change of a given clinical intervention. Verification of fidelity confirms that the manipulation of the independent variable occurred as planned, allowing for accurate and appropriate interpretation of results (Czajkowski, 2011; Bellg et al., 2004; Hogue et al., 2008; Naleppa & Cagle, 2010; Perepletchikova & Kazdin, 2005). Without this confirmation, it is impossible to draw accurate conclusions regarding treatment effects as significant results could be due to unknown active components added to the intervention, inactive components omitted from the intervention, or to an effective intervention (Moncher & Prinz, 1991). The overall goal in enhancing treatment fidelity is to “increase scientific confidence that changes in the dependent variable are attributable to the independent variable” (Borrelli et al., 2005; p. 852).

Emerging research suggests that fidelity studies promote important methodological, statistical and practical benefits, and strong fidelity is critical for successful dissemination of research-based clinical interventions. First and foremost, when studies adequately monitor and control for the consistent implementation of an intervention, outcomes can be attributed to the treatment itself with greater confidence, thereby enhancing the study’s
internal validity (Calsyn, 2000; Hohmann & Shear, 2002; Naleppa & Cagle, 2010).

Establishing treatment fidelity also improves a study’s construct validity (Farrington, 2003), content validity (Calsyn, 2000), and enhances statistical power and external validity by minimizing random and unintended variability in data (Bellg et al., 2004; Crits-Christoph & Mintz, 1991). Thus, verification of fidelity in clinical intervention research is necessary to maintain internal and external validity, to make fair comparisons between replicable treatments, and to draw accurate conclusions regarding treatment efficacy. Bellg and colleagues (2004) also suggest that verification of fidelity can have significant implications in successful dissemination of research focusing on conceptualization, comparison and application of efficacious clinical interventions.

Despite the demand for accountability in the discipline of psychotherapy and the associated increase in clinical intervention research over the past several decades, much of this research has neglected issues of treatment fidelity. Early intervention research was generally remiss in differentiating between treatment conditions, provided only vague descriptions of treatment conditions, and often presented insufficient information to compare or replicate treatment methods. Following Eysenck’s (1952) challenge regarding the effectiveness of psychotherapy and the rise of the community mental health movement of the early 1960s, concern for treatment fidelity in research and practice increased (Moncher & Prinz, 1991). Rogers’ Client-Centered Therapy (Rogers & Dymond, 1954) was among the first clinical interventions to be examined systematically. Increased emphasis on gathering in-session data occurred in the 1970s to promote adherence to treatment protocols, differentiation of treatment conditions and control of extraneous variables. Although these practices increased awareness of issues related to treatment
fidelity and lead to the proliferation of treatment manuals, Moncher and Prinz (1991) state that the methodological problems associated with the failure to demonstrate treatment fidelity has “plagued” the study of psychotherapy (p. 249). Bellg and colleagues (2004) also purport that despite the importance of methodological procedures promoting treatment fidelity in research, these strategies “are not emphasized in research-training curricula, and their relative lack of perceived importance is also evidenced by the scant reporting of treatment fidelity practices in journal articles” (p. 443).

Meta-analyses of clinical intervention research suggest that the majority of existing studies have failed to adequately address issues of treatment fidelity. Moncher and Prinz (1991) evaluated 359 treatment outcome studies conducted from 1980 – 1988 to determine the degree to which investigators considered treatment fidelity in research articles published in clinical psychology, behavior therapy, psychiatry, and marital and family therapy journals. Their evaluation focused on (1) the training of the researchers, (2) the procedures used to encourage fidelity, (3) the aspects of treatment that were confirmed, (4) the methods of assessing fidelity, and (5) the utilization of fidelity measures in interpreting results. Moncher and Prinz reported that although greater consideration of adherence to treatment and promotion of fidelity occurred over the decade, the majority (55%) of the studies included in the meta-analysis failed to address issues related to treatment fidelity. The authors also noted that there were no significant differences across journal domains in addressing the various aspects of fidelity. Borrelli et al.’s (2005) meta-analysis of 342 studies published in major health behavior change journals from 1990 – 2000 yielded similar results. Their evaluation focused on aspects of treatment fidelity encompassing study design, training, treatment delivery, treatment receipt, and treatment enactment
categories. The utilization of treatment fidelity strategies varied greatly across categories, ranging from 63 – 94% for study design, 16 – 25% for training, 6 – 46% for delivery, 40 – 53% for receipt, and 46 – 69% for enactment. Although the authors hypothesized increased utilization of strategies aiming to promote treatment fidelity over time, they reported similar results to Moncher and Prinz’s meta-analysis and found a non-significant trend, indicating a decrease in the use of strategies over time. Interestingly, they also noted that the lowest percentage of strategy use was found in the training category. The authors of both meta-analyses emphasized the importance of addressing issues pertaining to treatment fidelity in future research and proposed guidelines for the enhancement of treatment fidelity.

Mowbray and colleagues (2003) state that the “use of valid fidelity criteria is now an expected component of quality evaluation practice” (p. 316). Guidelines for assessing and enhancing treatment fidelity were described by the Treatment Fidelity Workgroup as part of the National Institutes of Health (NIH) Behavioral Change Consortium (BCC). The purpose of the BCC was to provide the necessary infrastructure to support collaboration between numerous NIH-funded health behavior change projects. It is important to note that preservation of treatment fidelity was imperative in these projects as they involved theory testing within real-world settings. As such, the BCC developed a comprehensive treatment fidelity framework relevant for health behavior change research and clinical practice with specific guidelines and recommendations for best practices across the categories of Design, Training, Delivery, Receipt, and Enactment (Bellg et al., 2004; Borrelli et al., 2002; 2005). The Design category describes factors that should be considered when designing a study as well as information that should be reported to allow
for study replication. The BCC recommends providing information on provider background (i.e. credentials, experience) and articulating the theoretical framework on which the clinical intervention is based. It is also recommended that researchers establish strategies to monitor and decrease the potential for contamination between the treatment and control conditions, and to specify the dose and intensity of the intervention. The Training category consists of important considerations when using human providers in intervention research. The BCC encourages consideration of specific competencies required for successful implementation of the intervention and recruiting providers who are not only capable of implementing the intervention but who also adhere to its theoretical foundation. Careful consideration and reporting of training methods, standardization of training, measurement of provider skill acquisition, and maintenance of skills is also recommended. The Delivery category focused on processes that monitor and improve delivery to verify that the intervention was implemented as intended. Strategies to improve fidelity in this category include examining whether the content and dose of the intervention delivery was as conceptualized and assessing provider adherence to various aspects of the intervention plan.

For outcome research, the BCC also provides recommendations for Receipt and Enactment. Treatment Receipt focuses on ensuring that participants understand the information provided in the intervention by assessing for literacy, education, and language proficiency and by assessing the participant’s ability to utilize the skills taught in the intervention. Treatment Enactment consists of processes to monitor and improve the participant’s ability to incorporate the intervention skills in their daily lives. The BCC describes their treatment fidelity categories as mutually exclusive and that inattention to
one category can compromise the internal validity of the overall study despite adherence in other fidelity categories (Bellg et al., 2004; Borrelli et al., 2002; 2005).

In summary, although the importance of establishing fidelity to treatments has been underscored in the literature for decades and recent research on clinical interventions has emphasized the development and dissemination of empirically-supported interventions, past and current research suggest that few studies of psychotherapeutic approaches address issues of treatment fidelity. As such, addressing this discrepancy in clinical intervention research is necessary.

Purpose of Study

Given the findings regarding the high personal, familial and societal costs associated with schizophrenia and the extant literature on negative outcomes related to poor insight into illness, limited therapeutic alliance, and low treatment adherence in this population, the importance of examining clinical interventions, such as LEAP, that aim to improve these aspects of the illness is underscored. It can be argued that the organizational structure and treatment philosophy of the ACT program are particularly suited for LEAP interventions as they primarily serve chronically mentally ill individuals who have demonstrated the severity of their illness through histories of multiple psychiatric hospitalizations as well as chronic service disengagement and treatment non-adherence. Any clinical intervention, such as LEAP, is only as effective as the level of adherence demonstrated by the practitioner who claims to utilize it. For this reason and given the literature emphasizing the importance of establishing intervention fidelity to the
development and dissemination of effective clinical interventions, as well as the dearth of research addressing intervention fidelity, the present study examines how closely trained mental health clinicians claim to adhere to the LEAP method. To understand those aspects of the intervention that are more or less easily learned and implemented, it is imperative to attempt identifying the principal components or the “active ingredients” that encompass the LEAP method and differentiate it from other treatment modalities. For that reason, the present study evaluates the psychometric properties of a new measure assessing core components of LEAP.

The overall goal of this study, in light of the literature on schizophrenia and clinical intervention research, is to explore the feasibility of training and implementing the LEAP method, an intervention designed specifically to address issues of insight, therapeutic alliance, and treatment adherence in the schizophrenia population, particularly within the context of the ACT community mental health practice setting. The specific aims of this study are (a) to examine the factor structure of the LEAP Fidelity Measure to identify the core components of the LEAP method and (b) to assess and compare ratings of the LEAP Fidelity Measure components between ACT program mental health clinicians who were assessed prior to and following LEAP training. Furthermore, as research evaluating therapist variables that contribute to differences in patient outcomes has been inconclusive, clinician gender, as well as years of general and ACT-specific clinical experience will be evaluated as potential moderator variables. By adding to the research literature concerning the feasibility of training clinicians on new interventions that are widely used, the present study will contribute to the development of innovative, credible, and clinically-applicable interventions and programs for chronically mentally ill individuals.
Hypotheses and Analysis Plan

This study examines LEAP principal components derived from the LEAP Fidelity Measure and potential differences in component ratings between ACT clinicians who were assessed pre- and post-LEAP training. The contribution of therapists to client outcomes in therapy have been the focus of research, particularly within the context of establishing empirically-supported psychological interventions (for review, see Kazdin, 1997; Beutler, Machado & Neufeldt, 1994).

Research has evaluated specific therapist variables contributing to differences in outcomes, with specific focus on demographic characteristics (i.e., age, gender, race, religion), training characteristics (i.e., degree, training, years of experience), theoretical orientation, and personality characteristics. Studies examining the effects of therapist gender (Beutler et al., 1994) on treatment outcomes have yielded inconclusive results. In Bowman’s (1993) review of the literature, he concludes that the research presents three competing hypotheses regarding the effect of therapist gender on client outcomes: (a) female therapist are more effective than their male counterparts (e.g., Bowman, Scogin, Floyd, & McKendree-Smith, 2001; Fisher, 1989), (b) gender matching between client and therapist produce better outcomes (e.g., Luborsky, Auerbach, Chandler, Cohen, & Bachrach, 1971; Persons, Persons, & Newmark, 1974); and (c) therapist gender is not significantly associated with outcomes (e.g., Huppert et al., 2001; Sexton & Whiston, 1991; Zlotnick, Elkin, & Shea, 1998; Vociisano et al., 2004). Research has also evaluated the effect of amount of therapist clinical experience on treatment outcomes, and overall, therapist experience is considered a more robust predictor of outcomes than is the gender
of the therapist (Beutler et al., 1994). Some studies report that greater therapist experience is associated with better client outcomes, although the differences appear to be modest (Crits-Christoph et al., 1991; Huppert et al., 2001; Stein & Lambert, 1995). Furthermore, the literature evaluating the relationship between therapist degree and treatment outcomes reflect mixed conclusions. For example, the only meta-analysis on this variable (Smith, Glass & Miller, 1980) reported a slight outcome advantage when therapy was conducted by a psychologist rather than a psychiatrist. However, a Consumer Reports (1995) study on this relationship showed no differences in treatment outcomes between psychologists and psychiatrists, and showed better outcomes in clients seen by social workers. Given the mixed or modest results regarding the impact of clinician gender and years of clinical experience on treatment outcomes seen in the research literature, these variables will be evaluated as potential moderation factors.

Initial analyses will report descriptive data regarding the characteristics of the sample and the response pattern to the LEAP Fidelity Measure. To examine the factor structure of the LEAP Fidelity Measure, an exploratory principal components analysis will be performed and internal consistency reliabilities of the derived components will be calculated. Additionally, clinician gender, years of general clinical experience, and years of specific clinical experience within the ACT program will be evaluated for their possible moderating influence on the dependent variables examined in this study. Finally, a multivariate analysis of variance test will be performed to assess for differences in the two treatment groups. Specifics regarding analyses follow each hypothesis below.

Study Aim A: To examine the factor structure of the LEAP Fidelity Measure.
Proposed Data Analysis: An exploratory factor analysis or principal components analysis of the LEAP Fidelity Measure, a 17-item survey instrument designed to measure the construct of adherence to the LEAP method, will be conducted to assess whether the measure is uni- or multi-dimensional. Subsequent to deriving the LEAP principal components, the internal consistency reliabilities of the components will be evaluated using Cronbach’s alpha coefficient.

Study Aim B: To assess and compare LEAP fidelity ratings between ACT program clinicians randomized into control and intervention groups.

Hypothesis 1: ACT clinicians in the intervention group will demonstrate higher mean ratings on the LEAP Fidelity Measure than ACT clinicians assigned to the control group.

Hypothesis 2: Mean fidelity ratings will differ based on clinician gender, years of general clinical experience, and years of specific ACT experience, with female clinicians and clinicians with more general and ACT-specific clinical experience having higher mean fidelity ratings than male clinicians or those with less general and ACT-specific clinical experience.

Proposed Data Analysis: The principal question under examination in this study is whether mental health clinicians trained in LEAP do, in fact, differ with respect to their self-reported fidelity to this intervention protocol when compared to clinicians not trained in this method. Fidelity to LEAP will be operationalized by conducting exploratory factor analysis or principal components analysis of the LEAP Fidelity Measure designed to
measure this construct. The factors or components derived from this analysis will serve as dependent variables, i.e. “outcome” measures, in a one-way multivariate analysis of variance (MANOVA). This data analytic strategy is predicated on the presumption that the intervention and control groups will not differ with respect to various demographic or background variables such as gender, years of overall clinical experience, and years of specific clinical experience within the ACT framework. If the two conditions do differ on these characteristics, they will be used initially as controlled variables, in which case, the MANOVA will be replaced by one-way analyses of covariance (ANCOVAs). In addition, these variables will also be evaluated as potential moderators of the expected treatment effects measured by the outcome variables. Therefore, the one-way ANCOVA, if needed, will be “expanded” to include cross-product terms between each potential moderator and the ‘focal’ independent variable, treatment condition (intervention versus control). If there are no background differences between intervention and control groups, the MANOVA will be augmented to include cross-product terms in order to test for possible moderation effects.
Chapter II

METHOD

Sample

Participants in this study are 48 mental health professionals working in independent Assertive Community Treatment (ACT) programs in New York State. ACT is a treatment approach designed to provide comprehensive, community-based psychiatric treatment, rehabilitation, and support to persons with serious and persistent mental illness, such as schizophrenia. The services ACT clinicians provide to clients encompass case management, initial and ongoing assessments, psychiatric services, employment and housing assistance, family support and education, substance abuse services, and other programs and supports critical to an individual’s ability to live successfully in the community. ACT clinicians deliver these services in a variety of contexts including clients’ homes, community mental health clinic and hospital settings. ACT is comprised of clinical professionals whose backgrounds and training include social work, rehabilitation, counseling, nursing, and psychiatry. The clinical degrees that were represented in this sample included psychologists (i.e. Ph.D.), psychiatrists (i.e., M.D.), licensed social workers (i.e. LMSW and LCSW), and psychiatric nurses (i.e. RN). Based on their respective areas of expertise, ACT clinicians deliver integrated services of the client’s choice, assist in making progress towards goals, and adjust services over time to meet clients’ changing needs and goals. The staff-to-client ratio is approximately one
clinician to every ten clients and ACT services are available 24 hours a day, 365 days per year, for as long as the client requires. As an evidence-based treatment framework, ACT has been identified as an effective yet underutilized treatment modality for individuals with serious mental illness.

The ACT Institute at the Center for Practice Innovations at the Columbia University Department of Psychiatry was consulted regarding recruitment of participants and study design. ACT clinicians were recruited from independent community mental health agencies in Westchester, Duchess, Nassau, and Suffolk Counties in New York State. ACT programs operating in New York City were excluded from this study as these clinicians were in the process of implementing significant organizational changes during the recruitment phase. Of the 74 ACT clinicians who were contacted regarding recruitment, 52 were enrolled in the study and data was collected from 48 clinicians. Four clinicians were unable to participate in the study due to clinical emergencies or being absent from work on the day that LEAP training was held. Background information regarding the 22 clinicians who chose not to enroll in the study and the 4 clinicians who were unable to participate in the LEAP training and data collection was not available to the Principal Investigator. Of the 48 clinicians who participated in data collection, 13 were male and 35 were female. The clinicians in this study reported an average of 8 years of overall clinical experience (mean = 7.71, sd = 5.21) and 4 years of experience within the ACT treatment framework (mean = 4.24, sd = 3.36).

ACT clinicians complete a standardized assessment for each client within 30 days of admission, focusing on diagnosis and treatment planning, and for every six months until discharge from the program. The assessments capture client demographic characteristics,
living situation, educational and vocational activities, engagement in services, incidence of significant events (i.e. hospitalization, homelessness, arrest), functional impairment in self-care and social skills, and any incidence of harmful behaviors. This information is monitored, evaluated and published by the New York State Office of Mental Health (OMH). According to the latest OMH records dated December 2011, New York State ACT clients are older than age 18 with an average age of 45. The ACT programs recruited for this study serve between 45 to 65 clients with an average age ranging from 44 to 47. The gender distribution of all New York State ACT clients are 60% male and 40% female compared to 51 – 59% male and 41-49% female distribution of the clients served by the ACT clinicians participating in this study. Regarding racial/ethnic descent, compared to the overall New York State distribution of 39% African American, 37% Caucasian, 19% Hispanic, and 5% Asian clients, the programs participating in the current study worked with 13-23% African American, 57-76% Caucasian, 4-15% Hispanic, and 0-4% Asian clients.

In terms of the diagnostic characteristics of all New York State ACT clients, 78% have a diagnosis of Schizophrenia, 16% are diagnosed with Bipolar Disorder, 5% have Major Depressive Disorder, and 3% have another mental illness diagnosis. The diagnoses of clients served by the ACT programs recruited for this study were 62-74% with Schizophrenia, 20-29% with Bipolar Disorder, 3-5% with Major Depressive Disorder, and 2-5% with another mental illness diagnosis. Regarding other salient characteristics of the client population, 45% of all New York State ACT clients versus 21-36% of clients served by the ACT clinicians in this study had two or more psychiatric emergency room visits,
and 60% versus 39-51% had two or more psychiatric hospitalizations in the 12 months prior to their entry into ACT.

The specific demographic and clinical characteristics of the client population served by the ACT clinicians participating in this study during the period of data collection were not available to the Principal Investigator. Although collecting client outcome data was initially proposed, the inclusion of ACT clients in this study was not approved by the Teachers College Institutional Review Board. As such, the client participation portion of the study design was excluded from the current study.

Procedure

Following standard IRB guidelines, participants were informed of the purpose of the study, what their participation entails, and the risks and benefits associated with participation. A recruitment email (see Appendix A) describing the study was distributed to ACT clinicians in Westchester, Duchess, Nassau, and Suffolk Counties in New York State before they were directly contacted by the Principal Investigator. ACT clinicians were informed that they would be provided LEAP training and certification as part of study participation. Clinicians were informed that if they chose to participate in the study, they would be randomized into either the control or intervention groups affecting the order of training and data collection. For clinicians randomized into the control condition, data was collected prior to their participation in the LEAP training (see Figure 1 for timeline of study procedures for the intervention and control groups). Prior to enrollment in the study, approval for study participation was obtained from the Executive Directors at each agency.
Participants were assured that their responses would be kept completely confidential, with no record of personal identifying information, and that they could withdraw from participation at any time during the study without any consequences to their employment. All participants were required to give written informed consent (Appendix B) for enrollment in the study and were provided a copy of the signed document.

Following informed consent, 52 clinicians were randomized into the control and intervention groups. However, data was collected from 24 clinicians assigned to the control group and from 24 clinicians assigned to the intervention group. The attrition rate for this study was 8% as four clinicians were unable to participate in the LEAP Training due to clinical emergencies or being absent from work. As the primary purpose of this study is to investigate whether fidelity to the LEAP method differs between clinicians trained in LEAP versus clinicians not trained in LEAP, data from the intervention group was collected following the LEAP training seminar and data from the control group was collected prior to the LEAP training. Separate training seminars for the control and intervention groups were conducted at host community mental health agencies.

Intervention group ACT clinicians were provided copies of I Am Not Sick I Don’t Need Help! (Amador, 2010), a book authored by the developer of LEAP, Xavier Amador, Ph.D., outlining the core principles and intervention techniques associated with the LEAP method. The intervention group ACT clinicians were asked to read the book prior to the training seminar. Immediately prior to the training, information regarding the participant’s years of clinical experience and years within the ACT program was obtained. The intervention group then participated in a five-hour LEAP training seminar incorporating
**Figure 1.** Timeline of study activities for intervention and control groups
an overview of the LEAP method, specific LEAP components, and role-play activities. The training was conducted by Dr. Amador, the author of LEAP (Amador 2000; 2007; 2008; 2010; and 2012) and was facilitated by the Principal Investigator of this study. Immediately following the training, the participant’s knowledge of LEAP and skills acquisition was assessed using the LEAP Post-Training Questionnaire (see Appendix C). A description of how this measure was developed is provided below. Incorrect responses on the questionnaire were reviewed to address deficiencies in knowledge during the training.

Following LEAP training, intervention group participants were asked to identify clients in their caseload with a diagnosis of schizophrenia and were asked to employ LEAP interventions consistent with their clinical judgment. Participants were asked to employ LEAP interventions for a minimum of two encounters per client and were informed that there was no minimum or maximum time required for each encounter. Following six weeks of LEAP implementation, intervention group clinicians completed telephone interviews with the Principal Investigator assessing via self-report their fidelity to the LEAP method using the LEAP Fidelity Measure (see Appendix D). Fidelity to LEAP was assessed six weeks following training in order to provide clinicians’ sufficient opportunity to employ these methods with their clients. This duration was also recommended by the ACT Institute to allow ACT clinicians adequate opportunity to employ LEAP interventions with clients.

For the 24 participants randomized into the control group, written informed consent was obtained and ACT clinicians completed the LEAP Fidelity Measure via telephone with the Principal Investigator prior to LEAP training. After all participants in the control
group completed the interviews, copies of *I Am Not Sick I Don’t Need Help!* (Amador, 2010) were distributed and the participants were asked to read the book prior to the training seminar. The control group then participated in a five-hour LEAP training seminar conducted by Dr. Xavier Amador and facilitated by the Principal Investigator of this study, and their LEAP knowledge and skills acquisition was assessed using the LEAP Post-Training Questionnaire. Deficiencies in knowledge were addressed.

It should be noted that the Principal Investigator initially proposed the use of audio- or video-taped clinical encounters to independently rate ACT clinicians’ fidelity to the LEAP method. However, in consultation with the ACT Institute, this method of data collection was deemed too intrusive to the community mental health setting that ACT clinicians operate in. As such, ACT clinicians’ fidelity to the LEAP method was assessed via a self-report measure developed by the Principal Investigator in collaboration with Dr. Xavier Amador.

**Study Intervention**

Listen-Empathize-Agree-Partner (LEAP; Amador, 2000, 2007, 2010; Paillot, Goetz, & Amador, 2009) is a clinical intervention encompassing effective communication strategies designed to strengthen therapeutic alliance, by-pass issues related to limited insight into illness, and improve treatment adherence. Prior to LEAP training, all participants were provided Dr. Amador’s book *I Am Not Sick, I Don’t Need Help!* (Amador, 2010) outlining the core characteristics of LEAP. The five-hour LEAP training seminar incorporated an overview of the research on the issue of poor insight into mental illness and associated negative outcomes (i.e. compromised therapeutic alliance, low
treatment adherence, frequent hospitalizations, etc.) among individuals diagnosed with schizophrenia, teaching of the seven LEAP interventions, and role-play activities aimed at demonstrating and practicing these core LEAP communication strategies.

The LEAP principles that were discussed and role-played during the training seminar include: (1) Reflective Listening, (2) Empathizing, (3) Delaying, (4) The Three A’s, (5) Apologies, (6) Agreeing, and (7) Partnering. According to the LEAP principle of Reflective Listening, practitioners demonstrate respect towards the client’s perspectives and choices by listening actively to their frustrations, fears and desires and reflect back what was communicated. The primary purpose of this technique is to actively listen and to convey understanding to the client. Within this framework, LEAP practitioners are encouraged to make reflective comments without commenting, disagreeing, or arguing regarding the content of what the client communicated. Furthermore, particular emphasis is placed on making reflective statements without reacting, omitting, or reality testing content that is associated with the client’s delusions or hallucinations. In addition, the practitioner requests feedback regarding the accuracy of their reflected statements by asking questions such as, “Did I understand what you said correctly?” or “Did I get that right?” The training seminar focuses specifically on ways to use reflective listening techniques to diffuse anger, lower defenses, and gain trust with the client. This approach focuses on establishing safety and openness in the therapeutic relationship in an attempt to reduce the client’s resistance to discussing their experiences and to facilitate an accurate understanding of the client’s experiences, hopes and expectations. Focusing on establishing trust and openness in the therapeutic relationship also increases the likelihood that the client will be more receptive to the clinician’s treatment recommendations.
To further enhance the client’s experience of being heard and understood, the LEAP practitioner *empathizes* with the experiences that the client shares. The training seminar focuses on identifying appropriate opportunities and methods of empathizing with the client. The LEAP approach places particular emphasis on empathizing with any feelings that are associated with the client’s misperceptions or delusions without commenting on or challenging the content. By considering the client’s perspectives on their own experiences, including their views regarding diagnosis, treatment, and goals, this approach aims to validate the client’s experiences without reality testing.

It should be noted that LEAP differentiates between empathizing with a client’s delusions versus agreeing or encouraging delusional beliefs. This approach acknowledges the deficits in insight that many chronically mentally ill individuals including those with schizophrenia demonstrate that contribute to ruptures in the therapeutic alliance and resistance towards treatment recommendations. LEAP encourages practitioners to consider the client’s perspectives within the context of limited insight into their illness and to empathize with the client’s particular feelings regarding their illness and treatment within this framework. As such, the LEAP training seminar incorporates exercises that encourage clinicians to connect with client’s experiences associated with insight deficits. For example, the rationale for clients’ reluctance to take psychiatric medications is explored within the context of their belief that they do not have an illness that would warrant such treatment. To this end, one LEAP training exercise asks clinicians to reflect on whether they would take insulin injections if they knew they were not diabetic. The reasons for their refusal to take insulin are discussed (i.e. the medications could be physically harmful or the treatment is inconsistent with their knowledge regarding their
own physical health) and as part of the exercise, clinicians are encouraged to explore their emotional reactions to being advised to take medications for an illness they do not believe they are afflicted with. These reflections are then associated with clients’ potential experiences of not being understood or heard when therapeutic interventions neglect to consider the client’s belief that he/she is not ill. Through this perspective, LEAP practitioners are encouraged to empathize with the client’s experiences by making statements such as, “I can see why you don’t want to take these drugs” or “I can understand why you feel so angry when people don’t believe you.”

Another core principle in LEAP is making attempts to Delay giving the client contrary opinions and the training seminar focuses on reviewing effective delay techniques. In LEAP, specific emphasis is placed on making attempts to delay answering questions about the client’s delusions, psychiatric diagnosis and medications, such as, “Do you think I am mentally ill?” or “Do you believe me?” Practitioners are encouraged to delay giving their opinion with statements such as, “I would like to understand the situation better before I tell you what I think, if that’s alright with you” or “I don’t think my opinion is as important as yours right now, is it okay if I give you my opinion at a later time?” There are two rationales for utilizing this technique. The first is to preserve and build on the positive therapeutic alliance developed through reflective listening and empathizing. By delaying providing the client with a contrary opinion that may be disappointing or hurtful to them, the clinician creates the opportunity for the therapeutic alliance to strengthen over time. Furthermore, when the contrary opinion is eventually provided to the client, a strong therapeutic alliance will minimize the likelihood of a significant rupture in the relationship. The second rationale for implementing this
technique is to hold the client responsible for repeatedly requesting the clinician’s opinion. By requiring the client to repeatedly ask for the clinician’s opinion regarding their delusional beliefs, diagnosis, or treatment recommendations, the client is rendered “responsible” for the solicited opinion. For example, if the LEAP practitioner delays giving his/her opinion by informing the client, “I would rather not give you my opinion because I think it will upset you, are you sure you want to hear it?” the client’s agency in the relationship is increased by providing him or her with a choice. The delay approach in LEAP reflects the concept that a solicited opinion is more effective than an unsolicited opinion. As such, within the LEAP framework, practitioners are encouraged to only provide contrary opinions when solicited by the client.

When a strong therapeutic alliance has been established and the client has requested the clinician’s opinion, the LEAP practitioner is encouraged to share their opinions regarding the client’s delusional beliefs, diagnosis, or treatment plan using one or a combination of the Three A’s: Apologize, Acknowledge Fallibility, and Agree to Disagree. LEAP practitioners may apologize for sharing a contrary opinion that may hurt or disappoint the client by making a statement such as, “Before I tell you what I think about this, I want to apologize because it might be hurtful or disappointing. Prior to sharing a contrary opinion with the client, the LEAP practitioner may acknowledge the fallibility of his or her opinion by making a statement such as, “I want to acknowledge that I could be wrong about this because I don’t always have the right answer.” Finally, the LEAP practitioner may agree to disagree on their difference of opinion with the client by stating, “I hope that we can just agree to disagree on this because I respect your point of view and I hope you can respect mine.” By using the Three A’s, LEAP practitioners strive to avoid
confrontations that may invalidate the client’s experiences and to avoid eliciting a
defensive reaction from the client. The training seminar places particular emphasis on
determining appropriate situations to effectively use the Three A’s and to role-play
practitioners’ use of apologies, acknowledging fallibility, and agreeing to disagree.

The use of Apologies is not only emphasized within the context of prefacing the
communication of potentially hurtful information (i.e. contrary opinions). In LEAP,
apologies are frequently used to communicate humility on the part of the clinician and to
convey respect for the client’s feelings and opinions. As apologizing for one’s opinions is
not common in general clinical practice, trainees are encouraged to discuss their reactions
to this specific technique during the LEAP training seminar. The seminar also places
particular emphasis on identifying situations where empathic apologies may be helpful.
For example, clinicians may use apologies as a means of empathizing with a negative side
effect of medication by stating, “I’m so sorry you have to deal with the weight gain
associated with your medications.” The rationale of using apologies as a clinical
intervention is to increase trust in the therapeutic relationship by encouraging honest
communication between client and clinician.

Identifying areas of Agreement is another core technique defining the LEAP
approach. Rather than focusing on areas of disagreement with the client, the LEAP
practitioner attempts to further strengthen the therapeutic alliance by emphasizing the goals
shared by both the client and the clinician. To this end, the clinician is encouraged to
normalize the client’s experience by making statements such as, “I would feel the same
way if I were in your shoes,” and to focus on the client’s perceived problems and
symptoms. Reviewing the perceived advantages and disadvantages of treatment with the
client and correcting the client’s misconceptions regarding treatment options can further facilitate discussion of shared goals. The LEAP practitioner is encouraged to reflect back and emphasize the perceived benefits of treatment by making a statement such as, “If I have it right, you’re saying that when you stay on the medication you sleep better and fight less often with your family.” By focusing on the client’s perceptions of the problem, the LEAP practitioner avoids confrontations, increases the client’s sense of agency, and emphasizes areas of common ground between the client and clinician.

Practitioners of LEAP also strive towards collaboration with the client by establishing mutually agreed-upon goals and *Partnering* or collaborating in the pursuit of achieving these goals. To this end, clinicians are encouraged to articulate the shared goals to the client, develop concrete plans to achieve these goals, and engage in an ongoing assessment of progress made towards these goals. Special emphasis is placed on acknowledging the personal choices of the client and respecting that the client is responsible for the decisions they make in life.

The overarching goal of LEAP is to develop a trusting and accepting environment that enables the practitioner to become more persuasive in his or her treatment recommendations to the client. The specific techniques associated with each core principle were discussed and role-played during the LEAP training seminar. Immediately following the LEAP training seminar, participants’ acquisition of knowledge and skills was assessed using the LEAP Post-Training Questionnaire. Each item on the questionnaire was discussed as a group and any deficiencies in knowledge were addressed.
LEAP Post-Training Questionnaire

The LEAP Post-Training Questionnaire (LPTQ) was developed by the founder of LEAP, Xavier Amador, Ph.D., in collaboration with Lisa Hunter, Ph.D. and Elizabeth Pappadopolis, Ph.D. from the New York State Psychiatric Institute (NYSPI). The LPTQ assesses participants’ knowledge following the LEAP training seminar. The 31-item measure consists of 24 “True” or “False” items assessing specific LEAP principles such as “When faithfully following the LEAP approach, you should provide frequent and gentle reality testing,” and “When faithfully following the LEAP approach, you should reflect back what you have heard and ask the person whether or not you understood him correctly.” The measure also consists of 4 open-ended items assessing the Reflective Listening and Delaying Opinions components of the LEAP approach such as “In the space below, reflect back the following statement: ‘These medications are making me hear voices and I need your help suing the hospital. You’ve got to help me because no one else will. Will you help me?’” One item on the measure provides 10 possible delay tactics and asks the participant to circle the tactics that are aligned with the LEAP approach. The measure includes 2 open-ended items requesting feedback regarding the LEAP training seminar and the LEAP approach. The measure also includes one item asking whether the participant feels comfortable employing LEAP principles with clients following participation in the LEAP training seminar and self-study of *I Am Not Sick, I Don’t Need Help!* (Amador, 2010).
Psychometric properties of this measure have not been reported as its primary purpose is as a training tool designed to reveal misconceptions and stimulate discussion during the training session.

**LEAP Fidelity Measure**

The LEAP Fidelity Measure was developed by the Principal Investigator of this study in collaboration with Dr. Xavier Amador. The 17 items of the measure reflect the core principles of LEAP, including Reflective Listening, Delaying, The Three A’s, Apologizing, Empathizing, Agreeing, and Partnering, and were derived from Dr. Amador’s book, *I Am Not Sick, I Don’t Need Help!* (2010) and the specific items were developed in consultation with Dr. Amador. The self-report measure asks participants to rate their fidelity to LEAP principles using a 5-point Likert scale (1 = “Never,” 3 = “Sometimes,” 5 = “Always”). Four items were developed to assess the Reflective Listening LEAP principle including “Listened to the client’s frustrations, fears and desires” (LFM01), “Listened to the client’s discussions of delusions or hallucinations without reacting, omitting, or reality testing” (LFM02), “Reflected back to client what was heard” (LFM03), and “Requested feedback from client regarding the accuracy of my reflected statements” (LFM04). The three items rating the Delaying principle include “Made an attempt to delay giving a contrary opinion” (LFM05), “Only gave contrary opinions with the client’s permission” (LFM07), and “Did not offer contrary opinions unless necessary” (LFM08). Item 6, “Preceded contrary opinions using 1 or more of the 3 A’s (Apologize, Acknowledge Fallibility, Agree to Disagree)” (LFM06), was used to assess the clinician’s fidelity to the Three A’s LEAP principle and item 9, “Apologized for opinions that differ
from the client’s” (LFM09), was used to assess the Apologizing LEAP principle. Four items were developed to assess the LEAP principle of Empathizing with the client and included the following items: “Empathized with the client’s frustrations, fears and desires” (LFM10), “Empathized with the client’s feelings about their illness or diagnosis” (LFM11), “Empathized with the client’s feelings about treatment” (LFM12), and “Normalized the client’s feelings” (LFM13). The two items assessing the Agreeing LEAP principle were “Actively identified goals that both my client and I agree on” (LFM14) and “Articulated shared goals with client” (LFM15). Furthermore, the two items developed to assess the Partnering LEAP principle were “Developed a plan to achieve shared goals with client” (LFM16) and “Engaged the client in an ongoing assessment of progress made toward the shared goals” (LFM17).
Chapter III

RESULTS

Descriptive Statistics

The participants in this study are mental health clinicians (n = 48) from Assertive Community Treatment (ACT) programs working in independent community agencies in New York State who were randomly assigned to either the intervention condition (i.e. the LEAP training condition) or the control condition. As seen in Table 1, most of these clinicians are females (73%) with approximately eight years of general clinical experience (mean = 7.71, sd = 5.21) and slightly more than four years of specific clinical experience within the ACT treatment modality (mean = 4.24, sd = 3.36). The majority of the mental health clinicians represented in this sample are licensed social workers (LCSW: 27.1%; LMSW: 41.7%) followed by psychiatric nurses (RN: 20.8%), psychiatrists (M.D.: 8.3%),

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Descriptive Data for All Study Participants (n = 48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Frequency (Percent) Mean SD Minimum Maximum</td>
</tr>
<tr>
<td>Female</td>
<td>35 (72.9)</td>
</tr>
<tr>
<td>Male</td>
<td>13 (27.1)</td>
</tr>
<tr>
<td>Clinical Degree</td>
<td></td>
</tr>
<tr>
<td>Psychologist (Ph.D.)</td>
<td>1 (2.1)</td>
</tr>
<tr>
<td>Psychiatrist (M.D.)</td>
<td>4 (8.3)</td>
</tr>
<tr>
<td>Social Worker (LCSW)</td>
<td>13 (27.1)</td>
</tr>
<tr>
<td>Social Worker (LMSW)</td>
<td>20 (41.7)</td>
</tr>
<tr>
<td>Psychiatric Nurse (RN)</td>
<td>10 (20.8)</td>
</tr>
<tr>
<td>Years of General Clinical Experience</td>
<td>7.71 5.21 1.00 20.00</td>
</tr>
<tr>
<td>Years of Specific ACT Experience</td>
<td>4.24 3.36 1.00 14.00</td>
</tr>
</tbody>
</table>
and a psychologist (Ph.D.: 2.1%).

Prior to evaluating the effect of the intervention, the treatment and control groups were tested for possible “baseline” differences in the three background variables available in the study, (i.e., gender, years of general clinical experience and years of specific experience with ACT). These descriptive statistics and results are presented in Table 2. Given the random assignment of subjects to the treatment and control conditions, it was hypothesized that no such differences would be found.

<table>
<thead>
<tr>
<th></th>
<th>Control Group (n = 24)</th>
<th>Intervention Group (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Years of General Clinical Experience</td>
<td>7.48</td>
<td>4.98</td>
</tr>
<tr>
<td>Years of Specific ACT Experience</td>
<td>4.23</td>
<td>3.07</td>
</tr>
<tr>
<td>Categorical Variable</td>
<td>Frequency</td>
<td>Percent</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16</td>
<td>66.7%</td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>33.3%</td>
</tr>
</tbody>
</table>

A chi-square test was conducted in order to test for possible differences in the gender distributions of the treatment and control groups. As shown in Table 2, no significant difference in the gender distribution was found ($\chi^2 = 0.95$ (1), p = .33). T-tests were next conducted in order to test for possible mean differences between the treatment and control groups on years of general clinical experience and years of clinical experience in ACT. As also shown in Table 2, the treatment and control groups did not differ on either of these measures (years of general clinical experience, $t = -.30$, df = 46, p = .76; years of ACT experience, $t = -.02$, df = 46, p = .98).
There was not enough variability in this sample to discern whether the distribution of clinical degree differed between the control and intervention groups, as the majority of the clinicians represented in this sample held LCSW (27.1%) and LMSW (41.7%) clinical social work degrees.

**Factor Structure of the LEAP Fidelity Measure**

The primary purpose of this investigation is to evaluate the degree to which clinicians trained in the LEAP method can demonstrate fidelity to the intervention. In order to address this question, the 17 items of the LEAP Fidelity Measure (see Appendix IV), a self-report measure, were constructed to reflect the “core” principles of the LEAP method. Given the size of the available sample, an exploratory approach was taken to evaluate the dimensionality of the LEAP Fidelity Measure items. More specifically, the 17 items, which were completed by all study participants, were submitted to a principal components analysis using an oblique method of rotation (promax).

Visual inspection of the scree plot associated with this principal components analysis suggests that either a two-component or three-component solution best characterized the number of summary dimensions in the data. Consistent with the scree plot, the analysis extracted three components that “explained” or recovered 68% of the variance in the set of 17 items. As item LFM08, “Did not offer contrary opinions unless necessary,” loaded on both the first and second components, this item was excluded from further analyses. The principal components analysis pattern matrix appears in Table 3.
The first principal component is labeled “Reflective Listening, Delaying, and Opining” as this set of items reflects techniques that can be conceptualized as relatively unique to the LEAP approach. The eight items in this component encompass reflective listening without reacting, omitting or reality testing psychotic content, requesting feedback regarding the accuracy of reflected statements, making attempts to delay providing the client with a contrary opinion, and preceding contrary opinions with apologies, acknowledging the clinician’s own fallibility, or agreeing to disagree. These items represent the Listening, Delaying, the Three A’s, and Apologizing LEAP principles. The second component is labeled “Partnering on Shared Goals” as the four items that comprise this component measures the clinician’s ability to identify goals that both the client and clinician can partner on, and to communicate and assess progress made towards these shared goals with the client. The items reflected in this component represent the Agreeing and Partnering LEAP principles. Finally, the third component, labeled “Client-Centered Listening and Empathizing” is comprised of four items that emphasize listening to and empathizing with the client’s frustrations, fears and desires, as well as their feelings about their illness, diagnosis, and treatment.

Table 4 presents the descriptive statistics for the three principal components. Subsequent to deriving the three LEAP principal components, the internal consistency reliabilities of the components were generated using Cronbach’s alpha coefficient. For the first principal component, Reflective Listening, Delaying, and Opining, the internal consistency reliability coefficient is (\(\alpha = \)) .93. For the Partnering on Shared Goals component, the reliability coefficient is (\(\alpha = \)) .90, and, finally, for the third Client-Centered Listening and Empathizing principal component, the reliability coefficient is (\(\alpha = \)) .63.
Table 3
Rotated Pattern Matrix for Seventeen-Item LEAP Fidelity Measure

<table>
<thead>
<tr>
<th>Component</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>LFM01</td>
<td>.32</td>
<td>-.53</td>
<td>.58</td>
</tr>
<tr>
<td>LFM02</td>
<td>.81</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LFM03</td>
<td>.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LFM04</td>
<td>.97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LFM05</td>
<td>.72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LFM06</td>
<td>.52</td>
<td>.42</td>
<td></td>
</tr>
<tr>
<td>LFM07</td>
<td>.60</td>
<td>.40</td>
<td></td>
</tr>
<tr>
<td>LFM08</td>
<td>.47</td>
<td>.36</td>
<td></td>
</tr>
<tr>
<td>LFM09</td>
<td>.61</td>
<td>.37</td>
<td></td>
</tr>
<tr>
<td>LFM10</td>
<td></td>
<td></td>
<td>.58</td>
</tr>
<tr>
<td>LFM11</td>
<td></td>
<td></td>
<td>.72</td>
</tr>
<tr>
<td>LFM12</td>
<td></td>
<td></td>
<td>.82</td>
</tr>
<tr>
<td>LFM13</td>
<td></td>
<td></td>
<td>.73</td>
</tr>
<tr>
<td>LFM14</td>
<td></td>
<td></td>
<td>.80</td>
</tr>
<tr>
<td>LFM15</td>
<td></td>
<td></td>
<td>.81</td>
</tr>
<tr>
<td>LFM16</td>
<td></td>
<td></td>
<td>.83</td>
</tr>
<tr>
<td>LFM17</td>
<td></td>
<td></td>
<td>.87</td>
</tr>
</tbody>
</table>

Extraction Method: Principal Components Analysis.
Rotation Method: Promax with Kaiser Normalization.
Rotation converged in 6 iterations.
With respect to the Reflective Listening, Delaying, and Opining component, the sample, as a whole, reports using these particular techniques “Sometimes”, on average (mean = 3.19, sd = .96). A similar level of endorsement characterizes the second principal component, Partnering on Shared Goals (mean = 3.33, sd = 0.87). However, there is noticeable increase in the level or degree of endorsement of the Client-Centered Listening and Empathizing component, reflecting average responses between “Often” and “Always” (mean = 4.51, sd = 0.37). It should also be noted that the range of responses pertaining to this component was constricted to the upper range of the 5-point Likert scale, reflecting responses between “Sometimes” and “Always.” Conversely, the sample did not endorse responses in the “Never” or “Rarely” range on items comprising the Client-Centered Interventions component.

Table 4

<table>
<thead>
<tr>
<th>Component</th>
<th>Number of Items</th>
<th>Mean</th>
<th>SD</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component 1</td>
<td>&quot;Reflective Listening, Delaying and Opining&quot;</td>
<td>8</td>
<td>3.19</td>
<td>.96</td>
<td>1.38</td>
</tr>
<tr>
<td>Component 2</td>
<td>&quot;Partnering on Shared Goals&quot;</td>
<td>4</td>
<td>3.33</td>
<td>.87</td>
<td>1.00</td>
</tr>
<tr>
<td>Component 3</td>
<td>&quot;Client-Centered Listening and Empathizing&quot;</td>
<td>4</td>
<td>4.51</td>
<td>.37</td>
<td>3.75</td>
</tr>
</tbody>
</table>

Analysis of Hypotheses

For the purpose of evaluating the effect of the intervention, a one-way multivariate analysis of variance (MANOVA) was used. In this analysis, the independent variable was used as a grouping factor distinguishing between treatment (i.e., LEAP) and control
participants. The dependent variables were the three principal components. Table 5 presents the findings from this analysis. The multivariate F statistic was statistically significant indicating that the treatment and the control groups differed significantly on the set of the three outcome measures (F = 62.50, (3,44), p < .001). In order to “locate” which of the three components the treatment and controls differ on, the univariate results were examined. As seen in the table, the treatment and the control groups differed significantly on the first two components. With respect to the first of these components, Reflective Listening, Delaying and Opining, the treatment group’s mean was significantly higher than the control group’s mean (treatment group mean = 4.03, control group mean = 2.35, F = 161.85, (1,46), p < .001). Similarly, with regard to the second component, Partnering on Shared Goals, the treatment group’s mean was, again, significantly higher than the control group’s mean (treatment group mean = 3.97, control group mean = 2.69, F = 58.20, (1,46), p < .001). The treatment and the control groups did not significantly differ with respect to their means on the third component, Client-Centered Listening and Empathizing (F = .46, (1,46), p = .50).

Table 5

<table>
<thead>
<tr>
<th>Principal Component</th>
<th>Control Group (n = 24)</th>
<th>Intervention Group (n = 24)</th>
<th>F</th>
<th>Partial Eta Squared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Component 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Reflective Listening, Delaying</td>
<td>2.35 (.50)</td>
<td>4.03 (.41)</td>
<td>161.85***</td>
<td>.78</td>
</tr>
<tr>
<td>and Opining”</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Principal Component 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Partnering on Shared Goals”</td>
<td>2.69 (.69)</td>
<td>3.97 (.45)</td>
<td>58.20***</td>
<td>.56</td>
</tr>
<tr>
<td>Principal Component 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Client-Centered Listening and</td>
<td>4.47 (.40)</td>
<td>4.54 (.34)</td>
<td>.46</td>
<td>.01</td>
</tr>
<tr>
<td>Empathizing”</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*p < .05. **p < .01. ***p < .001.
Statistical significance tests address an important question, i.e., whether an effect is not zero, or in the case of this particular study, whether the difference in mean LEAP fidelity ratings between the control and treatment conditions is not zero. However, once the statistical significance tests indicate that an effect is not zero, understanding the magnitude of the difference between groups helps determine whether the effect size is “meaningful.” In this study, the partial eta-squared statistic ($\eta^2$) was used to determine the magnitude of the effect size. Drawing upon Cohen’s (1988) recommendations for the interpretation of mean differences in effect size terms, partial eta-squared statistics of .01 are considered “small” effects, .06 are considered “moderate” or “medium” in magnitude, and partial eta-squared statistics greater than .14 are considered “large” (Cohen, 1988, p. 283). As seen in Table 5, the partial eta-squared statistics for the Reflective Listening, Delaying and Opining ($\eta^2 = .78$) and Partnering on Shared Goals ($\eta^2 = .56$) LEAP components can be characterized as very large effect sizes. As the statistical significant test for the Client-Centered Listening and Empathizing component was not significant, the eta square statistic for this component was not interpreted.

**Table 6**

<table>
<thead>
<tr>
<th>Outcome Variables</th>
<th>Gender</th>
<th>Years of General Clinical Experience</th>
<th>Years of Specific ACT Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Reflective Listening, Delaying and Opining”</td>
<td>-.11</td>
<td>-.26</td>
<td>-.26</td>
</tr>
<tr>
<td>“Partnering on Shared Goals”</td>
<td>-.18</td>
<td>-.06</td>
<td>-.23</td>
</tr>
<tr>
<td>“Client-Centered Listening and Empathizing”</td>
<td>.28*</td>
<td>-.21</td>
<td>-.27</td>
</tr>
</tbody>
</table>

* *p < .05. **p < .01. ***p < .001.

There were no significant differences between the intervention and control groups based on gender, years of general clinical experience, and years of specific ACT experience. Furthermore, the interaction or moderation effect of gender was found to be
non-significant. Although not part of the formal hypotheses, a post hoc analysis assessing potential correlations between these “baseline” variables and the outcome variables (the three LEAP Fidelity Measure principal components: Reflective Listening, Delaying and Opining; Partnering on Shared Goals; and Client-Centered Listening and Empathizing) was conducted. The Pearson correlations are presented in Table 6. In terms of gender, although there was a general trend for female clinicians to report higher fidelity to Reflective Listening, Delaying and Opining ($r = -0.11$) and Partnering on Shared Goals ($r = -0.18$), this gender association was not statistically significant. However, there was a significant gender correlation on clinicians’ reports of fidelity to the Client-Centered Listening and Empathizing component ($r = 0.28$, $p = 0.05$), with male clinicians reporting greater fidelity to this set of interventions. Additionally, although there was a general trend for clinicians with more general clinical experience and specific ACT experience to be less likely to report fidelity to Reflective Listening, Delaying and Opining ($r = -0.26$), Partnering on Shared Goals ($r = -0.06$), and Client-Centered Listening and Empathizing ($r = -0.27$), these associations were not statistically significant.

Furthermore, when the relationships between these variables were assessed based on treatment group, no significant correlations were found.
Chapter IV

DISCUSSION

The primary purpose of this study was to assess ACT clinicians’ fidelity to the LEAP method, a set of clinical interventions that address issues of poor insight, therapeutic alliance, and treatment adherence prevalent in the schizophrenia population. A secondary purpose of this study was to examine the factor structure and psychometric properties of a measure developed to examine the core components comprising the LEAP approach.

Study results indicated a three factor structure of the LEAP Fidelity Measure that were labeled “Reflective Listening, Delaying and Opining,” “Partnering on Shared Goals,” and “Client-Centered Listening and Empathizing.” Analyses revealed significantly higher LEAP fidelity ratings among clinicians in the intervention group in the Reflective Listening, Delaying and Opining and Partnering on Shared Goals components when compared to the control group clinicians. No significant differences were found between the two groups on the Client-Centered Listening and Empathizing LEAP component. Although no differences were found based on gender or years of clinical experience between the two groups, a post hoc analysis evaluating the effect of baseline characteristics on the three LEAP components revealed a modest correlation between gender and the Client-Centered Listening and Empathizing component. The specific results are discussed below within the context of existing literature. From clinical and mental health service perspectives, these results suggest that dissemination and implementation of LEAP is feasible within a community mental health setting.
Patterns of LEAP Fidelity Ratings

*The Three LEAP Fidelity Measure Principal Components*

The results of this study indicate that mental health clinicians who participated in a one-day training on LEAP demonstrated a significantly higher level of fidelity to this clinical intervention when compared to those who did not receive the training. Although it was hypothesized that the intervention group would demonstrate higher fidelity ratings on all components of the LEAP method, the ACT clinicians who were assigned to the LEAP intervention group reported higher fidelity to the Reflective Listening, Delaying and Opining and Partnering on Shared Goals components of LEAP but did not differ from the control group on the Client-Centered Listening and Empathizing LEAP component.

These findings may illustrate components that are unique to LEAP interventions versus those that represent a fundamental theoretical framework that is common across psychotherapeutic approaches. The Reflective Listening, Delaying and Opining and the Partnering on Shared Goals components may represent novel clinical intervention techniques that are particularly unique to the LEAP method and differentiate LEAP from other psychotherapeutic modalities. These components reflect the LEAP interventions that acknowledge the neurologically-based insight deficits in schizophrenia by putting aside improving clients’ insight into their illness as a primary goal of therapy. Clinical interventions that do not emphasize increasing insight as a treatment goal may be particularly relevant to this population as research suggests that improvements in overall symptom severity and treatment adherence among individuals with schizophrenia do not necessarily correlate with better insight (Carroll et al., 1999; Cuesta, Peralta, & Zarzuela,
confronting insight deficits in this population may, in fact, prove detrimental to developing a strong therapeutic alliance which may consequently contribute to service disengagement and poor treatment outcomes prevalent among individuals diagnosed with schizophrenia.

Thus, the LEAP approach may differ from interventions derived from psychodynamic and psychosocial perspectives that emphasize the importance of gaining insight into one’s illness and the psychological processes that contribute to one’s difficulties as a necessary step in facilitating meaningful therapeutic change (for review, see Wampold et al., 2007). Rather, these particular LEAP interventions place special emphasis on bypassing issues related to these deficits within the therapeutic relationship by accurately reflecting the experiences of the client, refraining from reality testing, and partnering with the client on treatment goals that do not confront his or her poor insight into mental illness. Therefore, the suggestion that these components are reflective of techniques that are unique to the LEAP method helps explain the finding that the intervention group that received LEAP training demonstrated significantly higher levels of fidelity to these specific intervention strategies when compared to clinicians who were not trained in LEAP.

Anecdotal evidence also supports this conclusion. During phone interviews, several participants from the intervention group commented on the qualitative changes they experienced in the therapeutic alliance with particularly difficult clients. It should be noted that these clinicians attributed this change in the therapeutic alliance to their use of LEAP techniques that de-emphasize “trying to convince” clients that they have a mental illness. Several clinicians in the intervention group also commented on the effectiveness of
reflective listening and using apologies, acknowledging fallibility, and agreeing to disagree despite the initial discomfort and “skepticism” they had towards these techniques during the LEAP training. However, these clinicians reported that these techniques in particular have been effective in conveying respect towards the client’s experiences and in helping the clinician focus on the client’s perspectives, rather than working towards their own personal or professional “agendas.” These clinicians also reported feeling less “burnt out” by clients with severe insight deficits as the LEAP approach provided them techniques to bypass issues related to poor insight in treatment and to identify goals that both the client and clinician are motivated to work towards achieving.

In contrast to the intervention group, the clinicians assigned to the control group expressed general skepticism regarding LEAP techniques during the phone interviews that occurred prior to the training. Several clinicians shared particularly strong negative reactions to the use of the Three A’s (apologizing, acknowledging fallibility, and agreeing to disagree) by making statements such as, “I would never apologize for my professional opinion” or expressed concern that using these techniques would jeopardize their “credibility” as clinicians. Furthermore, several clinicians in this group also expressed their reluctance to use LEAP interventions associated with delaying providing the client with a contrary opinion as they felt that these techniques may be potentially “evasive” and “manipulative.” As such, anecdotally, clinicians in the intervention and control groups expressed varied perspectives and degrees of openness towards LEAP techniques.

In contrast to the Reflective Listening, Delaying and Opining and Partnering on Shared Goals components that may be unique to the LEAP method, the aspects of the LEAP approach that are represented in the Client-Centered Listening and Empathizing
component may illustrate a clinical stance that is common across different psycho-
therapeutic approaches. This component encompasses techniques focusing on non-
directive listening and empathizing with a client’s fears, frustrations, and desires, as well as their feelings towards their diagnosis and treatment. This finding is consistent with the suggestion that the client-centered approaches of empathy, genuineness and positive regard are critical aspects of a positive therapeutic alliance that facilitate the healing process in therapy and are fundamental aspects that have become integrated across therapy modalities (Farber 2007; Horvath, 2001; Stricker & Gold, 1996; Watson, 2007). As such, these aspects are not particularly unique to the LEAP approach and may represent what Carl Rogers called the “necessary and sufficient” components (1957, p. 87) that have become the generalized foundation of a positive therapeutic stance explaining the high fidelity ratings to this component demonstrated across the intervention and control groups.

**Gender and Years of Clinical Experience**

The results of this study revealed that the two groups were comparable based on the distribution of gender, years of general clinical experience, and years of specific ACT clinical experience. Furthermore, no significant interaction effects were found between the intervention and control groups on these baseline variables and LEAP fidelity ratings on the three principal components.

Although an overall gender difference in the three LEAP components was not specifically hypothesized, the finding that male clinicians reported significantly higher levels of fidelity to the Client-Centered Listening and Empathizing component presents an interesting trend. Although existing literature portrays an overall pattern suggesting that
females may be generally more empathic than males (Eisenberg & Lennon, 1983; Gilligan, 1993; Jordan, 1995; Lennon & Eisenberg, 1987), there are few studies examining gender differences in self-reported empathy among mental health clinicians. In a study of self-reported and observed empathy among therapists, Hatcher and colleagues (2005) found that not only did female therapists rate themselves as significantly higher on empathic concern and perspective taking, they were also observed to demonstrate responses that were rated as more empathic than their male counterparts. However, both male and female therapists rated empathic interventions as extremely important to their clinical work. Though it is difficult to identify a definitive explanation for the modest gender difference found in this study, perhaps the male clinicians working with the chronically mentally ill client population is a self-selected group with a particularly high capacity for empathy. Furthermore, it may be possible that male clinicians may feel the need to “overcompensate” on characteristics, such as empathy, that are socially viewed to be stereotypically female.

The results of this study also indicate that there was a general trend for clinicians with greater years of general clinical experience and specific experience within the ACT framework to report lower levels of fidelity to all three components of LEAP. Although this trend was not statistically significant, it poses an interesting question regarding clinicians’ openness towards learning and implementing new clinical interventions. Although few studies have investigated the relationship between clinician years of experience and their willingness towards new clinical practices, existing research supports the general trend that clinicians with relatively limited experience tend to be more open to the acquisition of new practices (Aarons, 2004, 2005; Day, Arthur, & Gettman, 2001;
Rentsch & Klimoski, 2001). Aaron (2005) suggests that novice clinicians may have more malleable knowledge structures that allows for flexibility facilitating integration of newly-learned clinical skills into their existing clinical repertoire.

Limitations of Study

This study has a number of limitations. The sampling method used in this study may limit the generalizability of the results. ACT clinicians working in Westchester, Duchess, Suffolk, and Nassau counties in New York State were recruited for this study. Although 65% of the ACT clinicians in these counties participated in the study, demographic information on the 35% who chose not to participate in the study was not available to the Principal Investigator. Thus, possible differences between these two groups of clinicians as well as the possibility of a non-response bias could not be evaluated. Furthermore, as all ACT clinicians in New York State were not recruited for participation, the clinicians in this study may not be a representative sample and the results of this study may not be generalizable to the larger group of New York State ACT clinicians or the general population of mental health clinicians.

The sample size, while large enough to provide sufficient statistical power for the analyses included in this study, was too limited to conduct a Confirmatory Factor Analysis (CFA) to examine the dimensions of the LEAP Fidelity Measure. Ideally, a CFA would have provided the optimal measurement strategy since the seventeen items were written to reflect the seven, theoretically-derived treatment principles proposed by the LEAP founder as the critical elements that define this intervention. However, given the size of the
available sample and the data requirements for the CFA, this analysis was infeasible. Therefore, a more exploratory approach was taken to evaluate the dimensionality of the seventeen LEAP Fidelity Measure items. Furthermore, a larger sample size may have captured a more heterogeneous distribution of clinical degree allowing an examination of this background characteristic as a potential moderator variable affecting clinicians’ fidelity to the LEAP approach. In addition, the inclusion of this clinician characteristic in the post hoc analysis may have yielded patterns of intervention fidelity informing future research into the LEAP method.

A blind experimental study design may have improved the reliability and validity of this study as the Principal Investigator who was not blind to the study hypotheses conducted all of the recruitment and data collection activities. There is a risk of experimenter bias influencing participants’ responses in this study as the Principal Investigator may have inadvertently communicated differing response expectancies to the intervention and control groups. This risk is further amplified as the Principal Investigator also facilitated the LEAP training for the participants in this study. However, Rosenthal and Rosnow (1991) suggest that measuring the dependent variable in a setting that differs from the training environment and removed in time from the treatment may minimize the experimenter-subject artifacts in experimental settings.

The findings of this study are also limited by the potential biases of self-report as there are demand characteristics inherent in the data collection procedure associated with a positive response bias. There was no direct observation of clinicians’ actual fidelity to LEAP, which could be very different from reported practices, particularly due to the 6-week time lapse between training and assessment of LEAP fidelity (Carroll et al., 2002).
The literature in treatment fidelity research encourages the use of objective ratings via in-person evaluations as well as audiotaped or videotaped clinical interactions (for review, see Bellg et al., 2004). However, the intrusiveness of this method and the possible obstacles this approach poses for study recruitment efforts and the impact of experimenter involvement in clinical interactions has been acknowledged (Naleppa & Cagle, 2010). The focus of efficacy studies is on the demonstration of a direct causal relationship between an intervention and outcomes, requiring controlled environments and strict adherence to standardized protocols thereby increasing internal validity and replicability (Nathan, Stuart & Dolan, 2000). However, when studies explore the effectiveness, feasibility, and adoptability of an intervention, a singular focus on standardized procedures may be counterproductive as this approach is invariably at odds with the complicated nature of the practice of psychotherapy in “real world” settings. The translation of evidence-supported interventions into practice settings often require modifications to the original protocol while also acknowledging the variability in diagnosis, comorbid psychopathology and duration of illness among the client population in addition to the fact that treatment method, frequency and duration are driven by clinical considerations rather than standardized procedures in clinical settings (Castro, Barrera, & Martinez, 2004; Green & Glasgow, 2006; Naleppa & Cagle, 2010).

This study presents areas of improvement when compared to the BCC best practices guidelines for establishing treatment fidelity in clinical intervention research (Bellg et al., 2004; Borrelli et al., 2002; 2005). According to the BCC recommendations for the Design category, this study provided a clear description of the study design and methods for future replication. This study also articulated the theoretical framework of the
study intervention in addition to minimizing the possibility of contamination of the intervention and control groups by preventing overlap in study activities between these two groups. This study addressed the Training guidelines presented by the BCC through careful reporting of training methods as well as measurement of participant skill acquisition through the use of the role-play activities during LEAP training and assessment via the LEAP Post-Training Questionnaire. However, maintenance of these skills was not promoted through ongoing supervision of LEAP techniques in the current study. The BCC also recommends objective monitoring of Delivery of interventions through independent confirmation of techniques implemented by clinicians. Furthermore, in their comprehensive review of empirical evaluation of training clinicians in evidence-based therapies, Beidas and Kendall (2010) suggest that the “gold standard” of training include a workshop, treatment manual, and clinical supervision. Research indicates that although didactic training is a necessary component of dissemination of empirically-supported interventions, there is little evidence of their effect on clinicians’ ability to implement the techniques they were trained in (Beidas & Kendall, 2010; Carroll et al., 2006; Carroll, Martino, & Rounsaville, 2010). Therefore, augmenting the LEAP didactic seminar with additional training components including videotapes exemplifying the optimal use of LEAP strategies, a treatment manual, and ongoing clinical supervision would approximate what is considered to be standard practice in intervention research. In addition, although the use of audio- or video-taped sessions was initially proposed as the ideal strategy to assess clinicians’ fidelity to LEAP interventions, these methods could not be implemented in this study as they were deemed too intrusive to ACT clinicians’ encounters with clients.
by the ACT Institute. As such, although a less reliable measure, clinicians’ ratings of fidelity to LEAP were assessed via a self-report measure.

Another limitation of this study is that the control condition did not include a comparable duration of training in an alternative intervention. The inclusion of a control group in psychotherapy research generally proposes the use of a placebo design or an alternative treatment design that does not emulate the active ingredients of the intervention that is being evaluated (Nathan, Stuart & Dolan, 2000). The literature on the recommended standards of efficacy and effectiveness research raises the question regarding whether an inert placebo control, although the control condition of choice in pharmacological research, is possible to achieve in psychotherapy studies as most control conditions encompass even non-specific benefits. Therefore, researchers support the use of a comparable treatment with minimal overlap with the intervention condition that is the focus of the study (for review, see Nathan, Stuart & Dolan, 2000). Despite these recommendations, the use of an alternative treatment, such as mindfulness training, as a control condition was not feasible for this particular study. The participants in the study were specifically interested in acquisition of LEAP skills and the Executive Directors overseeing all training activities at the independent ACT agencies would not accommodate an additional day of training for this control condition as the control group clinicians were also provided LEAP training at the conclusion of the study.

Although the literature on treatment fidelity underscores the importance of standardizing core intervention elements towards the larger goal of developing and disseminating effective treatments, Naleppa and Cagle (2010) also encourage researchers to avoid “cookie-cutter” approaches to patient care by effectively adapting treatment
protocols to maximize feasibility and adoptability in real-world practice settings. Despite the limitations of using self-report measures in evaluating treatment fidelity, the feasibility and value of conducting research in a “real-world” clinical setting while minimizing the intrusiveness or obtrusiveness of study participation was prioritized in this pilot study. However, the influence of a social desirability effect on the participants’ responses was mitigated by guaranteeing confidentiality of responses and by encouraging respondents to answer questions as honestly as possible. Furthermore, the use of a telephone interview to administer the self-report measure may mitigate some of the demand characteristics of this method of data collection (Rosenthal & Rosnow, 1991).

Implications for Future Research

Research suggests that efforts to disseminate and implement evidence-based practices must take into account the complexities of mental health service in “real world” settings (Fraser & Greenhalgh, 2001; Hasenfeld, 1992; Henggeler & Schoenwald, 2002; Jankowicz, 2000; Simpson, 2002). As such, one of the strengths of the current study is that it focused on “real world” clinicians who work in community mental health settings. In that respect, this study differs from the vast majority of extant research of manualized interventions primarily involving doctoral-level clinicians (Aarons, Woodbridge, & Carmazzi, 2003; Cohen, Sargent & Sechrest, 1987). It should be noted that the majority of the clinicians in this study were licensed social workers and there was only one psychologist who was a participant in this study. The relatively low distribution of doctoral-level clinicians in this sample is representative of public mental health services
and these non-doctoral-level providers are likely to be essential agents of widespread delivery of evidence-based practices (Aarons, Woodbridge, & Carmazzi, 2003).

Although this study focused on the application of LEAP with clients diagnosed with schizophrenia, LEAP was primarily developed as a means of strengthening the therapeutic alliance and can be implemented in a variety of clinical settings and with various forms of psychopathology. For instance, LEAP strategies are applicable to a variety of individuals seeking help with a particular mental illness, regardless of other co-occurring conditions or the duration of illness. Moreover, the applicability of LEAP has implications even broader than clinical settings. Many family members have attended LEAP trainings to learn skills for the purpose of effectively managing the challenges of having a mentally-ill loved one and law enforcement officers have also been trained in LEAP to de-escalate potentially dangerous situations with mentally-ill individuals (Amador, 2012).

Ideally, future research should focus on comparisons of self-reported versus independent assessments of LEAP fidelity as well as inclusion of client outcomes in assessing the effectiveness of LEAP interventions among various client populations. Future research should also assess how LEAP as an adjunctive intervention interacts with various therapy modalities in order to identify which psychotherapeutic modalities integrate ideally with this set of communication strategies. Also, research focusing on examining the various clinical and social contexts in which LEAP may be applicable will widen the scope of training, dissemination and implementation of LEAP interventions.
Conclusions

In conclusion, this study focused on developing and evaluating the psychometric properties of a fidelity measure of clinicians’ adherence to a widely-used new clinical intervention known as LEAP and to assess and compare the fidelity ratings of clinicians who were trained in this approach versus those who were not. The findings suggest that the LEAP Fidelity Measure is a reliable instrument that supports a three factor structure of principal components. Furthermore, following a one-day training, clinicians assigned to the intervention group reported significantly higher fidelity to LEAP when compared to those who did not receive LEAP training.

From a clinical perspective, anecdotal report from clinicians who were trained in LEAP supports the conclusion that this set of interventions appears to improve qualitative aspects of the therapeutic alliance. Clinicians identified insight deficits as a significant clinical problem adversely affecting the therapeutic alliance and treatment engagement in this population and expressed a willingness to learn new interventions specifically addressing these particular challenges. Moreover, the clinicians who participated in this study expressed a willingness to implement these techniques and to assess for themselves the effectiveness of LEAP interventions in not only improving client outcomes, but also in enhancing their own experiences of working with this challenging population. As the positive and negative symptoms of schizophrenia and the associated impairments in global functioning often pose serious challenges in working with this population, interventions that improve the clinician-client relationship by enhancing understanding, effective
communication, and collaboration are paramount in affecting client outcomes and in preventing clinician burn-out.

However, interventions meant for “real world” application can only be effective if dissemination and implementation of the approach is feasible and the complexities of the mental health service system are met with careful consideration. Within this context, LEAP encompasses a set of adjunctive clinical interventions that can be easily disseminated and implemented in community mental health settings with minimal investment of time and resources. By adding to the literature concerning the feasibility of training clinicians on new interventions that are widely used, the present study will contribute to the development of innovative, credible, and clinically-applicable interventions for chronically mentally-ill individuals.
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APPENDIX A: Recruitment Letter

Date: 12/06/2011

To: ACT clinicians

You are being asked to participate in a pilot fidelity study of the Listen-Empathize-Agree-Partner (LEAP) approach to communicating with clients. LEAP is a communication intervention that incorporates components of motivational enhancement, client-centered, and cognitive therapies with the primary focus of strengthening the therapeutic alliance and improving treatment adherence. LEAP emphasizes the importance of strengthening the therapeutic alliance with the objective of optimizing respectful and non-judgmental communication with the client. The ultimate goal of LEAP is to develop a trusting and accepting environment that enables the practitioner to become more persuasive in his or her treatment recommendations to the client. We believe that implementation of LEAP interventions with ACT consumers will (1) improve treatment adherence, (2) improve service engagement, and (3) reduce the risk for repeated psychiatric crises.

If you decide to participate in the study, you will be assigned to either the control or intervention group. For intervention group clinicians, you will be trained in LEAP by Dr. Xavier Amador, the developer of the intervention. LEAP training and certification will be offered at no cost (tuition of $750 will be waived) and you will be provided a copy of Dr. Amador’s book *I am not sick I don’t need help!* (Amador, 2010). Following training, you will be asked to employ LEAP interventions with ACT consumers during your regular interactions and 6 weeks following training, you will be asked to complete a brief LEAP fidelity interview via telephone.

For ACT clinicians assigned to the control group, you will be asked to complete a brief LEAP fidelity interview via telephone within 6 weeks after you agree to participate in the study. After you complete the interview, your team will be trained in LEAP by Dr. Xavier Amador and LEAP training and certification will be offered at no cost. You will also be provided a copy of Dr. Amador’s book *I am not sick I don’t need help!* (Amador, 2010).

The principal investigator of this study, Mia Ihm, M.Phil., will be contacting you in two weeks to ask if you would like to participate. You can also contact her at 646-775-8736 or mai2105@columbia.edu should you have any questions or comments; or if you decide that you would prefer not to be contacted regarding the study.

Your decision to participate or not to participate will not affect your employment status.

Thank you for your consideration,

Mia A. Ihm, M.Phil., Principal Investigator
Xavier Amador, Ph.D., Co-Investigator
Barry Farber, Ph.D., Sponsor
APPENDIX B: Informed Consent Form

December 6, 2011

INFORMED CONSENT

DESCRIPTION OF THE RESEARCH: You are being asked to participate in a pilot fidelity study of the Listen-Empathize-Agree-Partner (LEAP) approach to communicating with clients. LEAP is a communication intervention that incorporates components of motivational enhancement, client-centered, and cognitive therapies with the primary focus of strengthening the therapeutic alliance and improving treatment adherence. LEAP emphasizes the importance of strengthening the therapeutic alliance with the objective of optimizing respectful and non-judgmental communication with the client. The ultimate goal of LEAP is to develop a trusting and accepting environment that enables the practitioner to become more persuasive in his or her treatment recommendations to the client. We believe that implementation of LEAP interventions with ACT consumers will (1) improve treatment adherence, (2) improve service engagement, and (3) reduce the risk for repeated psychiatric crises.

The alternative to taking part in this study would be to continue with your regular job duties without participating in the LEAP training, implementation, and fidelity interview.

If you agree to participate in the study, you will be randomly assigned to either the control group or the intervention group. For the intervention group, the principal investigators, Mia Ihm and Dr. Amador, will provide LEAP training and certification at no cost (tuition of $750 will be waived) at an ACT office. You will be provided a copy of Dr. Amador’s book *I am not sick, I don’t need help!* (Amador, 2010) and will be asked to read the book prior to the training seminar. The training will last approximately 5 hours and lunch will be provided.

Following the training, you will be asked to employ LEAP interventions and strategies with ACT consumers during your normal clinical interactions. Six weeks after training, you will be asked to participate in a brief telephone interview that will involve an assessment of your fidelity to LEAP principles. The interview will last approximately 20-30 minutes.

For ACT clinicians assigned to the control group, you will be asked to complete the LEAP Fidelity Interview prior to receiving LEAP training. You will receive LEAP training and certification at no cost within 6 weeks after giving informed consent to participate in the study at an ACT office. You will be provided a copy of Dr. Amador’s book *I am not sick, I don’t need help!* (Amador, 2010) and will be asked to read the book prior to the training seminar. The training will last approximately 5 hours and lunch will be provided.

RISKS AND BENEFITS: We anticipate minimal risk of injury due to participation. Although you may be concerned about how participation in this study may influence your employment status, your decision to participate will have no bearing on your employment.
In addition, should you decide to participate, your responses will also have no bearing on your employment. We anticipate that you may receive some professional benefits due to participation. You may professionally benefit as the LEAP training may assist in your clinical practice with Severe and Persistent Mentally Ill (SPMI) consumers.

PAYMENTS: LEAP training and certification will be provided at no cost to you (tuition of $750 will be waived). In addition, you will be provided a copy of Dr. Amador’s book *I am not sick I don’t need help!* (Amador, 2010) at no cost.

DATA STORAGE TO PROTECT CONFIDENTIALITY: No identifying information will be entered electronically. Rather, a numerical code will be used to link electronic and paper records. Consequently, no one but the Principal Investigator will have access to the personal identities of study participants.

All study documents (consent form, notes, interview responses) will be stored in locked files in the Principal Investigator’s office and will be kept confidential to the extent permitted by law. Electronic data will be kept on a password protected drive accessible only to Mia Ihm.

Study documents will only be available to research staff, and State and Institutional regulatory personnel who may review documents as part of routine audits.

TIME INVOLVEMENT: Your participation in the LEAP training will take approximately 5 hours. For intervention group ACT clinicians, you will be asked to practice the LEAP method twice with each consumer on your caseload for 6 weeks following the training. There is no minimum or maximum time implied for each encounter. In addition, the LEAP Fidelity Measure will take approximately 20-30 minutes to complete.

For control group ACT clinicians, your participation in the LEAP training will take approximately 5 hours. In addition, the LEAP Fidelity Measure will take approximately 20-30 minutes to complete.

HOW WILL RESULTS BE USED: The results of the study will be used for the Principal Investigator’s dissertation and may be published in professional journals. Furthermore, overall results will be presented to ACT and the Office of Mental Health regarding further implementation of LEAP training.
PARTICIPANT'S RIGHTS

Principal Investigator:  ____Mia Ihm, M.Phil.__________________________________

Research Title: A Pilot Fidelity Study of Listen-Empathize-Agree-Partner (LEAP) with Assertive Community Treatment (ACT) Mental Health Clinicians

• I have read and discussed the Research Description with the researcher. I have had the opportunity to ask questions about the purposes and procedures regarding this study.

• My participation in research is voluntary. I may refuse to participate or withdraw from participation at any time without jeopardy to future medical care, employment, student status or other entitlements.

• The researcher may withdraw me from the research at his/her professional discretion.

• If, during the course of the study, significant new information that has been developed becomes available which may relate to my willingness to continue to participate, the investigator will provide this information to me.

• Any information derived from the research project that personally identifies me will not be voluntarily released or disclosed without my separate consent, except as specifically required by law.

• If at any time I have any questions regarding the research or my participation, I can contact the investigator, who will answer my questions. The investigator's phone number is (646) 775-8736.

• If at any time I have comments, or concerns regarding the conduct of the research or questions about my rights as a research subject, I should contact the Teachers College, Columbia University Institutional Review Board /IRB. The phone number for the IRB is (212) 678-4105. Or, I can write to the IRB at Teachers College, Columbia University, 525 W. 120th Street, New York, NY, 10027, Box 151.

• I should receive a copy of the Research Description and this Participant's Rights document.

• If video and/or audio taping is part of this research, I ( ) consent to be audio/video taped. I ( ) do NOT consent to being video/audio taped. The written, video and/or audio taped materials will be viewed only by the principal investigator and members of the research team.

• Written, video and/or audio taped materials ( ) may be viewed in an educational setting outside the research, or ( ) may NOT be viewed in an educational setting outside the research.

• My signature means that I agree to participate in this study.
Participant's signature: ________________________________ Date:___/___/____

Name: ________________________________

Investigator's Verification of Explanation

I certify that I have carefully explained the purpose and nature of this research to ____________________ (participant’s name) in age-appropriate language. He/She has had the opportunity to discuss it with me in detail. I have answered all his/her questions and he/she provided the affirmative agreement (i.e. assent) to participate in this research.

Investigator’s Signature: ________________________________

Date: ______________________
APPENDIX C: LEAP Post-Training Questionnaire

Your Name: 

Today’s Date: 

The purpose of this brief questionnaire is to obtain your feedback about the LEAP training and to identify areas where you would benefit from receiving additional information. We will have a brief discussion of your answers then ask that you turn in your completed test.

*Following the initial LEAP training session as well as your self-study review of the LEAP materials and Dr. Amador’s book, “I Am Not Sick, I Don’t Need Help;” Do you feel you would be comfortable employing LEAP principles with your clients?*

Circle one:  

YES  

NO  

**Directions:** Circle True or False for each statement listed below. All questions refer to your use of the LEAP approach with someone who has serious mental illness. Please do not refer to your copy of the book, slides or notes as this test is designed as a teaching tool.

**When faithfully following the LEAP approach, you should:**

<table>
<thead>
<tr>
<th>T or F</th>
<th>1. Provide frequent and gentle reality testing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>T or F</td>
<td>2. Ask questions and never make statements or give your opinion.</td>
</tr>
<tr>
<td>T or F</td>
<td>3. Not remind the person about bad treatment experiences if they have not brought them up, and instead focus only on the positives.</td>
</tr>
<tr>
<td>T or F</td>
<td>4. Ask few questions as this can cause some consumers to feel threatened and paranoid.</td>
</tr>
<tr>
<td>T or F</td>
<td>5. Never make statements or give your opinion unless invited to do so repeatedly.</td>
</tr>
<tr>
<td>T or F</td>
<td>6. Not agree to help with, or partner on, goals that you think are unrealistic.</td>
</tr>
<tr>
<td>T or F</td>
<td>7. Say things that make the person believe that you agree with his delusions (e.g., “I can see how the CIA has been harassing you. That must be very frustrating, yes?”)</td>
</tr>
<tr>
<td>T or F</td>
<td>8. Gently and consistently point to the evidence that this person is mentally ill to help them develop insight into the illness and to feel less stigmatized.</td>
</tr>
</tbody>
</table>
9. Be sure to immediately clarify any misconceptions the person has about your opinion (e.g., if he thinks you believe his delusion or agree with him when he says, “I am not sick.”)

10. Not ever allow the person to assume you agree with her when she says “I am not sick!” Instead, be sure to tell her your views on the matter to quickly correct her misunderstanding and ask that she agree to disagree with you.


12. Focus your questions and listening on, among other things, what the person wants most no matter how bizarre or seemingly irrelevant it may seem (e.g., to have the alien transmitter taken out of his brain).

13. After being asked your opinion on the matter, strongly encourage the person to take medicine telling her that you are absolutely certain it is indicated.

14. When empathizing, try not to empathize with the person’s wish to avoid treatment.

15. Allowing someone to mistakenly assume you agree with their delusion, without immediately correcting their mistake, is colluding with the delusion and will worsen it.

16. Avoid reality testing.

17. Reflect back what you have heard and ask the person whether or not you understood him correctly.

18. Not have to apologize for your professional opinion (e.g., regarding the diagnosis, treatments indicated, etc.).

19. Reflect back the perceived benefits of treatment, as the consumer describes them, even if they are incorrect (e.g., “the medication seems to improve my telepathy”).

20. Never tell the person they need, or would benefit from, treatment.

21. Focus, first and foremost, on helping the person develop insight into their illness.

22. Not attempt to normalize abnormal experiences.
23. Feel comfortable having a friendly debate about whether the person should be in treatment or not.

24. Never give a contrary opinion.

Please answer the following questions in the space provided:

1. The 3 A’s stand for:

2. In the space below, reflect back the following statement: “These medications are making me hear voices and I need your help suing the hospital. You’ve got to help me because no one else will. Will you help me?”

3. In the space below, reflect back the following statement: “My problem is you and everyone else that is telling me I am sick and have to take these medicines. I know what you’re up to repeating everything I say, I see how you’re working with my family to keep me locked up and poison me. They want me dead so they can sell my secrets to the CIA.”
4. When asked for your opinion, which of the following are recommended delay tactics (circle all that apply):
   a. I don’t think it’s a good idea to tell you that right now. Okay?
   b. I would like to keep listening if that’s okay with you?
   c. Wouldn’t you agree that you’re opinion is far more important than mine?
   d. Can you tell me more first?
   e. Why do you want to know?
   f. I promise I will tell you what I think, but if it’s alright with you I would like to hear more about what we were talking about. Okay?
   g. That’s an interesting question, can you tell me more?
   h. Would you mind if we kept talking about_____ and I’ll tell you what I think later on?
   i. I am not allowed to answer that question just yet but I will get to it later.
   j. I will tell you what I think, but if it’s agreeable to you I would like to wait and hear some more because frankly, your opinion is far more important than mine anyway.

5. You have been asked to give your opinion about whether treatment would be helpful or not. You have delayed as long as you can. The person asking believes that medicine will make him unable to work. In the space below describe what you would say when giving your opinion (note: you believe treatment would be helpful).

6. In the space below, please feel free to ask any questions you may have regarding the LEAP program:

7. Additional Comments/Feedback:
APPENDIX D: LEAP Fidelity Measure

LEAP FIDELITY MEASURE

<table>
<thead>
<tr>
<th>Clinician ID:</th>
<th>Date:</th>
</tr>
</thead>
</table>

Please think about clinical encounters you have had over the past six weeks with a client diagnosed with Schizophrenia and who has demonstrated a lack of insight into their diagnosis. Rate how often you have used the following techniques on a scale of 1 (Never), 3 (Sometimes), and 5 (Always). You can use any rating between 1 through 5.

<table>
<thead>
<tr>
<th>LEAP Intervention</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Listened to the client’s frustrations, fears and desires.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2. Listened to client’s discussions of delusions or hallucinations without reacting, omitting, or reality testing.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3. Reflected back to client what I heard.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>4. Requested feedback from client regarding accuracy of my reflected statements.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>5. Made attempts to delay giving opinions that are contrary to the client’s.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>6. Preceded contrary opinions with an Apology, Acknowledging my Fallibility, or Agreeing to Disagree (3 A’s).</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>7. Only gave contrary opinions with the client's permission.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>8. Did not offer contrary opinions unless necessary.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>9. Apologized for opinions that differ from the client’s.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>10. Empathized with client's frustrations, fears and desires.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>11. Empathized with the client's feelings about their illness/diagnosis.</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>5</td>
<td>4</td>
<td>3</td>
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<td>-----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>12</td>
<td>Empathized with the client's feelings about treatment.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Normalized the client's feelings.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>14</td>
<td>Actively identified goals that both my client and I agree on.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>15</td>
<td>Articulated shared goals with client.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>16</td>
<td>Developed a plan to achieve shared goals with the client.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>17</td>
<td>Engaged the client in an ongoing assessment of progress made toward the shared goals.</td>
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